

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Parts 431, 433, 438, 440, 457 and 495

[CMS–2390–F]

RIN 0938–AS25

Medicaid and Children’s Health Insurance Program (CHIP) Programs; Medicaid Managed Care, CHIP Delivered in Managed Care, and Revisions Related to Third Party Liability

AGENCY: Centers for Medicare & Medicaid Services (CMS), HHS.

ACTION: Final rule.

SUMMARY: This final rule modernizes the Medicaid managed care regulations to reflect changes in the usage of managed care delivery systems. The final rule aligns, where feasible, many of the rules governing Medicaid managed care with those of other major sources of coverage, including coverage through Qualified Health Plans and Medicare Advantage plans; implements statutory provisions; strengthens actuarial soundness payment provisions to promote the accountability of Medicaid managed care program rates; and promotes the quality of care and strengthens efforts to reform delivery systems that serve Medicaid and CHIP beneficiaries. It also ensures appropriate beneficiary protections and enhances policies related to program integrity. This final rule also implements provisions of the Children’s Health Insurance Program Reauthorization Act of 2009 (CHIPRA) and addresses third party liability for trauma codes.

DATES: Except for 42 CFR 433.15(b)(10) and § 438.370, these regulations are effective on July 5, 2016. The amendments to §§ 433.15(b)(10) and 438.370, are effective May 6, 2016.

Compliance Date: See the Compliance section of the **SUPPLEMENTARY INFORMATION**.

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Acronyms

Because of the many organizations and terms to which we refer by acronym in this final rule, we are listing these acronyms and their corresponding terms in alphabetical order below:

ACO Accountable Care Organization [the] Act Social Security Act
 Affordable Care Act The Affordable Care Act of 2010 (which is the collective term for the Patient Protection and Affordable Care Act (Pub. L. 111-148) and the Health Care Education Reconciliation Act (Pub. L. 111-152))
 ARRA American Recovery and Reinvestment Act of 2009
 ASOP Actuarial Standard of Practice
 BBA Balanced Budget Act of 1997
 BIA Bureau of Indian Affairs
 CPE Certified Public Expenditure
 CFR Code of Federal Regulations
 CBE Community Benefit Expenditures
 CHIP Children's Health Insurance Program
 CHIPRA Children's Health Insurance Program Reauthorization Act of 2009
 CMS Centers for Medicare & Medicaid Services
 DUR Drug Utilization Review [program]
 EQR External Quality Review
 EQRO External Quality Review Organization
 FFM Federally-Facilitated Marketplaces
 FFP Federal Financial Participation
 FFS Fee-For-Service
 FMAP Federal Medical Assistance Percentage
 FQHC Federally Qualified Health Center
 FY Fiscal Year
 HHS [U.S. Department of] Health and Human Services
 HIO Health Insuring Organization
 HIPAA Health Insurance Portability and Accountability Act of 1996
 ICD International Classification of Diseases
 IGT Intergovernmental Transfer
 IHCP Indian Health Care Provider
 LEP Limited English Proficiency
 LTSS Long-Term Services and Supports
 MA Medicare Advantage
 MACPAC Medicaid and CHIP Payment and Access Commission
 MMC QRS Medicaid Managed Care Quality Rating System
 MCO Managed Care Organization
 MFCU Medicaid Fraud Control Unit
 MHPA Mental Health Parity Act of 1996
 MH/SUD Mental Health/Substance Use Disorder Services
 MHPAEA Mental Health Parity and Addiction Equity Act
 MLTSS Managed Long-Term Services and Supports
 MLR Medical Loss Ratio
 MSIS Medicaid Statistical Information System
 NAMD National Association of Medicaid Directors
 NCQA National Committee for Quality Assurance
 NEMT Non-Emergency Medical Transportation

NQF National Quality Forum
 OMB Office of Management and Budget
 PCCM Primary Care Case Manager
 PHS Public Health Service Act
 PIP Performance Improvement Project
 PMPM Per-member Per-month
 PAHP Pre-paid Ambulatory Health Plan
 PIHP Pre-paid Inpatient Health Plan
 QAPI Quality Assessment and Performance Improvement
 QHP Qualified Health Plan(s)
 QRS Quality Rating System
 SHO State Health Official Letter
 SBC Summary of Benefits and Coverage
 SBM State-Based Marketplaces
 SIU Special Investigation Unit
 SMDL State Medicaid Director Letter
 T-MSIS Transformed Medicaid Statistical Information System
 TPL Third Party Liability

Compliance

States must be in compliance with the requirements at § 438.370 and § 431.15(b)(10) of this rule immediately. States must be in compliance with the requirements at §§ 431.200, 431.220, 431.244, 433.138, 438.1, 438.2, 438.3(a) through (g), 438.3(i) through (l), 438.3(n) through (p), 438.4(a), 438.4(b)(1), 438.4(b)(2), 438.4(b)(5), 438.4(b)(6), 438.5(a), 438.5(g), 438.6(a), 438.6(b)(1), 438.6(b)(2), 438.6(e), 438.7(a), 438.7(d), 438.12, 438.50, 438.52, 438.54, 438.56 (except 438.56(d)(2)(iv)), 438.58, 438.60, 438.100, 438.102, 438.104, 438.106, 438.108, 438.114, 438.116, 438.214, 438.224, 438.228, 438.236, 438.310, 438.320, 438.352, 438.600, 438.602(i), 438.610, 438.700, 438.702, 438.704, 438.706, 438.708, 438.710, 438.722, 438.724, 438.726, 438.730, 438.802, 438.806, 438.808, 438.810, 438.812, 438.816, 440.262, 495.332, 495.366 and 457.204 no later than the effective date of this rule.

For rating periods for Medicaid managed care contracts beginning before July 1, 2017, States will not be held out of compliance with the changes adopted in the following sections so long as they comply with the corresponding standard(s) codified in 42 CFR part 438 contained in 42 CFR parts 430 to 481, edition revised as of October 1, 2015: §§ 438.3(h), 438.3(m), 438.3(q) through (u), 438.4(b)(7), 438.4(b)(8), 438.5(b) through (f), 438.6(b)(3), 438.6(c) and (d), 438.7(b), 438.7(c)(1) and (2), 438.8, 438.9, 438.10, 438.14, 438.56(d)(2)(iv), 438.66(a) through (d), 438.70, 438.74, 438.110, 438.208, 438.210, 438.230, 438.242, 438.330, 438.332, 438.400, 438.402, 438.404, 438.406, 438.408, 438.410, 438.414, 438.416, 438.420, 438.424, 438.602(a), 438.602(c) through (h), 438.604, 438.606, 438.608(a), and 438.608(c) and (d), no later than the rating period for Medicaid managed care contracts starting on or after July 1, 2017. States must comply with these

requirements no later than the rating period for Medicaid managed care contracts starting on or after July 1, 2017.

For rating periods for Medicaid managed care contracts beginning before July 1, 2018, states will not be held out of compliance with the changes adopted in the following sections so long as they comply with the corresponding standard(s) codified in 42 CFR part 438 contained in the 42 CFR parts 430 to 481, edition revised as of October 1, 2015: §§ 438.4(b)(3), 438.4(b)(4), 438.7(c)(3), 438.62, 438.68, 438.71, 438.206, 438.207, 438.602(b), 438.608(b), and 438.818. States must comply with these requirements no later than the rating period for Medicaid managed care contracts starting on or after July 1, 2018.

States must be in compliance with the requirements at § 438.4(b)(9) no later than the rating period for Medicaid managed care contracts starting on or after July 1, 2019.

States must be in compliance with the requirements at § 438.66(e) no later than the rating period for Medicaid managed care contracts starting on or after the date of the publication of CMS guidance.

States must be in compliance with § 438.334 no later than 3 years from the date of a final notice published in the **Federal Register**. Until July 1, 2018, states will not be held out of compliance with the changes adopted in the following sections so long as they comply with the corresponding standard(s) codified in 42 CFR part 438 contained in the 42 CFR parts 430 to 481, edition revised as of October 1, 2015: §§ 438.340, 438.350, 438.354, 438.356, 438.358, 438.360, 438.362, and 438.364. States must begin conducting the EQR-related activity described in § 438.358(b)(1)(iv) (relating to the mandatory EQR-related activity of validation of network adequacy) no later than one year from the issuance of the associated EQR protocol. States may begin conducting the EQR-related activity described in § 438.358(c)(6) (relating to the optional EQR-related activity of plan rating) no earlier than the issuance of the associated EQR protocol.

Except as otherwise noted, states will not be held out of compliance with new requirements in part 457 of this final rule until CHIP managed care contracts as of the state fiscal year beginning on or after July 1, 2018, so long as they comply with the corresponding standard(s) in 42 CFR part 457 contained in the 42 CFR, parts 430 to 481, edition revised as of October 1, 2015. States must come into compliance

with § 457.1240(d) no later than 3 years from the date of a final notice published in the **Federal Register**. States must begin conducting the EQR-related activity described in § 438.358(b)(1)(iv) (relating to the mandatory EQR-related activity of validation of network adequacy) which is applied to CHIP per § 457.1250 no later than one year from the issuance of the associated EQR protocol.

I. Medicaid Managed Care

A. Background

In 1965, amendments to the Social Security Act (the Act) established the Medicaid program as a joint federal and state program to provide medical assistance to individuals with low incomes. Under the Medicaid program, each state that chooses to participate in the program and receive federal financial participation (FFP) for program expenditures, establishes eligibility standards, benefits packages, and payment rates, and undertakes program administration in accordance with federal statutory and regulatory standards. The provisions of each state's Medicaid program are described in the state's Medicaid "state plan." Among other responsibilities, the Centers for Medicare and Medicaid Services (CMS) approves state plans and monitors activities and expenditures for compliance with federal Medicaid laws to ensure that beneficiaries receive timely access to quality health care. (Throughout this preamble, we use the term "beneficiaries" to mean "individuals eligible for Medicaid benefits.")

Until the early 1990s, most Medicaid beneficiaries received Medicaid coverage through fee-for-service (FFS) arrangements. However, over time that practice has shifted and states are increasingly utilizing managed care arrangements to provide Medicaid coverage to beneficiaries. Under managed care, beneficiaries receive part or all of their Medicaid services from health care providers that are paid by an organization that is under contract with the state; the organization receives a monthly capitated payment for a specified benefit package and is responsible for the provision and coverage of services. In 1992, 2.4 million Medicaid beneficiaries (or 8 percent of all Medicaid beneficiaries) accessed part or all of their Medicaid benefits through capitated health plans; by 1998, that number had increased fivefold to 12.6 million (or 41 percent of all Medicaid beneficiaries). As of July 1, 2013, more than 45.9 million (or 73.5 percent of all Medicaid beneficiaries)

accessed part or all of their Medicaid benefits through Medicaid managed care.¹ In FY 2013, approximately 4.3 million children enrolled in CHIP (or about 81 percent of all separate CHIP beneficiaries) were enrolled in managed care.

In a Medicaid managed care delivery system, through contracts with managed care plans, states require that the plan provide or arrange for a specified package of Medicaid services for enrolled beneficiaries. States may contract with managed care entities that offer comprehensive benefits, referred to as managed care organizations (MCOs). Under these contracts, the organization offering the managed care plan is paid a fixed, prospective, monthly payment for each enrolled beneficiary. This payment approach is referred to as "capitation." Beneficiaries enrolled in capitated MCOs must access the Medicaid services covered under the state plan through the managed care plan. Alternatively, managed care plans can receive a capitated payment for a limited array of services, such as behavioral health or dental services. Such entities that receive a capitated payment for a limited array of services are referred to as "prepaid inpatient health plans" (PIHPs) or "prepaid ambulatory health plans" (PAHPs) depending on the scope of services the managed care plan provides. Finally, applicable federal statute recognizes primary care case managers (PCCM) as a type of managed care entity subject to some of the same standards as MCOs; states that do not pursue capitated arrangements but want to promote coordination and care management may contract with primary care providers or care management entities for primary care case management services to support better health outcomes and improve the quality of care delivered to beneficiaries, but continue to pay for covered benefits on a FFS basis directly to the health care provider.

Comprehensive regulations to cover managed care delivery mechanisms for Medicaid were adopted in 2002 after a series of proposed and interim rules. Since the publication of those Medicaid managed care regulations in 2002, the landscape for health care delivery has continued to change, both within the Medicaid program and outside (in Medicare and the private sector market). States have continued to expand the use of managed care over the past decade, serving both new geographic areas and

broader groups of Medicaid beneficiaries. In particular, states have expanded managed care delivery systems to include older adults and persons with disabilities, as well as those who need long-term services and supports (LTSS). In 2004, eight states (AZ, FL, MA, MI, MN, NY, TX, and WI) had implemented Medicaid managed long-term services and supports (MLTSS) programs. By January 2014, 12 additional states had implemented MLTSS programs (CA, DE, IL, KS, NC, NM, OH, PA, RI, TN, VA, WA).

States may implement a Medicaid managed care delivery system under four types of federal authorities:

(1) Section 1915(a) of the Act permits states with a waiver to implement a voluntary managed care program by executing a contract with organizations that the state has procured using a competitive procurement process.

(2) Through a state plan amendment that meets standards set forth in section 1932 of the Act, states can implement a mandatory managed care delivery system. This authority does not allow states to require beneficiaries who are dually eligible for Medicare and Medicaid (dually eligible), American Indians/Alaska Natives, or children with special health care needs to enroll in a managed care program. State plans, once approved, remain in effect until modified by the state.

(3) CMS may grant a waiver under section 1915(b) of the Act, permitting a state to require all Medicaid beneficiaries to enroll in a managed care delivery system, including dually eligible beneficiaries, American Indians/Alaska Natives, or children with special health care needs. After approval, a state may operate a section 1915(b) waiver for up to a 2-year period (certain waivers can be operated for up to 5 years if they include dually eligible beneficiaries) before requesting a renewal for an additional 2 (or 5) year period.

(4) CMS may also authorize managed care programs as part of demonstration projects under section 1115(a) of the Act using waivers permitting the state to require all Medicaid beneficiaries to enroll in a managed care delivery system, including dually eligible beneficiaries, American Indians/Alaska Natives, and children with special health care needs. Under this authority, states may seek additional flexibility to demonstrate and evaluate innovative policy approaches for delivering Medicaid benefits, as well as the option to provide services not typically covered by Medicaid. Such flexibility is approvable only if the objectives of the Medicaid statute are likely to be met, the demonstration satisfies budget

¹ CMS, 2013 Medicaid Managed Care Enrollment Report, available at <https://www.medicaid.gov/medicaid-chip-program-information/by-topics/data-and-systems/medicaid-managed-care/medicaid-managed-care-enrollment-report.html>.

neutrality requirements, and the demonstration is subject to evaluation.

All of these authorities may permit states to operate their programs without complying with the following standards of Medicaid law outlined in section 1902 of the Act:

- Statewideness [section 1902(a)(1) of the Act]: States may implement a managed care delivery system in specific areas of the State (generally counties/parishes) rather than the whole state;

- Comparability of Services [section 1902(a)(10) of the Act]: States may provide different benefits to beneficiaries enrolled in a managed care delivery system; and

- Freedom of Choice [section 1902(a)(23)(A) of the Act]: States may require beneficiaries to receive their Medicaid services only from a managed care plan or primary care provider.

The health care delivery landscape has changed substantially, both within the Medicaid program and outside of it. Reflecting the significant role that managed care plays in the Medicaid program and these substantial changes, this rule modernizes the Medicaid managed care regulatory structure to facilitate and support delivery system reform initiatives to improve health care outcomes and the beneficiary experience while effectively managing costs. The rule also includes provisions that strengthen the quality of care provided to Medicaid beneficiaries and promote more effective use of data in overseeing managed care programs. In addition, this final rule revises the Medicaid managed care regulations to align, where appropriate, with requirements for other sources of coverage, strengthens actuarial soundness and other payment regulations to improve accountability of capitation rates paid in the Medicaid managed care program, and incorporates statutory provisions affecting Medicaid managed care passed since 2002. This final rule also recognizes that through managed care plans, state and federal taxpayer dollars are used to purchase covered services from providers on behalf of Medicaid enrollees, and adopts procedures and standards to ensure accountability and strengthen program integrity safeguards to ensure the appropriate stewardship of those funds.

B. Summary of Proposed Provisions and Analysis of and Responses to Comments

In the June 1, 2015 **Federal Register** (80 FR 31097 through 31297), we published the “Medicaid and Children’s Health Insurance Program (CHIP) Programs; Medicaid Managed Care, CHIP Delivered in Managed Care,

Medicaid and CHIP Comprehensive Quality Strategies, and Revisions Related to Third Party Liability” proposed rule which proposed revisions to align many of the rules governing Medicaid managed care with those of other major sources of coverage, where appropriate; enhance the beneficiary experience; implement statutory provisions; strengthen actuarial soundness payment provisions and program integrity standards; and promote the quality of care and strengthen efforts to reform delivery systems that serve Medicaid and CHIP beneficiaries. We also proposed to require states to establish comprehensive quality strategies that applied to all services covered under state Medicaid and CHIP programs, not just those covered through an MCO or PIHP.

In the proposed rule and in this final rule, we restated the entirety of part 438 and incorporated our changes into the regulation text due to the extensive nature of our proposals. However, for many sections within part 438, we did not propose, and do not finalize, substantive changes.

Throughout this document, the use of the term “managed care plan” incorporates MCOs, PIHPs, and PAHPs and is used only when the provision under discussion applies to all three arrangements. An explicit reference is used in the preamble if the provision applies to PCCMs, PCCM entities, or only to MCOs. In addition, many of our proposals incorporated “PCCM entities” into existing regulatory provisions and the proposed amendments.

Throughout this document, the term “PAHP” is used to mean a prepaid ambulatory health plan that does not exclusively provide non-emergency medical transportation (NEMT) services. Whenever this document is referencing a PAHP that exclusively provides NEMT services, it will be specifically addressed as a “Non-Emergency Medical Transportation (NEMT) PAHP.”

We received a total of 879 timely comments from State Medicaid agencies, advocacy groups, health care providers and associations, health insurers, managed care plans, health care associations, and the general public. The comments ranged from general support or opposition to the proposed provisions to very specific questions or comments regarding the proposed changes. In response to the proposed rule, many commenters chose to raise issues that are beyond the scope of our proposals. In this final rule, we are not summarizing or responding to those comments in this document. However, we may consider whether to

take other actions, such as revising or clarifying CMS program operating instructions or procedures, based on the information or recommendations in the comments.

Brief summaries of each proposed provision, a summary of the public comments we received (with the exception of specific comments on the paperwork burden or the economic impact analysis), and our responses to the comments are provided in this final rule. Comments related to the paperwork burden and the impact analyses included in the proposed rule are addressed in the “Collection of Information Requirements” and “Regulatory Impact Analysis” sections in this final rule. The final regulation text follows these analyses.

The following summarizes comments about the proposed rule, in general, or regarding issues not contained in specific provisions:

Comment: We received several comments specific to provider reimbursement for federally qualified health centers (FQHCs) and hospice providers. Many commenters submitted concerns about state-specific programs or proposals.

Response: While we did not propose explicit regulations in those areas, we acknowledge receipt of these comments and may consider the concerns raised therein for future guidance. We have addressed concerns raised by these providers when directly responsive to provisions in the proposed rule. In addition, we appreciate commenters alerting us to concerns and considerations for state-specific programs or proposals and have shared those comments within CMS.

I.B.1. Alignment With Other Health Coverage Programs

a. Marketing (§ 438.104)

As we noted in the proposed rule in section I.B.1.a., the current regulation at § 438.104 imposes certain limits on MCOs, PIHPs, PAHPs, and PCCMs in connection with marketing activities; our 2002 final rule based these limits on section 1932(d)(2) of the Act for MCOs and PCCMs and extended them to PIHPs and PAHPs using our authority at section 1902(a)(4) of the Act. The creation of qualified health plans (QHPs) by the Affordable Care Act and changes in managed care delivery systems since the adoption of the 2002 rule are the principal reasons behind our proposal to revise the marketing standards applicable to Medicaid managed care programs. QHPs are defined in 45 CFR 155.20.

We proposed to revise § 438.104(a) as follows: (1) To amend the definition of

“marketing” in § 438.104 to specifically exclude communications from a QHP to Medicaid beneficiaries even if the issuer of the QHP is also an entity providing Medicaid managed care; (2) to amend the definition of “marketing materials;” (3) to add a definition for “private insurance” to clarify that QHPs certified for participation in the Federally-Facilitated Marketplace (FFM) or a State-Based Marketplace (SBM) are excluded from the term “private insurance” as it is used in this regulation; and (4) in recognition of the wide array of services PCCM entities provide in some markets, to include PCCM entities in § 438.104 as we believed it was important to extend the beneficiary protections afforded by this section to enrollees of PCCM entities. This last proposal was to revise paragraphs (a) and (b) to include “or PCCM entity” wherever the phrase “MCO, PIHP, PAHP or PCCM” appears. We did not propose significant changes to paragraph (b), but did propose one clarifying change to (b)(1)(v) as noted below.

Prior to the proposed rule, we had received several questions from Medicaid managed care plans about the implications of current Medicaid marketing rules in § 438.104 for their operation of QHPs. Specifically, stakeholders asked whether the provisions of § 438.104(b)(1)(iv) would prohibit an issuer that offers both a QHP and a MCO from marketing both products. The regulatory provision implements section 1932(d)(2)(C) of the Act, titled “Prohibition of Tie-Ins.” In issuing regulations implementing this provision in 2002, we clarified that we interpreted it as intended to preclude tying enrollment in the Medicaid plan to purchasing other types of private insurance (67 FR 41027). Therefore, it would not apply to the issue of a possible alternative to the Medicaid plan, which a QHP could be if the consumer was determined as not Medicaid eligible or loses Medicaid eligibility. Section 438.104(b)(1)(iv) only prohibits the marketing of insurance policies that would be sold “in conjunction with” enrollment in the Medicaid plan.

We recognized that a single legal entity could be operating separate lines of business, that is, a Medicaid MCO (or PIHP or PAHP) and a QHP. Issuers of QHPs may also contract with states to provide Medicaid managed care plans; in some cases the issuer might be the MCO, PIHP, or PAHP itself, or the entity offering the Medicaid managed care plan, thus providing coverage to Medicaid beneficiaries. Many Medicaid managed care plan contracts with states

executed prior to 2014 did not anticipate this situation and may contain broad language that could unintentionally result in the application of Medicaid standards to the non-Medicaid lines of business offered by the single legal entity. For example, if a state defines the entity subject to the contract through reference to something shared across lines of business, such as licensure as an insurer, both the Medicaid MCO and QHP could be subject to the terms of the contract with the state. To prevent ambiguity and overly broad restrictions, contracts should contain specific language to clearly define the state’s intent that the contract is specific to the Medicaid plan being offered by the entity. This becomes critically important in the case of a single legal entity operating Medicaid and non-Medicaid lines of business. We recommended that states and Medicaid managed care plans review their contracts to ensure that it clearly defined each party’s rights and responsibilities.

Consumers who experience periodic transitions between Medicaid and QHP eligibility, and families who have members who are divided between Medicaid and QHP coverage may prefer an issuer that offers both types of products. Improving coordination of care and minimizing disruption to care is best achieved when the consumer has sufficient information about coverage options when making a plan selection. We noted that our proposed revisions would enable more complete and effective information sharing and consumer education while still upholding the intent of the Medicaid beneficiary protections detailed in the Act. Section 438.104 alone does not prohibit a managed care plan from providing information on a QHP to enrollees who could potentially enroll in a QHP as an alternative to the Medicaid plan due to a loss of eligibility or to potential enrollees who may consider the benefits of selecting an MCO, PIHP, PAHP, or PCCM that has a related QHP in the event of future eligibility changes. We proposed minimum marketing standards that a state would be able to build on as part of its contracts with entities providing Medicaid managed care.

Finally, we had received inquiries about the use of social media outlets for dissemination of marketing information about Medicaid managed care. The definition of “marketing” in § 438.104 includes “any communication from” an entity that provides Medicaid managed care (including MCOs, PIHPs, PAHPs, etc.) and “marketing materials” include materials that are produced in any

medium. These definitions are sufficiently broad to include social media and we noted in the proposed rule that we intended to interpret and apply § 438.104 as applicable to communication via social media and electronic means.

In paragraph (b)(1)(v), we proposed to clarify the regulation text by adding unsolicited contact by email and texting as prohibited cold-call marketing activities. We believed this revision necessary given the prevalence of electronic forms of communication.

We intended the proposed revisions to clarify, for states and issuers, the scope of the marketing provisions in § 438.104, which generally are more detailed and restrictive than those imposed on QHPs under 45 CFR 156.225. We indicated that while we believed that the Medicaid managed care regulation correctly provided significant protections for Medicaid beneficiaries, we recognized that the increased prevalence in some markets of issuers offering both QHP and Medicaid products and sought to provide more clear and targeted Medicaid managed care standards with our proposed changes.

We received the following comments in response to our proposal to revise § 438.104.

Comment: We received many supportive comments for the proposed clarification in § 438.104 that QHPs, as defined in 45 CFR 155.20, be excluded from the definitions of marketing and private insurance, as used in part 438. Commenters believed this would benefit enrollees and potential enrollees by providing them with more comprehensive information and enable them to make a more informed managed care plan selection.

Response: We thank the commenters for their support of the proposed clarification regarding the applicability of § 438.104 to QHPs.

Comment: One commenter recommended that CMS not allow the non-benefit component of the capitation rate to include expenses associated with marketing by managed care plans, and only permit expenses related to communications that educate enrollees on services and behavioral changes as a permissible type of non-benefit expense.

Response: Marketing is permitted under section 1932(d)(2) of the Act, subject to the parameters specified in § 438.104; therefore, we decline to remove proposed § 438.104 or to add a prohibition on marketing altogether. Marketing conducted in accordance with § 438.104 would be a permissible component of the non-benefit costs of the capitation rate.

Comment: We received several comments on the definition of marketing in proposed § 438.104(a). A few commenters requested that CMS clarify that a managed care plan sending information to its enrollees addressing only healthy behavior, covered benefits, or the managed care plan's network was not considered marketing. A few commenters requested that CMS clarify that incentives for healthy behaviors or receipt of services (such as baby car seats) and sponsorships by a managed care plan (such as sporting events) are not considered marketing. We also received a comment requesting that CMS clarify that health plans can market all of their lines of business at public events, even if Medicaid-enrolled individuals may be in attendance.

Response: We agree that a managed care plan sending information to its enrollees addressing healthy behaviors, covered benefits, the managed care plan's network, or incentives for healthy behaviors or receipt of services (for example, baby car seats) would not meet the definition of marketing in § 438.104(a). However, use of this information to influence an enrollment decision by a potential enrollee is marketing. In § 438.104(a), marketing is defined as a communication by an MCO, PIHP, PAHP, PCCM or PCCM entity to a Medicaid beneficiary that is not enrolled with that MCO, PIHP, PAHP, PCCM or PCCM that could reasonably be interpreted to influence the beneficiary to change enrollment to the organization that sent the communication. The act of sponsorship by a managed care plan may be considered communication under the definition of marketing if the state determines that the sponsorship does not comply with § 438.104 or any state marketing rules; managed care plans should consult with their state to determine the permissibility of such activity. In addition, managed care plans should consult their contracts and state Medicaid agency to determine if other provisions exist that may prohibit or limit these types of activity. We appreciate the opportunity to also clarify that providing information about a managed care plan's other lines of business at a public event where the Medicaid eligibility status of the audience is unknown also would not be prohibited by the provisions of § 438.104. However, marketing materials at such events that are about the Medicaid health plan are subject to § 438.104(b) and (c). Materials or activities that are limited to other private insurance that is offered by an entity that also offers the Medicaid

managed care contract would not be within the scope of § 438.104. We believe that at public events where a consumer approaches the managed care plan for information, the provisions of § 438.104 do not prohibit a managed care plan from responding truthfully and accurately to the consumer's request for information. While the circumstance described in the comment does not appear to violate § 438.104, managed care plans should consult their contract and the state Medicaid agency to ascertain if other prohibitions or limitations on these types of activity exist.

Comment: A few commenters requested that CMS codify the information published in FAQs on Medicaid.gov in January 2015² that clarified that managed care plans are permitted to provide information to their enrollees about their redetermination of eligibility obligation.

Response: As published in the FAQs on January 16, 2015, there is no provision in § 438.104 specifically addressing a Medicaid managed care plan's outreach to enrollees for eligibility redetermination purposes; therefore, the permissibility of this activity depends on the Medicaid managed care plan's contract with the state Medicaid agency. Materials and information that purely educate an enrollee of that Medicaid managed care plan on the importance of completing the State's Medicaid eligibility renewal process in a timely fashion would not meet the federal definition of marketing. However, Medicaid managed care plans should consult their contracts and the state Medicaid agency to ascertain if other provisions exist that may prohibit or limit such activity. We believe that addressing this issue in the 2015 FAQs and again in this response is sufficient and decline to revise § 438.104.

Comment: One commenter recommended that CMS prohibit QHP marketing materials from referencing Medicaid or the Medicaid managed care plan. Another commenter recommended that CMS exempt a Medicaid managed care plan that is also a QHP from all of the provisions in § 438.104. Another commenter recommended that CMS prohibit QHPs from doing targeted marketing, such as to healthy populations.

Response: We do not agree with the commenter that QHPs should be prohibited from referencing their Medicaid managed care plan in their materials. Further, this Medicaid managed care regulation is not the

forum in which to regulate QHPs directly, as opposed to regulating the activities of Medicaid managed care plans that are also (or also offer) QHPs. We believe that the inclusion of information on a QHP and the Medicaid managed care plan from the same issuer could provide potential enrollees and enrollees with information that will enable them to make more informed managed care plan selections. To the comment recommending exemption from § 438.104 when the Medicaid managed care plan is the QHP, that is not possible since the Medicaid managed care plan must be subject to § 438.104 to be compliant with section 1932(d)(2) of the Act. Additionally, some provisions in § 438.104 are critical beneficiary protections, such as the prohibitions on providing inaccurate, false or misleading information. As explained in the preamble, to prevent ambiguity and overly broad restrictions, contracts should contain specific language to clearly define the state's intent and address whether the contract is specific to the Medicaid plan being offered by the entity or imposes obligations in connection with other health plans offered by the same entity. This becomes critically important in the case of a single legal entity operating Medicaid and non-Medicaid lines of business. To the comment regarding QHPs targeting their marketing efforts, placing prohibitions on QHPs that are not the managed care plan is outside the scope of this rule. However, as discussed above in this response, if the QHP and the Medicaid managed care plan are the same legal entity and the managed care plan's contract with the state Medicaid agency is not sufficiently clear, then the provisions of § 438.104 could be incorporated into the contract to apply to the QHP. As stated in the preamble to the proposed rule, we recommend that states and Medicaid managed care plans review their contracts to ensure that they clearly define each party's rights and responsibilities in this area.

Comment: Several commenters recommended that § 438.104(a) exempt all types of health care coverage from the definition of Private Insurance. The commenters believed that issuers should be able to provide information to potential enrollees and enrollees on all of the sources of coverage and health plan products that they offer, including Medicare Advantage (MA), D-SNPs, and FIDE SNPs.

Response: We do not agree that the definition of Private Insurance in § 438.104(a) should exempt all types of health care coverage. We specifically proposed, and finalized, an exemption

² <https://www.medicaid.gov/federal-policy-guidance/federal-policy-guidance.html>.

for QHPs because of the high rate of Medicaid beneficiaries that move between Medicaid and the Marketplace, sometimes within short periods of time, and QHPs are provided through the private market. In the past, we have received questions as to whether “private insurance” included QHPs since QHPs are provided in the private market. As discussed in the proposed rule (80 FR 31102), section 1932(d)(2)(C) of the Act, which is implemented at § 438.104(b)(1)(iv), prohibits the influence of enrollment into a Medicaid managed care plan with the sale or offering of any private insurance. Since 2002, the “offering of any private insurance” has been interpreted as any other type of insurance, unrelated of its relationship to health insurance, such as burial insurance. The explicit exemption for QHPs was to avoid any confusion that “private insurance” included health insurance policies through the private market. Types of health care coverage, such as integrated D-SNPs, are public health benefit programs that are not insurance. Therefore, they cannot be considered “private insurance.”

Comment: One commenter recommended that CMS remove the definition of private insurance proposed in § 438.104(a). The commenter believes it could cause confusion since QHPs have been called private plans in other public documents and references. One commenter stated that by excluding QHPs from the definition of “private insurance,” some readers may assume that CMS intended to imply that QHPs were considered public plans. The commenter requested that CMS clarify its intent to be clear that QHPs are not public plans for the purposes of discount cards, copayment assistance, and coupon programs.

Response: We understand the commenter’s concern but do not agree that the definition and use of the term “private insurance” in § 438.104(a) and (b)(iv) will cause confusion for other uses of the term in other contexts. We also do not agree that consumers will infer that because we excluded QHPs from the definition of private insurance in § 438.104(a) and (b)(iv) that they are to be considered public plans. We do not believe our definition will have implications for discount cards, copayment assistance, and coupon programs. Proposed § 438.104(a) limits the definition of “private insurance” to the context of § 438.104 and we believe that disclaimer is sufficient to avoid confusion over the use of “private insurance” in other contexts and for other purposes.

Comment: We received one comment pointing out that, inconsistent with the rest of § 438.104, the definition of marketing materials in proposed § 438.104(a) does not include “PCCM entity” in paragraph (1).

Response: We appreciate the commenter bringing this omission to our attention; we are revising the definition of marketing materials to include the term “PCCM entity” in this final rule.

Comment: One commenter suggested that CMS consider making the marketing regulation apply to both prospective and existing plan membership and allow issuers to provide information on their QHP to existing plan Medicaid membership, as well as individuals who may lose eligibility with another managed care plan.

Response: We interpret the comment to reference an issuer that is both a QHP and a Medicaid managed care plan. Regardless whether the state contracts with a Medicaid managed care plan (or other state regulation of QHPs), § 438.104 as amended in this final rule does not prohibit a Medicaid managed care plan from including materials about a QHP in the Medicaid plan’s marketing materials. However, such materials are subject to all provisions in § 438.104, including requirements that the marketing materials be reviewed by the state prior to distribution and be distributed throughout the entire service area of the Medicaid managed care plan. Whether potential enrollees within the service area are enrolled in another Medicaid managed care plan or QHP is not relevant.

Communication from the Medicaid managed care plan to its current enrollees is not within the definition of marketing in § 438.104(a); the definition is clear that marketing is communication to a Medicaid beneficiary who is not enrolled in that plan. Communications to the managed care plan’s current enrollees, however, are subject to § 438.10.

Comment: We received a few comments suggesting that CMS require that plans that develop marketing materials for specific populations, ethnicities, and cultures be required to produce those materials in the prevalent non-English languages in that state.

Response: While this suggestion may make marketing materials more effective, we decline to add it as a requirement in § 438.104. In proposed § 438.10(d)(4), we did specify that written materials that are critical to obtaining services must be translated into the prevalent non-English languages in the state. We do not believe

marketing materials are critical to obtaining services.

Comment: A few commenters recommended that the state must review marketing materials as proposed in § 438.104(c) for accuracy of information, language, reading level, comprehensibility, cultural sensitivity and diversity; to ensure that the managed care plan does not target or avoid populations based on their perceived health status, disability, cost, or for other discriminatory reasons; and that materials are not misleading for a person not possessing special knowledge regarding health care coverage.

Response: We agree with the suggestions offered by these commenters for state review of marketing materials. However, we believe accuracy of information, language, reading level, comprehensibility, cultural sensitivity and diversity, and ensuring materials are not misleading are already addressed in § 438.104 (b)(1)(iii) and (b)(2); we expect that state review of marketing materials will include the full scope of standards in the rule and in the state contract. In considering the commenters’ concern that managed care plans may target or avoid populations based on their perceived health status, cost, or for other discriminatory reasons, we remind commenters that all contracts must comply with § 438.3(f)(1) regarding anti-discrimination laws and regulations. Section 438.104 (b)(1)(ii) adds an additional protection by requiring that managed care plans distribute marketing materials to their entire service area, thus lessening the ability to target certain populations. We decline to revise § 438.104 in response to these comments.

Comment: Some commenters suggested that CMS permit flexibility for states to determine which materials should be subject to review in proposed § 438.104(c), particularly when using social media outlets. A few commenters also requested flexibility on the use of the Medical Care Advisory Committee as referenced in proposed § 438.104(c). We received one comment suggesting that any materials being sent to enrollees, including those from a QHP, be reviewed and approved by the state.

Response: We do not agree that states should have flexibility to identify which marketing materials they must review. Section 1932(d)(2)(A)(i)(I) of the Act requires state approval of marketing materials of MCOs and PCCMs, before distribution. Likewise, section 1932 (d)(2)(A)(ii) of the Act requires consultation with a Medical Care Advisory Committee by the state in the

process of reviewing and approving such materials. We believe these provisions are clear about the requirements for MCOs and PCCMs and we have extended those requirements to PIHPs and PAHPs; we do not see a basis for adopting different rules for PIHPs and PAHPs in connection with state review.

Comment: We also received one comment that managed care plans may be unclear about what they can do to coordinate benefits across Medicaid managed care and MA lines of business for individuals who are dually eligible without it being categorized as marketing.

Response: It is unclear how activities performed for coordination of benefits would be confused with marketing activities, given that the purpose of these two types of activities is completely unrelated. The commenter should consult with their state for clarification.

Comment: We received one comment that requested that CMS allow managed care plans to conduct marketing activities during the QHP open enrollment period.

Response: We want to clarify that the provisions of proposed § 438.104 do not specify times of the year when managed care plans are permitted or prohibited from conduct marketing activities. Managed care plans are allowed to market consistent with state approval.

Comment: We received a few comments requesting that CMS permit agents, brokers, and providers to conduct marketing activities for managed care plans.

Response: Section 438.104(a) provides that MCO, PIHP, PAHP, PCCM or PCCM entity includes any of the entity's employees, network providers, agents, or contractors. As such, any person or entity that meets this definition is subject to the provisions of § 438.104 and may only conduct marketing activities on behalf of the plan consistent with the requirements of § 438.104, including state approval.

After consideration of the public comments, we are adopting these provisions as proposed with the revision to the definition of marketing materials to include PCCM entities, as discussed above.

b. Appeals and Grievances (§§ 438.228, 438.400, 438.402, 438.404, 438.406, 438.408, 438.410, 438.414, 438.416, 438.424, 431.200, 431.220 and 431.244)

We proposed several modifications to the current regulations governing the grievance and appeals system for Medicaid managed care to further align and increase uniformity between rules

for Medicaid managed care and rules for MA managed care, private health insurance, and group health plans. As we noted in the preamble to the proposed rule, the existing differences between the rules applicable to Medicaid managed care and the various rules applicable to MA, private insurance, and group health plans concerning grievance and appeals processes inhibit the efficiencies that could be gained with a streamlined grievance and appeals process that applies across markets. A streamlined process would make navigating the appeals system more manageable for consumers who may move between coverage sources as their circumstances change. Our proposed changes in subpart F of part 438 would adopt new definitions, update appeal timeframes, and align certain processes for appeals and grievances. We also proposed modifying §§ 431.200, 431.220 and 431.244 to complement the changes proposed to subpart F of part 438.

We are concerned that the different appeal and grievance processes for the respective programs and health coverage causes: (1) Confusion for beneficiaries who are transitioning between private health care coverage or MA coverage and Medicaid managed care; and (2) inefficiencies for health insurance issuers that participate in both the public and private sectors. We proposed to better align appeal and grievance procedures across these areas to provide consumers with a more manageable and consumer friendly appeals process and allow health insurers to adopt more consistent protocols across product lines.

The grievance, organization determination, and appeal regulations in 42 CFR part 422, subpart M, govern grievance, organization determinations, and appeals procedures for MA members. The internal claims and appeals, and external review processes for private insurance and group health plans are found in 45 CFR 147.136. We referred to both sets of standards in reviewing current Medicaid managed care regulations regarding appeals and grievances. (1) §§ 431.200, 431.220, 431.244, subpart F, part 438, and § 438.228.

Two of our proposals concerning the grievance and appeals system for Medicaid managed care were for the entire subpart. First, we proposed to add PAHPs to the types of entities subject to the standards of subpart F and proposed to revise text throughout this subpart accordingly. Currently, subpart F only applies to MCOs and PIHPs. Unlike MCOs which provide comprehensive benefits, PIHPs and PAHPs provide a

narrower benefit package. While PIHPs were included in the standards for a grievance system in the 2002 rule, PAHPs were excluded. At that time, most PAHPs were, in actuality, capitated PCCM programs managed by individual physicians or small group practices and, therefore, were not expected to have the administrative structure to support a grievance process. However, since then, PAHPs have evolved into arrangements under which entities—private companies or government subdivisions—manage a subset of Medicaid covered services such as dental, behavioral health, and home and community-based services. Because some PAHPs provide those medical services which typically are subject to medical management techniques such as prior authorization, we believe PAHPs should be expected to manage a grievance process, and therefore, proposed that they be subject to the grievance and appeals standards of this subpart. In adding PAHPs to subpart F, our proposal would also change the current process under which enrollees in a PAHP may seek a state fair hearing immediately following an action to deny, terminate, suspend, or reduce Medicaid covered services, or the denial of an enrollee's request to dispute a financial liability, in favor of having the PAHP conduct the first level of review of such actions. We relied on our authority at sections 1902(a)(3) and 1902(a)(4) of the Act to propose extending these appeal and grievance provisions to PAHPs.

We note that some PAHPs receive a capitated payment to provide only NEMT services to Medicaid beneficiaries; for these NEMT PAHPs, an internal grievance and appeal system does not seem appropriate. The reasons for requiring PAHPs that cover medical services to adhere to the grievance and appeals processes in this subpart are not present for a PAHP solely responsible for NEMT. We proposed to distinguish NEMT PAHPs from PAHPs providing medical services covered under the state plan. Consequently, we proposed that NEMT PAHPs would not be subject to these internal grievance and appeal standards. Rather, beneficiaries receiving services from NEMT PAHPs will continue to have direct access to the state fair hearing process to appeal adverse benefit determinations, as outlined in § 431.220. We requested comment on this approach.

As a result of our proposal to have PAHPs generally follow the provisions of subpart F of part 438, we also proposed corresponding amendments to §§ 431.220 and 431.244 regarding state fair hearing requirements, and changes

to § 431.244 regarding hearing decisions. In § 431.220(a)(5), we proposed to add PAHP enrollees to the list of enrollees that have access to a state fair hearing after an appeal has been decided in a manner adverse to the enrollee; and in § 431.220(a)(6), we proposed that beneficiaries receiving services from NEMT PAHPs would continue to have direct access to the state fair hearing process. We proposed no additional changes to § 431.220. In § 431.244, as in part 438 subpart F generally, in each instance where MCO or PIHP is referenced, we proposed to add a reference to PAHPs.

Second, throughout subpart F, we proposed to insert “calendar” before any reference to “day” to remove any ambiguity as to the duration of timeframes. This approach is consistent with the timeframes specified in regulations for the MA program at 42 CFR part 422, subpart M.

We did not propose any changes to § 438.228 but received comments that require discussion of that provision in this final rule. We received the following comments in response to our proposals.

Comment: Many commenters supported CMS’ proposal to insert “calendar” before “day” to remove ambiguity as to the duration of timeframes throughout subpart F. Many commenters also supported the CMS proposal to add PAHPs to the types of entities subject to the standards of subpart F of this part. A few commenters recommended that CMS add NEMT PAHPs to the types of entities subject to the standards, while a few commenters agreed with the CMS proposal to exclude NEMT PAHPs and allow beneficiaries receiving services from NEMT PAHPs to continue to have direct access to the state fair hearing process.

Response: We thank commenters for their support regarding our proposal to insert “calendar” before “day” to remove ambiguity as to the duration of timeframes throughout subpart F. We also thank the commenters who supported our proposal to make non-NEMT PAHPs subject to the appeal and grievance system requirements in subpart F. For adding NEMT PAHPs to the types of entities subject to the same standards, we restate our position that it seems unreasonable and inappropriate for such entities to maintain an internal grievance and appeal system, as these entities only receive a capitated payment to provide NEMT. We believe that it is more efficient to allow beneficiaries who receive services from NEMT PAHPs to continue to have direct access to the state fair hearing process

to appeal adverse benefit determinations.

Comment: A few commenters recommended that CMS allow additional time for states and managed care plans to establish and implement their grievance and appeal systems to comply with the requirements for subpart F of this part. One commenter recommended that CMS give states and managed care plans 6 months to come into compliance with subpart F of this part. One commenter recommended that CMS give states and managed care plans 18 months to come into compliance with subpart F of this part, as the new requirements are so extensive.

Response: We appreciate the commenters’ recommendations on how much time CMS should allow for states and managed care plans to come into compliance with subpart F of this part. We believe that the changes and revisions throughout subpart F of this part are consistent with the standards in MA and the private market. We did not propose a separate, or longer, compliance timeframe for these revisions to the appeal and grievance system and do not believe that additional time is necessary. Therefore, we decline to give states and managed care plans an additional 6 months or 18 months to specifically come into compliance with the standards and requirements in subpart F of this part. Contracts starting on or after July 1, 2017, must be compliant with the provisions in subpart F.

After consideration of the public comments, we are finalizing our proposal to add PAHPs (other than NEMT PAHPs) to the types of entities subject to the standards of subpart F of this part and our proposal to insert “calendar” before any reference to the “day” regarding duration of timeframes throughout subpart F of this part.

Comment: A few commenters recommended that CMS clarify at § 438.228(a) that appeals are included as part of the state’s grievance system.

Response: We agree with commenters that § 438.228(a) should be revised to clarify that each managed care plan must have a grievance and appeal system that meets the requirements of subpart F of this part. We are modifying the regulatory text, as recommended, to explicitly address this. We note that commenters recommended this change throughout subpart F of this part to clarify that a state’s grievance system was inclusive of appeals. We have made this change throughout subpart F of this part as recommended.

Comment: A few commenters recommended that CMS revise the term “action” to “adverse benefit

determination” at § 438.228(b) to be consistent with subpart F of this part.

Response: We clarify for commenters that § 438.228(b) refers to the “action” specified under subpart E of part 431. It would not be appropriate to revise the term “action,” as this term is used in subpart E of part 431 and was not proposed to be changed. However, during our review of these public comments, we identified a needed revision in § 431.200 to update the terminology from “takes action” to “adverse benefit determination” when referring to subpart F of part 438 of this chapter. We have revised the term “action” to “adverse benefit determination” in subpart F of part 438 and revised the phrase “takes action” to “adverse benefit determination” in § 431.200 when referring to subpart F of part 438 of this chapter.

Comment: A few commenters recommended that CMS revise the language “dispose” and “disposition” to “resolve” and “resolution” throughout subpart F of this part to be consistent when referring to the final resolution of an adverse benefit determination.

Response: We agree with commenters that the terms “dispose” and “disposition” should be revised to “resolve” and “resolution” to be consistent throughout subpart F of this part when referring to the final resolution of an adverse benefit determination. We are modifying the regulatory text accordingly in this final rule.

After consideration of the public comments, we are modifying the regulatory text at § 438.228(a) to include the term “appeal” when referencing the grievance system and to be inclusive of both grievances and appeals. Since commenters recommended this change throughout subpart F of this part, we have made this change accordingly as recommended. We are also replacing the terms “dispose” and “disposition” with “resolve” and “resolution” in connection with an appeal and grievance throughout our finalization of subpart F of this part when referring to the final resolution of an adverse benefit determination; this ensures that the phrasing for appeals and grievances is consistent. Finally, we are modifying § 431.200 to update the terminology from “takes action” to “adverse benefit determination” when referring to subpart F of part 438 of this chapter.

(2) Statutory Basis and Definitions (§ 438.400)

In general, the proposed changes for § 438.400 are to revise the definitions to provide greater clarity and to achieve alignment and uniformity for health

care coverage offered through Medicaid managed care, private insurance and group health plans, and MA plans. We did not propose to change the substance of the description of the authority and applicable statutes in § 438.400(a) but proposed a more concise statement of the statutory authority.

In § 438.400(b), we proposed a few changes to the defined terms. First, we proposed to replace the term “action” with “adverse benefit determination.” The proposed definition for “adverse benefit determination” included the existing definition of “action” and revisions to include determinations based on medical necessity, appropriateness, health care setting, or effectiveness of a covered benefit in revised paragraph (b)(1). We believed this would conform to the term used for private insurance and group health plans and would lay the foundation for MCOs, PIHPs, or PAHPs to consolidate processes across Medicaid and private health care coverage sectors. By adopting a uniform term for MCO, PIHP, or PAHP enrollees and enrollees in private insurance and group health plans, we hoped to enable consumers to identify similar processes between lines of business, and be better able to navigate different health care coverage options more easily. Our proposal was also to update cross-references to other affected regulations, delete the term “Medicaid” before the word “enrollee,” and consistently replace the term “action” in the current regulations in subpart F with the term “adverse benefit determination” throughout this subpart.

In addition to using the new term “adverse benefit determination,” we proposed to revise the definition of “appeal” to be more accurate in describing an appeal as a review by the MCO, PIHP, or PAHP, as opposed to the current definition which defines it as a request for a review. In the definition of “grievance,” we proposed a conforming change to delete the reference to “action,” to delete the part of the existing definition that references the term being used to mean an overall system, and to add text to clarify the scope of grievances.

For clarity, we proposed to separately define “grievance system” as the processes the MCO, PIHP, or PAHP implements to handle appeals and grievances and collect and track information about them. By proposing a definition for “grievance system,” we intended to clarify that a MCO, PIHP, or PAHP must have a formal structure of policies and procedures to appropriately address both appeals and grievances. We also proposed to remove the reference to the state’s fair hearing

process from this definition as it is addressed in part 431, subpart E. This continued to be a significant source of confusion, even after the changes were made in the 2002 final rule, and these proposed changes were intended to add clarity.

We received the following comments in response to our proposal to revise § 438.400.

Comment: A few commenters requested that CMS clarify the statutory authority at § 438.400(a) regarding changes to the grievance and appeal system in general, as well as the statutory authority to align timeframes with MA and/or the private market.

Response: We appreciate the opportunity to clarify the statutory authority summarized at § 438.400(a). As noted in the authority for part 438 generally, section 1102 of the Act provides authority for CMS to adopt rules to interpret, implement, and administer the Medicaid program. Section 1902(a)(3) of the Act requires that a state plan provide an opportunity for a fair hearing to any person whose claim for assistance is denied or not acted upon promptly. Section 1932(b)(4) of the Act is the statutory authority that requires MCOs to offer an internal grievance and appeal system. Subpart F, as a whole and as finalized in this rule, implements these requirements and sets standards for how a Medicaid program complies with these when an MCO is used to provide Medicaid covered services to beneficiaries. Section 1902(a)(4) of the Act requires that the state plan provide for methods of administration that the Secretary finds necessary for the proper and efficient operation of the plan and is the basis for extending the internal grievance and appeal system to PIHPs and PAHPs. We also rely on section 1902(a)(4) of the Act to align grievance and appeal timeframes with either MA and/or the private market to build efficiencies both inside Medicaid, including for managed care plans, and across public and private programs.

Comment: Many commenters recommended changes to the definition of “adverse benefit determination” at § 438.400(b). Several commenters stated that the CMS proposal to change and expand the definition from “action” to “adverse benefit determination” will create confusion for enrollees and result in additional administrative burden and costs to managed care plans and states to change existing policies and materials. Several commenters stated that the definition is not broad enough and should be expanded to include more options for enrollees to request an appeal. Several commenters supported

the proposed definition and applauded the effort to align the definition across health care markets. Several commenters specifically recommended that CMS revise the definition of “adverse benefit determination” to include disputes regarding an enrollee’s financial liability, such as deductibles, copayments, coinsurance, premiums, health spending accounts, out-of-pocket costs, and/or other enrollee cost sharing. A few commenters also recommended that CMS revise the definition of “adverse benefit determination” to include disputes regarding an enrollee’s request to receive services outside of the managed care plan’s network or an enrollee’s choice of provider.

Response: We appreciate the opportunity to consider commenters’ recommendations regarding the definition of “adverse benefit determination” at § 438.400(b). We disagree with commenters who believed the change from “action” to “adverse benefit determination” will be confusing to enrollees, as the term “adverse benefit determination” is the standard terminology used throughout the health care industry. We favor aligning terms across health care markets and programs as much as possible to support enrollees who may transition across health care coverage options.

We agree with commenters that the definition should be broadened to include potential enrollee financial liability, as we recognize that state Medicaid programs have some discretion regarding cost sharing and there can be variations in financial requirements on enrollees. We are modifying the regulatory text to adopt this recommendation.

For broadening the definition to include disputes regarding an enrollee’s request to receive services outside of the managed care plan’s network or an enrollee’s choice of provider, we do not believe it is necessary to include this specifically in the definition of “adverse benefit determination.” Section 438.206(b)(4), as proposed and as we would finalize, requires that managed care plans adequately and timely cover services outside of the network when the managed care plan’s network is unable to provide such services; the definition already includes the denial or limited authorization for a service and the denial of payment for a service, which we believe adequately includes a denial of a request to receive covered services from an out-of-network provider. The proposed definition also contains a provision for enrollees of rural areas with only one MCO to exercise their right to obtain services

outside of the managed care plan's network consistent with § 438.52(b)(2)(ii). We believe that broadening the definition of "adverse benefit determination" to include additional language specific to out-of-network services would be duplicative.

Comment: Many commenters recommended that CMS specifically define "medical necessity," "appropriateness," "health care setting," "effectiveness," and "denial of payment for a service" used within the definition of "adverse benefit determination." A few commenters also recommended that CMS remove references to "health care setting" or revise the language to "setting" within the definition of "adverse benefit determination" to be more inclusive of MLTSS programs and populations.

Response: We appreciate the recommendations about the terms used in the definition for an "adverse benefit determination." We disagree with commenters that we need to define the terms "medical necessity," "appropriateness," "health care setting," "effectiveness," and "denial of payment for a service" within that definition. We believe it is inappropriate for CMS to define these terms at the federal level when states need to define these terms when establishing and implementing their grievance and appeal system and procedures for their respective programs. That said, we do agree with commenters that the term "health care setting" may not be inclusive of MLTSS programs and populations; therefore, we will finalize the definition to use the term "setting" only.

Comment: A few commenters disagreed with the CMS proposal to revise the term "appeal" at § 438.400(b) and instead recommended that CMS retain the original language "a request for a review." Commenters stated that the current definition of "appeal" does not include any action by the enrollee.

Response: In the preamble of the proposed rule (80 FR 31104), we described the deletion of the phrase "request for review" in terms of accuracy. We proposed to revise the definition of "appeal" to add accuracy by stating that an appeal is a review by the MCO, PIHP, or PAHP, as opposed to the current definition, which defines it as a request for a review. This revision is consistent with MA and the private market. In light of these public comments and to add clarity to the regulation text, we will add the term "request" throughout subpart F of part 438 when referring to "filing" an appeal. We will retain the proposed language for "filing" a grievance.

Specifically, we will make this change in §§ 438.402(c)(1)(i) and (ii), 438.402(c)(2)(i) and (ii), 438.402(c)(3)(i) and (ii), 438.404(b)(3), 438.404(c)(4)(i), and 438.408(c)(2)(ii). We believe this change will add accuracy to the regulation text as commenters requested. We will retain and finalize the definition of "appeal" as proposed.

Comment: Several commenters recommended that CMS clarify why the definition of "grievance system" at § 438.400(b) includes appeals, but the definition of "grievance" is not the same as an "appeal." Commenters stated concern that enrollees might be confused by the inconsistency in the language. A few commenters also recommended that CMS retitle subpart F of this part to include appeals.

Response: We agree with commenters that clarification is needed to ensure consistency throughout subpart F of this part. Therefore, we agree with commenters that subpart F of this part should be retitled "Grievance and Appeal System" to be inclusive of both grievances and appeals. We note that the longstanding title of subpart F was based on section 1932(b)(4) of the Act. We also agree with commenters that the definition "grievance system" should be revised to "grievance and appeal system" to be inclusive of both grievances and appeals. We are modifying the regulatory text in the definitions in § 438.400 and throughout subpart F to adopt these recommendations.

After consideration of the public comments, we are finalizing § 438.400 as proposed with several modifications. In the final definition of "adverse benefit determination" in § 438.400(b), we are adding to the proposed text a new category that addresses potential enrollee financial liability; we are also modifying the definition to replace the term "health care setting" with "setting" to be inclusive of MLTSS programs and populations.

We are also modifying the regulatory text to retitle subpart F of this part as "Grievance and Appeal System" to be inclusive of both grievances and appeals and revising the term "grievance system," defined in § 438.400(b) and throughout subpart F of part 438, to "grievance and appeal system" to be inclusive of both grievances and appeals. We are also modifying the regulation text to add the term "request" throughout subpart F of part 438 when referring to "filing" an appeal to improve clarity and accuracy. We are finalizing all other provisions in § 438.400 as proposed.

(3) General Requirements (§ 438.402)

We proposed in paragraph (a) to add "grievance" in front of "system" and to delete existing language that defines a system in deference to the proposed new definition added in § 438.400. We also proposed to add text to clarify that subpart F does not apply to NEMT PAHPs.

In paragraph (b), we proposed to revise the paragraph heading to "Level of appeals" and limit MCOs, PIHP, and PAHPs to only one level of appeal for enrollees to exhaust the managed care plan's internal appeal process. Once this single level appeal process is exhausted, the enrollee would be able to request a state fair hearing under subpart E of part 431. In conjunction with this proposal, we proposed amending § 438.402(c)(1)(i) and § 438.408(f) with corresponding text that would have enrollees exhaust their MCO, PIHP, or PAHP appeal rights before seeking a state fair hearing. Our proposal was designed to ensure that the MCO, PIHP, or PAHP process will not be unnecessarily extended by having more than one level of internal review. This proposal was consistent with the limit on internal appeal levels imposed on issuers of individual market insurance under 45 CFR 147.136(b)(3)(ii)(G) and MA organizations at § 422.578, although we acknowledge that issuers of group market insurance and group health plans are not similarly limited under 45 CFR 147.136(b)(2) and 29 CFR 2560.503-1(c)(3). We believed this proposal would not impair the administrative alignment we seek in this context and ensure that enrollees can reach the state fair hearing process within an appropriate time. We requested comment on this proposal.

In paragraph (c)(1)(i), we proposed to revise this section to permit an enrollee to request a state fair hearing after receiving notice from the MCO, PIHP, or PAHP upholding the adverse benefit determination. We proposed in paragraph (c)(1)(ii) to remove the standard for the enrollee's written consent for the provider to file an appeal on an enrollee's behalf. The current standard is not specified in section 1932(b)(4) of the Act and is inconsistent with similar MA standards for who may request an organization determination or a reconsideration at §§ 422.566(c)(1)(ii) and 422.578, so we believe it is not necessary.

We proposed in paragraph (c)(2) to delete the state's option to select a timeframe between 20 and 90 days for enrollees to file a request for an appeal and proposed to revise paragraphs (c)(2)(i) and (ii) to set the timing

standards for filing grievances (at any time) and requesting appeals (60 calendar days), respectively. For grievances, we do not believe that grievances need a filing limit as they do not progress to a state fair hearing and thus do not need to be constrained by the coordination of timeframes. For appeals, we proposed paragraph (c)(2)(ii) to permit an enrollee or provider to request an appeal within 60 calendar days of receipt of the notice of an adverse benefit determination. Medicare beneficiaries in a MA plan and enrollees in private health care coverage each have 60 calendar days to request an appeal under regulations governing MA plans (§ 422.582) and private insurance and group health plans (45 CFR 147.136(b)(2) and (b)(3) and 29 CFR 2560.503-1(h)(2)). By adjusting the timeframe for MCO, PIHP, or PAHP enrollees to request appeals to 60 calendar days from the date of notice of the adverse decision, our proposal would achieve alignment and uniformity across Medicaid managed care plans, MA organizations, and private insurance and group health plans, while ensuring adequate opportunity for beneficiaries to appeal. We note that the existing provisions of § 438.402(b)(2)(i) were subsumed into our proposal for paragraphs (c)(1)(i) and (ii) while the existing provisions of paragraph (b)(2)(ii) would be deleted consistent with our proposal in § 438.408(f)(1) concerning exhaustion of the MCO's, PIHP's, or PAHP's appeal process.

In paragraph (c)(3), we proposed to add headings to paragraphs (c)(3)(i) and (c)(3)(ii) and to make non-substantive changes to the text setting forth the procedures by which grievances are filed or appeals are requested. Under our proposal, as under current law, a standard grievance may be filed or an appeal may be requested orally or in writing (which includes online), and standard appeal requests made orally must be followed up in writing by either the enrollee or the enrollee's authorized representative. Expedited appeal requests may be requested either way, and if done orally, the enrollee does not need to follow up in writing.

We requested comment on the extent to which states and managed care plans are currently using or plan to implement an online system that can be accessed by enrollees for filing and/or status updates of grievances and appeals. If such systems are not in use or in development, we requested comment on the issues influencing the decision not to implement such a system and whether an online system for tracking the status of grievances and appeals

should be required at the managed care plan level.

We received the following comments in response to our proposal to revise § 438.402.

Comment: Many commenters supported proposed § 438.402(b) which limits each MCO, PIHP, and PAHP to only one level of appeal for enrollees. Many commenters supported the goals of alignment, administrative simplification, and efficiency for both managed care plans and enrollees. Many commenters also disagreed with our proposal to limit managed care plans to one level of appeal and offered a number of recommendations. These commenters recommended that CMS allow two levels of appeal for managed care plans, as a second level of appeal at the managed care plan can generally resolve the issue before proceeding to state fair hearing. Several commenters recommended that CMS allow states to define this process, as states have procedures in place today.

Response: We thank commenters for their thoughtful comments regarding proposed § 438.402(b). We agree with the comments that limiting managed care plans to one level of appeal is both efficient and beneficial to enrollees; such a limitation allows enrollees to receive a more expedient resolution to their appeal and minimizes confusion for enrollees during the appeals process. Aligning with the requirements of MA and the private market will promote administrative simplicity. We disagree with commenters that recommended that states be allowed to decide whether to limit Medicaid managed care plans to one level of appeal or not based on their state-specific program. We believe it is beneficial to create a national approach that aligns with other health care coverage options and will allow enrollees to transition across public and private health care programs with similar requirements. This consistency will aid enrollees in understanding the benefits of the appeal process and how to effectively utilize it regardless of which type of coverage they have.

Comment: Many commenters disagreed and offered alternative proposals regarding proposed § 438.402(c)(1)(i), which requires enrollees to exhaust the one level of appeal at the managed care plan before requesting a state fair hearing. Many commenters recommended that CMS continue to allow direct access or concurrent access to the state fair hearing, as this is a critical beneficiary protection, especially for vulnerable populations with complex, chronic, and special health care needs. Commenters stated that vulnerable populations might

be easily overburdened by the additional process and have health care needs that require an immediate review by an independent and impartial authority to prevent any further delays or barriers to care. Many commenters recommended that CMS allow state flexibility to ensure that current beneficiary protections in place today are not unnecessarily eroded. A few commenters stated that some states currently allow the state fair hearing in place of the managed care plan appeal and recommended that CMS retain this as an option.

Several commenters also recommended that CMS allow for an optional and independent external medical review, which is independent of both the state and the managed care plan. Commenters stated that such an optional external review can better protect beneficiaries and reduce burden on state fair hearings, as these external processes have proven to be an effective tool in resolving appeals before reaching a state fair hearing. Several commenters also recommended that CMS adopt the deemed exhaustion requirement from the private market rules at 45 CFR 147.136(b)(2)(ii)(F) to ensure that enrollees maintain access to a state fair hearing if the managed care plan does not adhere to the notice and timing requirements in § 438.408, including specific timeframes for resolving standard and expedited appeals. Finally, a few commenters supported the provision as proposed without change and stated that it builds a better relationship between enrollees and their managed care plans.

Response: We appreciate the many thoughtful and specific recommendations regarding proposed § 438.402(c)(1)(i) and recognize the need to carefully consider the impact of the exhaustion requirement on enrollees. While we understand commenters' concerns and recommendations regarding direct access to a state fair hearing for vulnerable populations, we also have concerns regarding inconsistent and unstructured processes. We believe that a nationally consistent and uniform appeals process (particularly one consistent with how other health benefit coverage works) benefits enrollees and will better lead to an expedited resolution of their appeal. As we proposed, this final rule shortens the managed care plan resolution timeframe for standard appeals from 45 days to 30 calendar days and shortens the managed care plan resolution timeframe for expedited appeals from 3 working days to 72 hours; we believe this will address concerns about the length of time an enrollee must wait

before accessing a state fair hearing. This final rule also lengthens the timeframe for enrollees to request a state fair hearing from a maximum of 90 days to 120 calendar days. We have aligned these timeframes with other public and private health care markets and believe this ultimately protects enrollees by establishing a national approach for a uniform appeals process. Therefore, CMS is not allowing direct access or concurrent access to the state fair hearing in this rule.

We also agree with commenters that adopting the deemed exhaustion requirement from the private market rules at 45 CFR 147.136(b)(2)(ii)(F) will ensure that enrollees maintain access to a state fair hearing if the managed care plan does not adhere to the notice and timing requirements in § 438.408, including specific timeframes for resolving standard and expedited appeals. In addition, this will further align the rules for the grievance and appeal system for Medicaid managed care plans with the system for private health insurance; we note as well that Medicare Advantage plans are subject to a somewhat similar standard under § 422.590(c) and (g) in that failure of a Medicare Advantage plan to resolve timely a reconsideration of an appeal decision results in the appeal being forwarded automatically to the next level of review. We also note that states would be permitted to add rules that deem exhaustion on a broader basis than this final rule. We are modifying the final text of § 438.402(c) and 438.408(f) to adopt the recommendation to add a deemed exhaustion requirement.

While we disagree with commenters that recommended that states be allowed to establish their own processes and timeframes for grievances and appeals that differ from the requirements of the proposed rule, we are persuaded by commenters' recommendations regarding an optional and independent external medical review. We agree with commenters that an optional, external medical review could better protect enrollees and be an effective tool in resolving appeals before reaching a state fair hearing. Under the rule we are finalizing here, if states want to offer enrollees the option of an external medical review, the review must be at the enrollee's option and must not be a requirement before or used as a deterrent to proceeding to the state fair hearing. Further, if states want to offer enrollees the option of an external medical review, the review must be independent of both the state and managed care plan, and the review must be offered without any cost to the

enrollee. Finally, this final rule requires that any optional external medical review must not extend any of the timeframes specified in § 438.408 and must not disrupt the continuation of benefits in § 438.420. Accordingly, the regulation text in this final rule at §§ 438.402(c)(1)(i)(B) and 438.408(f)(ii) adopts this recommendation.

Comment: Many commenters were opposed to the proposal in § 438.402(c)(1)(ii) to remove the requirement for the provider to obtain the enrollee's written consent before acting on the enrollee's behalf in requesting an appeal. Commenters stated that enrollees have the right to know and give their consent before a provider acts on their behalf. Commenters also stated concerns regarding potential conflicts of interest or potential fraud, waste, and abuse if the enrollee does not know that a provider is requesting an appeal on their behalf. Other commenters stated concern that without the enrollee's written consent, this could result in duplicative appeals from both providers and enrollees. A few commenters noted that because enrollees can be held financially liable for services received during an appeal, enrollees should be informed and give their explicit written consent before a provider requests an appeal on their behalf. A few commenters supported the proposed provision and stated that obtaining the enrollee's written consent is an unnecessary barrier to requesting the appeal. A few commenters also recommended that CMS remove the state's discretion in recognizing and permitting the provider to act as the enrollee's authorized representative. Several commenters also recommended that CMS expand the list of authorized representatives who can request appeals and grievances and request state fair hearings on the enrollee's behalf to include legal representatives, attorneys, enrollee advocates, legal guardians, and other representatives authorized by the enrollee to act on their behalf.

Response: We appreciate the many comments and recommendations regarding proposed § 438.402(c)(1)(ii). Given the volume of comments and potential issues raised by commenters, we were persuaded to modify our proposal and recognize the benefit of requiring a provider to obtain an enrollee's written consent before requesting an appeal on their behalf. We were particularly persuaded by commenters who noted that because enrollees can be held financially liable for services received during an appeal, enrollees should give their explicit written consent before a provider

requests an appeal on their behalf. Therefore, we will finalize the regulatory text to require that providers obtain the enrollee's written consent before requesting the appeal, consistent with the current rule.

However, we disagree with commenters regarding the recommendation to remove the state's discretion to recognize the provider as an authorized representative of the enrollee; we believe the state should be permitted to make this decision when designing and implementing their grievance and appeal system. We note as well that the ability of a provider to act as an authorized representative of an enrollee could vary based on state law. We also did not accept commenters' recommendation to explicitly expand our list of authorized representatives. Although, in principle, we agree that legal representatives, beneficiary advocates, and similar parties may effectively serve as authorized representatives, we defer to state determinations regarding the design of their grievance and appeal system; state laws could vary regarding who the state recognizes as an authorized representative. Nothing in § 438.402(c)(1)(ii) would prohibit a legally authorized representative from acting on the enrollee's behalf in requesting an appeal, as long as the state recognizes and permits such legally authorized representative to do so. However, in response to these comments, we will clarify that when the term "enrollee" is used throughout subpart F of this part, it includes providers and authorized representatives consistent with this paragraph, with the exception that providers cannot request continuation of benefits as specified in § 438.420(b)(5). This exception applies because an enrollee may be held liable for payment for those continued services, as specified in § 438.420(d), and we believe it is critical that the enrollee—or an authorized representative who is not a provider—initiate the request.

Comment: A few commenters recommended that CMS add a separate appeals process for providers to dispute the denial of payment for services rendered.

Response: We disagree with commenters that a separate appeals process should be added to accommodate providers who are disputing the denial of payment for services rendered. We believe that managed care plans already have internal processes and procedures for providers who are disputing the denial of payment for services under the

contract between the provider and the managed care plan. In addition, the only appeals process dictated by statute in section 1932(b)(4) of the Act involves an enrollee's challenge to the denial of coverage for medical assistance. We encourage providers to work with managed care plans to address any potential concerns or issues.

Comment: Several commenters recommended that CMS cap the timeframe for enrollees to submit a grievance at § 438.402(c)(2)(i). Commenters recommended a number of specific timeframes, including 30 calendar days, 60 calendar days, 90 calendar days, 120 calendar days, 180 calendar days, and 1 year. Commenters stated that without a timeframe to submit grievances, enrollees will be confused about how long they have to file a grievance, and managed care plans will expend additional resources to track down and revisit grievance issues that occurred in the past.

Response: We appreciate commenters' concerns regarding this issue; however, we decline to add a timeframe cap that requires enrollees to file a grievance within a specific amount of time. As we previously noted in the proposed rule, grievances do not progress to the level of a state fair hearing; therefore, we find it unnecessary to include filing limits or constrain grievances to the coordination of timeframes. We understand that managed care plans may be concerned about revisiting grievance issues that occurred in the past, but we believe this is a normal part of doing business and that enrollees should be permitted to file a grievance at any time.

Comment: Many commenters supported proposed § 438.402(c)(2)(ii), which requires enrollees to request an appeal within 60 calendar days of an adverse benefit determination. Commenters stated that alignment in this area will create administrative efficiencies and be easier for enrollees transitioning across health care coverage options. Several commenters disagreed with the proposal and recommended that CMS align with the rules governing QHPs (45 CFR 147.136(b)(2)(i) and (3)(i), incorporating 29 CFR 2560.503–1(h)(3)(i)) to allow enrollees 180 days to request an appeal. Other commenters recommended alternative timeframes, including 10 calendar days, 30 calendar days, 90 calendar days, and 120 calendar days. Several commenters recommended that CMS clarify the language regarding “following receipt of a notification.” Commenters stated concern that states, managed care plans, and enrollees will be confused regarding the actual date the 60 calendar day

clock starts, as it is hard to know when enrollees will receive the notice.

Response: We thank commenters for their support and recommendations regarding proposed § 438.402(c)(2)(ii). We agree with commenters that alignment in this area will create administrative efficiencies and be easier for enrollees transitioning across health care coverage options. We note that the preamble in the proposed rule (80 FR 31104) contained inaccurate information regarding the 60-day appeal filing limit for QHPs and group health plans. QHPs and group health plans have a 180 calendar day filing limit for appeals under 45 CFR 147.136(b)(2)(i) and (3)(i) (incorporating 29 CFR 2560.503–1(h)(3)(i)). However, we believe that our proposal should align with MA and use the filing limit for appeals at 60 calendar days. In this final rule, we allow 60 calendar days for enrollees to file the appeal with the managed care plan, and upon notice that the managed care plan is upholding their adverse benefit determination, the enrollee has an additional 120 calendar days to file for state fair hearing. We believe it is important for enrollees to file appeals as expeditiously as possible. We are therefore finalizing our proposal to keep the appeal filing deadline for the plan level appeal at 60 calendar days. This approach strikes the appropriate balance between aligning with other coverage sources while taking into account the specific features of the Medicaid program. Finally, we agree with commenters that the proposed language “following receipt of a notification” is ambiguous as to when the 60 calendar day clock starts. We clarify that the 60 calendar day appeal filing limit begins from the date on the adverse benefit determination notice. We note that it is our expectation that managed care plans mail out the notices on the same day that the notices are dated. We are finalizing the rule with modified regulatory text to adopt this recommendation.

Comment: Several commenters recommended that CMS revise § 438.402(c)(3)(ii) to remove the requirement for enrollees or providers to follow-up an oral standard appeal with a written and signed appeal. Commenters stated that this requirement adds an unnecessary barrier to enrollees filing an appeal with the managed care plan. A few commenters stated that this requirement is confusing, as it is ambiguous from which date (the date of the oral request or of the written request) the resolution timeframe applies. One commenter recommended that CMS include language at § 438.402(c)(3)(ii) to require

that managed care plans close all oral appeals within 10 calendar days, if they have not received the follow-up written and signed appeal.

Response: We understand commenters' concerns regarding the requirement to follow-up an oral standard appeal with a written and signed appeal; however, we believe that this requirement is necessary to ensure appropriate and accurate documentation. Consistent with § 438.406(b)(3), we clarify that the resolution timeframe begins from the date of the oral appeal. We also clarify that the requirement to follow-up with a written and signed appeal does not apply to oral expedited appeals. The resolution timeframe would begin from the date the oral expedited appeal is received by the managed care plan and no further written or signed appeal is required. We also disagree with the commenter that recommended that all oral appeals be closed within 10 calendar days if no written or signed follow-up is received. This is not consistent with our general approach to allow enrollees to submit appeals orally and in writing. Managed care plans should treat oral appeals in the same manner as written appeals.

Comment: Many commenters provided recommendations and feedback regarding the preamble discussion in the proposed rule (80 FR 31104) related to online grievance and appeal systems. Several commenters stated that such a system would be onerous on both enrollees and managed care plans, as many enrollees may not have internet access readily available and many managed care plans will have budgetary concerns in implementing such a system. Many commenters also stated concerns over the potential for privacy breaches and the extra resources that managed care plans and states would have to deploy to protect and secure such systems. Some commenters were highly supportive of such systems and recommended that CMS make online grievance and appeal systems a requirement on managed care plans. Several commenters also recommended alternative approaches, such as enrollee and provider portals.

Response: We appreciate all of the comments related to online grievance and appeal systems. At this time, we have decided to not move forward with a requirement for managed care plans to implement such a system. We encourage states and managed care plans to think more about this concept and engage the stakeholder community regarding the pros and cons of implementing an online grievance and appeal system. We agree with certain commenters that

there may be tangible benefits for enrollees, but we also understand other commenters' concerns regarding both costs and privacy.

Comment: A few commenters recommended that CMS require states and managed care plans to monitor the volume of appeals and grievances from enrollees. One commenter recommended that CMS set specific quantitative thresholds and benchmarks for states and managed care plans to follow. The commenter also recommended that CMS set specific penalties and sanctions for states and managed care plans with a volume of appeals and grievances that exceeds the quantitative threshold or benchmark.

Response: States are required to address the performance of their appeal and grievance systems in the managed care program assessment report required at § 438.66. We disagree with commenters that we should set a specific quantitative threshold or benchmark regarding the number of appeals and grievances, as we believe that this would vary greatly depending on the size and scope of the managed care program, the populations served, and the service area of each managed care plan. States are responsible for monitoring appeals and grievances within their respective programs.

After consideration of the public comments, we are finalizing the regulatory text at § 438.402 with some modifications from the proposal as discussed above. Specifically, we are finalizing § 438.402(c)(1)(i) with a deemed exhaustion requirement, similar to the requirement in 45 CFR 147.136(b)(2)(ii)(F), to ensure that enrollees maintain access to a state fair hearing if the managed care plan does not adhere to the notice and timing requirements in § 438.408. We are also finalizing the regulatory text at § 438.402(c)(1)(i) with modifications to permit states to offer an optional and independent external medical review within certain parameters; the external review must be at the enrollee's option, it must not be a requirement before or used as a deterrent to proceeding to the state fair hearing, it must be offered without any cost to the enrollee, it must not extend any of the timeframes specified in § 438.408, and must not disrupt the continuation of benefits in § 438.420. We are finalizing a modification to the regulatory text at § 438.402(c)(1)(ii) to require that providers obtain the enrollee's written consent before filing an appeal and to clarify that when the term "enrollee" is used throughout subpart F of this part, it includes providers and authorized representatives, with the exception that

providers cannot request continuation of benefits as specified in § 438.420(b)(5). As explained above, this exception applies because an enrollee may be held liable for payment for those continued services, as specified in § 438.420(d), and we believe it is critical that the enrollee—or an authorized representative of the enrollee who is not a provider—initiate the request. Finally, we are finalizing the regulatory text at § 438.402(c)(2)(ii) with a modification to clarify that the 60 calendar day appeal filing limit begins from the date on the adverse benefit determination notice. We are finalizing all other provisions in § 438.402 as proposed.

(4) Timely and Adequate Notice of Adverse Benefit Determination (§ 438.404)

In § 438.404, we proposed to revise the section heading to a more accurate and descriptive title, "Timely and adequate notice of adverse benefit determination." In paragraph (a), we proposed a non-substantive wording revision to more accurately reflect the intent that notices must be timely and meet the information requirements detailed in proposed § 438.10.

In paragraph (b), describing the minimum content of the notice, we proposed to delete paragraph (b)(4) (about the state option to require exhaustion of plan level appeal processes) to correspond to our proposal in § 438.408(f) and redesignate the remaining paragraphs accordingly. In paragraph (b)(2), we proposed to clarify that the reason for the adverse benefit determination includes the right of the enrollee to be provided upon request and free of charge, reasonable access to and copies of all documents, records, and other information relevant to the enrollee's adverse benefit determination. This additional documentation would include information regarding medical necessity criteria, consistent with § 438.210(a)(5)(i) as appropriate, and any processes, strategies, or evidentiary standards used in setting coverage limits. In new paragraph (b)(5), we proposed to replace expedited "resolution" with expedited "appeal process" to add consistency with wording throughout this subpart. We further proposed to add the phrase "consistent with State policy" in paragraph (b)(6) to be consistent with a proposed change in § 438.420(d) regarding the MCO's, PIHP's, or PAHP's ability to recoup from the enrollee under a final adverse decision be addressed in the contract and that such practices be consistent across both FFS and managed care delivery systems

within the state. While notice of the possibility of recoupment under a final adverse decision is an important beneficiary protection, we noted that such notice may deter an enrollee from exercising the right to appeal. We indicated that we would issue guidance following publication of the rule regarding the model language and content of such notice to avoid dissuading enrollees from pursuing appeals.

In paragraph (c), we proposed to revise paragraph (c)(4) to replace "extends the timeframe in accordance with . . ." with "meets the criteria set forth . . ." to more clearly state that MCOs, PIHPs, and PAHPs cannot extend the timeframes without meeting the specific standards of § 438.210(d)(1)(ii). Lastly, in paragraph (c)(6), we proposed to update the cross reference from § 438.210(d) to § 438.210(d)(2).

We received the following comments in response to our proposal to revise § 438.404.

Comment: Several commenters broadly supported the proposed requirements in § 438.404. A few commenters recommended adding specific language at § 438.404(a) to reference the language and format requirements at § 438.10(d), specifically, § 438.10(d)(3) and (4). One commenter also recommended that CMS define "timely" at § 438.404(a).

Response: We thank commenters for their broad support of proposed § 438.404. The language at § 438.404(a) requires that managed care plans give enrollees timely and adequate notice of adverse benefit determination in writing consistent with the requirements in § 438.10 generally; therefore, we find the recommendation to specifically add references for § 438.10(d)(3) and (4) duplicative and unnecessary. We also decline to define "timely" at § 438.404(a), as the requirements for timing of notices are found at § 438.404(c)(1) through (c)(6).

Comment: Several commenters recommended revisions to § 438.404(b)(2). A few commenters recommended that CMS require managed care plans to specifically explain their medical necessity criteria. One commenter recommended that CMS require managed care plans to specifically explain how their medical necessity criteria is the same for physical health, mental health, and substance use disorders. One commenter recommended that CMS revise language at (b)(2) to specify that all "documents and records are relevant to the specific enrollee appeal." One commenter recommended that CMS add

“policies and procedures” to the language at (b)(2). A few commenters recommended that CMS define “reasonable access” and “relevant.” Finally, a few commenters recommended that CMS clarify that providers and authorized representatives can request access to all of the same information and documentation specified at (b)(2).

Response: We understand commenters’ concerns regarding medical necessity criteria; however, it is unclear what specific requirements should be imposed on managed care plans to “explain” their medical necessity criteria. We have included requirements at (b)(2) for managed care plans to disclose their medical necessity criteria regarding any adverse benefit determination and believe this to be sufficient. Because the adverse benefit determination notice must include the reasons for the determination, to the extent that the denial is based on a lack of medical necessity, the regulation requires that managed care plans explain the medical necessity criteria applied, consistent with § 438.210(a)(5)(i) as appropriate, under the managed care plan’s policies. Therefore, we are not adopting this recommendation.

We also decline commenters’ recommendations to add (“documents and records are relevant to the specific enrollee appeal” and “policies and procedures”) or define (“reasonable access” and “relevant”) terms. We find this language duplicative and unnecessary. In addition, we believe the standard at (b)(2) is clear that managed care plans must disclose all documents, records, and other information relevant to the enrollee’s adverse benefit determination. We are not familiar with any existing federal standard for “reasonable access” or “relevant” that we can draw upon in this context. We believe that these terms are adequately defined and understood in common discourse. We encourage commenters to work with states and managed care plans when specific issues arise regarding an enrollee’s “reasonable access” to documentation, or the “relevance” of such documentation. Finally, we restate that state laws could vary regarding who the state recognizes as an authorized representative. Nothing in § 438.404(b)(2) would prohibit an authorized representative (including a provider who is acting on behalf of an enrollee) from requesting the same information and documentation specified at (b)(2), as long as the state recognizes and permits such legally authorized representative to do so.

Comment: Several commenters recommended that CMS include additional requirements at § 438.404(b)(3) to include information on exhausting the one level of managed care plan appeal and enrollees’ rights to request a state fair hearing at § 438.402(b) and (c).

Response: We agree with commenters that it is important for enrollees to understand the totality of the grievance and appeal process. It would improve transparency and provide enrollees clear information if § 438.404(b)(3) specified that the notice must include the enrollee’s and provider’s right to request an appeal of the managed care plan’s adverse benefit determination and include information on exhausting the one level of managed care plan appeal and enrollees’ rights to request a state fair hearing at § 438.402(b) and (c). We are modifying the regulatory text to adopt this recommendation accordingly.

Comment: Several commenters recommended that CMS correct a typographical error at § 438.404(b)(6) to correct “right to have benefits continue pending resolution . . .”

Response: We thank commenters for catching this typographical error, and we are modifying the regulatory text accordingly.

Comment: A few commenters provided additional recommendations for CMS to implement at § 438.404 generally. One commenter recommended that CMS require Medicaid managed care plans to use the same notice templates already adopted in the MA context. One commenter recommended that CMS remove all notice requirements, as such requirements are administratively burdensome on managed care plans.

Response: One of the goals of the proposed rule was alignment across public and private health care coverage markets; however, we do not believe it feasible to require Medicaid managed care plans to use the MA notice templates given the different nature and administrative structures of the programs. We have attempted to ensure that many of the notice requirements are similar across both MA and Medicaid. We also decline to remove all notice requirements. While we understand the commenter’s concern regarding managed care plan burden, we believe this is a normal part of doing business in the health care market and that notices provide important protections for beneficiaries.

After consideration of the public comments, we are finalizing the regulation text at § 438.404 as proposed with two modifications. We are finalizing additional regulatory text at

§ 438.404(b)(3) to specify that the notice must include the enrollee’s and provider’s right to request an appeal of the managed care plan’s adverse benefit determination and include information on exhausting the one level of managed care plan appeal and enrollees’ rights to request a state fair hearing at § 438.402(b) and (c). We are also modifying the regulatory text at § 438.404(b)(2) to make a technical correction and § 438.404(b)(6) to correct a typographical error. We are finalizing all other sections as proposed.

(5) Handling of Grievances and Appeals (§ 438.406)

In addition to language consistent with our overall proposal to make PAHPs subject to the grievance and appeals standards for MCOs and PIHPs, we proposed to reorganize § 438.406 to be simpler and easier to follow and to revise certain procedural standards for appeals. Existing paragraph (a) was proposed to be revised by adding the existing provision in paragraph (a)(1) to paragraph (a), which specifies that each MCO, PIHP, and PAHP must give enrollees any reasonable assistance, including auxiliary aids and services upon request, in completing forms and taking other procedural steps. In paragraph (b), we proposed to revise the paragraph heading and redesignate existing provisions in paragraphs (a)(2) and (a)(3) as (b)(1) and (b)(2), respectively; we also proposed to add grievances to the provisions of both. MCOs, PIHPs, or PAHPs would have to send an acknowledgment receipt for each appeal and grievance and follow the limitations on individuals making decisions on grievances and appeals in paragraphs (b)(2)(i) and (ii). In new paragraph (b)(2)(i), we proposed to add that individuals who are subordinates of individuals involved in any previous level of review are, like the individuals who were involved in any previous level of review, excluded from making decisions on the grievance or appeal. This final proposed revision added assurance of independence that we believe is appropriate and is consistent with standards under the private market rules in 45 CFR 147.136 that incorporate 29 CFR 2560.503–1(h)(3)(ii). Redesignated paragraph (b)(2)(ii) was proposed to remain unchanged from its current form. Consistent with the standards under the private market rules in 45 CFR 147.136 that incorporate 29 CFR 2560.503–1(h)(2)(iv), we proposed to add a new paragraph (b)(2)(iii) to specify that individuals that make decisions on appeals and grievances take all comments, documents, records, and other information submitted by the

enrollee into account regardless of whether the information had been considered in the initial review. We also proposed to redesignate current paragraph (b)(2) as (b)(4) and add “testimony” in addition to evidence and legal and factual arguments. We also proposed to use the phrase “legal and factual arguments” to replace the phrase “allegations of fact or law” in the current text for greater clarity.

We noted that current paragraph (b)(3) required the enrollee to have the opportunity before and during the appeal process to examine the case file, medical record and any documents or records considered during the appeal process. We proposed to redesignate this paragraph as paragraph (b)(5) and to replace “before and during” with “sufficiently in advance of the resolution”, to add specificity. We also proposed to add “new or additional evidence” to the list of information and documents that must be available to the enrollee. The proposed language in paragraph (b)(5) would more closely align with the disclosure standards applicable to private insurance and group health plans in 45 CFR 147.136(b)(2)(ii)(C)(1). Existing paragraph (b)(4) was proposed to be redesignated as paragraph (b)(6) without change.

We received the following comments in response to our proposal to revise § 438.406.

Comment: Many commenters broadly supported the revised § 438.406 that we proposed. A few commenters recommended that CMS add references in § 438.406(a) to include that each MCO, PIHP, and PAHP must comply with the requirements in § 438.10(d)(3) and (4).

Response: We decline to add cross-references in § 438.406(a) to § 438.10(d)(3) and (4), as we find such text to be duplicative and unnecessary. Managed care plans must comply with all of the requirements in § 438.10, and we included the appropriate references in § 438.404 regarding notices.

Comment: Many commenters recommended that CMS clarify at § 438.406(b)(1) how managed care plans should acknowledge the receipt of each grievance and appeal. Several commenters recommended that CMS add timeframe requirements to § 438.406(b)(1), with a few commenters specifically recommending 3 calendar days for managed care plans to acknowledge receipt of each grievance and appeal.

Response: We appreciate commenters' recommendations but believe that it is not necessary to set such detailed requirements in the regulation. We

believe that such details are better set forth in the contracts between states and managed care plans. We encourage managed care plans to provide written acknowledgment of the receipt of each grievance and appeal as soon as possible to ensure that enrollees receive timely and accurate information.

Comment: Several commenters recommended that CMS remove the language at § 438.406(b)(2)(i) in regard to managed care plans ensuring that individuals who make decisions on grievances and appeals are individuals who were neither involved in any previous level of review or decision-making, nor a subordinate of any such individual. A few commenters found this language to be confusing and requested that CMS clarify the requirement. One commenter recommended that CMS define the meaning of “subordinate.” A few commenters recommended that CMS allow state flexibility on this issue, as states can better negotiate such requirements with managed care plans. One commenter stated that such a requirement would add administrative costs and burden on managed care plans, as the language requires managed care plans to conduct multiple levels of review with multiple individuals from separate departments.

Response: We appreciate the opportunity to clarify the requirement at § 438.406(b)(2)(i). We believe that this requirement is important, as it adds an additional level of beneficiary protection and is consistent with standards in the private market. It is not only reasonable but consistent with the concept of the appeal as a fair and impartial review of the underlying facts and situation that individuals reviewing and making decisions on grievances and appeals are not the same individuals, nor subordinates of individuals, who made the original adverse benefit determination; it seems unlikely that an individual would bring the necessary impartiality and open-mindedness when reviewing his or her own prior decision and analysis. Similarly, a subordinate may have concerns or hesitation with challenging or overruling a determination made by his or her supervisor that are unrelated to the specific facts and policies for an appeal. We disagree with commenters that this language should be removed.

We decline to define explicitly the term “subordinate,” in the regulation as we believe it is clear that in this context, subordinates are individuals who report to or are supervised by the individuals who made the original adverse benefit determination. We also decline to allow states to enforce a different standard, as

we believe this standard is clear and should serve as a national benchmark for handling grievances and appeals and that states have discretion within their standard to develop particular approaches with their plans. Finally, while we understand the commenter's concern regarding managed care plan burden, we believe this is a normal part of doing business in the health care market. We further clarify that § 438.406(b)(2)(i) does not require multiple levels of review from separate departments. The standard requires that individuals reviewing and making decisions about grievances and appeals are not the same individuals, nor subordinates of individuals, who made the original adverse benefit determination. Reviewers hearing an appeal of an adverse benefit determination may be from the same department (or a different department) so long as the necessary clinical expertise and independence standards are met and the reviewer takes into account the information described in § 438.406(b)(2)(iii).

Comment: Several commenters recommended that CMS add more specificity at § 438.406(b)(2)(ii) regarding the health care professionals who have the appropriate clinical expertise in treating the enrollee's condition or disease. A few commenters recommended that CMS revise the language to specify that health care professionals must be licensed to specifically treat the enrollee's condition or disease. A few commenters recommended that CMS add language for pediatric specialists and expertise in treating pediatric patients. Some commenters also recommended that CMS revise the language to specifically add that health care professionals must have clinical expertise in treating the enrollee's specific condition and disease.

Response: We understand commenters' concerns regarding the appropriate clinical expertise of the individuals making decisions on grievances and appeals; however, we decline to adopt these specific recommendations. The language at § 438.406(b)(2)(ii) specifies that individuals should have the appropriate clinical expertise as determined by the state. Depending on the scope of the program, the populations served, and the specific services or benefits in question, we believe this could vary greatly from appeal to appeal. We believe, as the current text requires, that states are in the best position to make these decisions about their respective programs. States are also in the best position to monitor a managed care

plan's appeals and grievances and make the necessary changes as appropriate when unsatisfactory patterns emerge. We note that states are required to address the performance of their appeal and grievance systems in the managed care program assessment report required at § 438.66. As discussed in section I.B.9.a. of this final rule, "health care professional" has been changed to "individual" in § 438.406(b)(2)(ii).

Comment: Many commenters recommended that CMS define at § 438.406(b)(4) "reasonable opportunity" and "sufficiently in advance" in regard to an enrollee's right to present evidence and testimony and make legal and factual arguments. One commenter recommended that CMS remove the language "make legal and factual arguments" as enrollees are only able to make allegations of fact or law.

Response: We appreciate the commenters' recommendations to add more specificity at § 438.406(b)(4) but decline to do so, as we believe such specificity could have unintended consequences. We believe it would be operationally difficult for CMS to specify an exact timeframe for when a managed plan should allow an enrollee to present evidence and testimony. We also believe that under certain circumstances, such as in the case of an expedited appeal or an extension of the standard resolution timeframe, it would be difficult to apply an exact standard across all grievances and appeals. We encourage managed care plans to work with enrollees or an enrollee's representative to allow as much time as possible for enrollees to present evidence and testimony. We also encourage managed care plans to inform enrollees of this opportunity as soon as feasible to improve transparency during the process. We also encourage states to think about how they might set such standards with their managed care plans. We also disagree with the commenter's recommendation to remove the language "make legal and factual arguments" as we believe this language adds more clarity than "allegations of fact or law." We believe that enrollees have the right to make legal and factual arguments and defend their position to individuals who are making decisions on the outcomes of grievances and appeals, who will ultimately decide the validity of such legal and factual arguments.

Comment: Several commenters recommended specific revisions to § 438.406(b)(5). A few commenters recommended that CMS add language to clarify that providers can also access this same information. One commenter recommended that CMS add "or

otherwise relevant" to the regulatory text in regard to additional evidence. A few commenters recommended that CMS clarify that such information is only available upon request. One commenter disagreed with CMS and recommended the removal of the language "new or additional evidence . . . generated by the MCO, PIHP, or PAHP" as the commenter stated it is not appropriate for managed care plans to allow access to information or documents that were generated internally. A few commenters recommended that CMS clarify that the documents and information available at § 438.404(b)(2) are the same documents and information available at § 438.406(b)(5). Finally, one commenter recommended regulatory text changes to remove the phrase in parentheses and recommended the creation of a new sentence.

Response: We appreciate the many thoughtful recommendations regarding § 438.406(b)(5). We do not believe it is necessary to specifically add "providers" as we believe it is clear that "his or her representative" can include a provider. We reiterate that state laws could vary regarding who the state recognizes as an authorized representative. Nothing in § 438.406(b)(5) would prohibit an authorized representative from requesting the same information and documentation specified at (b)(5), as long as the state recognizes and permits such legally authorized representative to do so. We also disagree with the commenter's recommendation to add "or otherwise relevant" to the regulatory text in regard to additional evidence. We believe the current text is clear that any new or additional evidence considered, relied upon, or generated by the MCO, PIHP, or PAHP in connection with the appeal of the adverse benefit determination should be made available for review. We also disagree that such information is only available upon request, as this standard does not exist in regulation today.

We disagree with the commenter's recommendation to remove the language "new or additional evidence . . . generated by the MCO, PIHP, or PAHP" as we believe it is necessary and appropriate for managed care plans to make this information available to enrollees and their representatives to ensure a fair and impartial appeal. We clarify that the documents and information referenced at § 438.404(b)(2) and § 438.406(b)(5) are similar; however, it is possible that the enrollee's case file used for the appeal at § 438.406(b)(5) could contain additional documents and information

that were not available at the time of the adverse benefit determination under § 438.404(b)(2). We agree with the commenter's recommendation to restructure the sentence to remove the parentheses. We are modifying the regulatory text to adopt this recommendation accordingly.

After consideration of the public comments, we are finalizing § 438.406 with a modification at § 438.406(b)(5) to restructure the sentence and remove the parentheses. We are also finalizing § 438.406(b)(2)(i), as discussed more fully in section I.B.9.a. of this final rule, to replace the term "health care professional" with "individual." Finally, we are modifying § 438.406(a) to add the language "related to a grievance or appeal" to improve the accuracy of the sentence. We are finalizing all other sections as proposed.

(6) Resolution and Notification: Grievances and Appeals (§§ 438.408 and 431.244(f))

We proposed to make significant modifications to § 438.408 to further align Medicaid managed care standards with MA and private insurance and group health plan standards. We proposed several significant modifications as explained in more detail below: (1) Changes in the timeframes to decide appeals and expedited appeals; (2) strengthen notice standards for extensions; and (3) change the processes for receiving a state fair hearing for enrollees of MCOs, PIHPs, and PAHPs. In addition, we proposed to reorganize the regulation for greater clarity and to add the phrase "consistent with state policy" to paragraph (e)(2)(iii) to be consistent with our proposal in § 438.420(d).

In § 438.408(b)(2), we proposed to adjust the timeframes in which MCOs, PIHPs, and PAHPs would have to make a decision about an enrollee appeal to align with the standards applicable to a MA organization. Currently, MCOs and PIHPs may have up to 45 days to make a decision about a standard (non-expedited) appeal. In § 422.564(e), MA plans must make a decision about first level appeals in 30 days, while Part D plans must provide a decision in 7 days under § 423.590(a)(1). Federal regulations on the private market permit up to 60 days for a standard decision on an internal appeal (*see* § 147.136(b)(2)(i) and (b)(3), incorporating 29 CFR 2560.503-1(b)(1) for individual health insurance issuers and group health insurance issuers and plans). We proposed to shorten the timeframe for MCO, PIHP, and PAHP appeal decisions from 45 days to 30 calendar days, which would achieve alignment with MA

standards while still allowing adequate time for decision-making and response.

In paragraph (b)(3), we proposed to adjust the Medicaid managed care timeframes for expedited appeals to align with standards applicable to MA and the private market. Currently under subpart F, MCOs and PIHPs have 3 working days from receipt of a request to make a decision in an expedited review. The MA (§ 422.572(a)) and private market regulations (29 CFR 2590.715–2719(c)(2)(xiii)) stipulate that a plan must make a decision within 72 hours of receiving a request for expedited review. We proposed to modify our expedited appeal decision timeframes from 3 working days to 72 hours. The change would improve the speed with which enrollees would receive a MCO, PIHP, or PAHP decision on critical issues, and align Medicaid managed care with Medicare and private insurance and group health plans.

For extensions of the timeframe to resolve an appeal or grievance when the enrollee has not requested the extension (§ 438.408(c)(2)), we proposed to strengthen the notification responsibilities on the MCO, PIHP, or PAHP by setting new specific standards and to add existing text in § 438.408(c) to paragraph (c)(2). We proposed to add the current standards in § 438.404(c)(4)(i) and (ii) to § 438.408(c)(ii) and (iii), which describe the standards on the MCO, PIHP, or PAHP for an extension of the timeframe for standard or expedited appeals for clarity and consistency.

In § 438.408(d)(1) and (2), we proposed to add a provision requiring that grievance notices (as established by the state) and appeal notices (as directed in the regulation) from a MCO, PIHP, or PAHP ensure meaningful access for people with disabilities and people with limited English proficiency by, at a minimum, meeting the standards described at § 438.10.

In § 438.408(e), we proposed to add “consistent with state policy” in paragraph (e)(2)(iii) to be clear that such practices must be consistent across both FFS and managed care delivery systems within the state. This is added here to be consistent with a proposed change in § 438.420(d) that stipulates that the MCO’s, PIHP’s, or PAHP’s ability to recoup from the enrollee under a final adverse decision must be addressed in the contract and that such practices be consistent across both FFS and managed care delivery systems within the state. For example, if the state does not exercise the authority for recoupment under § 431.230(b) for FFS, the same

practice must be followed by the state’s contracted MCOs, PIHPs, and PAHPs.

In § 438.408(f), we proposed to modify the Medicaid managed care appeals process such that an enrollee must exhaust the MCO, PIHP, or PAHP appeal process prior to requesting a state fair hearing. This would eliminate a bifurcated appeals process while aligning with MA and the private market regulations. Under current Medicaid rules, states have the discretion to decide if enrollees must complete the MCO, PIHP, or PAHP appeal process before requesting a state fair hearing or whether they can request a state fair hearing while the MCO, PIHP, or PAHP appeal process is still underway. Depending on the state’s decision in this regard, this discretion has led to duplicate efforts by the MCO, PIHP, or PAHP and the state to address an enrollee’s appeal. Both MA rules and regulations governing private market and group health plans have a member complete the plan’s internal appeal process before seeking a second review. Our proposed change would be consistent with both those processes.

Specifically, under the proposed change in paragraph (f)(1), a MCO, PIHP, or PAHP enrollee would have to complete the MCO, PIHP, or PAHP appeal process before requesting a state fair hearing. The proposed change would enable consumers to take advantage of the state fair hearing process in a consecutive manner which would lead to less confusion and effort on the enrollee’s part and less administrative burden on the part of the managed care plan and the state; the use of a federal standard for this would eliminate variations across the country and lead to administrative efficiencies for the MCOs, PIHPs, and PAHPs that operate in multiple states. Moreover, our proposed reduction in the timeframes that a MCO, PIHP, or PAHP would have to take action on an appeal (from 45 to 30 calendar days) in § 438.408(b)(2) would permit enrollees to reach the state fair hearing process more quickly. We believed that our proposal would achieve the appropriate balance between alignment, beneficiary protections, and administrative simplicity.

We proposed in new paragraph (f)(2) to revise the timeframe for enrollees to request a state fair hearing to 120 calendar days. This proposal would extend the maximum period under the current rules and would give enrollees more time to gather the necessary information, seek assistance for the state fair hearing process and make the request for a state fair hearing.

We also proposed a number of changes to § 431.244, Hearing Decisions, that correspond to these proposed amendments to § 438.408. In § 431.244, we proposed to remove paragraph (f)(1)(ii) which references direct access to a state fair hearing when permitted by the state. As that option is proposed to be deleted in § 438.408(f)(1), it should also be deleted in § 431.244(f)(1). In § 431.244(f)(2), we considered whether to modify the 3 working day timeframe on the state to conduct an expedited state fair hearing. In the interest of alignment, we examined the independent and external review timeframes in both MA and QHPs and found no analogous standard or consistency for final administrative action regarding expedited hearings. We therefore proposed to keep the state fair hearing expedited timeframe at 3 working days. We proposed to delete current paragraph (f)(3) as it is no longer relevant given the deletion of direct access to state fair hearing proposed revision to § 438.408(f)(1). We proposed no additional changes to § 431.244.

We received the following comments in response to our proposal to revise § 438.408 and § 431.244.

Comment: Many commenters supported the proposed revisions to § 438.408 and recommended specific revisions throughout the section. A few commenters recommended that CMS remove the 90 calendar day requirement to resolve grievances at § 438.408(b)(1), as some grievances are not resolvable, such as the rudeness of an employee or provider. A few commenters also recommended that CMS shorten the 90 calendar day requirement to 60 calendar days or 30 calendar days to be more consistent with the timeframe for appeals at § 438.408(b)(2).

Response: We disagree with commenters that we should remove the 90 calendar day requirement to resolve grievances. While the rudeness of an employee or provider might be outside of the managed care plan’s control, the managed care plan can acknowledge the complaint, monitor complaints for unsatisfactory patterns, and take action as necessary. We also decline to shorten the 90 calendar day requirement, as the regulatory text already gives states the flexibility to set a timeframe that does not exceed 90 calendar days from the day the MCO, PIHP, or PAHP receives the grievance. Grievances are not as urgent as appeals, and they do not proceed to the state fair hearing level; therefore, we believe a national standard of less than 90 days is not necessary or beneficial.

Comment: Many commenters recommended alternative timeframes at

§ 438.408(b)(2) for the resolution of a standard appeal. A few commenters recommended the CMS retain 45 calendar days, while other commenters recommended that CMS expand the timeframe to 60 calendar days. Several commenters supported the 30 calendar day requirement, and one commenter recommended that CMS remove the language that allows states to establish a timeframe less than 30 calendar days. A few commenters recommended that CMS remove all timeframes and allow complete state flexibility on the resolution timeframes for standard appeals.

Response: We disagree with commenters that CMS should retain the 45 calendar day requirement or expand the timeframe to 60 calendar days. We believe that it is important to align with MA in this area to build consistency between the two programs, and we believe that 30 calendar days allow for the appropriate amount of time that decision makers need to evaluate the standard appeal. We also believe that a timeframe of 30 calendar days will allow enrollees to move to the state fair hearing in a more expedient manner, which is an important consideration in light of the new exhaustion requirement before a request for a state fair hearing can be made. We also disagree with commenters' recommendations to remove state flexibility to establish a timeframe that is less than 30 calendar days, and we disagree with commenters' recommendations that states should be allowed greater flexibility to establish all resolution timeframes for standard appeals. We believe it is critical to strike the appropriate balance among state flexibility, national minimum standards, and requirements that align across different health care coverage options. In this context, we believe it is appropriate to set a national benchmark that standard appeals be resolved for enrollees in a set amount of time. If states find that managed care plans can resolve standard appeals faster than 30 calendar days, we believe that enrollees benefit from providing flexibility for states to impose tighter timeframes. We also note that managed care plans will have the authority to extend the timeframe beyond 30 calendar days in accordance with § 438.408(c) when the specified requirements are met.

Comment: Many commenters recommended alternative timeframes at § 438.408(b)(3) for the resolution of an expedited appeal. Some commenters recommended that CMS retain the current standard of 3 working days. Several commenters recommended that CMS revise the proposed 72 hour requirement to 24 hours, 1 business day,

2 business days, or 3 business days. A few commenters recommended that CMS remove the 72 hour requirement in whole and allow states to define the standard for their respective programs. One commenter recommended that CMS clarify that the 72 hour clock only starts after all medical documentation has been received. A few commenters supported the 72 hour requirement but recommended special timeframes for specific benefits. One commenter recommended a 24 hour requirement for expedited prescription appeals to ensure that there is no delay in an enrollee's prescription benefit. One commenter recommended a 3 business day requirement for all expedited LTSS appeals, as these appeals generally have more complex documentation and records. Most commenters that recommended alternative timeframes stated concern regarding the 72 hour requirement as being too burdensome and costly for managed care plans to maintain.

Response: We appreciate the many comments that we received regarding this issue. We believe that 72 hours is the appropriate amount of time for Medicaid managed care plans to make a decision on expedited appeals, as this timeframe reflects the industry standard for expedited appeals and aligns with both MA and the private market. This requirement improves the speed at which enrollees receive decisions regarding care that may be urgently needed. For these reasons, we are adopting it as the national minimum standard for expedited appeals across all Medicaid managed care programs. States will retain the flexibility to set thresholds earlier than the 72 hour requirement. We also decline to add language to the regulatory text to clarify that the 72 hour clock does not begin until after all medical documentation has been received, as in the interest of timely resolution of matters affecting enrollee health, we believe that managed care plans should be working as expeditiously as possible to obtain the necessary medical documentation to resolve the expedited appeal. We note that managed care plans will have the authority to extend the timeframe beyond 72 hours in accordance with § 438.408(c) when the appropriate and specified requirements are met. We also decline to set special timeframes for specific benefits, such as pharmacy and LTSS. We believe that expedited appeals for these benefits should also follow the 72 hour requirement. We clarify that some commenters confused expedited pharmacy appeals and the 24 hour prior authorization requirement

added at § 438.3(s)(6) to comply with section 1927(d)(5) of the Act; as noted in section I.B.2., the prior authorization process for the provision of outpatient covered drugs is not an appeal but is a step toward the determination of whether the drug will be covered by the managed care plan. We understand commenters' concerns regarding administrative burden and costs, but we believe this is similar to the requirements in other markets and an expectation of doing business in the health care market.

Comment: Several commenters recommended that CMS revise § 438.408(c) to remove the 14 calendar day extension for expedited appeals. A few commenters also recommended that CMS revise the number of calendar days allowed for the extension, as they found 14 calendar days to be too long. One commenter recommended that CMS define "reasonable efforts" at § 438.408(c)(2)(i). A few commenters recommended that CMS clarify that if the MCO, PIHP, or PAHP extends the timeframe, and the extension is not at the request of the enrollee, that the managed care plan must cover the cost of all services or benefits provided during that 14 calendar day period. A few commenters recommended that CMS consider a deemed exhaustion requirement when managed care plans fail to meet the timeframe of the extension.

Response: We disagree with commenters that we should remove the 14 calendar day extension for standard or expedited appeals. We recognize the need for enrollees to expediently move through the appeals process, but we believe there are extenuating circumstances that require the option of the 14 calendar day extension. Current language at § 438.408(c)(1)(i) and (ii) allows the enrollee to request the 14 calendar day extension, or require the managed care plan to demonstrate the need for additional information and how the delay will be in the enrollee's interest. We believe it is necessary and appropriate to continue allowing this option, and we believe that 14 calendar days is enough time for both enrollees and managed care plans to gather the additional information that is needed to resolve the appeal.

We decline to define "reasonable efforts" at § 438.408(c)(2)(i) as we do not believe it is necessary. We encourage managed care plans to make every effort to reach enrollees and give prompt oral notice of the delay. However, we have also required at § 438.408(c)(2)(ii) that managed care plans provide enrollees written notice of the delay within 2 calendar days. We believe that this is

sufficient action from the managed care plan to ensure that enrollees know about any delay of their appeal. We decline to assign, at the federal level, the financial liability on the enrollee or the managed care plan for services furnished while the appeal is pending, including in the context of the 14 calendar day extension. Consistent with the notice requirements at §§ 438.404(b)(6) and 438.408(e)(2)(iii), and the requirements specified at § 438.420(d), enrollees may be held responsible or may be required to pay the costs of these services, consistent with state policy. Such requirements must be consistently applied within the state under both managed care and FFS, as specified at § 438.420(d).

Finally, consistent with our preamble discussion about § 438.402(c)(1)(i), we agree with commenters that adopting the deemed exhaustion requirement from the private market rules at 45 CFR 147.136(b)(2)(ii)(F) will ensure that enrollees maintain access to a state fair hearing if the managed care plan does not adhere to the notice and timing requirements in § 438.408, including specific timeframes for resolving standard and expedited appeals and the 14 calendar day extension. We are finalizing the regulatory text to adopt this recommendation.

Comment: A few commenters recommended that CMS clarify that the format of the notice at § 438.408(d)(1) and (2) should specifically reference the requirements at § 438.10(d).

Response: The language at § 438.408(d)(1) and (2) require managed care plans to format the notice consistent with the requirements in § 438.10 generally; therefore, we believe that to specifically add references to § 438.10(d) would be duplicative and unnecessary.

Comment: Many commenters disagreed with our proposed exhaustion requirement in § 438.408(f)(1) and offered alternatives. Many commenters recommended that CMS continue to allow direct access or concurrent access to the state fair hearing, as this is a critical beneficiary protection, especially for vulnerable populations with complex, chronic, and special health care needs that may be overburdened by the additional process and require an immediate review by an independent and impartial authority to prevent any further delays or barriers to care. Many commenters recommended that CMS allow state flexibility to ensure that current beneficiary protections in place today are not unnecessarily eroded. A few commenters stated that some states currently allow the state fair hearing in

lieu of the managed care plan appeal and recommended that CMS retain this as an option. Several commenters also recommended that CMS allow for an optional and independent external medical review, which is both outside of the state and the managed care plan. Commenters stated that such an optional external review can better protect beneficiaries and reduce burden on state fair hearings, as these external processes have proven to be an effective tool in resolving appeals before reaching a state fair hearing. Several commenters also recommended that CMS adopt the deemed exhaustion requirement from the private market rules at 45 CFR 147.136(b)(2)(ii)(F) to ensure that enrollees maintain access to a state fair hearing if the managed care plan does not adhere to the notice and timing requirements in § 438.408, including specific timeframes for resolving standard and expedited appeals.

Response: We thank the commenters for the many thoughtful and specific recommendations regarding proposed § 438.408(f)(1) and acknowledge the need to carefully consider the impact of this requirement on enrollees. Consistent with our preamble discussion at § 438.402(c)(1)(i), we understand commenters' concerns and recommendations regarding direct access to a state fair hearing for vulnerable populations; however, we decline to adopt this requirement. We believe that a consistent and uniform appeals process benefits enrollees and will better lead to an expedited resolution of their appeal. We have shortened the managed care plan resolution timeframe for standard appeals from 45 days to 30 calendar days and shortened the managed care plan resolution timeframe for expedited appeals from 3 working days to 72 hours. We have also lengthened the timeframe for enrollees to request a state fair hearing from a maximum of 90 days to 120 calendar days, counting from the receipt of the adverse appeal decision from the managed care plan. We have aligned these timeframes with other public and private health care markets and believe this ultimately protects enrollees by establishing a national framework for a uniform appeals process.

We agree with commenters that adopting the deemed exhaustion requirement from the private market rules at 45 CFR 147.136(b)(2)(ii)(F) will ensure that enrollees maintain access to a state fair hearing if the managed care plan does not adhere to the notice and timing requirements in § 438.408, including specific timeframes for resolving standard and expedited

appeals. As noted in our discussion of § 438.402, we are including a deemed exhaustion provision in this final rule; we are finalizing text in several regulation sections, including § 438.408(c)(3) and (f)(1)(i) to implement the deemed exhaustion requirement.

In addition, we disagree with commenters that recommended that states be allowed to establish their own processes and timeframes for grievances and appeals that differ from our proposed rule, we are persuaded by commenters' recommendations regarding an optional and independent external medical review. We agree that an optional external medical review could better protect enrollees and be an effective tool in resolving appeals before reaching a state fair hearing. Therefore, we are finalizing this rule with provisions in several sections, including § 438.408(f)(1)(ii), that permit a state to implement an external appeal process on several conditions: the review must be at the enrollee's option and cannot be a requirement before or used as a deterrent to proceeding to the state fair hearing; the review must be independent of both the state and managed care plan; the review must be offered without any cost to the enrollee; and any optional external medical review must not extend any of the timeframes specified in § 438.408 and must not disrupt the continuation of benefits in § 438.420.

Comment: Many commenters disagreed with CMS and recommended alternative timeframes at § 438.408(f)(2) for enrollees to request a state fair hearing. Commenters recommended that CMS not expand the amount of time enrollees have to file and request a state fair hearing up to 120 calendar days. Many commenters stated that 120 calendar days was too long and would expose managed care plans, states, and enrollees to unnecessary financial liability. Commenters also stated that the 120 calendar days is not consistent with the 90 calendar days in Medicaid FFS at § 431.244(f). Commenters recommended that CMS revise the 120 calendar days to 45 calendar days, 60 calendar days, or 90 calendar days. Many commenters also supported the proposed 120 calendar days and stated that the new requirement would give enrollees extra time to gather the information and documentation they need before proceeding to the state fair hearing.

Response: We disagree with commenters that we should shorten the amount of time given to enrollees to request a state fair hearing. We believe that 120 calendar days is the necessary and appropriate amount of time to give

enrollees the time they need to gather information and documentation before proceeding to the state fair hearing. We note that while the 120 calendar day requirement may not be consistent with Medicaid FFS at § 431.244(f), that Medicaid FFS requirement is only related to the first level of appeal. We also note that enrollees have 60 calendar days to file the appeal with the managed care plan, and upon notice that the managed care plan is upholding their adverse benefit determination, the enrollee has the additional 120 calendar days to file for state fair hearing. We believe it is important for enrollees to file appeals as expediently as possible, but that between the managed care plan appeal level and state fair hearing, the total timeframe is generally consistent with the private market.

Comment: One commenter stated that the language “the earlier of the following” was missing in the proposed change to § 431.244(f)(1).

Response: We clarify for the commenter that the language “the earlier of the following” was deleted in the proposed regulatory text to be consistent with the removal of direct access to a state fair hearing.

After consideration of the public comments, we are finalizing § 438.408 of the rule with some changes from the proposed rule. As compared to the proposed rule, the final text at §§ 438.408(c)(3) and 438.408(f)(1) is modified to adopt the deemed exhaustion requirement from the private market rules at 45 CFR

147.136(b)(2)(ii)(F) to ensure that enrollees maintain access to a state fair hearing if the managed care plan does not adhere to the notice and timing requirements in § 438.408. The regulatory text at § 438.408(f)(1) now contains an optional and independent external medical review that must be at the enrollee’s option, must not be a requirement before or used as a deterrent to proceeding to the state fair hearing, must be offered without any cost to the enrollee, must not extend any of the timeframes specified in § 438.408, and must not disrupt the continuation of benefits in § 438.420. Consistent with the discussion throughout subpart F, we are replacing the term “dispose” with “resolve” in § 438.408 references to resolution of the appeal. We are finalizing all other sections as proposed.

(7) Expedited Resolution of Appeals (§ 438.410)

In addition to the revisions to add PAHPs to the scope of this regulation, we proposed to revise § 438.410(c)(2) to replace the current general language on oral and written notification with a

cross reference to § 438.408(c)(2), to more specifically identify the responsibilities of the MCO, PIHP, or PAHP when extending timeframes for resolution. We also proposed a grammatical correction to paragraph (b) to replace the word “neither” with “not.” We proposed no other changes to this section.

We received the following comments in response to our proposal to revise § 438.410.

Comment: A few commenters recommended that CMS revise the language at § 438.410(a) to include physical and mental health, as well as settings of care, when referring to urgent circumstances that require an expedited resolution.

Response: We agree with commenters that § 438.410(a) could be strengthened to include both physical and mental health. We are modifying the regulatory text to include this recommendation. However, we disagree with commenters that § 438.410(a) should include additional language related to settings of care. We believe that the current language is clear and requires a managed care plan to maintain an expedited appeals process for urgent circumstances, regardless of the setting, when taking the time for a standard resolution could seriously jeopardize the enrollee’s life or health (both physical and mental health) or ability to attain, maintain, or regain maximum function.

Comment: A few commenters recommended that CMS revise the requirements at § 438.410(b) to add sanctions and penalties for managed care plans that do not comply with the prohibition against punitive action. One commenter recommended that CMS give examples of punitive action.

Response: We disagree with the commenters’ recommendation to add sanctions and penalties at § 438.410(b), as such issues are addressed elsewhere. Consistent with § 438.700, states determine whether an MCO, PCCM, or PCCM entity has violated any regulations or requirements and whether to impose corresponding sanctions; under to § 438.730, CMS may also impose sanctions for certain failures or lack of compliance by an MCO. Further, states have discretion under state law to develop enforcement authority and impose sanctions or take corrective action. We note that examples of punitive action can include a managed care plan’s decision to terminate a provider’s contract, to no longer assign new patients, or to reduce the provider’s rates; however, we reiterate that the standards in subpart I apply.

Comment: A few commenters recommended that CMS revise requirements at § 438.410(c) to add an appeal right regarding the denial of a request for expedited resolution. One commenter recommended that CMS add direct access to the state fair hearing if the request for expedited resolution is denied. One commenter recommended that CMS add requirements to prohibit managed care plans from overriding the decision of a health care provider in requesting an expedited resolution.

Response: We appreciate commenters’ recommendations but decline to add such additional requirements at § 438.410(c). If the request for expedited resolution is denied, managed care plans must transfer the appeal to the timeframe for standard resolutions. Additionally, managed care plans must follow the requirements at § 438.408(c)(2), which requires managed care plans to give enrollees notice of their right to file a grievance if he or she disagrees with the managed care plan’s decision to deny the expedited resolution request. Further, we do not believe that direct access to the state fair hearing is necessary, as the appeal will proceed through the managed care plan’s one level of appeal, and then if necessary, the enrollee can request a state fair hearing if the adverse benefit determination is upheld. Finally, we decline to add requirements to prohibit managed care plans from overriding the decision of a health care provider in requesting an expedited resolution. Managed care plans maintain both medical necessity criteria and clinical standards and consult regularly with health care providers when making the decision to grant or deny an expedited resolution.

After consideration of the public comments, we are finalizing § 438.410 as proposed with a modification to § 438.410(a) to include both physical and mental health as discussed above.

(8) Information About the Grievance System to Providers and Subcontractors (§ 438.414)

In addition to the change proposed throughout this subpart in connection with PAHPs, we proposed to update the cross reference from § 438.10(g)(1) to § 438.10(g)(2)(xi) to be consistent with our proposed revisions to § 438.10, discussed in more detail below in section I.B.6.d. of this final rule.

We received the following comments in response to our proposal to revise § 438.414.

Comment: A few commenters recommended that CMS add references to the term “appeal” when referencing the grievance system in § 438.414.

Response: We agree with commenters that § 438.414 should be revised to include the term “appeal” when referencing the grievance system and to be inclusive of both grievances and appeals.

After consideration of the public comments, we are finalizing § 438.414 as proposed with a modification to include the term “appeal” when referencing the grievance system.

(9) Recordkeeping Requirements (§ 438.416)

In § 438.416, we proposed to modify the recordkeeping standards under subpart F to impose a consistent, national minimum recordkeeping standard. The current recordkeeping provisions do not set standards for the type of appeals and grievance information to be collected, and only stipulate that states must review that information as part of an overall quality strategy.

Specifically, we proposed to redesignate the existing provisions of § 438.416 as a new paragraph (a), adding that the state must review the information as part of its monitoring of managed care programs and to update and revise its comprehensive quality strategy. We proposed to add a new paragraph (b) to specifically list the information that must be contained in the record of each grievance and appeal: A description of the reason for the appeal or grievance, the date received, the date of each review or review meeting if applicable, the resolution at each level, the date of resolution, and the name of the enrollee involved. Finally, we proposed to add a new paragraph (c) to stipulate that the record be accurately maintained and made accessible to the state and available to CMS upon request.

We received the following comments in response to our proposal to revise § 438.416.

Comment: Several commenters supported § 438.416(a) and recommended additional requirements for CMS to include. A few commenters recommended that CMS require an annual report from states as part of their ongoing monitoring processes. A few commenters recommended that CMS require states to track the numbers of appeals and grievances and make such data available to the public. One commenter recommended that CMS make aggregate level appeals and grievances data available. One commenter also recommended that CMS require states to monitor and evaluate their appeals and grievances processes.

Response: States are required to address the performance of their appeal

and grievance systems in the managed care program assessment report required at § 438.66 of this final rule. States are also required to post this program report on their state public Web site for public viewing. We do not believe that any additional requirements are needed to ensure that states are monitoring and evaluating their appeals and grievances processes. While we understand the commenters’ recommendations regarding access to public and aggregate level data, this is not a feasible or practical requirement to add at this time. We do not believe that all states or managed care plans have electronic systems for tracking appeals and grievances that would easily be consumable or transferable for public viewing. While we encourage states and managed care plans to be transparent about their appeals and grievances processes, we do not believe that additional data requirements are appropriate at this time.

Comment: Several commenters supported the requirements at § 438.416(b)(1) through (6). One commenter recommended that CMS make (1) through (6) optional for states and managed care plans, as some states do not need all of the information listed. One commenter recommended that CMS add one more requirement to capture the names of staff and individuals, including health care professionals, who decided the outcome of each appeal and grievance. The commenter stated that the actual names of staff may be useful in identifying and/or addressing patterns and trends in the grievance and appeal resolution process.

Response: We disagree with commenters that requirements at § 438.416(b)(1) through (6) should be optional and at the state’s discretion. We believe that all of these record requirements are needed to ensure accurate and thorough monitoring and evaluation of a state’s and managed care plan’s grievance and appeal system. We also decline to add new record requirements for states and managed care plans to capture the names of staff and individuals who decided the outcome of each appeal and grievance, as we believe this to be an operational and internal matter for states and managed care plans. States have the authority to require managed care plans to track and record additional appeal and grievance elements.

After consideration of the public comments, we are finalizing § 438.416 as proposed without modification.

(10) Effectuation of Reversed Appeal Resolutions (§ 438.424)

In addition to adding PAHPs to § 438.424, we proposed to revise the current rule in paragraph (a) so that the MCO, PIHP, or PAHP must effectuate a reversal of an adverse benefit determination and authorize or provide such services no later than 72 hours from the date it receives notice of the adverse benefit determination being overturned. This is consistent with the timeframes for reversals by MA organizations and independent review entities in the MA program, as specified in § 422.619 for expedited reconsidered determinations, when the reversal is by the MA organization or the independent review entity. In addition to providing consistency across these different managed care programs, and the increases in efficiency that we predict as a result of this alignment, we believe that 72 hours is sufficient time for an MCO, PIHP, or PAHP to authorize or provide services that an enrollee has successfully demonstrated are covered services. We solicited comment on this proposal and on our assumptions as to the amount of time that is necessary for an MCO, PIHP, or PAHP to authorize or provide services.

We received the following comments in response to our proposal to revise § 438.424.

Comment: Many commenters supported § 438.424(a) regarding the 72 hour requirement for managed care plans to reverse the adverse benefit determination. Some commenters recommended that CMS revise the requirement from 72 hours to 24 hours to ensure quick access to needed services. Several commenters disagreed with CMS and recommended a longer time requirement, as 72 hours was not feasibly possible to reverse an adverse benefit determination. Commenters stated that the 72 hour requirement would require more managed care plan resources and would increase administrative costs to states. One commenter recommended that CMS clarify whether the MCO, PIHP, or PAHP must authorize or provide the service within 72 hours. One commenter recommended that CMS address services that have lapsed while the appeal process was pending.

Response: We appreciate the broad support at § 438.424(a) but decline to adopt commenters’ recommendations. While we encourage managed care plans to reverse the adverse benefit determination as quickly as possible and as quickly as the enrollee’s health condition requires, we do not believe that 24 hours provides enough time for

managed care plans to authorize or provide the disputed service in many cases. We also decline to increase the timeframe, as we believe that 72 hours is the appropriate amount of time for managed care plans to authorize or provide the disputed service. We also note that the 72 hour requirement is consistent with MA requirements and should be familiar to most managed care plans operating across both markets. We understand commenters' concerns regarding administrative burden and costs, but we believe this is a usual part of doing business in the health care market. We clarify for commenters that § 438.424(a) requires managed care plans to authorize or provide the disputed services promptly; therefore, the MCO, PIHP, or PAHP must, at a minimum, authorize the service within 72 hours. We also clarify for commenters that lapsed services are the same as services not furnished, and managed care plans should promptly authorize or provide such disputed services as quickly as the enrollee's health condition requires.

Comment: One commenter recommended that CMS clarify at § 438.424(a) the requirement if a state or federal court orders the reversal of an adverse benefit determination.

Response: We clarify for the commenter that state and federal court orders should be followed and recommend that managed care plans reverse the adverse benefit determination consistent with such state and federal court order and the requirements at § 438.424(a) and (b).

Comment: A few commenters recommended that CMS clarify at § 438.424(b) that enrollees are not responsible for the cost of services furnished while the appeal is pending, if the adverse benefit determination is reversed. One commenter recommended that managed care plans be required to pay for the cost of services and reimburse the state for the cost of the appeal.

Response: We agree with commenters that enrollees should not be responsible for the cost of services and note that § 438.424(b) requires the state or managed care plan to pay for the services in accordance with state policy and regulations. If an enrollee paid for such services himself or herself, the enrollee must be reimbursed. We decline to add requirements that managed care plans pay the state for the cost of the appeal, as this is a state-specific issue and should be addressed between the state and managed care plan.

Comment: One commenter recommended that CMS add

requirements at § 438.424 to establish MCO, PIHP, and PAHP appeal rights regarding the reversal of adverse benefit determinations.

Response: We decline to add requirements at § 438.424 to establish MCO, PIHP, and PAHP appeal rights regarding the reversal of adverse benefit determinations, as this is a state-specific issue and should be addressed between the state and managed care plan.

After consideration of the public comments, we are finalizing § 438.424 as proposed without modification.

c. Medical Loss Ratio (§§ 438.4, 438.5, 438.8, and 438.74)

In keeping with our goals of alignment with the health insurance market whenever appropriate and to ensure that capitation rates are actuarially sound, we proposed that the MLR for MCOs, PIHPs, and PAHPs be calculated, reported, and used in the development of actuarially sound capitation rates. Under section 1903(m)(2) of the Act and regulations based on our authority under section 1902(a)(4) of the Act, actuarially sound capitation rates must be utilized for MCOs, PIHPs, and PAHPs. Actuarial soundness requires that capitation payments cover reasonable, appropriate and attainable costs in providing covered services to enrollees in Medicaid managed care programs. A medical loss ratio (MLRs) is one tool that can be used to assess whether capitation rates are appropriately set by generally illustrating how those funds are spent on claims and quality improvement activities as compared to administrative expenses, demonstrating that adequate amounts under the capitation payments are spent on services for enrollees. In addition, MLR calculation and reporting results in responsible fiscal stewardship of total Medicaid expenditures by ensuring that states have sufficient information to understand how the capitation payments made for enrollees in managed care programs are expended. We proposed to incorporate various MLR standards in the actuarial soundness standards proposed in §§ 438.4 and 438.5, and to add new §§ 438.8 and 438.74. The new regulation text would impose the requirement that MLR be calculated, reported and used in the Medicaid managed care rate setting context by establishing, respectively, the substantive standards for how MLR is calculated and reported by MCOs, PIHPs, and PAHPs, and state responsibilities in oversight of the MLR standards.

(1) Medical Loss Ratio as a Component of Actuarial Soundness (§§ 438.4 and 438.5)

In § 438.4(b)(8), we proposed that capitation rates for MCOs, PIHPs, and PAHPs must be set such that, using the projected revenues and costs for the rate year, the MCO, PIHP, or PAHP would achieve an MLR of at least 85 percent, but not exceed a reasonable maximum threshold that would account for reasonable administrative costs. We proposed 85 percent as it is the industry standard for MA and large employers in the private health insurance market. Considering the MLR as part of the rate setting process would be an effective mechanism to ensure that program dollars are being spent on health care services, covered benefits, and quality improvement efforts rather than on potentially unnecessary administrative activities.

We explained that it is also appropriate to consider the MLR in rate setting to protect against the potential for an extremely high MLR (for example, an MLR greater than 100 percent). When an MLR is too high, it means there is a possibility that the capitation rates were set too low, which raises concerns about enrollees' access to services, the quality of care, provider participation, and the continued viability of the Medicaid managed care plans in that market. We did not propose a specific upper bound for the MLR because states are better positioned to establish and justify a maximum MLR threshold, which takes into account the type of services being delivered, the state's administrative requirements, and the maturity of the managed care program.

In § 438.5(b)(5), we proposed that states must use the annual MLR calculation and reporting from MCOs, PIHPs, or PAHPs as part of developing rates for future years.

Comments received in response to §§ 438.4(b)(8) and 438.5(b)(5) are addressed at section I.B.3.b and c. of this final rule.

(2) Standards for Calculating and Reporting Medical Loss Ratio (§ 438.8)

We proposed minimum standards for how the MLR must be calculated and the associated reports submitted to the state so that the MLR information used in the rate setting process is available and consistent.

In paragraph (a), we proposed that states ensure through their contracts with any risk based MCO, PIHP, or PAHP that starts on or after January 1, 2017, the MCO, PIHP, or PAHP meet the standards proposed in § 438.8. Non-risk PIHP or PAHP contracts by their nature

do not need to calculate a MLR standard since contractors are paid an amount equal to their incurred service costs plus an amount for administrative activities. We also proposed that MLR reporting years would start with contracts beginning on or after January 1, 2017. We requested comment on this timeframe.

Paragraph (b) proposed to define terms used in this section, including the terms MLR reporting year and non-claims cost; several terms that are relevant for purposes of credibility adjustments were also proposed but are discussed in connection with § 438.8(h). Regarding the MLR reporting year, we acknowledged that states vary their contract years and we proposed to give states the option of aligning their MLR reporting year with the contract year so long as the MLR reporting year is the same as the rating period, although states would not be permitted to have a MLR reporting year that is more than 12 months. The 12 month period is consistent with how the private market and MA MLR is calculated. In the event the state changes the time period (for example, transitions from paying capitation rates on a state fiscal year to a calendar year), the state could choose if the MLR calculation would be done for two 12 month periods with some period of overlap. Whichever methodology the state elects, the state would need to clarify the decision in the actuarial certification submitted under § 438.7 and take this overlap into account when determining the penalties or remittances (if any) on the MCO, PIHP, or PAHP for not meeting the standards developed by the state.

Paragraph (c) addressed certain minimum standards for the use of an MLR if a state elects to mandate a minimum MLR for an MCO, PIHP, or PAHP. We acknowledged that some states have imposed MLR percentages on certain managed care plans that equal or exceed 85 percent and we did not want to prohibit that practice. Therefore, as proposed, paragraph (c) would permit each state, through its law, regulation, or contract with the MCO, PIHP, or PAHP to establish a minimum MLR that may be higher than 85 percent, although the method of calculating the MLR would have to be consistent with at least the standards in § 438.8.

Paragraphs (d), (e) and (f) proposed the basic methodology and components that make up the calculation of the MLR. We proposed the calculation of the MLR as the sum of the MCO's, PIHP's, or PAHP's incurred claims, expenditures on activities that improve health care quality, and activities

specified under § 438.608(a)(1) through (5), (7), (8) and (b) (subject to the cap in § 438.8(e)(4)), divided by the adjusted premium revenue collected, taking into consideration any adjustments for the MCO's, PIHP's, or PAHP's enrollment (known as a credibility adjustment). Our proposal used the same general calculation as the one established in 45 CFR 158.221 (private market MLR) with proposed differences as to what is included in the numerator and the denominator to account for differences in the Medicaid program and population. The proposal for MCOs, PIHPs, and PAHPs required calculation of the MLR over a 12-month period rather than the 3-year period required by 45 CFR 158.120.

The total amount of the numerator was proposed in paragraph (e) which, as noted above, is equal to the sum of the incurred claims, expenditures on activities that improve health care quality, and, subject to the cap in paragraph (e)(4), activities related to proposed standards in § 438.608(a)(1) through (5), (7), (8) and (b). Generally, the proposed definition of incurred claims comported with the private market and MA standards, with the proposed rule differing in several ways, such as:

- We proposed that amounts the MCO, PIHP, or PAHP receives from the state for purposes of stop-loss payments, risk-corridor payments, or retrospective risk adjustment would be deducted from incurred claims (proposed § 438.8(e)(2)(ii)(C) and (e)(2)(iv)(A)).

- Likewise, if a MCO, PIHP, or PAHP must make payments to the state because of a risk-corridor or risk adjustment calculation, we proposed to include those amounts in incurred claims (proposed § 438.8(e)(2)(iv)(A)).

- We proposed that expenditures related to fraud prevention activities, as set forth in § 438.608(a)(1) through (5), (7), (8) and (b), may be attributed to the numerator but would be limited to 0.5 percent of MCO's, PIHP's, or PAHP's premium revenues. We also proposed that the expenses for fraud prevention activities described in § 438.8(e)(4) would not duplicate expenses for fraud reduction efforts for purposes of accounting for recoveries in the numerator under § 438.8(e)(2)(iii)(C), and the same would be true in the converse. We specifically requested comment on the approach to incorporating fraud prevention activities and the proportion of such expenditures in the numerator for the MLR calculation, as this proposal was unique to Medicaid managed care.

We proposed that non-claims costs would be considered the same as they

are in the private market and MA rules. We proposed in § 438.8(e)(2)(v)(A)(3) that certain amounts paid to a provider are not included as incurred claims; we noted an intent to use the illustrative list in the similar provisions at § 422.2420(b)(4)(i)(C) and 45 CFR 158.140(b)(3)(iii) to interpret and administer this aspect of our proposal. Incurred claims would also not include non-claims costs and remittances paid to the state from a previous year's MLR experience.

In paragraph (e)(2)(iii)(A), we proposed that payments made by an MCO, PIHP, or PAHP to mandated solvency funds must be included as incurred claims, which is consistent with the private market regulations on market stabilization funds at 45 CFR 158.140(b)(2)(i).

Paragraph (e)(2)(iv) would take a consistent approach with the private market rules at 45 CFR 158.140(b)(4)(ii) that amounts that must either be included in or deducted from incurred claims are net payments related to risk adjustment and risk corridor programs. We proposed in paragraph (e)(2)(v) that the following non-claims costs are excluded from incurred claims:

Amounts paid to third party vendors for secondary network savings, network development, administrative fees, claims processing, and utilization management; and amounts paid for professional or administrative services. This approach is consistent with the expenditures that must be excluded from incurred claims under the private market rules at 45 CFR 158.140(b)(3).

Proposed paragraph (e)(2)(vi) would incorporate the provision in MA regulations (§ 422.2420(b)(5)) for the reporting of incurred claims for a MCO, PIHP, or PAHP that is later assumed by another entity to avoid duplicative reporting in instances where one MCO, PIHP, or PAHP is assumed by another.

We also proposed at § 438.8(e)(3) that an activity that improves health care quality can be included in the numerator as long as it meets one of three standards: (1) It meets the requirements in 45 CFR 158.150(b) (the private market MLR rule) for an activity that improves health care quality and is not excluded under 45 CFR 158.150(c); (2) it is an activity specific to Medicaid managed care External Quality Review (EQR) activities (described in § 438.358(b) and (c)); or (3) it is an activity related to Health Information Technology and meaningful use, as defined in 45 CFR 158.151 and excluding any costs that are deducted or excluded from incurred claims under paragraph (e)(2). Regarding activities related to Health Information

Technology and meaningful use, we encouraged states to support the adoption of certified health information technology that enables interoperability across providers and supports seamless care coordination for enrollees. In addition, we referred MCOs, PIHPs, and PAHPs to the Office of the National Coordinator for Health Information Technology's 2016 Interoperability Standards Advisory (2016 ISA) published on November 6, 2015 (available at <https://www.healthit.gov/sites/default/files/2016-interoperability-standards-advisory-final-508.pdf>), which contains a list of the best available standards and implementation specifications enabling priority health information exchange use cases.

Because of our understanding that some managed care plans cover more complex populations in their Medicaid line of business than in their private market line(s) of business, we believed that the case management/care coordination standards are more intensive and costly for Medicaid managed care plans than in a typical private market group health plan. We proposed to use the definition of activities that improve health care quality in 45 CFR 158.150 to encompass MCO, PIHP, and PAHP activities related to service coordination, case management, and activities supporting state goals for community integration of individuals with more complex needs such as individuals using LTSS but specifically requested comment on this approach and our proposal not to specifically identify Medicaid-specific activities separately in the proposed rule. We indicated our expectation that MCOs, PIHPs, and PAHPs would include the cost of appropriate outreach, engagement, and service coordination in this category.

Paragraph (f) proposed what would be included in the denominator for calculation of the MLR. Generally, the denominator is the MCO's, PIHP's, or PAHP's premium revenue less any expenditure for federal or state taxes and licensing or regulatory fees. In proposed § 438.8(f)(2), we specified what must be included in premium revenue. We noted our expectation that a state will have adjusted capitation payments appropriately for every population enrolled in the MCO, PIHP, or PAHP so that the capitated payment reasonably reflects the costs of providing the services covered under the contract for those populations and meets the actuarial soundness standards in § 438.4 through § 438.7. We proposed that any payments by states to managed care plans for one-time, specific life events of enrollees—events that do not

receive separate payments in the private market or MA—would be included as premium revenue in the denominator. Typical examples of these are maternity “kick-payments” where a payment to the MCO is made at the time of delivery to offset the costs of prenatal, postnatal and labor and delivery costs for an enrollee.

Paragraph (f)(3) proposed that taxes, licensing and regulatory fees be treated in the same way as they are treated in the private market and MA, as deductions from premium revenue. Similar to the private market MLR rule in 45 CFR 158.161(b), fines or penalties imposed on the MCO, PIHP, or PAHP would not be deducted from premium revenue and must be considered non-claims costs (proposed § 438.8(e)(2)(v)(A)(4)). Consistent with MA, we proposed in paragraph (f)(3)(v) to allow Community Benefit Expenditures (CBE), as defined in 45 CFR 158.162(c) (which is analogous to the definition in § 422.2420(c)(2)(iv)(A)), to be deducted up to the greater of 3 percent of earned premiums or the highest premium tax rate in the applicable state multiplied by the earned premium for the MCO, PIHP, or PAHP. We requested comment on this proposal. In proposed paragraph (f)(4), we incorporated the provision for MLR under MA regulations at § 422.2420(c)(4) for the reporting of the denominator for a MCO, PIHP, or PAHP that is later assumed by another entity to avoid duplicative reporting in instances where one MCO, PIHP, or PAHP is assumed by another.

Paragraph (g) proposed standards for allocation of expenses. MCOs, PIHPs, and PAHPs would use a generally accepted accounting method to allocate expenses to only one category, or if they are associated with multiple categories, pro-rate the amounts so the expenses are only counted once.

We also proposed regulation text to address credibility adjustments after summarizing how section 2718(c) of the Public Health Service Act (PHS Act) addresses them and the work on credibility adjustments by the National Association of Insurance Commissioners (NAIC). In paragraph (h), we proposed to adopt the method of credibility adjustment described in the NAIC's model regulation on MLR and, to the extent possible, to follow the approach used in both the private market (45 CFR 158.230) and MA and Medicare Part D MLR rules (§§ 422.2440, 423.2440). For our detailed explanation of credibility adjustments, see 80 FR 31111–31112.

In paragraph (i)(1), we proposed that the MLR be calculated and reported for the entire population enrolled in the

MCO, PIHP, or PAHP under the contract with the state unless the state directed otherwise. Our proposal permitted flexibility for states to separate the MLR calculation by Medicaid eligibility group based on differences driven by the federal medical assistance percentage (FMAP) (to simplify accounting with the federal government), by capitation rates, or for legislative tracking purposes. However, while states could divide eligibility groups for MLR calculation and reporting purposes, we explained that our proposal would not allow different calculation standards or use of different MLR percentages for different eligibility groups. The state may choose any aggregation method described, but proposed paragraph (k)(1)(xii) stipulated that the MCO, PIHP, and PAHP must clearly show in their report to the state which method it used.

We proposed in paragraph (j) minimum standards for when a state imposed a remittance requirement for failure to meet a minimum MLR established by the state. Under our proposal, an MCO, PIHP, or PAHP would pay a remittance to the state consistent with the state requirement. We encouraged states to incent MCO, PIHP, and PAHP performance consistent with their authority under state law. While states would not have to collect remittances from the MCOs, PIHPs, or PAHPs through this final rule, we encourage states to implement these types of financial contract provisions that would drive MCO, PIHP, and PAHP performance in accordance with the MLR standard. In section 1.B.1.c.(3) of this final rule, we address the treatment of any federal share of potential remittances.

In paragraph (k), we proposed that MCOs, PIHPs, and PAHPs would submit a report meeting specific content standards and in the time and manner established by the state; we proposed that such deadline must be within 12 months of the end of the MLR reporting year based on our belief that 12 months afforded enough time after the end of the MLR reporting year for the state to reconcile any incentive or withhold arrangements they have with the MCOs, PIHPs, and PAHPs and for the managed care plans to calculate the MLR accurately. We requested comment on whether this is an appropriate timeframe. Our proposal would have permitted the state to add content requirements to the mandatory reports.

In paragraph (l), we proposed that MCOs, PIHPs, and PAHPs need not calculate or report their MLR in the first year they contract with the state to provide Medicaid services if the state

chooses to exclude that MCO, PIHP, or PAHP from the MLR calculation in that year. If the state chose that exclusion option, the first MLR reporting year for the MCO, PIHP, or PAHP would be the next MLR reporting year and only the experience of the MCO, PIHP, or PAHP for that MLR reporting year would be included. We considered whether to provide similar flexibility for situations where a Medicaid MCO, PIHP, or PAHP covers a new population (that is, the state decides to cover a new population of Medicaid beneficiaries in managed care), but determined that additional considerations did not need to be factored in since capitation payments and any risk mitigation strategy employed by the state would already be considered in the numerator and denominator. We requested comment on this proposal and whether we should further define when a managed care plan newly contracts with the state.

We proposed in paragraph (m) that in any case where a state makes a retroactive adjustment to the rates that affect a MLR calculation for a reporting year, the MCO, PIHP, or PAHP would need to recalculate the MLR and provide a new report with the updated figures.

In paragraph (n), we proposed that the MCO, PIHP, or PAHP provide an attestation when submitting the report specified under proposed paragraph (k) that gives an assurance that the MLR was calculated in accordance with the standards in this final section.

We received the following comments in response to our proposals in § 438.8.

Comment: There were several commenters that supported the proposed implementation date of the MLR requirement by 2017, while other commenters recommended that implementation should be extended by at least a year past the proposed date to permit states and managed care plans adequate time to make system changes and contractual modifications to comply with the provisions. Another commenter suggested phasing in the implementation of the MLR.

Response: We believe that with the changes to the proposed rule in this final rule, some systems modifications and contract terms will need to be updated to accurately report the MLR; however, because states only need to include this provision in the contracts and the reporting of the MLR will not actually occur until 2018, we believe there is adequate time for managed care plans and states to make any necessary systems modifications during the 2017 contract year. We also believe that it would not be feasible to devise a phase-in strategy that would be fair to all the

managed care plans and states. In consideration of the generally applicable compliance date of contracts starting on or after July 1, 2017, we are finalizing the effective date in the proposed rule for MLR reporting requirements for contracts that start on or after July 1, 2017.

Comment: We received numerous comments supporting the proposed rule which allows states, consumers and stakeholders the ability to review the MLR results, based on a consistent methodology, across managed care plans. Alternately, we received comments requesting that CMS allow more discretion to states and managed care plans as they believe that additional flexibility is necessary to ensure there is adequate managed care plan participation in states and ensure that managed care plans have the ability to provide services in a flexible manner to support the overall health of their beneficiaries. Some commenters provided that states should be able to implement other types of mitigation strategies, such as profit caps or gain sharing maximums, rather than an MLR.

Response: We agree that the calculation of the MLR should be consistent so that there will be some level of meaningful comparison across states and that it should be as consistent as possible with other markets. Per § 438.66(e)(2)(i), the MLR experience of the managed care plans will be included in the financial performance section of the annual program report that is made available on the state's Web site. With these rules, states may choose to require managed care plans to meet a specific MLR threshold that is 85 percent or higher and to require a remittance if a managed care plan fails to meet the specified MLR percentage. We believe that including additional flexibility beyond what is in this final rule would hinder CMS and other stakeholders from having an accurate picture of the Medicaid managed care landscape. States have the flexibility to use other risk mitigation strategies in addition to the MLR calculation, reporting, and rate development standards in this part so long as the MLR requirements are met.

Comment: Several commenters supported CMS' position to allow states to set a MLR standard that is higher than 85 percent or even believe that CMS should require an MLR standard higher than 85 percent, while others thought states should have the ability to set an MLR lower than 85 percent. Other commenters believed that Medicaid managed care plans are more similar to the individual market than the large group market and that the 80 percent standard applicable to individual

market insurance should be used for Medicaid managed care plans. In addition, some commenters believed that certain types of managed care plans, such as dental only plans and other managed care plans, may be disadvantaged by the 85 percent standard and thought that such managed care plans should only be held to an 80 percent standard (consistent with the individual market at 45 CFR 158.210(c)) or that they should be excluded from the MLR standard altogether. The dental-only plans stated that the claims expenditures for dental-only claims is very low while they still have similar operating margins to managed care plans that cover much more expensive benefits, which makes an 85 percent MLR nearly impossible to meet. They also noted that dental-only plans are not subject to the private market MLR reporting and rebate requirements as they are an excepted benefit under the PHS Act, and in the interest of alignment, this final rule should similarly exempt dental PAHPs.

Some commenters expressed concern about allowing states to set an MLR standard that is higher than 85 percent. These commenters provided that states currently have discretion to include expenses in either the numerator or the denominator and have set MLRs with those principles in mind; however, this final rule would remove that flexibility from states to develop and establish rules governing the calculation of the MLR. In addition, these commenters were concerned that if a state requires an MLR to be met that is too high, managed care plans will be incentivized to leave the market. These commenters recommended that CMS set an upper limit to a state-established MLR requirement to protect managed care plans from a MLR standard that is too high by requiring an additional payment to managed care plans if the managed care plans have an MLR that exceeds a state-imposed MLR standard that is greater than 85 percent. Commenters provided that such an additional payment to the managed care plans would be necessary to ensure that there is adequate funding in every year, as managed care plans are currently able to keep excess funds from one year to offset future losses.

Response: We maintain that requiring capitation rate development to project an 85 percent MLR is appropriate to apply to Medicaid managed care plans due to their similarity with large group health plans. Most Medicaid managed care programs are mandatory for covered populations which results in enrollment that is larger, more predictable, and with potentially less

adverse selection than what occurs in the individual market. Therefore, we are retaining the minimum target of 85 percent in the final rule for the projected MLR used in ratesetting. As this rule only requires the MCOs, PIHPs, and PAHPs to calculate and report their MLR experience and that the state take it into consideration while setting actuarially sound rates, we do not believe that dental-only or other PAHPs will be negatively impacted. States, when determining whether to require dental-only or other PAHPs to meet a specified MLR standard or be subject to a remittance, should take the concerns raised by the commenters into consideration.

We appreciate the concern that states may have a desire to set an excessively ambitious MLR requirement, but we believe that states, with their understanding of managed care plan's historical experience and the unique characteristics of the state's population, are best equipped to determine an appropriate MLR when setting minimum MLR requirements, which could be above 85 percent. We encourage managed care plans to address concerns about state-established MLR requirement with the state. Note that the actuarial soundness requirements in § 438.4(a) provide that capitation rates project the reasonable, appropriate, and attainable costs under the contract and are developed in accordance with § 438.4(b).

Comment: We received some comments that requested CMS allow for a process whereby the state has the ability to request an MLR that is lower than 85 percent if it is found that the standard would destabilize the market or create issues with plan choice or competition. They believe that this would be consistent with the individual market requirement at 45 CFR 158.301. We also received comments that suggested that CMS allow for states to set different MLRs for different programs and geographic areas.

Response: We maintain that the Medicaid managed care market is most similar to that of group health plans or the MA market; therefore, we do not agree that an MLR standard lower than 85 percent is appropriate. As noted in our proposed rule, CMS has allowed states to impose a MLR standard higher than 85 percent and to also determine the level at which the MLR is calculated and reported (that is, at the contract level or by population under the contract).

Comment: A number of commenters requested clarification as to whether their specific managed care plans or products would be subject to the MLR

reporting requirements in this section. A commenter requested clarification as to how the MLR rules would apply to Medicaid managed care programs and contracts that cover a small group of individuals.

Response: All Medicaid managed care plans that are an MCO, PIHP or PAHP, and states that contract with such managed care plans, need to meet the MLR-related requirements of this final rule as of the effective date or, if later, the compliance date. Specific requests for clarification as to the applicability of this final rule to a particular plan or product should be directed to the state or appropriate CMS contact. The final rule includes a credibility adjustment at § 438.8(h) for those managed care plans with a small number of enrollees. Those managed care plans may have credibility adjustment(s) applied to the MLR calculation.

Comment: We received a few comments requesting an explanation as to how this MLR provision would be applied to Medicare-Medicaid coordinated products approved under financial alignment demonstrations under section 1115A of the Act. Commenters stated that these products should either be exempted from this requirement or that the MLR be compared across both lines of business, rather than individually, due to the potential high amount of administrative expenditures associated with the Medicaid product. Commenters also suggested that the MLR standard be 80 percent for these products to account for that issue.

Response: Per the requirements in this rule, all Medicaid MCOs, PIHPs and PAHPs need to calculate and report their MLR experience for Medicaid, unless an MLR covering both Medicare and Medicaid experience is calculated and reported consistent with the CMS requirements for an integrated Medicare-Medicaid product. We are available to provide state specific technical assistance to determine how best to calculate and report the MLR in these instances.

Comment: One commenter requested that CMS clarify that this requirement does not apply to PACE programs.

Response: The rules applicable to PACE are in 42 CFR part 460.

Comment: A commenter requested that CMS simplify the definition of "MLR reporting year" in § 438.8(b) to reference the state's rating period. The commenter suggested that the MLR reporting year (as the 12 month period that MLR experience is calculated and reported) align with the 12 month rating period for which capitation rates were developed. The proposed definition of

MLR reporting year provided that the 12 month period could be on a calendar, fiscal, or contract year basis but must ultimately be consistent with the state's rating period.

Response: We agree with the commenter that the definition for MLR reporting year could be simplified through a reference to the rating period. We will finalize the definition of MLR reporting year as a period of 12 months consistent with the rating period selected by the State. This change does not diminish the flexibility of the state to define the rating period. In conjunction with that change, we will add a definition for "rating period" in § 438.2. The discussion of that change is provided in section I.B.3.a. of this final rule.

Comment: We received a number of comments requesting that CMS revise the standard for the MLR calculation to a 3-year rolling average basis instead of the 1-year calculation as proposed. Other commenters supported the proposed 1-year MLR reporting year. Supporters of the 3-year data aggregation believe that a 3-year rolling average will allow anomalies in membership or other fluctuation to be averaged over time and provide a more accurate and predictable result of managed care plan performance. Although these commenters acknowledged that the 1-year calculation timeframe was consistent with Medicare MLR rules, they stated that the Medicaid MLR rules are not governed by statute to require a 1-year calculation period and that a 3-year period should be adopted.

Response: The commenters are correct that the Medicare MLR rules provide for a 1-year time period. Due to the link between MLR experience and the development of actuarially sound capitation rates at § 438.4(b)(8) (redesignated in the final at § 438.4(b)(9)), a 1-year time period will provide more accurate information to the states about the performance of their managed care plans. This way, the state can match the assumptions underlying the rate setting for that time period with the actual MLR experience to better inform rate setting in future periods. As we expect rate setting to be done on an annual basis, we do not believe a 3-year rolling average should be used for the Medicaid MLR calculation. Therefore, we are finalizing the rule with the 1-year MLR reporting year.

Comment: Some commenters requested that CMS standardize the MLR reporting year on a calendar year basis. Commenters provided that allowing states to choose the 12 month period for the MLR reporting year

would hinder the ability to make comparisons of managed care plans' MLR experience across states. Additionally, MLR reporting years that are different than a calendar year would not be able to be based on annual, audited financial reporting. Another commenter requested information as to how CMS would compare programs when states have different benefit sets and enrolled populations.

Response: We agree that a difference in the MLR reporting year and other variables in program design may make it challenging to compare managed care plan MLR experience across states. However, § 438.4(b)(8) (redesignated in the final at § 438.4(b)(9)), links MLR to the development of actuarially sound rates and states need the flexibility to define the MLR reporting year for purposes of comparing the assumptions in the rating period to the actual experience in the MLR reporting year. We intend to use these reports to help us understand how accurate the assumptions were in the development of capitation rates. This evaluation may entail comparing MLR experience across the states, but such a comparison would not have to be for the same time periods and would otherwise be focused on managed care contracts that covered similar populations. Our primary comparison will be between the managed care plans' MLR experience and the assumptions used in the rate development for that same period within a state.

Comment: Some commenters requested clarification of the phrase in § 438.8(c) that read "If a state elects . . ." as this appears to imply that meeting the minimum MLR standard is optional, whereas the preamble to the proposed rule appeared to make the minimum MLR a requirement.

Response: Under this final rule at § 438.8, the calculation and reporting of the MLR is a requirement on the managed care plans. For capitation rates to be actuarially sound in accordance with § 438.4(b)(8) (redesignated in the final at § 438.4(b)(9)), the capitation rates must be set so that the managed care plan is projected to meet at least an 85 percent MLR and failure to meet that MLR threshold (or exceeding that threshold) for a rating year must be taken into account in setting capitation rates for subsequent periods. However, this final rule in and of itself does not require managed care plans, as a matter of contract compliance, to meet a specific MLR.

The regulation text noted by the commenters ("If a state elects to mandate a minimum MLR for its . . .") identifies how the state may impose a

requirement to meet a minimum MLR—not just calculate and report the managed care plan's MLR experience—and that such a minimum MLR must be at least 85 percent. We will review the MLR reports during the review of the annual rate certification and will inquire about current assumptions if it is found that the historical MLR is found to be below 85 percent.

No comments were received on § 438.8(d); however, we will finalize that section with a technical edit to remove the designation of paragraphs (1) and (2). The substantive regulatory text proposed at § 438.8(d)(1) will be finalized as § 438.8(d).

Comment: One commenter requested that CMS describe what would be counted towards the administrative and profit categories rather than what would be counted towards the 85 percent in the numerator of the MLR calculation.

Response: We maintain that it is best to be consistent with the private and Medicare markets which define the MLR as we proposed; therefore, we will continue to define the expenditures that can be counted towards the 85 percent in the numerator.

Comment: A few commenters requested that CMS remove the term "medical" from § 438.8(e)(2)(i)(A) when cross-referencing the services defined in § 438.3(e), as some of those services may not be medical in nature. Commenters suggested that retaining the term "medical" in the definition of incurred claims would inadvertently exclude ancillary or other LTSS services from the numerator. In addition, a commenter requested clarification that, in addition to services included in the state plan, managed care plans be able to treat extra services beyond what is outlined in the state plan as incurred claims for purposes of the MLR calculation.

Response: We agree that services meeting the definition of § 438.3(e) may not always be medical in nature and are removing the term medical from § 438.8(e)(2)(i)(A). We remind commenters that all services, including behavioral health, acute care, pharmacy, NEMT, and LTSS are included in this definition. Regarding the commenter that questioned the treatment of services provided in addition to those covered under the state plan, we believe the commenter is referencing value-added services. We confirm that these services may be considered as incurred claims in the numerator for the MLR calculation.

Comment: One commenter recommended that CMS change the term "reserves" to "liability" in § 438.8(e)(2)(i)(B) as "reserves" in this context has additional meaning beyond an estimate of what has already

occurred. In addition, the commenter recommended that CMS also include "incurred but not reported" amounts, as well as amounts withheld from paid claims or capitation payments which would make the inclusion of § 438.8(e)(2)(i)(C) unnecessary. The commenter further stipulated that CMS should clarify that any remittances should not be calculated until the amounts withheld from network providers are either paid out or retained by the managed care plan.

Response: We agree with the commenter that the use of the term "reserves" in § 438.8(e)(2)(i)(B) was too broad and we have modified the text to indicate that unpaid claims liabilities should be counted towards incurred claims for purposes of the MLR calculation. We also agree that the addition of "incurred but not reported claims" should be in this paragraph. We do not agree that the provision in § 438.8(e)(2)(i)(C), pertaining to withholds from payments made to network providers, should be removed. This should remain a distinct category of incurred claims in consideration of the expansion of value-based purchasing. While we agree that in best practice all of these payments would either be made or retained by the managed care plan before determining remittances, states have the flexibility to develop a remittance strategy and to determine whether to calculate the remittance before or after these payments are finalized.

Comment: One commenter stated its understanding of § 438.8(e)(2)(i)(B) as being that incurred claims would account for changes in claims reserves without limitation and that such an approach was important for safety-net managed care plans that do not typically have larger parent corporations to draw funding from if claims expenditures are higher than expected. Another commenter specifically requested that certain components of claims reserves noted on the NAIC form, such as policy reserves, unpaid claims adjustment expenses, or administrative expense liability, be excluded as they are not applicable to Medicaid.

Response: While we agree with the commenter that the provision does not specify a limit to changes in claims reserves, we believe this is something that states should review when looking at the MLR calculation. If a managed care plan is consistently making significant changes to claims reserves in the fourth quarter of the MLR reporting year, that could be an indication that the managed care plan may have not met the MLR standard absent those changes and may not actually need those

additional claims reserves. We do not agree that policy reserves, unpaid claims adjustment expenses, or administrative expense liability should be excluded from claims reserves. An explicit exclusion of those expenses could have the effect of inhibiting innovations in program design and, if these items are inapplicable to Medicaid as the commenter suggested, there would be minimal amounts reported under those reserve categories.

Comment: One commenter indicated that § 438.8(e)(2)(i)(D) and (E) provides that incurred claims include “[c]laims that are recoverable for anticipated coordination of benefits” or “[c]laims payment recoveries received as a result of subrogation.” The commenter noted that these provisions could be interpreted to mean that claims recoverable or received are to be added to the other listed items, when in actuality such amounts would be a deducted from incurred claims. To the extent that recoveries are identified and included in the overall estimate of claims liability, the recoveries would be included in § 438.8(e)(2)(i)(B). The commenter provided that this interpretation would result in only recoveries not included in the estimated liability to be accounted for in § 438.8(e)(2)(i)(B).

Response: The commenter is correct insofar as recoverable and recovered claims should be included in incurred claims as negative adjustments; the private market MLR rule notes that these should be “included” with the expectation that issuers understand this to mean a negative adjustment. The same expectations apply to the Medicaid MLR calculation.

Comment: One commenter requested that CMS clarify why claims that are recoverable for anticipated coordination of benefits (COB) and claims payment recoveries received as a result of subrogation are classified separately at § 438.8(e)(2)(i)(D) and § 438.8(e)(2)(i)(E).

Response: The private market rules at 45 CFR 158.140(a)(2) distinguish claims that are recoverable for anticipated coordination of benefits and claims payment recoveries received as a result of subrogation. We do not see a reason to deviate from that standard and have implemented it here for calculation of MLR for Medicaid managed care plans.

Comment: One commenter suggested that § 438.8(e)(2)(i)(H), which would include reserves for contingent benefits and the medical claim portion of lawsuits under incurred claims, was duplicative of § 438.8(e)(2)(i)(G), which would include changes in other claims-related reserves under incurred claims.

Response: While we appreciate the commenter alerting us to this possible duplication, we think that it is helpful to specify in the rule that only the medical and no other portions of litigation reserves are allowable as an inclusion in incurred claims.

Comment: One commenter requested that CMS change net adjustments for risk corridors or risk adjustment from § 438.8(e)(2)(iv)(A), to either be deducted or included under incurred claims in the numerator, to the denominator. The commenter stated that this change would be more consistent with how premium revenues are calculated in Medicaid.

Response: We agree with commenters that net adjustments for risk corridors or risk adjustment should be in the denominator, rather than the numerator, consistent with the MA requirements at § 422.2420(c)(1)(i). The requirements at 45 CFR 158.140(a)(4)(ii) were based on provisions in the Affordable Care Act that were unique to the risk corridor program in the private market. Therefore, we agree that it is appropriate to align with MA for the treatment of risk adjustment in the MLR calculation. To effectuate this change, the proposed text at § 438.8(e)(2)(iv)(A) is moved to § 438.8(f)(vi).

Comment: We received a comment requesting that CMS specify at § 438.8(e)(2)(v)(A)(3) that expenditures for subcontractors’ administrative activities need to be considered as administrative costs of the managed care plan and treated accordingly for purposes of the MLR calculation. The commenter stated that in instances where the subcontractor is only providing medical or LTSS services, all of their fee can be included in incurred claims, but in cases where they are providing a mix of medical or LTSS services and administrative activities, the managed care plan should not be able to count that entire expense towards incurred claims. Another commenter requested that CMS impose the four-part test included in CCHIO technical guidance when considering subcontractors’ payments as incurred claims.

Response: We agree that in cases where the amount of the payment to the subcontractor includes an amount for administrative activities, that amount should be counted as an administrative expense included in the MLR calculation. Section 438.8(e)(2)(v)(A)(3) excludes amounts paid to subcontractors for administrative activities from inclusion in incurred claims. We do not believe we need to impose the four-part test at this time, as when a managed care plan is using a

subcontractor to deliver some of the services under the contract (which may be medical or LTSS services) they will count as incurred claims up to the point where payments are divided according to medical or LTSS services and administrative functions. States have the discretion to apply the four-part test. A state’s decision to use the four-part test, or to not use the four-part test, is consistent with the requirements for the calculation of the MLR in § 438.8.

Comment: One commenter requested that CMS clarify what is meant by “amounts paid to third party vendors for secondary network savings,” as stated in § 438.8(e)(2)(v)(A)(3). Another commenter believed that including this provision may prohibit value-based purchasing and requested that CMS remove it to incent state innovation in this area.

Response: The amounts paid to third party vendors for secondary network savings would be payments made by one managed care plan to another vendor to purchase their network for use as a secondary network. In practice, the managed care plan purchases another managed care plan’s network to serve as contracted, out-of-network providers so as to avoid single-case agreements with those providers, resulting in savings on out-of-network service costs. We do not believe including this provision would prohibit value-based purchasing or disincent managed care plans from entering into such arrangements; issuers in the private markets utilize this same business practice. Furthermore, in consideration of changes made to the denominator to exclude incentive payments from premium revenue, we believe there are adequate incentives for value-based purchasing within the scope of the MLR calculation.

Comment: One commenter requested clarification as to whether payments to solvency funds are incurred claims. This commenter noted that in their state, the managed care plans may pay into the solvency fund at the beginning of the year, but may receive some or all of that money back depending on how the managed care plan performed.

Response: To clarify the treatment of payments to and from solvency funds, we are finalizing the rule to move the provision of net payments to or receipts from solvency funds under the provision of incurred claims that either includes or deducts the payments or receipts related to solvency funds from incurred claims at § 438.8(e)(2)(iv). The designation of this provision at § 438.8(e)(2)(iv) is due to other modifications to proposed § 438.8(e)(2)(iv)(A) relating to risk

adjustment and risk corridors addressed earlier in this section of the preamble. This revision should address the instances where a managed care plan receives funding from the solvency fund.

Comment: One commenter noted that § 438.8(e)(2)(ii)(B) provides that items to be deducted from incurred claims include, “Prescription drug rebates received.” The commenter recommended that we change this wording to reflect rebates received and accrued. In addition to pharmaceutical rebates receivable and claim overpayment receivables, the NAIC Annual Statement also includes the following categories of health care receivables: loans and advances to providers, capitation arrangement receivables, risk sharing receivables, and other health care receivables. The commenter also requested clarification regarding whether both admitted and non-admitted health care receivables are included in incurred claims.

Response: We agree that the language should be changed to reference rebates that have been received and accrued and will finalize the rule with this language included in § 438.8(e)(2)(ii)(B). We also confirm that both admitted and non-admitted health care receivables are included when determining the amount of incurred claims.

Comment: One commenter noted that § 438.8(e)(2)(ii)(C) provides that the incurred claims in the numerator are to be reduced by “State subsidies based on a stop-loss payment methodology,” but the denominator does not also allow for a specific inclusion or exclusion based on premiums paid or received from the reinsurance provider with whom the managed care plan may contract. This commenter suggested some parameters that CMS should consider in allowing those revisions to the denominator.

Response: The intention was to address these types of risk sharing mechanisms under § 438.8(e)(2)(iv)(A) rather than § 438.8(e)(2)(ii)(C). We recognize that the language initially proposed was potentially limited to only risk corridors or risk adjustment programs and therefore we have revised this paragraph to reference risk sharing mechanisms broadly to encompass risk corridors, risk adjustment, reinsurance and stop-loss programs that are included in the contract with the MCO, PIHP or PAHP. We believe this change along with the deletion of § 438.8(e)(2)(ii)(B), addresses the issue.

Comment: One commenter noted that § 438.8(e)(2)(iii)(B) provides that incurred claims used in the MLR calculation include, “The amount of incentive and bonus payments made to

network providers.” Commenters stated that those payments should not be limited to payments actually made and should include accruals for amounts expected to be paid.

Response: We agree that amounts expected to be paid should also be included in this calculation. We encourage managed care plans and states to exercise caution and ensure that these payments are made within the 12 month period after the end of the MLR reporting year. We believe this should provide sufficient time for managed care plans to calculate incentive or bonus payments and issue such payments to network providers.

Comment: Several commenters opposed including unpaid cost sharing amounts in the premium revenue component of the MLR denominator because they did not want to provide additional incentives for managed care plans to collect cost sharing from enrollees. Commenters did not believe that managed care plans should always collect the cost sharing amounts from the enrollees.

Response: We believe that the incentives to collect cost sharing, or for managed care plans to pay providers their claim amount less the cost sharing that the provider should be collecting, is already an incentive for managed care plans based on the way actuarially sound rates are set. States now reduce the claims expense by cost sharing when determining the amount to be paid to the managed care plans. We do not believe that including unpaid cost sharing in the denominator would further incentivize managed care plans to collect those amounts. Further, most cost sharing in Medicaid is collected at the provider level at the point of service. Only in limited circumstances would we expect this to be a factor in the Medicaid MLR calculation due to the cost sharing structure.

Comment: We received multiple comments requesting that CMS specifically include activities related to service coordination, case management and activities supporting state goals for community integration in the definition of quality improvement activities. Commenters stressed that these activities should not be excluded from the numerator as they believe they are important activities that the managed care plans should be doing for a population with complex health care needs. Other commenters recommended more specific definitions to preclude managed care plans from including general operating expenses under this category for the MLR calculation. Commenters recommended that CMS conduct or require states to implement

an approval or audit process to make sure that the activities are actually improving the quality of health care.

Response: We appreciate the need for these types of activities to be considered health care quality improving activities and agree that the types of activities described by the commenters should be included in the numerator. We disagree with the commenters that these activities should be listed explicitly in the rule. After reviewing the description in 45 CFR 158.150, we believe that all the activities described by the commenters are already included in the definition and do not require explicit reference in the rule outlined in § 438.8. For example, 45 CFR 158.150(b)(2)(i)(A)(1) provides that case management and care coordination are explicitly included in activities that improve health outcomes which would encompass these activities for all individuals enrolled in the plan including enrollees using LTSS, or other enrollees with other chronic conditions. We are concerned that if we provide a specific list of these activities, some unique state programs that offer similar types of activities with a different name would be precluded from the category and potentially not included in the numerator.

While the definition of quality improvement activities is broad, the requirements for accounting for general operating expenses, also known as non-claims costs, are not. Section 438.8(b) explicitly provides that non-claims costs are administrative services that are not expenditures on quality improving activities as defined at § 438.8(e)(3). We decline to institute an approval process for activities that could qualify as quality improvement activities as that would be inconsistent with the MA and private market MLR requirements; however, states are able to do so if they choose.

Comment: Some commenters requested that CMS make clear that activities related to Health Improvement Technology (HIT) not be limited to what qualifies as “meaningful use” because some providers, such as behavioral health or LTSS providers, do not meet the requirements for meaningful use. These commenters also requested that CMS allow states to receive matching funds for efforts to help providers improve their HIT for those providers left out of the initial meaningful use program.

Response: The private market rules at 45 CFR 158.151 allow payments to providers who do not qualify for the HHS meaningful use payments to be included in the numerator of the MLR calculation. The ability to claim federal

matching funds on HIT activities for other provider types is outside the scope of this rule.

Comment: Some commenters requested that CMS expand the types of activities that can be counted as activities that improve health care quality related to wellness incentives so that managed care plans can count the costs associated with providing those payments to more than the Medicaid population. They believe that these activities are necessary to ensure better quality of life and care and that limiting the expenditures to just the Medicaid population will cause the managed care plans to limit the scope and eligibility of the programs and make them less effective.

Some commenters requested that additional costs related to calculating and administering enrollee incentives for the purposes of improving quality be included either as an activity that improves health care quality or as a separate category under the numerator. Commenters stated that such a change should address social determinants of care, promoting patient engagement, and improving self-sufficiency.

Response: We agree that wellness programs have the potential to positively impact the community and the Medicaid population, but we disagree that the cost of providing these activities to those outside of the Medicaid population should be included in quality improvement activities as part of the MLR calculation. Managed care plans that have other lines of business or that may be considered non-profit have other opportunities to include any additional expenses for wellness activities in the MLR calculation in accordance with the regulatory requirements for those respective product lines or as part of CBE. Therefore, we are not changing the wellness program definition to allow additional expenditures other than what is already included in the current private market rule at 45 CFR 158.150.

We believe that only those enrollee incentive program expenses that meet the requirements of 45 CFR 158.150 should be counted towards the numerator, and would already qualify without specifying that in these rules. Administrative costs for incentive programs that do not meet the requirements under 45 CFR 158.150 cannot be included in the numerator; therefore, we will finalize the rule as proposed.

Comment: One commenter requested guidance on the activities that increase the likelihood of desired health outcomes in 45 CFR 158.150. The commenter also requested that CMS

remove the requirement that these quality improvement activities be “grounded in evidence-based medicine” on the basis that retaining it may exclude emerging quality improving activities.

Response: We do not intend to publish guidance on what constitutes “grounded in evidence-based medicine” specifically for Medicaid purposes as we believe this is a generally accepted and understood concept. As noted in the proposed rule, the language in 45 CFR 158.150 is sufficiently broad to cover the range of quality improving activities that occur in Medicaid managed care programs.

Comment: We received a few comments about the types of activities that should be considered quality improvement activities. One commenter requested that CMS consider accreditation activities and costs as activities that improve health care quality. Another commenter requested that CMS include provider credentialing activities as an activity that improves health care quality in the MLR calculation. A commenter requested that CMS include Medication Therapy Management (MTM) as an activity that improves health care quality. Several commenters listed specific activities performed by managed care plans and requested clarification as to whether those activities would be considered activities that improve health care quality.

Response: We do not believe that all fees incurred by the managed care plan related to accreditation should be considered quality improvement activities. The private market rules at 45 CFR 158.150(b)(2)(i)(A)(5) allow for accreditation fees directly associated with quality of care activities to be accounted for as a quality improvement activity in the numerator and the same standard applies to the Medicaid MLR calculation. Per 45 CFR 158.150, provider credentialing activities are specifically excluded from quality improvement activities. As quality improvement activities for the Medicaid MLR calculation incorporate 45 CFR 158.150, provider credentialing activities are similarly excluded. In some cases MTM may be considered quality management but in others it may actually be a service covered under the contract. If managed care plans have questions about inclusion of any services or additional activities they provide to their enrollees in the context of quality improvement activities, they should discuss those services or additional activities with the state to determine if they qualify as quality

improvement activities, incurred claims, or administrative expenses.

Comment: One commenter suggested that claims for the high-risk populations be excluded from incurred claims to reduce pricing volatility and provide for better predictability in the calculation of the MLR.

Response: We understand that high risk populations may have more claims volatility but this is generally mitigated by the capitation payments for these individuals, as well as by any stop-loss or reinsurance payments. Therefore, these claims should be included as incurred claims in the MLR calculation.

Comment: One commenter requested that CMS consider telehealth as part of incurred claims.

Response: Telehealth is considered a method of delivery for state plan services and such expenditures would be included in incurred claims.

Comment: One commenter requested clarification as to how a network provider incentive arrangement would be accounted for in the MLR calculation.

Response: We believe that these types of network provider incentive programs, which are different than incentive arrangements for managed care plans described in § 438.6(b)(2), can be considered in the MLR calculation. Specifically, the funds for payments related to network provider incentives are included in the managed care plan's premium revenue and would therefore be reported in the denominator and the payments made to network providers as a result of the incentive program would be considered incurred claims.

Comment: One commenter requested that CMS define “community integration activities” such that those expenses could be included in the numerator of the MLR calculation.

Response: We believe that some activities that could be considered community integration could be categorized differently within the numerator for purposes of the MLR calculation. For example, some activities may be actual non-medical state plan benefits and could be included as part of incurred claims whereas others may be considered quality improvement activities. Since the rule provides flexibility, we decline to establish federal parameters for the treatment of community integration activities and encourage states to work with their contracted managed care plans to determine the appropriate treatment for reporting the expenses of these activities in the numerator of the MLR calculation.

Comment: One commenter noted the absence of a reference to “cost

avoidance” in the MLR calculation, which is the proactive process that managed care plans use to find other insurance coverage or sources of payment for enrollees’ covered services and which account for managed care plan savings in TPL activities. The commenter requested that CMS modify the rule to allow for this expense to be included in incurred claims or in another appropriate classification within the numerator.

Response: We decline to modify the rule to permit managed care plans to include their “cost avoidance” expenses in the calculation of the MLR numerator. Expenses of this nature are not an adjustment to an issuer’s MLR calculation under 45 CFR part 158 and such expenses are correctly treated as a managed care plan’s administrative, or non-claims, expense.

Comment: We received several comments that requested clarification as to how pass-through payments would be treated in the numerator and denominator for the MLR calculation and recommended that these payments should be deducted from both components of the calculation. Commenters provided that pass-through payments could include GME or supplemental payments to network providers that are not considered risk-based payments to the managed care plan as the additional pass-through payment built into the capitation rate is expected to be made to the network provider.

Response: We agree that in the instances where the managed care plan is directed to pay certain amounts to specified providers in a way that is not tied to utilization or quality of services delivered, that those pass-through payments should not be counted in either the numerator or the denominator as they could artificially inflate the managed care plan’s reported MLR. We are finalizing this rule to explicitly exclude pass-through payments, in new text in paragraphs § 438.8(e)(2)(v)(C) and (f)(2)(i), so that such payments are not included in the MLR calculation. We discuss permissible pass-through payments in § 438.6(d) and at I.B.3.d. of this final rule.

Comment: One commenter requested that CMS clarify that the premium revenue used in the denominator be on a restated or adjusted basis rather than a reported basis.

Response: The significance of the commenter’s use of “restated or adjusted basis” is not clear. However, the basis for the premium revenue for purposes of determining the denominator for the MLR calculation may be the direct earned premium as

reported on annual financial statements filed with state regulators or the direct earned premium attributable solely to coverage provided in the reporting year that reflects retroactive eligibility adjustments and uses the same run-out period as that for claims. We anticipate that the only time a managed care plan would use the first approach is when the MLR reporting year is on a calendar year basis since annual financial statements are based on a calendar year. If the MLR reporting year is not on a calendar year basis, the second approach would apply.

Comment: Some commenters objected to the proposal at § 438.8(e)(4) that would include the cost of fraud prevention activities in the numerator of the MLR calculation. They stated that the program integrity activities referenced in § 438.608(a)(1) through (5), (7), (8) and (b) were activities that managed care plans should be engaged in as part of normal business operations. Some of these commenters suggested that a better alternative to assuring enhanced program integrity would be development and implementation of additional performance measures that managed care plans must meet to include fraud prevention activities in the numerator for the MLR calculation. Commenters opposed to this proposal stated that § 438.8(e)(2)(iii)(C) provides sufficient financial incentive to the managed care plans to conduct fraud prevention activities. Commenters that supported the proposal requested that CMS include a similar provision in the private market and Medicare rules. Others stated that it is administratively challenging to differentiate administrative activities in general from others related to fraud prevention and could result in managed care plans attributing expenditures in excess of what was actually related to fraud prevention activities in the MLR numerator.

Several commenters supported the proposal at § 438.8(e)(4) to include the cost of fraud prevention activities in the numerator of the MLR calculation but requested that CMS further define these activities and recommended that such activities not be subject to a cap. Commenters that supported the proposal requested that CMS include a similar provision in the private market and Medicare rules.

Response: In light of our recent decision not to incorporate expenses for fraud prevention activities in the MLR for the private market within the Patient Protection and Affordable Care Act; HHS Notice of Benefit and Payment Parameters for 2017 final rule, which published in the March 8, 2016 **Federal**

Register (81 FR 12204, 12322), we believe that it is similarly premature for Medicaid to adopt a standard for incorporating fraud prevention activities in the MLR. Consideration of fraud prevention activities should be aligned, to the extent possible, across MLR programs. Therefore, we will finalize § 438.8(e)(4) with the heading “Fraud prevention activities” and specify that “MCO, PIHP, or PAHP expenditures on activities related to fraud prevention as adopted for the private market at 45 CFR part 158” would be incorporated into the Medicaid MLR calculation in the event the private market MLR regulations are amended. We will retain the proposed requirement in this paragraph that: “Expenditures under this paragraph shall not include expenses for fraud reduction efforts in § 438.8(e)(2)(iii)(C).”

While expenses related to program integrity activities compliant with § 438.608 will not be explicitly included in the MLR calculation at this time, we underscore the importance of those activities. Consistent with § 438.608, contracts must require that managed care plans adopt and implement measures to protect the integrity of the Medicaid program.

After consideration of public comments, we are finalizing § 438.8(e)(4) to incorporate standards for fraud prevention activities in the MLR calculation as adopted for the private market at 45 CFR part 158.

Comment: Some commenters requested that CMS exclude withhold and incentive payments from premium revenue so that managed care plans are not disincentivized to meet performance measures under such arrangements in light of potential remittance requirements within a state if a state-established MLR threshold is not satisfied. In addition, commenters requested guidance as to how the 5 percent limit on incentive payments relates to the MLR calculation.

Response: We agree with the commenters that incentive payments made to the managed care plan in accordance with § 438.6(b)(2) should not be included in the denominator as such payments are in addition to the capitation payments received under the contract. The limit on incentive arrangements in § 438.6(b)(2) is not impacted by the requirements in § 438.8. However, payments earned by managed care plans under a withhold arrangement, as specified at § 438.6(b)(3), should be accounted for in premium revenue for purposes of the MLR calculation because the amount of the withhold is considered in the rate development process and reflected in

the rate certification. To that end, we are finalizing § 438.8(f)(2)(iii) to clarify that payments to the MCO, PIHP, or PAHP that are approved under § 438.6(b)(3) are included as premium revenue. Amounts earned by the managed care plans under a withhold arrangement will be included in the denominator as premium revenue. Any amounts of the withhold arrangement that are not paid to the managed care plans would not be included as premium revenue.

Comment: CMS received a comment that requested clarification that all taxes (state, city, and the Health Insurance Provider Fee) are deducted from the premium revenue in the denominator under § 438.8(f)(3)(iv).

Response: We agree that all taxes applied to the managed care plan's premium should be deducted from premium revenue. We have modified the regulation text at § 438.8(f)(3)(iv) to specify what other types of taxes in addition to state taxes may also be deducted from premium revenue. The Health Insurance Provider Fee is addressed at § 438.8(f)(3)(iii) and is treated as a federal tax.

Comment: Some commenters requested further guidance as to the expenditures that qualify as community benefit expenditures (CBE) and would therefore be subtracted from premium revenue in the denominator under § 438.8(f)(3)(v). These commenters also requested that states and CMS receive stakeholder input in determining which CBE are actually benefiting the community.

Response: We will not specify in the regulation which expenditures qualify as CBE beyond the incorporation of the definition of CBEs in 45 CFR 158.162(c), as it may differ across state Medicaid managed care programs. We are available to provide technical assistance to states on this issue.

Comment: One commenter stated that CBE should only be excluded from the denominator if the CBE is required to meet the managed care plan's non-profit or tax-exempt status. The commenter suggested that if CMS permitted CBE to be excluded from the denominator, such deductions should be limited to 1 percent of premium. Another commenter commended CMS for proposing that CBE be deducted from the denominator so that non-profit managed care plans would not be disadvantaged in the MLR calculation and they supported the proposed limit of higher of 3 percent or the highest premium tax rate in the applicable state.

Response: We agree that not permitting deductions of CBE from the denominator would discourage managed care plans that are exempt

from federal income taxes from participating in this market. We believe that the proposed cap at the higher of 3 percent or the highest premium tax rate in the applicable state is consistent with other markets and is an equitable approach across managed care plans contracted with the state. Therefore, we are finalizing § 438.8(f)(3)(v) as proposed to permit the deductions of CBE from premium revenue.

Comment: Some commenters supported CMS' proposal in § 438.8(h) that a credibility adjustment should be applied. One commenter requested that CMS simplify the credibility adjustment by using beneficiary thresholds or by using the population enrolled as opposed to the current credibility factors used for private market plans and developed by the NAIC, as they do not believe that the NAIC methodology is appropriate for Medicaid.

Response: Although we agree that populations in the Medicaid program as compared to the Medicare or private markets may have different characteristics, we maintain that the approach in the proposed rule will best allow smaller plans to account for their membership differences. In setting credibility factors by population such as TANF, SSI or CHIP as the commenter proposed, states are likely to have smaller membership of each population by managed care plan and would likely not achieve full credibility across the contract.

Comment: Some commenters requested that CMS specify at § 438.8(i) that the MLR can only be calculated at the contract level and requested that CMS not allow states to require managed care plans to calculate the MLR by population. These commenters suggested that there are certain functions of a managed care plan that would be difficult to separate according to population and would complicate the calculation of an accurate population-specific MLR. Other commenters requested that if a state does require a remittance, that the managed care plan must only pay a remittance on the entire contract and not on specific populations.

Response: While we agree that there may be some functions that are easier to calculate on a contract wide basis, we believe that some states may wish to have an MLR calculated on a population-specific basis and a remittance paid separately to further inform rate development for a specific population. In instances where the state may not have sufficient historical information for a population, it may be beneficial to have the MLR calculated separately, especially in the early years

of operation. Considering these circumstances, states should retain the flexibility to choose whether the MLR is to be calculated, and a remittance requirement applied, on a contract-wide or population-specific basis.

Comment: One commenter requested clarification as to how to aggregate the data if the managed care plan has more than one contract with the state and, if aggregation is allowed between contracts, the criteria by which such aggregation is conducted.

Response: In instances where a managed care plan has more than one contract with the state, the state can determine how to aggregate the data. In § 438.8(a), the MLR reporting year must be the contract year or rating period; therefore, any aggregation across contracts must use a consistent MLR reporting year. If aggregation occurs, states should consider any differences in the rate development for contracts held by the same managed care plan to determine how the MLR experience should be taken into account when setting capitation rates for future rating periods.

Comment: One commenter requested that CMS allow aggregation of data for the calculation of the MLR across all Medicaid and CHIP product lines in the state. The commenter provided that this flexibility would minimize pricing volatility and reduce administrative burden on the managed care plans.

Response: We do not believe that aggregating the MLR calculation across both Medicaid and CHIP product lines is in the best interest of the states or the federal government for oversight of its Medicaid and CHIP managed care plans. The Medicaid requirements for actuarial soundness do not apply to CHIP. Separate reporting of MLR experience for Medicaid and CHIP product lines is imperative as § 438.4(b)(8) (redesignated in the final at § 438.4(b)(9)), incorporates MLR into the development of actuarially sound capitation rates for Medicaid managed care plans.

After consideration of public comments, we will finalize § 438.8(i) with technical edits to delete designations for paragraphs (1) and (2), as such designations are unnecessary.

Comment: Several commenters urged CMS to require that a minimum MLR percentage be met and to require that managed care plans pay remittances if they fail to meet the MLR. They believed that with the regulations as proposed, an MLR of 85 percent appeared optional and that CMS would not achieve the high quality care if such requirements were not in place. Alternately, other commenters supported the proposal to allow states to

decide whether to require remittances. Some commenters urged CMS to include provisions similar to those in the Medicare Advantage and Part D MLR regulation, where, if over multiple years the plans are not meeting the MLR, the state must stop new enrollment or terminate the contract.

Response: We agree that a minimum MLR with a remittance requirement is a reasonable and favorable approach to ensure high quality of care and appropriate service delivery in Medicaid managed care programs. However, there is no statutory basis to implement a federal mandatory minimum MLR or a remittance requirement in Medicaid.

Comment: CMS received a comment requesting that we clarify that if a state does require a remittance under § 438.8(j), it should require the amount of the remittance to bring the managed care plan's incurred claims up to the state-established MLR standard, as is done for the private market. Additionally, this commenter requested that CMS direct states, in the cases where they require a remittance, to do so using a lower minimum MLR standard than is used to set capitation rates as the MLR standard for rate setting is the average expected across all managed care plans. Otherwise, if a remittance was collected from each managed care plan that was below the 85 percent MLR standard, then the average MLR would actually be higher than 85 percent. Some commenters requested that CMS specify that when states require managed care plans to provide remittances, they delay the application of a remittance requirement until a population has been enrolled in the managed care program for 2 years. In addition, commenters requested that states consider a 3-year average when applying a remittance requirement instead of a single MLR reporting year. Commenters stated that these approaches would reduce volatility and any anomalies in the data while the covered population stabilizes.

Response: This final rule does not set the methodology for calculating remittances. This rule requires the use of the MLR calculation and reporting standards set forth in §§ 438.8 and 438.74, requires that actuarially sound capitation rates be developed so that a managed care plan may achieve an MLR of at least 85 percent as described in § 438.4(b)(8) (redesignated in the final at § 438.4(b)(9)), and requires the return to CMS of the federal government's share of any remittance a state collects. Because remittances under this final rule will be imposed under state authority, we believe the state is best

sued to determine the methodology for remittances.

Comment: We received some comments that suggested CMS require states that opt to impose remittances to develop plans for reinvesting the remittances to provide greater access to home and community-based services (HCBS) or investment into other public health initiatives. Another commenter recommended that CMS require the states and managed care plans to implement a tiered savings rebate program instead of remittances.

Response: While we agree that investments for greater access to HCBS services or other public health programs are important, we have not proposed and do not finalize requirements on how states use the state share of any remittance collected from a managed care plan. Per the requirements in § 438.74, if a state receives a remittance from a managed care plan, the state is required to repay the federal share of that remittance to CMS. We do not intend to require states to use the state share of that remittance for any specific purpose, although we urge commenters to discuss with their states the best use of the state share of any remittance.

Comment: One commenter expressed concern about the lack of clarity in the regulation for states that currently have rebate methodologies.

Response: We assume that when the commenter discusses rebate methodologies they mean remittance requirements, and is asking how CMS reviews or oversees such approaches across states. As part of the contract review, CMS will be able to note states that include a specific remittance requirement and will be able to monitor the remittances on the CMS-64 form that states use for purposes of claiming FFP. When states receive a remittance, they will need to specify a methodology to CMS as to how they determined the appropriate amount of the federal share that is paid back. CMS will review those methodologies at the time of repayment.

Comment: A commenter requested clarification as to how to interpret the MLR reporting year definition in conjunction with the provision in § 438.8(k)(1)(xi) that requires the managed care plan to reconcile the reported MLR experience to the audited financial report, as the two may not cover the same time period.

Response: To clarify our expectations for this activity, we will finalize § 438.8(k)(1)(xi) to change the term "reconcile" to "compare". Although a managed care plan may not be able to completely reconcile the MLR experience to the dollars reported in the audited financial report, we believe that

a comparison to the audited financial report should be conducted to ensure that the MLR calculation is accurate and valid as compared to other financial reporting. We acknowledge that the time period of the MLR reporting year and the audited financial report may differ in ways that should be taken into account during the comparison.

Comment: Some commenters suggested that managed care plans would not be able to complete the final MLR calculation within the 12 month period following the MLR reporting year as proposed at § 438.8(k)(2). Commenters stated that some payments such as maternity case rate payments, incentive payments or pharmacy rebate payments take longer to finalize and may not be fully accounted for in the 12 months after the MLR reporting year.

Response: We do not agree that these payments cannot be finalized within the 12 months following the MLR reporting year. Further, extending the timeframe beyond the 12 month period would be inconsistent with MA or the private market MLR regulations. Therefore, we will finalize § 438.8(k)(2) as proposed without modification.

Comment: One commenter requested that CMS clarify that the provision in § 438.8(k)(3), regarding managed care plan reporting of the MLR experience only applies to third party vendors that provide claims adjudication for the MCO, PIHP or PAHP.

Response: We proposed in § 438.8(k)(3) that managed care plans must require third party vendors that provide services to enrollees to supply all underlying data to the managed care plan within 180 days of the end of the MLR reporting year or within 30 days of such data being requested by the managed care plan, whichever date is earlier, so that the managed care plan can validate that the cost allocation, as reported by the managed care plans on their MLR reporting form submitted to the state per § 438.8, accurately reflects the breakdown of amounts paid to the vendor between incurred claims, activities that improve health care quality, and non-claims costs. For purposes of the MLR calculation, the commenter is correct that only vendors that provide claims adjudication activities need to supply the data to the managed care plan in accordance with the timeframes in § 438.8(k)(3). The proposed regulatory text referred to third party vendors that provide services to enrollees rather than vendors that provide claims adjudication activities. We have clarified the regulatory text in this final rule accordingly. We encourage states and managed care plans to consider

receiving additional information from other subcontractors that perform utilization management and other activities, such as network development, for purposes of oversight, data validation, rate setting, and encounter data submission activities that are the responsibility of the state and/or managed care plan.

Comment: We received several comments that urged CMS and states to provide strong oversight of the MLR provisions to ensure that the benefits of applying the MLR requirement are realized.

Response: We agree with commenters that oversight of the MLR provision in the final rule will be necessary to ensure managed care plan compliance with the federal minimum standards. Oversight protections are built into this final rule, including CMS' review and approval of managed care plan contracts as well as CMS' review and approval of the rate certifications for consistency with § 438.4(b)(8) (redesignated in the final at § 438.4(b)(9)). In conjunction with the review of the rate certification, we will review the state's summary description of the MLR reports under § 438.74(a). States may want to consider confirming managed care plans' compliance with § 438.8(k)(1)(xi) (reconciliation of the MLR with the audited financial report) to ensure the amounts in the numerator and denominator are accurate and appropriate.

Comment: Several commenters requested that CMS require either the states or the managed care plans to publicly report MLR experience. Other commenters requested that CMS publish the MLR calculations in a centralized location.

Response: We agree that MLR experience may be important information for potential enrollees when selecting a managed care plan and may be of interest to other parties. In § 438.66(e), we require that states develop an annual assessment on the performance of their managed care program(s). This assessment includes reporting on the financial performance of each MCO, PIHP and PAHP as required by § 438.66(e)(2)(i). To clarify that requirement, we are finalizing § 438.66(e)(2)(i) with an explicit reference to MLR experience. States will be required to publish the assessment annually on their Web sites. At this time, we do not intend to publish these annual performance assessments on www.Medicaid.gov, but may consider doing so in the future if we determine it would be beneficial to the Medicaid program.

Comment: One commenter recommended that CMS require the

MLR to be measured and reported by managed care plans for the first year of participation in a managed care program, which is contrary to the proposal at § 438.8(l). The commenter stated that reporting of the MLR experience in the first year of the managed care plan's operation in a state should be required even though such experience would not have been considered in the development of the capitation rates for the first contract year. Alternatively, another commenter requested that CMS exempt managed care plans from calculating and reporting a MLR for the first 2 years of operation in a state's managed care program in order to allow the population in the managed care plan to stabilize.

Response: We proposed in § 438.8(l), and finalize here, that states have the discretion to exclude a newly contracted managed care plan from the MLR calculation and reporting requirements in § 438.8 for the first contract year. We do not agree that it should be a federal requirement that the MLR be calculated and reported by a managed care plan for the first year of operation in a state's managed care program. Such a requirement could cause confusion for enrollees or other stakeholders and lead them to believe that the managed care plan is not operating efficiently. There are many start up activities and expenses that managed care plans incur in the first year of operation that are not ongoing after start-up; we do not want states, enrollees, or other stakeholders to assume that a managed care plan is not operating efficiently when, in fact, administrative costs may level out in future years of operation. States may impose an MLR calculation and reporting requirement through the contract for a managed care plan's first year of operation, but that decision will remain at the state's discretion.

While we understand that the utilization of some covered populations may not be completely stabilized in the second year of operation, the over-inflation of startup costs will be mitigated at that point. Therefore, we do not believe a change is necessary to exempt a managed care plan from calculating and reporting the MLR in the second year so that such experience may be taken into account when developing actuarially sound capitation rates in accordance with § 438.4(b)(8) (redesignated in the final at § 438.4(b)(9)).

Comment: One commenter requested that CMS specify that where a new population is added to the contract, the administrative costs associated with adding that population be excluded

from the MLR calculation for the year prior to the new population being added. Additionally, a few commenters requested a modification that allows a managed care plan that expanded to a new geographic region to consider the experience of the enrollees in the new region as newer experience under § 438.8(l) and, therefore, be permitted to exclude that experience in their MLR calculation and reporting.

Response: We believe these commenters are seeking guidance and revision of § 438.8(l). We do not believe that adding a new population or geographic region under the contract should exempt a managed care plan from the MLR calculation and reporting requirement. We note that other commenters expressed concern over the difficulty with separating administrative functions by covered population; therefore, we are concerned that the managed care plan may find the commenter's suggestion that the administrative costs associated with a new population be excluded from the MLR calculation administratively burdensome. We disagree with the premise of these comments that adding new covered populations or service areas will skew MLR calculation and reports; we believe that there are limited additional expenses in these situations because the managed care plan is already in operation within the state.

Comment: One commenter requested that recalculations due to retroactive changes to capitation rates be limited to only once per MLR reporting year to avoid administrative burden on the managed care plans.

Response: With the changes in these rules related to retroactive rate changes in § 438.7(c)(2), we believe that the number and scope of retroactive changes to capitation rates will significantly decrease. Those changes will likely achieve the result the commenter sought and we are not making changes to the MLR provisions.

Comment: We received a comment recommending that CMS form a workgroup of states, actuaries, and managed care plan representatives to work through technical corrections necessary for the MLR requirement.

Response: We have addressed technical corrections in this final rule. In the event additional technical corrections are necessary, we will issue such a correction through the **Federal Register**.

Comment: One commenter noted that in the preamble to the proposed rule, CMS did not correctly reference the appropriate CFR citation for the Medicare MLR rules and the sentence appeared to indicate that the Medicare

MLR rules are in 45 CFR when in fact they are in 42 CFR.

Response: The commenter is correct that the Medicare rules for MLR are found at 42 CFR 422.2400 and 423.2400 and the private rules are found in 45 CFR part 158.

After consideration of the public comments and for the reasons discussed above, we are finalizing § 438.8 with the following changes from the proposed rule:

- Changed the definition of MLR reporting year in § 438.8(a) to reference the new definition of rating period.
- Modified definitions in § 438.8(b) to insert “MLR” for “medical loss ratio” for consistency within § 438.8.
- Modified the definition of “non-claims costs” in § 438.8(b) to refer to “activities that improve health care quality” for consistency with § 438.8(e)(3).
- Deleted designations for paragraphs (1) and (2) from § 438.8(d).
- Removed the term “medical” from § 438.8(e)(2)(i)(A) when referencing “services meeting the requirements of § 438.3(e).”
- Revised § 438.8(e)(2)(i)(B) to reference claims “liabilities” instead of claims “reserves” and to include amounts incurred but not reported.
- Revised § 438.8(e)(2)(ii)(A) to refer to “network providers” instead of “health care professionals” as we are not finalizing a definition for “health care professional” and are adding a definition for “network provider.”
- Revised § 438.8(e)(2)(ii)(B) to reference pharmacy rebates received and accrued as part of incurred claims and deleted “MCO, PIHP, or PAHP” as all aspects of the MLR calculation are based on the expenses of the MCO, PIHP, or PAHP and a specific reference is not needed in this paragraph.
- Deleted § 438.8(e)(2)(ii)(C) related to state subsidies for stop-loss payment methodologies.
- Deleted § 438.8(e)(2)(iii)(A) related to payments made by the MCO, PIHP, or PAHP to mandated solvency funds.
- Changed § 438.8(e)(2)(iii)(B), redesignated as § 438.8(e)(2)(iii)(A), to include amounts expected to be paid to network providers.
- To accommodate other modifications to proposed § 438.8(e)(2)(iii), the cross reference to paragraph (C) has been updated to paragraph (B).
- Redesignated § 438.8(e)(2)(iii)(C) as § 438.8(e)(2)(iii)(B), in light of the deletion of the proposed § 438.8(e)(2)(iii)(A) related to payment by the MCO, PIHP, or PAHP to mandated solvency funds.
- Revised § 438.8(e)(2)(iv) to include or deduct, respectively, net payments or

receipts related to state mandated solvency funds. To accommodate other modifications to proposed § 438.8(e)(2)(iv), paragraphs (A) and (B) were deleted.

- Excluded amounts from the numerator for pass-through payments under to § 438.6(d) in § 438.8(e)(2)(v)(C).
- Revised § 438.8(e)(4) to allow the Medicaid MLR numerator to include fraud prevention activities according to the standard that is adopted for the private market at 45 CFR part 158.
- Excluded amounts for pass-through payments made under to § 438.6(d) from the denominator in § 438.8(f)(2)(i).
- Revised § 438.8(f)(2)(iii) to exclude payments authorized by § 438.6(b)(2) from the denominator.
- Added local taxes as an item that can be deducted from premium revenue in § 438.8(f)(3)(iv).
- Changed the treatment of risk sharing mechanisms as proposed at § 438.8(e)(2)(iv)(A), which was revised to reference risk-sharing mechanisms broadly, to the denominator at § 438.8(f)(2)(vi).
- Removed designations for paragraphs (1) and (2) from § 438.8(i).
- Changed the term “reconcile” to “compare” in § 438.8(k)(1)(xi).
- Revised § 438.8(k)(3) to refer to third party vendors that provide claims adjudication services.

(3) State Requirements (§ 438.74)

We proposed minimum standards for state oversight of the MLR standards in § 438.74. Specifically, we proposed two key standards related to oversight for states when implementing the MLR for contracted MCOs, PIHPs, and PAHPs: (1) Reporting to CMS; and (2) repayment and reporting of the federal share of any remittances the state chooses to collect from the MCOs, PIHPs, or PAHPs. Proposed paragraph (a) required each state to provide a summary description of the MLR calculations for each of the MCOs, PIHPs, and PAHPs with the rate certification submitted under § 438.7. Proposed paragraph (b) applied if the state collects any remittances from the MCOs, PIHPs, or PAHPs for not meeting the state-specified minimum MLR standard. In such situations, we proposed that the state would return the federal share and submit a report describing the methodology for how the state determined the federal share. We explained that if a state decided not to segregate MLR reporting by population, the state would need to submit to CMS the methodology of how the federal share of the remittance was calculated that would be reviewed and approved

via the normal CMS–64 claiming protocol.

We received the following comments in response to our proposal to revise § 438.74.

Comment: Many commenters supported proposed § 438.74(a)(1) and (2) while other commenters recommended that CMS include additional requirements. Several commenters recommended that CMS include requirements for states to submit the actual MLR reports received from MCOs, PIHPs, and PAHPs in addition to the summary description and that such information be made public. Commenters also recommended that CMS establish a dedicated public Web site to provide states with an MLR reporting template, including instructions and definitions to improve the uniformity of MLR data and information.

Response: We believe that the availability of MLR information will help beneficiaries make more informed choices among managed care plans. We believe that the summary report as proposed provides enough information at the time of submission. If it is found that more information on the specific managed care plan’s MLR is necessary, CMS may ask the state for it at the time of actuarial certification review. As noted previously, we believe that we have provided for adequate public display of the MLR information through § 438.66 and expect the financial experience of each of the managed care plans, including their MLRs, to be reported annually and posted to the state’s public Web site. We do not intend to post these on a CMS-hosted Web site at this time.

Comment: A few commenters had concerns regarding proposed § 438.74(a)(1) and (2). One commenter stated that section § 438.5(b)(5) requires states to consider MLRs when developing rates, and as such, it is not necessary to coordinate the delivery of the MLR report with the actuarial certification as proposed in section § 438.74(a)(1). The commenter recommended that CMS clarify that section § 438.74(a)(1) does not mandate consideration of a single, two-year-old MLR report when setting current capitation rates. The commenter instead recommended that the MLR reports be submitted as part of the annual report required by section § 438.66(e). One commenter expressed its concern that CMS would publish MLRs from all Medicaid managed care plans and draw conclusions about how efficiently states are operating their managed care programs. The commenter recommended that CMS should not

publish such information without a discussion regarding the significant variation across states, including for taxes and program design.

Response: Because we will use the calculated MLR summary report in the review of the rate certification for actuarial capitation rates, we believe that a submission of the summary report is important to provide when submitting the actuarial certification for review and approval. Section 438.4(b)(8) (redesignated in the final at § 438.4(b)(9)), requires that one criterion for the development of actuarially sound capitation rates is that the capitation rate be developed in such a manner that the managed care plan could reasonably achieve an MLR of at least 85 percent. The MLR summary report for each managed care plan under § 438.74(a) is one source to be used to meet that criterion.

We do not intend to publish the MLR experience of each managed care plan of each state publically at this time, but we do expect the states to do so as part of its public annual report as required in § 438.66(e).

Comment: A few commenters supported proposed § 438.74(b)(1) and (2), which would require states to reimburse CMS for the federal share of any MLR remittances and to submit a report on the methodology used to calculate the state and federal share of such remittances. A few commenters recommended that CMS provide further guidance regarding how states should develop the methodology for how the federal share of the remittance was calculated or recommended that CMS clarify whether states have the flexibility to develop this methodology independently. These commenters also requested guidance on the timeframe within which the FFP would be required to be returned to CMS after a state collected a remittance.

Response: States have the flexibility to determine how to aggregate the data across the managed care plan contract for purposes of calculating the MLR. Consequently, there could be several methodologies used to calculate the amount of the federal share of a remittance. Consistent with the processes for CMS-64 reporting, the state would submit the methodology for determining the federal share of the remittance to CMS for review. States should return the federal share by the end of the following quarter in which the remittance was received.

Comment: One commenter recommended that CMS take a proactive approach in monitoring the requirements proposed at § 438.74. The commenter recommended that CMS be

prescriptive about how states approve and audit managed care plan calculations and reports. The commenter recommended that CMS audit state criteria and data every 2 years.

Response: As we intend to review the summary data submitted by the state with the actuarial certifications we believe that we will have sufficient ability to question the state about how they instructed their managed care plans to complete the calculation, as well as about the outcomes of these calculations. We do not intend to complete audits at this time, but may consider it in the future if we find it would benefit the program.

After consideration of the public comments, we are finalizing § 438.74 as proposed with the following modifications:

- Inserted “rate” in place of “actuarial” in § 438.74(a) to describe the certification in § 438.7 and rephrased the last half of the sentence to improve the accuracy of cross-references.
- Inserted “the amount of the” preceding “denominator” and replace “MLR experienced” with “the MLR percentage achieved” in § 438.74(a)(2) to improve readability.
- Inserted “separate” before “report” in § 438.74(b)(2) to clarify that, if a remittance is owed according to paragraph (b)(1), the state must submit a separate report from the one required under paragraph (a) to describe to methodology for determining the state and federal share of the remittance.

I.B.2. Standard Contract Provisions (§ 438.3)

We proposed to add a new § 438.3 to contain the standard provisions for MCO, PIHP, and PAHP contracts, including non-risk PIHPs and PAHPs, that are distinguishable from the rate setting process and the standard provisions that apply to PCCM and PCCM entity contracts. These provisions generally set forth specific elements that states must include in their managed care contracts, identify the contracts that require CMS approval, and specify which entities may hold comprehensive risk contracts. To improve the clarity and readability of part 438, we proposed that § 438.3 would include the standard contract provisions from current § 438.6 that are unrelated to standards for actuarial soundness and the development of actuarially sound capitation rates.

We proposed that the provisions currently codified in § 438.6 as paragraphs (a) through (m) be redesignated respectively as § 438.3(a) through (l), (p) and (q), with some

revisions as described below. These proposed paragraphs addressed standards for our review and approval of contracts, entities eligible for comprehensive risk contracts, payment, prohibition of enrollment discrimination, services covered under the contract, compliance with applicable laws and conflict of interest safeguards, provider-preventable conditions, inspection and audit of financial records, physician incentive plans, advance directives, subcontracts, choice of health professional, additional rules for contracts with PCCMs, and special rules for certain HIOs.

a. CMS Review (§ 438.3(a))
First, in § 438.3(a) related to our review and approval of contracts, we proposed to add the regulatory flexibility for us to set forth procedural rules—namely timeframes and detailed processes for the submission of contracts for review and approval—in sub-regulatory materials, and added a new standard for states seeking contract approval prior to a specific effective date that proposed final contracts must be submitted to us for review no later than 90 days before the planned effective date of the contract. Under our proposal, the same timeframe would also apply to rate certifications, as proposed § 438.7(a) incorporated the review and approval process of § 438.3(a). To the extent that the final contract submission is complete and satisfactory responses to questions are exchanged in a timely manner, we explained that we expected 90 days would be a reasonable and appropriate timeframe for us to conduct the necessary level of review of these documents to verify compliance with federal standards. Upon approval, we would authorize FFP concurrent with the contract effective date. In addition, for purposes of consistency throughout part 438, we proposed to remove specific references to the CMS Regional Offices and replace it with a general reference to CMS; we also noted our expectation that the role of the CMS Regional Offices would not change under the proposed revisions to part 438.

We received the following comments in response to proposed § 438.3(a).

Comment: Several commenters sought clarification or objected to the proposal in § 438.3(a) that the state submit contracts, and rate certifications based on the cross-reference in § 438.7(a), to CMS for review and approval no later than 90 days before the effective date of the contract if the state sought approval by the effective date of the contract. Some commenters were supportive of § 438.3(a) and suggested that CMS

extend the timeframe from 90 days to 180 days. Many commenters were concerned that the provision did not require CMS to complete review and approval within the 90 day timeframe and recommended that such requirements be imposed on CMS. A few commenters raised the issue that this provision would require prior approval of all contract types including PIHPs and PAHPs when the statute requires prior approval of MCO contracts only. Some commenters were concerned about the capacity for CMS to complete the review of contracts and rate certifications within 90 days. In addition, a few commenters suggested timeframes for the regulation, ranging from 15 to 45 days, by which CMS would take action on the contract and alert the state to any compliance issues to permit states time to remedy such issues before the effective date of the contract, or requested that CMS adopt a process similar to that used for State plan amendments. Some commenters suggested that we remove this provision from the final rule in light of the provision at § 438.807 that would permit partial deferral or disallowances and recommended that CMS continue to work with states on standard operating procedures for the approval of contracts and rate certifications. A few commenters were concerned that a requirement for the state to submit the rate certification at least 90 days prior to the effective date of the contract would result in the actuary relying on older data for rate setting purposes and requested that the rate certification be submitted at least 45 days for the effective date of the contract.

Response: As § 438.3(a) also applies to rate certifications under § 438.7(a), we address both contract and rate submissions in this response to comments. Commenters have misinterpreted the intention and scope of the 90 day timeframe in proposed (and finalized) in § 438.3(a). The text provides that the 90 day requirement applies to those states that seek approval of the contract prior to its effective date. We are aware that some states, through application of state law or long-standing policies, are required to have CMS approval prior to the effective date of the contract, while other states do not operate under similar requirements and may move forward with implementing the contract without CMS approval at the point of the effective date. In the former situation, states have submitted contracts and rate certifications to CMS shortly before the effective date and have urged CMS to conduct the necessary diligent level of

review within a constrained timeframe. This provision seeks to modify that practice. However, we believe that CMS approval of contracts and rate certifications prior to the effective date of the contract is a good business practice and would eliminate uncertainty and potential risk to the states and managed care plans that operate with unapproved contracts and rates. We recognize that this has not been a customary or usual practice and that states would have to modify their contracting and rate setting timeframes to submit this documentation to us 90 days prior to the effective date of the contract. In recognition of the administrative activities that would need to be modified in some states, we purposefully limited the requirement in § 438.3(a) to those states that seek approval prior to the effective date of the contract either through state law or policy. In that context, we stated in the proposed rule (80 FR 31114) that 90 days is a reasonable timeframe for CMS to complete that task assuming that the contracts and rate certifications are compliant with federal requirements; we decline to extend it to 180 days as some commenters suggested. We have internal standard operating procedures and resources dedicated to the review of contracts and rate certifications and will continue to monitor the effectiveness of those procedures to ensure that we are effective partners in this process. Further, approval of the contract and rate certification is necessary prior to the payment of FFP claimed on the CMS-64.

In regard to commenters' concerns as to how this provision relates to partial deferrals or disallowances in proposed § 438.807, that proposal (discussed below in section I.B.4.e) was to authorize us to take a partial deferral or disallowance when we find non-compliance on specific contractual or rate setting provisions. We did not propose to extend § 438.807 to contractual or rate setting provisions for which we have not completed our review; further this comment is moot in light of our decision with regard to § 438.807, as discussed in detail in section I.B.4.e. We decline to establish regulatory timeframes for CMS to finalize or notify the state of compliance issues; we also decline to adopt a deemed approval approach if the 90 days elapse without approval because this provision is not directly tied to the prior approval requirements in § 438.806.

We disagree with commenters that requested a 45 day timeframe for the submission of rate certifications to mitigate concerns about the actuary

relying on older data for rate setting purposes to meet the 90 day timeframe. Section 438.5(c)(2) would require states and their actuaries to use appropriate base data with the data being no older than the 3 most recent and complete years prior to the rating period. The additional claims data that would be used in a rate development process that would accommodate a 45 day timeframe for submission to CMS, rather than a 90 day timeframe, is not actuarially significant.

Comment: A few commenters objected to the provision in paragraph (a) that CMS reserved the ability to establish the form and manner of contract submissions through sub-regulatory guidance rather than through regulation. Since the regulatory language is vague, commenters stated it would be difficult to determine whether the state could meet this requirement and that such formatting requirements may conflict with state procurement and contract standards.

Response: As stated in the proposed rule (80 FR 31114), we proposed to reserve the flexibility set forth procedural rules—namely timeframes and processes for the submission of contracts for review and approval—in subregulatory materials. The substantive standards and requirements about the content of the contract and rate certifications are established in this final rule. We do believe that a standard operating procedure for the submission process would benefit all involved parties. We acknowledge that states and Medicaid managed care plans have concerns about the process and procedure for these submissions and intend to use a collaborative process, to the extent feasible, in the development and finalization of our procedures.

Comment: A commenter requested clarification whether the contract submitted for CMS review must be signed and fully executed.

Response: Under this rule, we will permit a state to submit a complete, non-executed contract so long as the signature pages are provided sufficiently ahead of time (and not accompanied by material changes to the contract) for CMS conduct our review.

Comment: Some commenters requested that providers have the ability to issue comments on the managed care contracts before they are approved by CMS through a public review and comment period.

Response: We acknowledge the valuable input that providers and other stakeholders have to offer to inform the development of a state's managed care program and that public notice and engagement requirements could

facilitate involvement of providers and stakeholders. However, the direct parties to the contracting process are the State and the managed care plans; we do not agree that it is reasonable or appropriate for us to institute a federal requirement for public comment on the managed care contracts.

After consideration of the public comments, we are finalizing § 438.3(a) as proposed.

b. Entities Eligible for Comprehensive Risk Contracts (§ 438.3(b))

We proposed to redesignate the existing provisions at § 438.6(b) to § 438.3(b), without substantive change. We did not receive comments on § 438.3(b) pertaining to entities that are eligible for comprehensive risk contracts and will finalize as proposed.

c. Payment (§ 438.3(c))

In proposed § 438.3(c), we restated our longstanding standard currently codified at § 438.6(c)(2)(ii) that the final capitation rates for each MCO, PIHP, or PAHP must be specifically identified in the applicable contract submitted for our review and approval. We also proposed to reiterate in this paragraph that the final capitation rates must be based only upon services covered under the state plan and that the capitation rates represent a payment amount that is adequate to allow the MCO, PIHP, or PAHP to efficiently deliver covered services in a manner compliant with contractual standards.³

We received the following comments in response to § 438.3(c).

Comment: One commenter noted that states may cover services in addition to the state plan (for example, home and community based services) and suggested that distinguishing between State plan services and other waiver services for purposes of capitation payments is unnecessary.

Response: We clarify here that services approved under a waiver (for example, sections 1915(b)(3) or 1915(c) of the Act) are considered State plan services and are encompassed in the reference to “State plan services” in § 438.3(c). Therefore, § 438.3(c) does not need to distinguish them.

Comment: A couple of commenters requested clarification that § 438.3(c)

and § 438.3(e) were consistent with section 3.2.5 of the Actuarial Standard of Practice (ASOP) No. 49.

Response: We maintain that § 438.3(c) and (e) in this final rule are consistent with ASOP No. 49. Section 3.2.5 of ASOP No. 49 is entitled “covered services” and provides the following: “When developing capitation rates under § 438.6(c), the actuary should reflect covered services for Medicaid beneficiaries, as defined in the contract between the state and the MCOs, which may include cost effective services provided in lieu of state plan services. When developing capitation rates for other purposes, the actuary should reflect the cost of all services, including enhanced or additional benefits, provided to Medicaid beneficiaries.” (emphasis added). We note that comments about in lieu of services are addressed below in connection with § 438.3(e); that section as finalized is consistent with the section 3.2.5 of ASOP No. 49. Section 3.2.5 of ASOP No. 49 distinguishes between developing capitation rates under § 438.6(c) (redesignated as 438.3(c) in this final rule) and developing capitation rates for other purposes. An actuary may develop and set two rates—one that includes only the Medicaid covered services under the contract (for example, state plan services and in lieu of services generally), which is described in the first sentence, and the other could include services not covered by Medicaid. Only capitation payments developed in accordance with § 438.3(c) are eligible for FFP. We also note that § 438.3(c) also directs that capitation rates under this section be based upon and include services that are necessary for compliance with mental health parity requirements; those requirements are discussed in the Medicaid and Children’s Health Insurance Programs; Mental Health Parity and Addiction Equity Act of 2008; the Application of Mental Health Parity Requirements to Coverage Offered by Medicaid Managed Care Organizations, the Children’s Health Insurance Program (CHIP), and Alternative Benefit Plans final rule which published in the March 30, 2016 **Federal Register** (81 FR 18390) (the March 30, 2016 final rule).

Since publication of the proposed rule, we have become aware of instances in a couple of states where capitation payments were made for enrollees that were deceased and the capitation payments were not recouped by the state from the managed care plans. It is unclear to us why such capitation payments would be retained by the managed care plans as these once Medicaid-eligible enrollees are no

longer Medicaid-eligible after their death. It is implicit in the current rule, and we did not propose to change, that capitation payments are developed based on the services and populations that are authorized for Medicaid coverage under the state plan which are covered under the contract between the state and the managed care plan and that capitation payments are made for Medicaid-eligible enrollees. This would not include deceased individuals or individuals who are no longer Medicaid-eligible. Therefore, we are including language in § 438.3(c) to specify that capitation payments may only be made by the state and retained by the MCO, PIHP or PAHP for Medicaid-eligible enrollees. As a corollary of this requirement and while we assume that states and managed care plans already operate in such a manner, we advise states to have standard contract language that requires individuals that are no longer Medicaid-eligible to be disenrolled from the managed care plan.

To effectuate the change to § 438.3(c), introductory text is added following the “Payment” heading for paragraph (c) that the requirements apply to the final capitation rate and the receipt of capitation payments under the contract. A new designation for paragraph (1) specifies that the final capitation rate for each MCO, PIHP or PAHP must be (i) specifically identified in the applicable contract submitted for CMS review and approval and (ii) the final capitation rates must be based only upon services covered under the State plan and additional services deemed by the state to be necessary to comply with the parity standards of the Mental Health Parity and Addiction Equity Act, and represent a payment amount that is adequate to allow the MCO, PIHP or PAHP to efficiently deliver covered services to Medicaid-eligible individuals in a manner compliant with contractual requirements. The requirements in finalized paragraphs (c)(1)(i) and (ii) mirror those that were proposed at § 438.3(c). A new paragraph (2) specifies that capitation payments may only be made by the state and retained by the MCO, PIHP or PAHP for Medicaid-eligible enrollees to address the issue of retention of capitation payments for Medicaid enrollees that have died, or who are otherwise no longer eligible.

After consideration of the comments, we are finalizing § 438.3(c) with a new paragraph (c)(2) to make clear that capitation payments may not be made by the state and retained by the managed care plan for Medicaid enrollees that have died, or who are

³ We note that in Medicaid and Children’s Health Insurance Programs; Mental Health Parity and Addiction Equity Act of 2008; the Application of Mental Health Parity Requirements to Coverage Offered by Medicaid Managed Care Organizations, the Children’s Health Insurance Program (CHIP), and Alternative Benefit Plans final rule published March 30, 2016 (81 FR 18390), we clarified that certain additional costs could also be used to develop capitation rates. That provision would be codified as part of § 438.6(e) and redesignated through this final rule as § 438.3(e).

otherwise no longer Medicaid-eligible and with non-substantive revisions to clarify text.

d. Enrollment Discrimination Prohibited (§ 438.3(d))

We proposed to redesignate the provisions prohibiting enrollment discrimination currently at § 438.6(d) as new § 438.3(d) and proposed to replace the reference to the Regional Administrator with “CMS”; this replacement was for consistency with other proposals to refer uniformly to CMS as one entity in the regulation text. We also proposed to add sex, sexual orientation, gender identity and disability as protected categories under our authority in section 1902(a)(4) of the Act; this proposal related to sex discrimination is discussed in the proposed changes in § 438.3(f) below.

We received the following comments on proposed § 438.3(d).

Comment: Several commenters supported § 438.3(d)(4) which would prohibit enrollment discrimination against individuals eligible to enroll on the basis of race, color, national origin, sex, sexual orientation, gender identity or disability. Many commenters suggested that CMS include individuals in the criminal justice system to the list of categories for which enrollment discrimination is prohibited.

Response: We appreciate commenters support for the inclusion of sex, sexual orientation, gender identity or disability as protected classes for purposes of prohibiting discrimination in enrollment. We note that our proposed rule discussed, in connection with §§ 438.206 and 440.262 (discussed in section I.B.6.a. below), the basis for inclusion of these new categories in the anti-discrimination standards. We believe that the obligation for the state plan to promote access and delivery of services without discrimination is necessary to assure that care and services are provided in a manner consistent with the best interest of beneficiaries under section 1902(a)(19) of the Act. Prohibiting a managed care plan from discriminating in enrollment on these bases is necessary to ensure access and provision of services in a culturally competent manner. We believe that the best interest of beneficiaries is appropriately met when access to managed care enrollment (as well as access to services themselves) is provided in a non-discriminatory manner; adopting these additional methods of administration is also necessary for the proper operation of the state plan under section 1902(a)(4) of the Act. However, we decline to include individuals in the criminal justice

system to § 438.3(d). First, neither that classification nor anything related to it are specified in the statutory authorities underlying this provision. Second, we do not believe that the same justification exists for adding the other categories, namely assurance of the provision of services in a culturally competent manner and assurance that care and services are provided in a manner consistent with the best interests of beneficiaries, applies to the category of individuals in the criminal justice system. We believe that the regulation as proposed and as finalized on this point is adequate.

After consideration of public comment, we are finalizing § 438.3(d) as proposed.

e. Services That May Be Covered by an MCO, PIHP, or PAHP (§ 438.3(e))

The current regulation at § 438.6(e) addresses the services that may be covered by the MCO, PIHP, or PAHP contract. We proposed to move that provision to § 438.3(e). The existing provision also prohibits services that are in addition to those in the Medicaid state plan from being included in the capitation rate and we proposed to incorporate that standard in new § 438.3(c).

We received the following comments on proposed § 438.3(e).

Comment: Several commenters requested that CMS specify requirements for in lieu of services in regulation.

Response: We agree that clarifying and codifying in regulation the requirements for the provision of in lieu of services is appropriate. Our proposed rule (80 FR 31116–31117) discussed the long-standing policy on in lieu of services; although that was in the context of our proposal related to payment of capitation payments for enrollees who spend a period of time as patients of an institution for mental disease, our proposal identified when in lieu of services are appropriate generally and several commenters raised the topic. In finalizing § 438.3(e), we are including regulation text in a new paragraph (2) to identify when and which services may be covered by an MCO, PIHP, or PAHP in lieu of services that are explicitly part of the state plan. If a state authorizes the use of in lieu of services under the contract in accordance with § 438.3(e)(2), the managed care plan does not have to use in lieu of services as the introductory language at paragraph (e)(2) specifies that the MCO, PIHP, or PAHP may voluntarily use in lieu of services. In addition, if the managed care plan wants to use the in lieu of services

authorized and identified in the contract, an enrollee cannot be required to use the in lieu of service. Specifically, the new regulation imposes four criteria for in lieu of services under the managed care contract. First, in paragraph (e)(2)(i), the state would determine that the alternative service or setting is a medically appropriate and cost effective substitute for the covered service or setting under the state plan as a general matter. Because the in lieu of service is a substitute setting or service for a service or setting covered under the state plan, the determination must be made by the state that the in lieu of service is a medically appropriate and cost effective substitute as a general matter under the contract, rather than on an enrollee-specific basis. This authorization is expressed through the contract, as any contract that includes in lieu of services must list the approved in lieu of services under paragraph (e)(2)(iii). Under paragraph (e)(2)(ii), the enrollee cannot be required by the MCO, PIHP, or PAHP to use the alternative service or setting. In paragraph (e)(2)(iii), the approved in lieu of services are authorized and identified in the MCO, PIHP, or PAHP contract and are offered at the managed care plans’ discretion, which is a corollary of paragraph (e)(2)(i). In paragraph (e)(2)(iv), the utilization and cost of in lieu of services are taken into account in developing the component of the capitation rates that represents the covered state plan services. This means that the base data capturing the cost and utilization of the in lieu of services are used in the rate setting process. This paragraph also specifies that this approach applies unless statute or regulation specifies otherwise (such as how § 438.6(e) relating to the use of services in an IMD as an in lieu of service requires a different rate setting approach). Additional discussion of in lieu of services is in provided in response to comments under section I.B.2.s., regarding the provision proposed at on § 438.3(u) (finalized and redesignated at § 438.6(e)) relating to capitation payments for enrollees with a short term stay in an IMD.

After consideration of public comments, we are finalizing § 438.3(e) with additional text to address requirements for the use of in lieu of services in managed care. First, the introductory text from proposed paragraph (e) is redesignated at paragraph (e)(1), without substantive change, and the paragraphs proposed as (e)(1) and (e)(2) (Reserved) are redesignated as (e)(1)(i) and (e)(1)(ii) in this final rule. Second, we are codifying

the requirements for coverage and provision of services in lieu of state plan services as paragraph (e)(2). In addition, we are redesignating and replacing provisions at § 438.6(e) finalized in the March 30, 2016 final rule (81 FR 18390), as follows: § 438.6(e)(1) is redesignated and replaced as § 438.3(e)(1)(ii) with the text at § 438.6(e)(1)(ii), and § 438.6(e)(2) and § 438.6(e)(3) (pertaining to services a managed care plan voluntarily provide and treatment of such services in rate setting) is redesignated and replaced § 438.3(e)(1)(i).

f. Compliance With Applicable Laws and Conflict of Interest Safeguards (§ 438.3(f))

We also proposed to redesignate the existing standard for compliance with applicable laws and conflict of interest standards from existing § 438.6(f) to § 438.3(f)(1) with the addition of a reference to section 1557 of the Affordable Care Act, which prohibits discrimination in health programs that receive federal financial assistance. We also proposed to add sex as a protected category for purposes of MCO, PIHP, PAHP, PCCM, or PCCM entity enrollment practices in the enrollment provisions proposed to be moved to § 438.3(d)(4), because adding this category is consistent with the scope of section 1557 of the Affordable Care Act. We also proposed to add sexual orientation and gender identity because managed care plans are obligated to promote access and delivery of services without discrimination and must ensure that care and services are provided in a manner consistent with the best interest of beneficiaries under section 1902(a)(19) of the Act. We noted that the best interest of beneficiaries is appropriately met when access is provided in a non-discriminatory manner; adopting these additional methods of administration is also necessary for the proper operation of the state plan under section 1902(a)(4) of the Act.

In addition, we proposed a new standard, at § 438.3(f)(2), to state more clearly the existing requirement that all contracts comply with conflict of interest safeguards (described in § 438.58 and section 1902(a)(4)(C) of the Act).

We received the following comments in response to proposed § 438.3(f).

Comment: A few commenters stated that contracts with managed care plans must specify how the managed care plan will comply with the Americans with Disabilities Act (ADA) and the *Olmstead vs. L.C.* Supreme Court decision. A few commenters wanted CMS to add an explicit reference to the

Olmstead vs. L.C. decision into the regulation, while other commenters recommended there should be a requirement that managed care plans rebalance their institutional and home and community based services so that individuals show a trend of moving from the institution to the community.

Response: We maintain that a reference to the ADA in regulation is sufficient as there may be other court decisions relevant to LTSS over time and we believe that identifying just one decision in the regulation that interprets the ADA could have an unintended limiting effect. We support rebalancing of HCBS and deinstitutionalization of persons when possible and encourage states in their efforts to comply with *Olmstead* and the ADA. After consideration of the public comments, we are finalizing § 438.3(f) as proposed.

g. Provider-Preventable Condition Requirements (§ 438.3(g))

We proposed to redesignate the standards related to provider reporting of provider-preventable conditions currently codified in § 438.6(f)(2)(i) to the new § 438.3(g). With this redesignation, we proposed to limit these standards to MCOs, PIHPs, and PAHPs, because those are the entities for which these standards are applicable. We did not receive comments on the proposals related to reporting of provider-preventable conditions at § 438.3(g) and will finalized as proposed.

h. Inspection and Audit of Records and Access to Facilities (§ 438.3(h))

We proposed to move the inspection and audit rights for the state and federal government from § 438.6(g) to new § 438.3(h) and to expand the existing standard to include access to the premises, physical facilities and equipment of contractors and subcontractors where Medicaid-related activities or work is conducted. In addition, we proposed to clarify that the state, CMS, and the Office of the Inspector General may conduct such inspections or audits at any time.

We received the following comments in response to proposed § 438.3(h).

Comment: Several commenters recommended that CMS specify at § 438.3(h) that audits will be coordinated to eliminate duplication and disruption of services and care. Commenters recommended that CMS include language in the final rule to identify how many inspections may be conducted in a contract year to minimize the frequency of unnecessary or duplicative audits.

Response: We decline to adopt commenters' recommendations at § 438.3(h) as we do not believe it is appropriate to arbitrarily set a maximum number of audits or inspections that may be conducted in a contract year, particularly when audits could have different focus and scope. We agree with commenters that audits should be coordinated when possible and as appropriate but decline to modify the proposed regulatory text to impose that as a requirement. We believe that efforts to coordinate audits and inspections should be considered at an operational level.

Comment: One commenter recommended that CMS require a Medicaid auditing project officer at § 438.3(h) to closely monitor auditors and identify issues within the auditing process and resolve those issues in a timely manner. The commenter also recommended that the project manager should serve as a point of contact to providers and be readily accessible to work with providers to address any concerns that the provider cannot resolve directly with the auditor.

Response: We decline to adopt the commenter's recommendation to require a Medicaid auditing project officer or project manager. We do not believe it is appropriate to include this operational consideration in federal regulation; rather, states could consider this as part of their auditing structure for state conducted audits.

Comment: One commenter recommended that CMS clarify at § 438.3(h) that audits may not look-back to exceed 18 months after a claim is adjudicated. The commenter stated that this approach would reduce the administrative burden of research on providers.

Response: We decline to adopt the commenter's recommendation to limit audits to 18 months after a claim is adjudicated. Under the False Claims Act at 31 U.S.C. 3731(b)(2), claims may be brought up to 10 years after the date on which a violation is committed. For clarification, we are adding the right to audit of 10 years provided in § 438.230(c)(3)(iii) to § 438.3(h) so that the timeframe is clear for managed care plans, PCCMs, and PCCM entities in § 438.3(h), as well as for subcontractors of MCOs, PIHPs, PAHPs, and PCCM entities in § 438.230.

Comment: One commenter recommended that CMS define "at any time" and "Medicaid-related activities" at § 438.3(h). One commenter stated concern that § 438.3(h) and § 438.230(c)(3)(i) do not align regarding audits that may occur "at any time" or audits that may occur when "the

reasonable possibility of fraud is determined to exist,” respectively. The commenter recommended that CMS clarify this discrepancy.

Response: The phrase “at any time” in § 438.3(h) means that the specified entities may inspect and audit records and access facilities of the MCO, PIHP, PAHP, PCCM, PCCM entity or subcontractors outside of regular business hours and such access is not conditioned on the reasonable possibility of fraud. The phrase “Medicaid-related activities” means any business activities related to the obligations under the Medicaid managed care contract. Because §§ 438.3(h) and 438.230(c)(3)(i) address the inspection and audit of the managed care plans (and PCCM entities and PCCMs) and their subcontractors, respectively, we will revise § 438.230(c)(3)(i) to indicate that audits and inspections may occur at any time.

Comment: A few commenters recommended that CMS clarify the list of entities that may inspect and audit in § 438.3(h). One commenter recommended that CMS specifically include “State MFCU” in the list. One commenter recommended that CMS include the list at § 438.230(c)(3)(i), which includes “designees.”

Response: We agree with commenters that §§ 438.3(h) and 438.230(c)(3)(i) should be consistent regarding the list of entities that may inspect and audit. Therefore, we will revise § 438.3(h) to include the list at § 438.230(c)(3)(i), including the Comptroller General and designees of the listed federal agencies and officials.

After consideration of the public comments, we are modifying the regulatory text at § 438.230(c)(3)(i) to indicate that audits and inspections may occur at any time to be consistent with § 438.3(h). We are modifying the regulatory text at § 438.3(h) to include the list at § 438.230(c)(3)(i), including the Comptroller General and designees. We are also adding the right to audit for 10 years to § 438.3(h) so that the timeframe is clear and consistent for managed care plans, PCCMs, and PCCM entities in § 438.3(h), as well as for subcontractors of MCOs, PIHPs, PAHPs, and PCCM entities in § 438.230. We are otherwise finalizing § 438.3(h) as proposed.

i. Physician Incentive Plans (§ 438.3(i))

As part of our proposal to redesignate the provisions related to physician incentive plans from § 438.6(h) to new § 438.3(i), we proposed to correct the outdated references to Medicare+Choice organizations to MA organizations.

We received the following comments on the regulation text concerning physician incentive plans at § 438.3(i).

Comment: One commenter encouraged CMS to allow the development of incentive plans for physicians and physician groups that are aligned with achieving goals for improving quality and efficiency of care delivery.

Response: Section 438.3(i) is based on section 1903(m)(2)(A)(x) of the Act, which requires physician incentive plans to comply with the requirements for physician incentive plans at section 1876(i)(8) of the Act, which have been implemented at § 417.479 of this chapter for reasonable cost plans and made applicable to MA organizations at § 422.208 of this chapter. To ensure that the identical requirements are made applicable to MCOs under section 1903(m)(2)(A)(x) of the Act and PIHPs and PAHPs under section 1902(a)(4) of the Act, we have cross-referenced the MA regulations. These are the only explicit limitations on physician incentive programs for network providers and we are supportive of managed care plans incentivizing providers to meet performance metrics that improve the quality and efficiency of care.

After consideration of the public comments, we are finalizing § 438.3(i) as proposed.

j. Advance Directives (§ 438.3(j))

We proposed to redesignate the provisions for advance directives currently in § 438.6(i) as § 438.3(j). We received the following comments on § 438.3(j) relating to advance directives.

Comment: Several commenters thought CMS should specify in this section of the regulation that there is a prohibition against coercion for individuals to sign an advance directive.

Response: The purpose of this section is for states to require managed care plans to have policies in place for advance directives when the managed care plan provides for institutional, home-based services, and/or LTSS. An identical set of requirements are imposed on MA organizations under section 1852(i) of the Act (by way of cross-reference to section 1866 of the Act) and have been implemented under § 422.128. Our regulation, by cross-referencing § 422.128, requires the managed care plans to have policies that include written information concerning the individual’s rights to make decisions concerning medical care, to refuse or accept medical or surgical treatment, and to formulate advance directives; a prohibition against discrimination whether or not the individual chooses to

execute an advance directive; and provision for individual and community education about advance directives. We believe that the regulatory language clearly provides for the rights of individuals to make decisions concerning medical care and to formulate an advance directive, and we are therefore not modifying § 438.3(j).

After consideration of the public comments, we are finalizing § 438.3(j) with “as if such regulation applied directly to . . .” in paragraphs (1) and (2) and “subject to the requirements of this paragraph (j) . . .” in paragraph (3) for clarification.

k. Subcontracts (§ 438.3(k))

We proposed to redesignate the provisions for subcontracts currently at § 438.6(l) as § 438.3(k) and also proposed to add a cross-reference to § 438.230 that specifies standards for subcontractors and delegation. We did not receive comments on § 438.3(k) and will finalize as proposed.

l. Choice of Health Professional (§ 438.3(l))

We proposed to redesignate the standards for choice of health care professional currently at § 438.6(m) at § 438.3(l).

We received the following comments on the standards for choice of health professional at § 438.3(l). We did not propose any substantive change to the current rule other than this redesignation.

Comment: One commenter supported § 438.3(l) regarding the choice of health professional. One commenter disagreed with the provision and stated that the provision would limit managed care plans from guiding enrollees to lower-cost and higher-quality providers. The commenter stated that it would also be more difficult to transition enrollees from a provider that is exiting the program. The commenter further stated that CMS should prohibit enrollees from insisting on services delivered by a specific provider when the managed care plan has offered the enrollee the services of a qualified provider who is available to provide the needed services.

Response: We disagree with the commenter that § 438.3(l) limits managed care plans from guiding enrollees to lower-cost and higher-quality providers. Section § 438.3(l) requires that the contract must allow each enrollee to choose his or her health professional to the extent possible and appropriate. If a provider is exiting the program, it would not be possible or appropriate to allow an enrollee to choose that specific health professional. We also decline to generally prohibit

enrollees from insisting on services delivered by a specific network provider when the managed care plan has offered the enrollee the services of another qualified provider who is available to provide the needed services. We believe this statement is overly broad and could vary greatly depending on the contract and the services being requested. The 2001 proposed rule, finalized in 2002, incorporated this section directly from § 434.29, which addressed contract requirements for health maintenance organizations (*see* 66 FR 43622).

In addition, this section uses the term “health professional” which is not currently defined in part 438. We address our proposal related to adding a definition for health care professional in section I.B.9.a. of this final rule. We have changed the term “health professional” to “network provider” in this final rule to clarify that the choice for enrollees is within the network.

After consideration of the public comments, we are finalizing § 438.3(l) with a modification to replace “health professional” with “network provider” in the heading and text.

m. Audited Financial Reports (§ 438.3(m))

In § 438.3(m), we proposed to add a new standard that MCOs, PIHPs, and PAHPs submit audited financial reports on an annual basis as this information is a source of base data that must be used for rate setting purposes in proposed § 438.5(c). We proposed that the audits of the financial data be conducted in accordance with generally accepted accounting principles and generally accepted auditing standards.

We received the following comments on proposed § 438.3(m).

Comment: Several commenters supported § 438.3(m) regarding annual audited financial reports. A few commenters recommended that CMS limit duplicative requirements for submission of such audited financial reports. Specifically, one commenter recommended that CMS permit managed care plans to submit previously audited financial reports. One commenter recommended that CMS align the federal requirement to provide audited financial reports with any state requirement to provide audited financial reports to state licensing authorities. One commenter recommended that CMS clarify whether such audited financial reports must be specific to the Medicaid contract.

Response: We clarify for commenters that managed care plans must submit audited financial reports on an annual basis in accordance with generally accepted accounting principles and

generally accepted auditing standards. Audited financial reports are a source of base data for purposes of rate setting at § 438.5(c) and such information must be provided to the state for such purposes. We encourage states to coordinate submission deadlines or other requirements with similar requirements for state licensing agencies, as appropriate, to mitigate duplicative reporting requirements. We proposed a general standard at § 438.3(m) to ensure that states had this information on an annual basis and it would be impracticable for us to attempt to align the federal requirement with each state’s requirement to provide audited financial reports to state licensing authorities. We intend the requirement in § 438.3(m) to be that the MCO, PIHP, or PAHP submit annual audited financial reports specific to the Medicaid contract(s), not to other lines of business or other plans administered or offered by the entity. We are adding text to the final rule to make this clear.

Comment: One commenter recommended that CMS include regulatory text at § 438.3(m) to prohibit states and managed care plans from using any audit program that bases its audited financial reports on extrapolation. The commenter recommended that CMS require states to develop standards and guidelines for managed care audits of financial reports that will ensure that all Medicaid audits of financial reports are conducted using generally accepted auditing standards and in accordance with state and federal law.

Response: We decline to adopt the commenter’s recommendation. We have already provided at § 438.3(m) that audits of financial reports must be conducted in accordance with generally accepted accounting principles and generally accepted auditing standards. We believe that such standards are adequate for this purpose and that additional requirements are unnecessary.

Comment: One commenter recommended that CMS define “audited financial report” at § 438.3(m). The commenter recommended that CMS clarify the term and encourage state-arranged audits of program-specific financial results. The commenter recommended that states be given some degree of discretion in selecting appropriate approaches to Medicaid financial data verification, while upholding a vigorous and professional methodology. The commenter also recommended that the emphasis on Generally Accepted Accounting Principles (GAAP) be tempered. The commenter stated that many costs that

are completely acceptable and allowable under GAAP are not allowable under Federal Acquisition Regulations (FAR). The commenter recommended that CMS allow flexibility for states in this regard. The commenter stated that CMS can mandate GAAP as a floor for audited financial reports but should also recognize the significance of FAR. The commenter recommended that states with more rigorous methods, such as cost principles that extend the concepts of FAR into specifics pertaining to capitated managed care, should be able to continue to utilize those methods. Finally, the commenter recommended that CMS clarify the sufficiency of whether states can utilize a desk review of financial data submitted by managed care plans for certain limited purposes when audited financial reports are not yet available.

Response: We decline to adopt a definition for “audited financial report” as these reports are part of the normal course of business within the health insurance industry and do not require further federal definition. We clarify for the commenter that nothing at § 438.3(m) prevents the state from utilizing state-arranged audits of program-specific financial results or selecting appropriate approaches to Medicaid financial data verification. We also clarify that § 438.3(m) does not preclude states from requiring managed care plans to apply the principles in the FAR in the auditing of financial reports. Generally, professional standards of practice acknowledge the effect of state or federal laws that may differ from the standards of practice. However, it is not clear to us how the FAR would directly impact the auditing of financial reports in this context. Finally, we clarify that states may utilize a desk review of financial data submitted by managed care plans for certain limited purposes when audited financial reports are not yet available with appropriate documentation.

After consideration of the public comments, we are finalizing all § 438.3(m) largely as proposed, with a modification to add the phrase “specific to the Medicaid contract” to clarify the scope of the audited financial report.

Paragraph (n) was reserved in the proposed rule and is finalized as a redesignation of § 438.6(n) in the March 30, 2016 final rule (81 FR 18390).

n. LTSS Contract Requirements (§ 438.3(o))

In § 438.3(o), we proposed that contracts covering LTSS provide that services that could be authorized through a waiver under section 1915(c) of the Act or a state plan amendment

through section 1915(i) or 1915(k) of the Act be delivered consistent with the settings standards in § 441.301(c)(4).

We received the following comments on the proposal to add § 438.3(o).

Comment: A number of commenters supported proposed § 438.3(o) that services that could be in a sections 1915(c), (i), or (k) of the Act authorized program delivered under managed care must meet the requirements of the home and community-based services regulation at § 441.301(c)(4) of this chapter, although a couple commenters noted the challenges posed by the HCBS settings requirements in that section. Many commenters thought that CMS should amend § 438.3(o) to include a transition period for settings to become compliant as is found in the HCBS regulation for existing programs.

Response: We appreciate the support for this provision and recognize the challenges posed by the HCBS settings requirements. The authority for a managed care delivery system is in conjunction with the authorities underlying LTSS, such as programs operating under sections 1915(c), (i), or (k) of the Act. The transition period specified in the HCBS final rule (79 FR 2948) for states to comply with the settings requirements at § 441.301(c)(4) for programs existing prior to March 17, 2014 would similarly apply to an MLTSS program that is subject to this requirement under § 438.3(o) as we view that transition period as a substantive part of § 442.301(c)(4) for purposes of applying those standards under § 438.3(o). We clarify that the intent of § 438.3(o) was to incorporate and apply the settings requirements at § 441.301(c)(4) (directly regulating Medicaid FFS) for LTSS in MLTSS programs.

After consideration of the public comments, we are finalizing § 438.3(o) as proposed.

o. Special Rules for Certain HIOs (§ 438.3(p))

We proposed to redesignate existing § 438.6(j) (special rules for certain HIOs) as § 438.3(p). As part of our proposed redesignation of the HIO-specific provisions from existing § 438.6(j) to new § 438.3(p), we also proposed to correct a cross-reference in that paragraph.

We received the following comments on the HIO-specific provisions at § 438.3(p).

Comment: One commenter stated that § 438.3(p) did not clearly explain when HIOs are subject to the provisions of part 438 and when they are exempt. The commenter stated that Title XIX of the Act only exempts a narrow subset of

HIOs from the rules that apply to other capitated managed care plans. The commenter recommended that CMS clarify that exempt HIOs are subject to the same rules as other capitated managed care plans, except where exemptions specific to the HIO's special features apply. The commenter recommended that CMS amend this section to omit reference to non-exempt HIOs and instead clarify that exempt HIOs must meet all provisions of part 438 except those to which they are explicitly exempted.

Response: This long-standing provision should be read in conjunction with the definition of an HIO in § 438.2 and we direct the commenter to 67 FR 40994 for a discussion of the HIOs that are exempt from section 1903(m)(2)(A) of the Act. Basically, a county-operated organization that would meet the definition of a comprehensive risk contract and does not meet the definition of an HIO in § 438.2 is an MCO that is subject to all provisions that apply to MCOs in this part.

After consideration of the public comments, we are finalizing 438.3(p) as proposed with a modification to correct the cross-reference to paragraph (b) of § 438.3.

p. Additional Rules for Contracts With PCCMs and PCCM Entities (§ 438.3(q) and § 438.3 (r))

We proposed to redesignate the additional contract standards specific to PCCM contracts from existing § 438.6(k) to new § 438.3(q) to separately identify them. In § 438.3(r), we proposed to set standards for contracts with PCCM entities, in addition to those standards specified for PCCM contracts in proposed § 438.3(q), including the submission of such contracts for our review and approval to ensure compliance with § 438.10 (information requirements). If the PCCM entity contract provides for shared savings, incentive payments or other financial reward for improved quality outcomes, § 438.330 (performance measurement), § 438.340 (managed care elements of comprehensive quality strategy), and § 438.350 (external quality review) would also be applicable to the PCCM entity contract. We address comments on § 438.3(q) and (r) at section I.B.6.e of this final rule.

q. Requirements for MCOs, PIHPs, or PAHPs That Provide Covered Outpatient Drugs (§ 438.3(s))

In § 438.3(s), we proposed that state Medicaid contracts with MCOs, PIHPs, or PAHPs meet the requirements of section 1927 of the Act when providing coverage of covered outpatient drugs.

The proposed managed care standards are based primarily on section 1903(m)(2)(A)(xiii) of the Act and we relied on our authority under section 1902(a)(4) of the Act to extend the section 1927 requirements to PIHPs and PAHPs that are contractually obligated to provide covered outpatient drugs. In addition, we relied on section 1902(a)(4) of the Act to address, for all managed care plans within the scope of this proposal, requirements that are outside the scope of section 1903(m)(2)(A)(xiii) of the Act, namely the proposed requirements at § 438.3(s)(1), (4) and (6).

Section 2501(c)(1)(C) of the Affordable Care Act amended section 1903(m)(2)(A) of the Act to add clause (xiii) to add certain standards applicable to contracts with MCOs. In the February 1, 2016 **Federal Register** (81 FR 51700), we published the "Medicaid Program; Covered Outpatient Drugs" final rule which included the definition for covered outpatient drugs in § 447.502. We have incorporated the appropriate definitions in § 447.502 related to covered outpatient drugs in part 438.3(s).

General Comments (§ 438.3(s))

We received the following comments about proposed § 438.3(s) generally.

Comment: A few commenters requested that the states be allowed 12 months from the effective date of the final rule to implement the provisions proposed in § 438.3(s). The commenters specifically referenced the requirements to identify 340B drug utilization, implement the formulary and prior authorization requirements, amend contracts, and develop DUR programs, as tasks contributing to the need for an extended implementation.

Response: As specified in the effective and compliance date sections of this final rule, states and managed care plans will have until contracts starting on or after July 1, 2017 to come into compliance with the provisions of § 438.3(s).

Comment: One commenter stated that the proposed rule should exclude hospital covered outpatient drugs from the Medicaid Drug Rebate program if the hospital bills Medicaid for covered outpatient drugs at no more than the hospital's purchasing costs per section 1927(j)(2) of the Act.

Response: Nothing in proposed § 438.3(s) changes the exemption found at section 1927(j)(2) of the Act from the requirements in section 1927 of the Act. Therefore, hospitals that dispense covered outpatient drugs using drug formulary systems and bill the managed care plan no more than the hospital's purchasing costs for covered outpatient

drugs would not be subject to the rebate requirements of section 1927 of the Act.

Comment: One commenter urged CMS to require states to develop provisions that would not only ensure enrollee choice, but would also prohibit managed care plans from imposing financial incentives for the use of mail order pharmacy services.

Response: We decline to implement the commenter's suggestion. While we agree that enrollee access and freedom of choice is essential, managed care plans may contract with mail order pharmacies in an effort to control costs and support enrollee compliance with medication therapies. If a managed care plan requires an enrollee to use a mail order pharmacy for maintenance or other appropriate medication therapies, that information should be in the member handbook or other appropriate informational materials to aid in the enrollee's choice of a managed care plan.

Comment: One commenter suggested that states and managed care plans should properly define specialty drugs and that states should develop standards on how managed care plans determine which drugs are included on specialty drugs lists. The commenter suggested a definition of specialty drug, as well as what are considered to be key policy principles that should be followed to ensure that specialty drugs are properly defined and categorized. In part, the commenter indicated that specialty drugs should not be subject to requirements or limitations that would require specialty drugs to be delivered through mail order or a restricted network; the definition should not be based solely on cost and should focus on the clinical aspect of the drugs; the definition should require that all drugs under consideration meet the listed criteria before being added to a specialty drug lists; and the definition should ensure stakeholders have sufficient advance notice of, and an opportunity to review and comment on, mail order only drugs lists, and to receive a written explanation of the reasons for the limitation of where such drugs may be dispensed.

Response: While we appreciate this comment and recognize the need for consistency in the use of terms within the healthcare industry, we believe it is beyond the scope of this final rule for CMS to adopt a specific definition of specialty drug or to require states to develop standards on how managed care plans define specialty drugs.

Comment: A few commenters had suggestions regarding requirements that CMS should place on managed care plan payments to providers and

pharmacies and pricing methodologies. One commenter stated that managed care plans should be required in their contracts with their pharmacies to clearly define drug pricing methodologies, routinely update drug pricing, pay pharmacies promptly, and allow pharmacies to contest changes in their reimbursement. The commenter believed that including such requirements would encourage pharmacy participation, which would result in increased access and options for Medicaid beneficiaries. Another commenter requested that CMS require states to ensure that provider payment rates are at levels that help to preserve enrollee access once the pharmacy benefit is transitioned from FFS to managed care plans. The commenter believed that CMS should require states to apply the same level of reassurance and reimbursement protections for all participating providers, including pharmacy providers, and that establishing a reimbursement rate floor for pharmacies will increase transparency as well as allow for fiscal stability and predictability of reimbursement in these private contracts. Another commenter indicated that CMS should require that managed care plans pay providers at least acquisition costs for drugs and that capitation rates be appropriately set.

Response: The payment terms negotiated between a managed care plan and its network pharmacies are outside the scope of this final rule and part 438 generally. Such payment terms are negotiated as part of the contract between the managed care plan and its participating providers. Each managed care plan must ensure that its enrollees have access to pharmacy services when covered by the Medicaid contract and that the pharmacy network is consistent with the access standards for delivery networks at § 438.206 and set by the state under § 438.68. We strongly encourage managed care plans to consider and treat compensation to providers as an important element in developing and maintaining adequate and robust networks.

Comment: One commenter requested that CMS urge states to develop rules that would require managed care plans to adequately define when a state Maximum Allowable Cost (MAC) list can be established; how such lists should be updated and provided to pharmacies; and how a pharmacy may challenge a particular rate decision. The commenter also provided specific criteria that it believes states should be required to consider when establishing its MAC. The commenter recommended that CMS require states to incorporate

the criteria in their managed care contracts. The commenter further stated that requiring fair and transparent contractual terms related to pharmacy pricing would benefit pharmacy providers, as well as the Medicaid program.

Response: While we appreciate this comment, the establishment of a state MAC is beyond the scope of this final rule.

Comment: One commenter indicated that the overall cost to dispense an over-the-counter (OTC) drug is the same as a prescription drug and therefore, urged CMS to require states to implement adequate and fair dispensing fees for all managed care claims, including OTC drugs.

Response: While we appreciate this comment, the dispensing fees paid by managed care plans for OTC drugs is part of the contract terms negotiated between the managed care plan and the pharmacy. Therefore, it is beyond the scope of this final rule.

Comment: One commenter stated that CMS should encourage states to require managed care plans to pay all pharmacy claims in a timely manner. The commenter suggested that all Medicaid pharmacy claims should follow the current requirements under Medicare Part D which require that clean claims submitted electronically should be paid within 14 days, and all other clean claims should be paid within 30 days. The commenter also suggested that managed care plans should be required to submit payment via Electronic Funds Transfer (EFT), if requested by provider, and at no charge to the provider. The commenter also stated that managed care plans should be required to pay interest for late payments, and have procedures in place to correct defective or unclean claims.

Response: Section 1932(f) of the Act incorporates the timely claim payment provisions in section 1902(a)(37)(A), which are specified in regulation at § 447.46. That regulation permits an alternative payment schedule if the managed care plan and provider agree. If a managed care plan contracts with a pharmacy benefit manager (PBM) for the pharmacy benefit, the provisions of section 1932(f) of the Act, governing prompt and timely payments by MCOs, still apply.

Comment: One commenter expressed concern regarding the lack of requirements around payment file updates for physician-administered drugs. The commenter requested that CMS consider requiring states to implement a quarterly requirement to update payment files to mirror Medicare

Part B, and provide an oversight plan for monitoring these important updates.

Response: While we appreciate this comment, payment file dates for physician-administered drugs is beyond the scope of this final rule.

Comment: One commenter urged CMS to clarify in the final rule that all Medicaid managed care plans must meet MH/SUD parity requirements related to prescription drugs for MH/SUD conditions.

Response: We appreciate the opportunity to clarify that all requirements related to MHPAEA under managed care were codified in subpart K of part 438 of the March 30, 2016 final rule (81 FR 18390). We do not believe a duplicative reference in § 438.3(s) is necessary.

Comment: One commenter recommended that CMS provide technical guidance to pharmacies, managed care plans, and other entities participating in care delivery that will result in all parties using a single, industry-standard code to identify relevant drug claims.

Response: The comment is outside of the scope of this final rule. However, to respond to the commenter's request for an industry standard code to identify Medicaid drug rebate claims, CMS requires that states provide the National Drug Code when invoicing the manufacturers for rebates and reporting utilization to CMS as authorized under section 1927(b)(2)(A) of the Act.

Comment: A commenter requested that CMS clarify that the requirements at § 438.3(s) do not apply to individuals enrolled in programs or plans for dually eligible beneficiaries, as these programs traditionally follow Medicare Part D requirements.

Response: Medicare Part D is responsible for paying for covered outpatient drugs dispensed to dual eligible individuals. The requirements at § 438.3(s) establish standards for states that contract with managed care plans to provide Medicaid coverage of covered outpatient drugs; as such, this regulation does not apply to covered outpatient drugs for individuals enrolled in Medicare Part D plans.

Comment: Several commenters supported the inclusion of section 1927 of the Act regarding prescription drug protections in proposed § 438.3(s), including the prior authorization timeline and that managed care plan contracts must cover prescription drugs consistent with federal Medicaid requirements. Other commenters urged CMS to simply reference the existing requirements under section 1927 of the Act, rather than adding confusion to the

contract requirements around outpatient drugs for managed care plan enrollees.

Response: We appreciate the support for including clarification in § 438.3(s) around the application of the covered outpatient drug requirements in section 1927 of the Act to state contracts with managed care plans. We decided not to provide a general reference to section 1927 of the Act to clarify exactly which drug provisions MCOs, PIHPS, and PAHPs must comply with.

Prescription Drug Coverage (438.3(s)(1))

In paragraph (s)(1), we proposed that the MCO, PIHP, or PAHP must provide coverage of covered outpatient drugs (as defined in section 1927(k)(2) of the Act) as specified in the contract and in a manner that meets the standards for coverage of such drugs imposed by section 1927 of the Act as if such standards applied directly to the MCO, PIHP, or PAHP. Under the proposal, when the MCO, PIHP, or PAHP provides prescription drug coverage, the coverage of such drugs must meet the standards set forth in the definition of covered outpatient drugs at section 1927(k)(2) of the Act. The MCO, PIHP, or PAHP may be permitted to maintain its own formularies for covered outpatient drugs, but when there is a medical need for a covered outpatient drug that is not included in their formulary but that is within the scope of the contract, the MCO, PIHP, or PAHP must cover the covered outpatient drug under a prior authorization process. This proposal was based on our authority under section 1902(a)(4) of the Act to mandate methods of administration that are necessary for the efficient operation of the state plan. Furthermore, if an MCO, PIHP, or PAHP is not contractually obligated to provide coverage of a particular covered outpatient drug, or class of drugs, the state is required to provide the covered outpatient drug through FFS in a manner that is consistent with the standards set forth in its state plan and the requirements in section 1927 of the Act.

We received the following comments on proposed § 438.3(s)(1).

Comment: Several commenters asked that we remove or reframe the language related to outpatient drug coverage at § 438.3(s)(1); the commenters said that existing regulation (§ 438.210) requires managed care plans to provide benefits consistent with the state plan. Therefore, the commenters believed that § 438.3(s)(1) could be duplicative. The commenters were concerned that the inclusion of this language in the proposed regulation could inadvertently limit states' actions around prior authorization and off-label use of

outpatient drugs, as well as shift costs onto the state. Commenters also indicated that the requirement under scope of coverage at § 438.210 between managed care programs and FFS is sufficient to ensure members have the same access to benefits, including prescription drug coverage.

Response: While the requirement at § 438.210 has been in place for some time, we believe some states have not adequately addressed these requirements in their contracts with managed care plans and are clarifying in this regulation the specific requirements that either the state, or the managed care plan, must adopt to ensure the availability of, and access to, equivalent covered outpatient drug services consistent with applicable law. Therefore, we generally agree that the requirements of this final regulation are not necessarily new to states and believe that these requirements should not necessitate a major overhaul of their programs or managed care contracts. We further note that states may continue to adopt prior authorization processes consistent with the minimum requirements at section 1927(d)(5) of the Act and provide covered outpatient drugs for medically accepted indications as defined in section 1927(k)(6) of the Act.

Comment: Commenters requested that CMS be very clear what a state is responsible for paying for versus the managed care plan, and requested clarification on how it is determined to be "within the scope of the contract" but not in the formulary. Commenters stated if a managed care plan is not contractually obligated to provide coverage of a particular covered outpatient drug, or class of drugs, the state is required to provide the covered outpatient drug through FFS in a manner that is consistent with the standards set forth in its state plan and the requirement in section 1927 of the Act. These commenters asked CMS to clarify if this applies only when the drug is already covered under Medicaid FFS, or if this means that Medicaid must cover every drug and, as written, it may make states responsible for FFS coverage of managed care covered drugs resulting in cost implications for the states. Commenters requested that CMS specify that a managed care plan's formulary may not be more restrictive than the comparable FFS program to avoid access disparities for individuals in FFS versus managed care.

Response: It is our intent to clarify contractual obligations on the managed care plan for covered outpatient drugs when this benefit is provided by the managed care plan under the contract

with the state. We consider “within the scope of the contract” to be the terms negotiated between the state and the managed care plan to administer the covered outpatient drug benefit to enrollees. States must ensure that when the managed care plan provides covered outpatient drugs to enrollees, such services that are available under the state plan are available and accessible to enrollees of managed care plans consistent with section 1903(m)(1)(A)(i) of the Act. How such services are made available to enrollees (either via the contract with the managed care plan or directly by the state) are negotiated between the state and the managed care plan.

We understand that each state may cover outpatient drugs differently for its managed care enrollees. For example, a state may contract with a managed care plan to include coverage of a limited set of drugs related to a specific disease state (for example, medications for substance abuse disorders). In these instances, the managed care plan should meet the coverage requirements of section 1927 of the Act to the extent they apply to the drugs covered by the plan within the scope of its contract. In other words, a managed care plan that agrees to provide coverage of a subset of covered outpatient drugs under the contract with the state would need to provide coverage of every covered outpatient drug included in the subset when the manufacturer of those drugs has entered into a rebate agreement with the Secretary. For example, if the managed care plan is only required in its contract to provide coverage of substance use disorder drugs, the managed care plan may choose to subject certain substance use disorder covered outpatient drugs to prior authorization as long as the prior authorization program it adopts meets the requirements in section 1927(d)(5) of the Act. Further, the state would be required, under section 1927 of the Act, to provide coverage of outpatient covered drugs that are not included in the managed care plan’s contract and the state may meet this obligation through FFS or another delivery system.

States that contract with managed care plans to cover outpatient drugs for the entire covered outpatient drug benefit under the state plan must ensure that the contract meets the standards set forth at § 438.3(s) for all of those drugs. That is, when applicable, the managed care plan’s contract must ensure that:

- The managed care plan’s drugs are covered outpatient drugs in accordance with section 1927(k)(2) of the Act and meet the standards for coverage under section 1927 of the Act;

- The managed care plan reports drug utilization data to the states to enable billing for Medicaid drug rebates;

- The managed care plan has procedures in place to exclude utilization data for covered outpatient drugs that are subject to 340B discounts covered by the managed care plan;

- The managed care plan operates a drug utilization program that complies with the requirements of section 1927(g) of the Act, provides a description of the DUR activities to the state on an annual basis, and conducts a prior authorization program, when applicable, consistent with the minimum requirements set forth at section 1927(d)(5) of the Act.

States may allow managed care plans to use their own formulary; however, if the managed care plan’s formulary does not include a covered outpatient drug that is otherwise covered by the state plan pursuant to section 1927 of the Act, the managed care plan must ensure access to the off-formulary covered outpatient drug consistent with the prior authorization requirements at section 1927(d)(5) of the Act. States may also choose to cover covered outpatient drugs not on the managed care plan’s formulary for enrollees by providing coverage of such drugs under the state plan using a prior authorization program that meets the requirements at section 1927(d)(5) of the Act. States and managed care plans should address these requirements in their contract documents so the responsibilities of each party are clearly identified when administering the Medicaid covered outpatient drug benefit.

Managed Care Drug Utilization Data Reporting (§ 438.3(s)(2))

In paragraph (s)(2), we proposed to implement section 1903(m)(2)(A)(xiii)(III) of the Act. Specifically, we proposed that MCOs, PIHPs, and PAHPs report drug utilization data necessary for the state to submit utilization data under section 1927(b)(2) of the Act and within 45 calendar days after the end of each quarterly rebate period to ensure that MCO, PIHP, or PAHP data is included in utilization data submitted by states to manufacturers. We further proposed that such utilization information must include, at a minimum, information on the total number of units of each dosage form and strength and package size by National Drug Code of each covered outpatient drug dispensed or covered by the MCO, PIHP, or PAHP.

We received the following comments on proposed § 438.3(s)(2).

Comment: Several commenters recommended that CMS set specific

deadlines that managed care plans should meet when reporting data utilization associated with the requirements of section 1927(b)(1)(A) of the Act. One commenter recommended that managed care plans report drug utilization data no later than 30 calendar days after the end of each quarterly rebate period and include utilization information at a minimum, on the total number of units of each dosage form, strength, and package size by National Drug Code of each covered outpatient drug dispensed or covered by the MCO, PIHP, or PAHP. Another commenter disagrees with the proposed timeframe of 45 days because it may not give enough time for the states to review the data prior to invoicing drug manufacturers for rebates within each quarter. The commenter continued that currently in their state, managed care plans must provide rebate data to the state within 25 days after the date the claim was adjudicated. The commenter believed that by giving managed care plans 30 days after the end of the quarter, states would have adequate time to load and process the data they get from the managed care plans and do pre-invoice editing prior to submitting the invoices to manufacturers. The commenter further requested clarification in the rule on language that the 45 day period is the maximum the state can allow and that the state can require managed care plans to provide the data within a period of time that is less than 45 days.

Response: In accordance with section 1927(b)(2)(A) of the Act, states are required to submit utilization data to manufacturers for rebates no later than 60 days after the end of each rebate period (quarter). The data submitted to manufacturers must include total number of units of each dosage form, strength, and package size of each covered outpatient drug. The 45 day requirement proposed at § 438.3(s)(2) is a maximum, and states may require their managed care plans to submit their drug utilization data on any time frame up to 45 calendar days after the end of the quarterly drug rebate period, as long as the state meets the 60 day statutory deadline.

Comment: One commenter supports CMS’ proposal to require managed care plans to report drug utilization data necessary for the states to bill for Medicaid rebates within 45 calendar days after the end of each quarterly rebate period, and believed that CMS should also specify that managed care plans must report utilization within 45 calendar days after the end of the calendar quarter in which the pharmacy was reimbursed and that any utilization

for dates prior to the most recently ended calendar quarter must be clearly segregated and marked as a prior quarter adjustment and contain the date on which the pharmacy was reimbursed. The commenter believed imposing a 45-day time limit for submitting utilization data to the state will help to ensure that states submit complete quarterly invoices to manufacturers within 60 days after the close of the quarter (as section 1927(b)(2)(A) of the Act requires). This in turn will provide manufacturers with timely and more complete information regarding their Medicaid rebate liability and result in timely rebate payments to state Medicaid programs. Another commenter stated that their state's managed care contract requires weekly submission of drug utilization data and while the managed care contractual requirements are aligned with this portion of the proposed regulation, knowing that managed care plan utilization data is lagged, CMS should be clear in this final rule and explain how this would be measured (for example, date of service, date paid to the pharmacy or date paid by the managed care plan).

Response: Section 1927(b)(1)(A) of the Act requires, in part, that manufacturers pay rebates on drugs dispensed to individuals enrolled in a MCO. Therefore, all managed care plans should report their utilization data to the state based upon the quarter in which the drug was dispensed (that is, date of service) to the enrollee, as opposed to the quarter in which the managed care plan paid the claim. In addition, just as states indicate on quarterly rebate invoices when utilization data reflects an earlier quarter (that is, a prior quarter adjustment), so should the utilization data that a managed care plan submits to the state for a paid claim, reflect adjustments to an earlier quarter by specifically referencing the earlier quarter/year date of service in which the drug was dispensed.

Exclusion of 340B Drug Utilization Data (§ 438.3(s)(3))

In paragraph (s)(3), we proposed that the MCO, PIHP, or PAHP must have procedures in place to exclude utilization data for drugs subject to discounts under the 340B Drug Pricing Program from the utilization reports submitted under proposed paragraph (s)(2). Section 2501(c) of the Affordable Care Act modified section 1927(j)(1) of the Act to specify that covered outpatient drugs are not subject to the rebate requirements if such drugs are both subject to discounts under section 340B of the PHS Act and dispensed by

health maintenance organizations, including Medicaid MCOs. In accordance with section 1927(a)(5) of the Act, states may not seek rebates with respect to drugs provided by covered entities when covered outpatient drugs are purchased at discounted 340B prices that are provided to Medicaid beneficiaries. Section 1903(m)(2)(A)(xiii)(III) of the Act specifies that MCOs report drug utilization data necessary for the state to bill for rebates under section 1927(b)(2)(A) of the Act; we extend those obligations to PIHPs and PAHPs using our authority under section 1902(a)(4) of the Act. In accordance with this provision, MCOs, PIHPs and PAHPs are not responsible for reporting information about covered outpatient drugs if such drugs are subject to discounts under section 340B of the PHS Act and dispensed by MCOs in accordance with section 1927(j)(1) of the Act. Therefore, covered outpatient drugs dispensed to Medicaid enrollees from covered entities purchased at 340B prices, which are not subject to Medicaid rebates, should be excluded from managed care utilization reports to the state. To ensure that drug manufacturers will not be billed for rebates for drugs purchased and dispensed under the 340B Drug Pricing Program, MCOs, PIHPs, or PAHPs must have mechanisms in place to identify these drugs and exclude the reporting of this utilization data to the state to prevent duplicate discounts on these products. Our proposal at § 438.3(s)(3) was designed to address this issue.

We received the following comments on proposed § 438.3(s)(3).

Comment: Several commenters indicated their concerns regarding the necessity of revenue from the 340B program to continue providing needed care to patients of 340B covered entities. Specifically, commenters stated that for many 340B covered entities, including FQHCs, the 340B Drug Discount Program is critical to their financial stability and that these entities rely upon the 340B program as a revenue stream to provide a safety net for uninsured and underinsured patients. Several commenters requested that CMS add language to the preamble and § 438.3(s) to clarify that neither states nor managed care plans may prohibit 340B providers, including hemophilia treatment providers, who are in managed care networks from using 340B drugs for their patients nor require providers to agree not to use 340B drugs for their patients as a condition of participating in a managed care network. One commenter asked that CMS protect the right of entities to use

340B drugs for managed care enrollees by explicitly acknowledging it in § 438.3(s) and by including guidelines and limits for how managed care plans can implement this provision.

Response: We recognize the importance of the 340B program to all covered entities. However, part 438 does not address the availability of 340B drugs to the Medicaid population or the revenue generated for covered entities from the 340B program. Instead, this rule implements the requirements of section 1903(m)(2)(A)(xiii)(III) of the Act, which provides that MCOs are not responsible for reporting information about covered outpatient drugs that are not subject to a Medicaid rebate if such drugs are both subject to discounts under section 340B of the PHS Act and dispensed by MCOs in accordance with section 1927(j)(1) of the Act. The regulation as finalized here requires the contracts between managed care plans and states to require the plans to establish procedures to exclude the necessary utilization from the reports to the state.

Comment: Several commenters believe that states should be prohibited from requiring that their managed care plans pay lower rates for drugs purchased by 340B covered entities than for the same drugs when purchased by other managed care network providers. Commenters also recommend that CMS prohibit managed care plans from using billing information obtained from 340B Medicaid claims to reduce reimbursement for 340B commercial claims and asked that CMS require that states have their managed care plans contract with 340B covered entities on the same terms and conditions and at rates that are not less than the rates paid to non-covered entities for the same services.

Response: This regulation does not address managed care payment for drugs purchased by 340B covered entities but rather implements the requirements of section 1903(m)(2)(A)(xiii)(III) of the Act which provides that the MCOs are not responsible for reporting information to states about covered outpatient drugs that are not subject to this rebate standard if such drugs are both subject to discounts under section 340B of PHS Act and dispensed by MCOs in accordance with section 1927(j)(1) of the Act. We extend that protection to PIHPs and PAHPs using our authority under section 1902(a)(4) of the Act under this rule. Reimbursement by managed care plans for drugs dispensed by 340B covered entities is negotiated between the managed care plans and covered

entities and is outside the scope of this rule.

Comment: Several commenters made suggestions on how states and managed care plans should identify 340B claims. The commenters suggested that CMS prohibit managed care plans from requiring 340B covered entities to identify 340B claims as it would make it highly difficult or impossible for these covered entities and their contract pharmacies to use 340B for Medicaid managed care patients. For example, commenters commended CMS for not proposing that pharmacies identify 340B claims at the point-of-sale (POS). They indicated that pharmacies that use a virtual 340B inventory normally do not know at the POS if a claim is 340B, so requiring pharmacies to identify all 340B drugs at POS effectively prohibits these providers from using 340B drugs for managed care patients. The commenters support CMS' decision to provide flexibility to managed care plans in developing procedures to exclude 340B drugs from their reports but ask that CMS protect a covered entity's right to carve Medicaid managed care drugs in or out by explicitly acknowledging the right in § 438.3(s). Commenters suggested that CMS provide guidance encouraging states and managed care plans to identify 340B claims retrospectively and that such reporting should be standardized so covered entities can comply without the need to develop a multitude of different methodologies.

Other commenters suggested that assigning unique Bank Identification Number (BIN)/Processor Control Number (PCN)/Group numbers for Medicaid managed care plans will allow pharmacies to clearly identify and handle Medicaid managed care claims and enable pharmacies dispensing 340B drugs to distinguish these claims from the managed care commercial claims for covered drugs. In addition, commenters believe that the use of unique BIN/PCN/Group numbers will give pharmacies the capability to properly coordinate benefits in cases when beneficiaries have third party coverage.

Several commenters indicated that collaboration among CMS, HRSA and state Medicaid Agencies will be necessary to ensure that guidance for plans and 340B covered entities clearly address the many potential challenges of operationalizing the prohibition on duplicate discounts. They also recommended that CMS clarify that states may require managed care plans to report drug claims that are subject to 340B discounts, outside of the utilization reports submitted under paragraph (s)(2) of the proposed rule.

Several commenters expressed support for CMS' proposal requiring managed care plans to establish procedures to exclude 340B drugs from the drug utilization reports provided to the states. Commenters indicated that this clarification is important because of confusion among 340B stakeholders regarding how the 340B program operates in Medicaid managed care relative to Medicaid FFS. One commenter asked that CMS ensure that managed care plans not only take responsibility for identifying 340B drugs but also absorb the costs associated with that process. The commenter encouraged CMS to ensure that the methodologies managed care plans use are not overly administratively burdensome for providers (particularly when contracting with multiple plans) and that participation in, or the benefit of, the 340B program is not limited in the managed care environment. One commenter recommended that because of the complexity of 340B claims identification and payment—including a lack of using industry claim transactions to amend claims transactions—separate guidance be provided to help resolve the technically complex nature of 340B claim identification issues.

And finally, several commenters appreciated that CMS explicitly stated that 340B providers are not legally responsible for protecting manufacturers from having to pay both a 340B discount and a Medicaid rebate on a managed care claim. The commenters believed that this interpretation is consistent with the statute, and is logical from an operational standpoint. Commenters requested that CMS address it explicitly in the regulation.

Response: We appreciate the concerns raised by the commenters and recognize the importance of preventing duplicate discounts on drugs purchased through the 340B program and dispensed to Medicaid managed care plan enrollees. The commenters identified a number of mechanisms currently in use by the states to ensure duplicate discounts are not paid by manufacturers on 340B drugs.

When states contract with managed care plans, the contracts should include specific language addressing which tools managed care plans can use to exclude 340B purchased drugs from utilization, the responsibility the MCO has with resolving manufacturer disputes or rebate invoices derived from MCOs, state's ability to access data and records related to the MCO's exclusion of 340B purchased drugs from utilization reports, and any liability the MCO may face in cases of unresolved

manufacturer disputes of rebate invoices derived from the MCO's utilization. For managed care plans, in accordance with section 1903(m)(2)(A)(xiii)(III) of the Act, MCOs should not report information about covered outpatient drugs to the states that are not subject to this rebate standard if such drugs are both subject to discounts under section 340B of the PHS Act and dispensed by MCOs in accordance with section 1927(j)(1) of the Act. We extend those reporting standards to PIHPs and PAHPs in this rule using our authority under section 1902(a)(4) of the Act. Managed care plans can use several methods to ensure they report consistent with section 1903(m)(2)(A)(xiii)(III) of the Act. For example, plans could include in their contracts with their pharmacy providers a reference to billing instructions or processes that must be followed when identifying a 340 patient and dispensing a 340B drug to a Medicaid patient. States may place certain requirements on plans to require that covered entities or contract pharmacies use specific identifiers on prescriptions so that a managed care plan recognizes that the claim should be billed as 340B. Managed care plans may issue billing instructions and can assign unique BIN/PCN/Group numbers for a particular Medicaid line of business and require pharmacies of managed care plan network providers to bill for the 340B drug to that specific BIN/PCN/Group. We believe that all parties (states, managed care plans, covered entities and pharmacies) should ensure that Medicaid rebates are not paid on 340B drugs and should work together to establish a standard process to identify 340B claims that is collectively effective.

Comment: Several commenters stated that HRSA has established a Medicaid Exclusion File to assist states in identifying 340B claims; however, HRSA has also clarified that the file is to be used for FFS Medicaid claim identification. Further, states are now mandating use of the Medicaid Exclusion File for managed care claims, even though that was not its intended purpose.

Commenters also suggested which entities should be responsible for ensuring that duplicate discounts are not paid on 340B drugs. Several commenters indicated that each state, not the covered entity, should be legally responsible under federal law for protecting manufacturers from having to pay both a 340B discount and a Medicaid rebate on a managed care claim. Commenters further indicated that it is the responsibility of the state and the managed care plans to have

internal controls including policies/procedures, monitoring, training, and audits to avoid duplicate discounts.

One commenter believed that the Affordable Care Act exempted 340B drugs provided to Medicaid managed care enrollees from the manufacturer Medicaid rebate requirement to avoid the possibility of duplicate discounts. Given that 340B managed care drugs are not subject to rebates, the provisions of the 340B statute imposing liability on covered entities for creation of duplicate discounts do not apply when the underlying drug is provided through managed care plans. Rather, it is the responsibility of the states and managed care plans to avoid duplicate discounts in the managed care environment. The commenter stated they support CMS' proposal to confirm that it is the managed care plan's responsibility to avoid duplicate discounts in managed care.

Finally, commenters requested that CMS and the states clearly identify what is considered the responsibility of the managed care plan and what is considered the responsibility of the state and believe it is important for CMS to understand that it is difficult, if not impossible, for managed care plans to identify such drugs unless the dispensing pharmacy itself identifies a drug as one for which it has obtained a 340B discount. Since all Medicaid managed care plans will be required to certify the completeness and accuracy of their reports, this will put these plans in the untenable position of having to certify to the accuracy of information which is not within the plan's knowledge.

Response: All entities (states, managed care plans, and covered entities) play a role in ensuring Medicaid rebates are not paid on 340B drugs. In accordance with section 1903(m)(2)(A)(xiii)(III) of the Act, MCOs are not responsible for reporting information about covered outpatient drugs that are not subject to this rebate standard if such drugs are both subject to discounts under section 340B of the PHS Act and dispensed by MCOs in accordance with section 1927(j)(1) of the Act. We extend that protection to PIHPs and PAHPs using our authority under section 1902(a)(4) of the Act in this rule.

We recognize that HRSA established a Medicaid Exclusion File to assist in identifying 340B covered entities to avoid duplicate discounts paid by manufacturers for FFS claims. As previously stated for MCO claims, states may place certain requirements on plans to require that covered entities use specific identifiers on prescriptions so a pharmacy knows that it is a 340B claim

and subsequently uses predetermined transaction standards to bill for the 340B purchased drug claim. Managed care plans can assign unique BIN/PCN/Group numbers for a particular Medicaid line of business.

We continue to encourage covered entities, states, and Medicaid managed care plans develop strategies to ensure accurate identification of 340B claims.

Comment: Several commenters believed that CMS should permit 340B providers to report claims data directly to the state or the states' rebate contractor, bypassing the managed care plans, such as is currently done in at least one state. For example, some managed care plans do not possess the technical capability to handle reporting, and/or do not have the necessary relationships with entities to develop successful reporting mechanisms. While this approach may not be appropriate for all states, commenters recommended that CMS grant states the flexibility to pursue the option if they deem it most appropriate.

Response: Section 438.3(s)(3) requires that the managed care plans have procedures to exclude utilization data for covered outpatient drugs that are subject to discounts under the 340B drug pricing program. We understand that what may work in one state may not in another. Therefore, if a state has a process in place where the covered entities are required to submit managed care enrollee drug claims data directly to the state (or the state's claims processor) prior to the state invoicing the manufacturer, the requirement of the managed care plan to establish procedures to exclude the utilization as required by § 438.3(s)(3) would not be applicable. Therefore, we are revising § 438.3(s)(3) to indicate that MCOs, PIHPs or PAHPs establish procedures to exclude utilization data for covered outpatient drugs that are subject to discounts under the 340B drug pricing program from the reports required under paragraph (s)(2) of this section when states do not require submission of Medicaid managed care drug claims data from covered entities directly.

Comment: One commenter stated that they believe some states are using their encounter files to help submit rebate utilization. Several commenters recommended that CMS withdraw its proposed requirement for the managed care plans to remove 340B claims utilization from rebate utilization reports, as the commenter believes these requirements could be extended to encounter files in some states. The commenters believe that this recommendation warrants additional study and stakeholder input as to the

potential ramifications of such a requirement. Another commenter stated that states currently use encounter data to review managed care plan expenditures, set capitation rates, as well as perform retrospective drug utilization review (DUR) and it already attests to having procedures in place to make sure that 340B drugs are not subject to rebates.

Response: We appreciate the comments but believe that a change to the proposal is not necessary. The regulation at § 438.3(s)(3) requires the managed care contract address reporting of data about drug claims for a specific purpose; to facilitate invoicing for rebates under section 1927 of the Act. It is imperative that the state work with the managed care plans to establish procedures to exclude the utilization data for covered outpatient drugs that are subject to discounts under the 340B drug pricing program if the state does not already have a mechanism in place to exclude the drug utilization data associated with 340B drugs dispensed to managed care plan enrollees. The encounter files are not addressed in § 438.3(s) and not subject to the terms of § 438.3(s)(3).

Comment: Several commenters encouraged CMS to standardize the systems and processes used by managed care plans and states to identify 340B claims, referencing the HRSA-developed Medicaid exclusion file, the NCPDP (National Council for Prescription Drug Programs)-developed identifier, state-developed methods and other separate systems for identifying 340B utilization in claims generated in the outpatient clinic. However, the commenter emphasized that there are burdens to a patchwork of systems for manufacturers. Thus, commenters believed the entire system would operate more effectively and efficiently if all parties used the same source data or, in the alternative, if managed care plans were required to use the system established by the relevant state.

Response: We do not believe it is appropriate for us to require states to use a particular process for identifying 340B drug claims. Rather, we encourage the establishment of state-specific systems and/or procedures that are effective at excluding 340B drug claims and preventing duplicate discounts. As noted earlier, there are a number of mechanisms managed care plans can utilize to assist states with identifying 340B drug claims, such as requiring pharmacies to use pre-determined standards or identifiers to submit claims for 340B-purchased drugs at the point of sale or utilization of a unique BIN/PCN/

Group combination related to the plan's Medicaid line of business.

Comment: One commenter requested that CMS direct states to provide manufacturers with access to Claim Level Detail ("CLD"), including detail on utilization data submitted by managed care plans so that manufacturers can evaluate rebate requests for 340B duplicate discounts. They believe that CLD would give manufacturers an important additional tool to investigate for non-compliant 340B utilization.

Response: We did not propose and do not seek to finalize a requirement of the scope that the commenter requests. Additionally, the state's process for billing for rebates is beyond the scope of this rule.

Comment: A commenter asks that CMS specifically address situations when a managed care plan (or state FFS program) requests a Medicaid rebate on units for which a state AIDS Drug Assistance Program (ADAP) has requested a 340B rebate. The commenter encourages CMS to require managed care plans to implement safeguards around potential ADAP duplicate or triplicate rebates.

Response: We agree that safeguards should be in place to avoid duplicative rebates on ADAP drug claims, but we decline to impose additional requirements beyond our proposal. Managed care plan contracts starting on or after July 1, 2017, must be in compliance with the provisions of § 438.3(s) as finalized here.

Comment: Another commenter requested that CMS require managed care plans to review past utilization dating back to 2010 which was submitted to states and revise any such requests that contained 340B utilization. Current period requests for rebates in past periods of time (that is, outside of the standard reporting cycle) should likewise be appropriately evaluated for improper 340B utilization.

Response: We will not require that managed care plans review past managed care drug utilization back to 2010 as part of this rule. However, to the extent states believe managed care utilization data have not been reported correctly during those time periods, states should work with their managed care plans to correct the data and establish processes with the managed care plan to ensure managed care plan utilization data is properly reported under this final rule.

Comment: One commenter recommends that formulary 340B pricing rules need to be reassessed given the increased presence of managed care. The commenter explained that managed

care plans may be able to negotiate better pricing than that afforded through historical methods. They further suggested an agency study of these pricing mechanisms in a managed care environment and adoption of regulatory changes, as appropriate, based on the recommendations.

Response: We thank the commenter for the comment; however, the suggestion is beyond the scope of this rule. We will consider addressing this issue in future guidance or rulemaking, if needed.

Drug Utilization Review (DUR) Program Requirements (§ 438.3(s)(4))

In paragraph (s)(4), we proposed that MCOs, PIHPs, or PAHPs that provide coverage of covered outpatient drugs also operate a DUR program that is consistent with the standards in section 1927(g) of the Act; this standard means that the DUR program operated by the MCO, PIHP, or PAHP would be compliant with section 1927(g) of the Act if it were operated by the state in fulfilling its obligations under section 1927 of the Act. We clarified that this would not mean that the DUR program operated by the MCO, PIHP, or PAHP must be the same as that operated by the state, but that the MCO's, PIHP's, or PAHP's DUR program meets the requirements in section 1927(g) of the Act. This proposal was based on our authority under section 1902(a)(4) of the Act. We recognized that MCOs, PIHPs, and PAHPs that are contractually responsible for covered outpatient drugs generally conduct utilization review activities as these activities promote the delivery of quality care in a cost effective and programmatically responsible manner. We stated that because the MCO, PIHP, or PAHP is providing coverage for covered outpatient drugs as part of the state plan instead of the state providing that coverage through FFS, it was appropriate to extend the DUR responsibilities associated with such coverage to the MCO, PIHP, or PAHP. Section 1927(g)(1)(A) of the Act provides, in part, that states must provide a DUR program for covered outpatient drugs to assure that prescriptions: (1) Are appropriate; (2) are medically necessary; and (3) are not likely to result in adverse medical results. The provisions proposed in paragraph (s)(4) would be satisfied if the managed care plan's DUR program met those standards.

We received the following comments on proposed § 438.3(s)(4).

Comment: Several commenters indicated support for the application of Medicaid FFS DUR activities to the

Medicaid managed care prescription drug benefit. One commenter stated that consideration should be given to the reporting requirements for managed care DUR programs, indicating that while requiring managed care plans to be transparent by posting their DUR activities highlighting the effectiveness of their DUR programs, this full disclosure of strategies may create unfair competitive disadvantages (or advantages) between managed care entities.

Response: We appreciate the comments in support of extending DUR operational and reporting requirements to the managed care prescription drug benefit. We will provide direction to states as to how managed care plans should report DUR activities, which will assist states with their annual DUR reporting requirements to CMS.

Comment: A few commenters stated that DUR was an effective tool for quality care and program integrity, but stated the current DUR operations and standards under section 1927(g) of the Act are outdated or failed to provide enrollees with adequate protections. The commenter urged CMS to improve DUR requirements applied to Medicaid managed care.

Response: We do not agree with the commenters' statements that current DUR standards and operations are outdated and fail to provide adequate protections. Section 1927(g) of the Act provides a framework within which the states are to operate their DUR programs. In accordance with the DUR requirements, states have flexibility to adopt new standards, such as permitting a portal for physicians to access a patient's prescription history before prescribing a new medication during electronic prescribing or implementing electronic prior authorization processes. Since the statute was enacted, states have worked to improve the scope and quality of the operation of their DUR programs, and their programs' oversight. In addition, we have improved the process by which states annually report on the operation of their DUR programs by: (1) Improving the questions in the Medicaid Drug Utilization Review Annual Report (https://www.medicicaid.gov/medicaid-chip-program-information/by-topics/benefits/prescription-drugs/downloads/dursurvey_20140617.pdf); (2) providing an electronic mechanism that the states use to enter their annual reports; (3) posting each state's Medicaid DUR Annual Report on the Medicaid.gov Web site; and (4) preparing and posting a comparison/summary report, which compiles all the states' responses on their programs' activities reported in the

Medicaid DUR Annual Report. In regard to DUR requirements for Medicaid managed care, CMS will provide direction to states as mentioned earlier in this document.

Comment: A few commenters recommended that DUR activities should incorporate quality and monitoring activities such as under-utilization of prescription drugs which might indicate low pharmacy inventories, access issues, or burdensome prior authorization practices.

Response: We appreciate these suggestions made by the commenters. In accordance with section 1927(g)(1)(A) of the Act, states are responsible for establishing a program for identifying underutilization of prescription drugs. In the state Medicaid DUR Annual Reports submitted to CMS, some states have included information on addressing under-utilization of prescription drugs by implementing medication adherence initiatives. In addition, CMS requests for states to report on their monitoring activities to ensure appropriate prescribing of several classes of prescription drugs, such as antipsychotics, stimulants, opioids and buprenorphine products. The Medicaid DUR Annual Report is unable to capture every DUR activity that states perform, but addresses prevalent DUR activities and helps to create standardization among these programs.

Comment: One commenter noted that while CMS proposes that managed care plans provide DUR programs that are consistent with the federal standards that Medicaid agencies must meet (for example, prescribed drugs are appropriate, medically necessary and not likely to result in adverse medical results), the managed care plan may prefer to screen for drug therapy problems of therapeutic duplication, age/gender contraindications, adherence, drug-drug interactions, correctness of dosage or duration of therapy, and drug-allergy contraindications.

Response: We agree that the aforementioned DUR activities are essential components of DUR; however, retrospective DUR activities listed in section 1927(g) of the Act are equally as important to improve recipients' quality of care. We defer to the states and if applicable, their MCOs, on specific DUR program requirements, as long as the minimum federal requirements at section 1927(g) of the Act are met.

Comment: One commenter expressed concern that since requirements of section 1927(g) of the Act were enacted, many states and Medicaid managed care

plans have changed the way in which their DURs operate, merging DUR Board activities with the activities of the Pharmacy and Therapeutics (P & T) Committees, and effectively changing Preferred Drug List or formulary development. The commenter also expressed concern that the cost considerations were being given priority over clinical effectiveness and safety. The commenter requested that CMS affirm that the purpose of DUR is not that of formulary development or cost comparison but primarily for clinical reasons.

Response: We recognize that over time, changes have taken place in the manner in which Medicaid state agencies operate their prescription drug coverage for the day to day operation of their programs. However, we do not agree with the commenter that the ultimate purpose of the state Medicaid DUR program has changed its mission or focus. In accordance with section 1927(g)(1)(A) of the Act, a DUR program is to assure that a state's coverage of covered outpatient drugs are appropriate, medically necessary, and are not likely to result in adverse medical results. In addition, the Act states that the DUR programs should be designed to educate physicians and pharmacists to identify and reduce the frequency of patterns of fraud, abuse, gross overuse, or inappropriate or medically unnecessary care, among physicians, pharmacists, and patients, or associated with specific drugs or groups of drugs, as well as potential and actual severe adverse reactions to drugs.

Comment: One commenter expressed concern that DUR programs will create barriers to treatment by undermining the clinical judgment of treating physicians, especially since mandatory utilization controls may vary from plan to plan. The commenter stated that it is important that managed care plans be transparent regarding their DUR activities.

Response: We do not agree with the commenter that DUR programs will create barriers. The requirements of DUR programs shall be designed to educate physicians and pharmacists to identify and reduce the frequency of patterns of fraud, abuse, gross overuse, or inappropriate or medically unnecessary care. Section 438.3(s)(5) requires managed care plans to provide a detailed description of its DUR program activities to the state on an annual basis, which we believe will enhance the transparency of managed care plan DUR practices when providing outpatient drug coverage to their Medicaid enrollees.

Comment: One commenter requested that CMS require that managed care plans coordinate with the State's DUR Board at least on a quarterly basis.

Response: We appreciate the comment. We will allow each state to determine the terms for the managed care plan's DUR operational requirements and specify them in the managed care plan contract.

Comment: One commenter requested that CMS provide further clarification and guidance on how states should conduct DUR with their managed care plans and their FFS population to minimize duplication and reduce administrative burden and expense. Alternatively, the commenter requested that CMS clarify why DUR is necessary from both parties, rather than have sole state oversight of managed care plan activities.

Response: We appreciate the commenter's request for clarification. We are requiring that states be responsible for ensuring that managed care plans operate a DUR program that is consistent with the standards in section 1927(g) of the Act when a managed care plan is required by the state to provide outpatient prescription drug coverage to the Medicaid population enrolled in the plan. We encourage states and managed care plans to share "lessons learned" and explore options that will work best depending on the number and size of the managed care plans in the state. Some states require all managed care plans to adhere to the preferred drug lists (PDL) and DUR oversight that they conduct on their fee-for-service (FFS) population. Other states may allow their managed care plans to develop their own DUR programs and submit a report on their annual activities. CMS is not requiring that the states or plans follow one specific model as long as the DUR activities performed by the states and plans meet the minimum requirements of section 1927(g) of the Act.

DUR Program Annual Report to the State (§ 438.3(s)(5))

In paragraph (s)(5), we proposed that the MCO, PIHP, or PAHP would have to provide a detailed description of its DUR program activities to the state on an annual basis. The purpose of the report was to ensure that the parameters of section 1927(g) of the Act are being met by the MCO's, PIHP's, or PAHP's DUR program, as proposed under paragraph (s)(4).

We received the following comments on proposed § 438.3(s)(5).

Comment: Several commenters expressed support for managed care plan's DUR Boards posting their annual

reports and coordination with the state DUR Board when reporting data and findings to CMS. One commenter suggested that the managed care plan's DUR data be included in the state's annual DUR report to CMS as well as be included in the Medicaid Drug Utilization Review Comparison/Summary Report that CMS produces.

Response: We appreciate the comments and will take the suggestion under advisement. Since all states may not have the same managed care plan DUR reporting requirements, we will work with states to develop a mechanism that will enable all states to report in a way as to ensure that the data submitted is compared in an appropriate manner in the various reports CMS produces.

Comment: One commenter suggested that the following language be added to § 438.3(s)(5) after the existing text: The MCO, PIHP, PAHP, or PCCM entity (if applicable) shall post to its Web site the annual report, and provide the report to the state DURB, MCAC, and the consumer stakeholder committees established under §§ 438.10 and 438.70.

Response: We will defer to the state as to how it will publicize the annual report and who the report should be disseminated to regarding managed care plan DUR activities.

Comment: One commenter expressed concern that managed care plans might object to changing their annual report of their DUR activities, stating that while a managed care plan's DUR may not be identical to that of the state's FFS DUR, it could be just as effective as, or more effective, than the state's process. The commenter urged CMS to allow flexibility for the managed care plan's internal operations. Other commenters recommended that a managed care plan should be able to choose to implement safety interventions either through a DUR program or prior authorization, and that plans have the discretion to determine which type of intervention will better support their safety goals.

Response: The proposed rule required that states ensure through their contracts with managed care plans that the plans operate a DUR program that complies with the requirements of section 1927(g) of the Act. Therefore, a managed care plan will only be required to change DUR activities to the extent their program does not meet the requirements of section 1927(g) of the Act. Prior authorization requirements are an important safety mechanism, but do not fulfil the full requirements of DUR.

Comment: One commenter indicated that the requirement for managed care plans to report to the state "in detail on

an annual basis" the managed care plans' DUR programs places a burden on the state to have additional staff to review such reports. Another commenter requested clarification from CMS on whether states are required to include managed care plan DUR in the state's annual DUR report as required by section 1927(g)(3)(D) of the Act.

Response: At the present time, there is no requirement that the state report to CMS on the specifics of the DUR activities of its managed care plans. Since each state will be preparing their own managed care plan DUR requirements, we will consider issuing future guidance as to how the states include oversight of their managed care plans DUR in the states' annual report. The annual DUR survey, that states complete to fulfill the requirement of reporting to CMS, includes questions on the type of oversight they perform on their managed care plans.

Prior Authorization Process (§ 438.3(s)(6))

Finally, in paragraph (s)(6), we proposed that the state stipulate that the MCO, PIHP, or PAHP conduct the prior authorization process for covered outpatient drugs in accordance with section 1927(d)(5) of the Act; we relied again on our authority under section 1902(a)(4) of the Act for this proposal. Since the MCO, PIHP, or PAHP is providing coverage for covered outpatient drugs as part of the state plan instead of the state providing that coverage through FFS, it is appropriate to extend the prior authorization standards associated with such coverage to the MCO, PIHP, or PAHP. Therefore, we proposed that the MCO, PIHP, or PAHP would provide a response to a request for prior authorization for a covered outpatient drug by telephone or other telecommunication device within 24 hours of the request and dispense a 72 hour supply of a covered outpatient drug in an emergency situation.

We received the following comments on proposed § 438.3(s)(6).

Comment: Several commenters supported CMS' clarification that consumers who need access to a drug not covered by their managed care plan will have access to the drug via FFS Medicaid. Specifically, commenters recommended that the drug be available when determined to be medically necessary, or necessary for beneficiaries whose medical situation makes it inadvisable for them to take a formulary drug. A commenter requested clarification that rare disease patients with a medical need for an orphan drug and enrolled in a managed care plan must receive coverage of the drug under

the managed care plan's prior authorization process; or, if the managed care plan is not contractually obligated to provide coverage of a particular drug under its contract, the state is required to provide the drug through FFS Medicaid (the State plan).

Response: The managed care plan must meet the prior authorization requirements specified in section 1927(d)(5) of the Act and implemented through regulation at § 438.3(s)(6) when providing covered outpatient drugs to its Medicaid enrolled population. If the managed care plan is not contractually required to cover a specific drug or group of drugs as part of its formulary, the state will be required to cover the drug for the managed care plan enrollee to the same extent it covers the drug for the Medicaid FFS population. If a managed care plan is required by its contract with the state to cover the orphan drug for Medicaid (that is, it is not "carved out"), the managed care plan must provide coverage for the drug as part of its formulary or use a prior authorization process for the patient to access the drug when medically necessary if not on the managed care plan's formulary.

Comment: A couple of commenters requested clarification around timelines for coverage of newly approved medications. One commenter indicated that if managed care plans are expected to comply with the standards in section 1927 of the Act, then CMS should indicate that managed care plans be given the same right to evaluate newly approved drugs as part of their drug utilization review process.

Response: Consistent with the state's FFS coverage policy for newly approved medications, once a drug becomes approved as a covered outpatient drug, it becomes eligible for manufacturer rebates, and therefore, must be covered by managed care plans providing drug coverage to their Medicaid enrollees. Managed care plans still have the ability to maintain their own formularies as long as they make these newly approved drugs available using prior authorization in accordance with section 1927(d)(5) of the Act.

Comment: A commenter requested that CMS provide guidance on establishing a prior authorization process that complies with the requirements of the Medicaid rebate statute. Another commenter requested that CMS add a new subsection to the regulation to require robust exceptions to allow plan enrollees to obtain non-formulary or off-label prescription drugs when clinically appropriate. A commenter also requested that CMS clarify patients' rights to obtain all

medically necessary medications by adding clear protections for non-formulary medications to the regulatory text at § 438.3(s)(6). Another commenter urged CMS and states to ensure that any standards for prior authorization or exceptions processes remain the responsibility of the Medicaid managed care plan.

Response: It is not our intent in this final rule to dictate to states and managed care plans how they will establish their formularies or prior authorization processes. As long as the requirements of section 1927 of the Act are met, states and managed care plans may adopt different formularies and apply different utilization management practices (for example, apply different prior authorization requirements to different drugs based upon the managed care plan's preferred drug list or formulary). As provided in prior responses to comments, if the managed care plan's formulary does not provide coverage of a drug that is otherwise covered by the state plan for individuals in FFS, the managed care plan must ensure access to the off-formulary covered outpatient drug consistent with the prior authorization requirements at section 1927(d)(5) of the Act.

Comment: A few commenters requested guidance on coverage of drugs for states that carve coverage out of the managed care contract. One commenter indicated that for some disease states, including mental health, there are legislative carve-outs which preclude traditional Medicaid programs or Medicaid managed care plans from placing coverage restrictions on drug products. The commenter requests that CMS clarify the contract requirements to ensure state carve-outs and mandates are maintained to preserve patient access.

Response: We understand that some states may specifically exclude or "carve-out" from their Medicaid managed care plan contracts, coverage of certain covered outpatient drugs that treat specific disease states or chronic conditions, such as drugs specific for treatment of HIV. In those instances, states will continue to cover these drugs under their state plan and provide that coverage to the managed care plan enrollees consistent with the requirements of section 1927 of the Act for covered outpatient drugs.

Comment: One commenter suggested that all managed care plans should function under a standard or state-wide formulary to ensure patient access to needed prescription medications thus preventing a need for more costly care. Another commenter indicated they did not support a statewide formulary

because plans have system-wide formularies and creating a different formulary for the Medicaid line of business would not support CMS' intent to streamline services across health systems and payers. Commenters noted that requiring a managed care plan to cover drugs that are not included on the formulary may affect a plan's ability to negotiate the best possible rebates. Another commenter indicated that it is counter to requirements in other government supported health programs that managed care plans be required to use a statewide formulary.

Response: We are not mandating as part of this final rule that states include in their contracts with their managed care plans that managed care plans use specific or state-required formularies. While we understand commenters' concerns that the use of a state-required formulary may not be optimal for managed care plans because it may hinder the managed care plan's ability to negotiate additional discounts or rebates on drugs, we believe that very few states, if any, maintain formularies of their own due to the requirements in section 1927(d)(4) of the Act. However, while there may be challenges to managed care plans being required to utilize a state-required formulary, there is nothing in statute that precludes a state from requiring such a formulary.

Comment: Commenters indicated that it is important that managed care plan formularies satisfy all applicable formulary rules in section 1927 of the Act, giving enrollee rights to obtain off-formulary or non-preferred medications in ways that are simple for both the enrollee and their prescribing physician. Other commenters recommended that CMS establish standards for managed care formularies and exceptions processes as it has done for Medicare Part D, QHPs offered on the Marketplace, and the broader private health insurance market through the essential health benefit rules and use clinical criteria, with appropriate clinical experts with improved patient health as the primary goal. The commenter recommended that the managed care plan's clinical coverage should be reviewed and updated regularly with evidence based protocols. Another commenter indicated that a benchmark or a floor that ensures that the managed care plan's formulary is not more restrictive than the FFS prescription drug coverage is necessary. Commenters urged CMS to establish minimum formulary requirements to ensure access to care and treatment for certain enrollees, such as Hepatitis C virus (HCV) patients, and preclude the

need for an individual to access the prior authorization processes.

Response: A state and its managed care plans may continue to have different formularies and prior authorization programs. This final rule clarifies that when a state is contracting with managed care plans to provide covered outpatient drug coverage, the state must ensure that the standards of coverage imposed by section 1927 of the Act are met when states enroll their beneficiaries into managed care plans. This ensures medically necessary drugs are available to plan enrollees to the same extent as beneficiaries receiving Medicaid prescription drug benefits under the state plan while also allowing the managed care plans to adopt their own formularies and drug utilization management tools that are consistent with the requirements of section 1927 of the Act.

Comment: We received several comments requesting clarification regarding what CMS meant at 80 FR 31115 that managed care plans may maintain their own formularies. Commenters stated it is not clear whether managed care plan formularies must comply with the formulary requirements in section 1927 of the Act, such as prior authorization requirements, or whether managed care plans would have flexibility to limit their drug coverage in comparison to what is required in the Medicaid rebate statute. The commenters requested that CMS clarify if managed care plans are permitted to continue to utilize tools and techniques to ensure patients receive the most clinically appropriate and cost effective medications. Another commenter requested that CMS clarify that permitting managed care plans to maintain their own formularies does not permit them to offer more limited coverage than that outlined in the formulary rules in section 1927 of the Act. Commenters requested that CMS clarify if plans and PBMs are allowed to negotiate with drug companies to place drugs on formularies and that CMS should apply the requirements in section 1927 of the Act to recognize the differences between FFS and managed care, permitting managed care plans and PBMs to negotiate with states to design formularies and deliver pharmacy benefits in a cost effective manner. A few commenters requested that CMS clarify when the state is responsible for providing access to non-formulary drugs. Commenters believed this would ensure that all drugs approved by the FDA are available when medically necessary. Commenters further stated that it is important that CMS clear up misconceptions created by 2010

guidance and indicate in regulation text that Medicaid managed care plans must comply fully with the rebate requirements, including formulary requirements.

Response: As stated previously, states may allow managed care plans to use their own formularies, as well as their own utilization management tools to the extent they are consistent with the requirements of section 1927 of the Act. Furthermore, nothing in this final rule precludes a managed care plan from using PBMs to negotiate what is covered on a managed care plan's formulary with manufacturers. However, if the managed care plan's formulary or utilization management tools do not provide access to a medically necessary covered outpatient drug that is otherwise covered by the state plan for individuals in FFS, the managed care plan and the state must ensure access to the drug consistent with the prior authorization requirements at section 1927(d)(5) of the Act. However, we do not believe a separate state prior authorization process is the most efficient way for managed care enrollees to access medically necessary drugs not on the managed care plan's formulary.

Comment: Several commenters requested that CMS ensure enrollee access to non-preferred or non-formulary drugs when there is a medical need and that prior authorization and utilization management tools (for example, step therapy) should be based on expert medical review and not used to primarily deny or restrict access for people with chronic and complex health conditions or discourage individuals from obtaining care. Specifically, some commenters recommended that CMS require plans to adopt the same standards for prior authorization as Medicare Part D or provide standards for the evaluation of medical need, as well as suggested that the final regulation recognize that prior authorization is inappropriate for certain patients such as those with HIV, HCV, cancer, developmental disabilities, cystic fibrosis, and mental illness and should not discriminate against based on patient diagnosis. For a vulnerable population like those living with mental illness, commenters believed products should have very limited to no prior authorizations placed on them to allow providers the full set of medications to utilize based on the clinical needs of the patients. Commenters indicated that fail-first policies for branded products which are not supported by the FDA labeling were not appropriate for these patients. Commenters indicated that to meet the standards of section 1927(k)(2) of the

Act, enrollees must be provided a medically necessary drug through a prior authorization process when there is a medical need for the covered outpatient drug.

Response: We agree with the commenters that any prior authorization requirements established by the managed care plan or state that result in patients being unable to access covered outpatient drugs of manufacturers participating in the drug rebate program when such drugs are medically necessary is not consistent with the coverage requirements of section 1927 of the Act. As stated in section 1927(d) of the Act, states may restrict or limit coverage of covered outpatient drugs but only to the extent the prescribed use is not for a medically accepted indication as defined at section 1927(k)(6) of the Act or included in the list of drugs subject to restriction at section 1927(d)(2) of the Act. In general, individuals enrolled in managed care plans or beneficiaries that receive covered outpatient drugs benefits under the state plan may not be denied access to covered outpatient drugs of manufacturers participating in the drug rebate program when such drugs are prescribed for a medically accepted indication. However, to determine whether the drug is prescribed for a medically accepted indication for the individual, the state or managed care plan may subject any covered outpatient drug to prior authorization as long as the prior authorization program meets the minimum requirements at section 1927(d)(5) of the Act.

Comment: Several commenters expressed concern with the 24 hour prior authorization response time at section 1927(d)(5)(B) of the Act, as incorporated at § 438.3(s)(6), and suggested that "respond" in the statutory language mean that the managed care plan must acknowledge the receipt of a clean prior authorization request or request additional information when necessary within 24 hours; or, the managed care plan must respond to a request within 24 hours after the receipt of all information necessary to make a determination. Other commenters suggested that the 24 hour time frame be equal to one business day since that would prevent the request from falling on a weekend, which would make it difficult to obtain necessary information from the prescribing provider. One commenter recommended that CMS revise the 24 hour requirement to allow providers to ask for a reconsideration of a prior authorization request and provide additional information, rather than requiring the provider to submit a

formal appeal. Commenters indicated that if a decision must be made and communicated within 24 hours, they would have significant concerns with this requirement because it would require entire systems to change their prior authorization practices and could impose administrative costs that make achieving a minimum medical loss ratio (MLR) difficult. Other commenters recommended a tiered determination system—24 hours of an expedited request and within 72 hours for a standard request. Commenters questioned the necessity of such an aggressive timeframe and it contradicts the timeframes under § 438.210(d) which requires PA decision are to be made within 14 calendar days for standard authorization decisions and 3 working days for expedited authorization decisions.

Response: Section 1927(d)(5) of the Act requires, in part, that a prior authorization program provide a response by telephone or other telecommunication device within 24 hours of a request for prior authorization and except for the drugs listed in section 1927(d)(2) of the Act, provides for the dispensing of at least a 72 hour supply of a covered outpatient drug in an emergency situation. The statute does not stipulate that the response be within one business day or what the response should entail. However, we understand that states and managed care plans typically have standard information collection tools such as prior authorization forms that must be completed by providers to process prior authorizations. We believe that as long as the provider has completed the managed care plan's standard information collection for prior authorization, the state and managed care plan should have all the information necessary for the determination to be made within 24 hours of the completed request. Any information collection by the state or managed care plan beyond what is required by the state's or managed care plan's standard information collection for prior authorization should not delay the response beyond the 24 hours of the completed request. Furthermore, in cases when there is an emergency situation and the provider cannot complete the request for prior authorization (for example, it is during a weekend or holiday), the state or plan must provide for the dispensing of a 72 hour supply of covered outpatient drug. We disagree with the commenter that implementing these timeframes would hinder the managed care plan's ability to meet the MLR requirements in this

final rule since most plans likely have a prior authorization process and the additional administrative expense of complying with section 1927(d)(5) of the Act should not be significant.

Comment: We received several comments supporting CMS' proposal to require managed care plans to respond to a request for prior authorization for a covered outpatient drug within 24 hours of the request and dispense a 72 hour supply of a covered outpatient drug in an emergency situation. Commenters indicated that a response to prior authorization for covered outpatient drugs within 24 hours of a request, and a 72 hour supply in an emergency situation, will mitigate, but not eliminate some of the most excessive procedural offenses against rare disease patients whose access to clinically important therapies has been delayed. The commenter believed that without clear regulatory protections and enforcement of these rules, it is not clear that patients will fully benefit from section 1927 of the Act protections.

Response: We appreciate the support for the proposed requirement that managed care plans meet the 24 hour response time and 72 hour supply of covered outpatient drugs in emergency situations when processing prior authorization requests. We are not aware of any excessive procedural offenses, which we assume the commenter means states or managed care plans have made it extremely difficult or impossible for their Medicaid patients to gain access to medically necessary therapies, and believe the protections in statute and part of this final rule will not permit restricted access for managed care plan enrollees to covered outpatient drugs when drugs are medically necessary.

Comment: Commenters urged CMS to mirror the prior authorization standards in Medicare Part D or MA which require a standard review be completed within 72 hours and an urgent request to be completed within 24 hours, not including notification. One commenter stated that conducting a prior authorization within 24 hours will essentially be treated as expedited which is inappropriate and impacts overall administration costs and resources. Another commenter believed that if the intent of CMS is for proper alignment of all health programs, Medicaid should adopt a standard prescription drug prior authorization form much like the suggested form in MA available on CMS' Web site.

Response: Section 1927(d)(5) of the Act sets forth the requirements for prior authorization of covered outpatient drugs under a Medicaid state plan.

Therefore, adoption of a specific prior authorization form, similar to that used by MA organizations and Part D sponsors, under this final rule is not necessary given the requirements in section 1927(d)(5) of the Act. Medicaid does not mandate the use of a standard prescription drug prior authorization form or methodology, as each managed care plan has the flexibility to establish their own prior authorization procedures.

Comment: One commenter seeks clarification as to whom the managed care plan should send the response to the prior authorization request.

Response: There is no federal requirement as to where the managed care plan should send the response regarding a prior authorization request. Prior authorization processes will vary, but typically the pharmacy or provider dispensing the drug will trigger the request for prior approval of a covered outpatient drug before dispensing by requesting that the prescribing provider complete a prior authorization information form and submit it to the state or managed care plan. Once the plan (or state) receives the completed prior authorization request, they will have 24 hours to respond to the pharmacy or provider regarding the coverage of the drug.

Comment: One commenter requested clarification on CMS' intent in proposing the requirement to provide a 72 hour supply of any covered outpatient drug for emergency medications. Another commenter recommended that CMS allow managed care plans the discretion to determine what constitutes an emergency warranting the dispensing of a 72 hour supply of a covered outpatient drug. The commenter believed a mandatory 72 hour supply requirement prevents managed care plans from using proven tools, such as prior authorization or step therapy, to manage prescription drugs for both clinical appropriateness and cost. Other commenters supported the dispensing a 72 hour supply of a covered outpatient drug in an emergency situation as it will benefit individuals with urgent medical needs (for example, people with bleeding disorders).

Response: Section 1927(d)(5) of the Act requires, in part, the dispensing of at least a 72 hour supply of a covered outpatient drug in an emergency situation. We have not defined what constitutes an emergency situation in this regard, and have generally relied upon what the state considers an emergency situation. Section 1903(m)(1)(A)(i) of the Act provides that an MCO make services it provides to

individuals eligible for benefits under this title accessible to such individuals, within the area served by the organization, to the same extent such services are made accessible to individuals eligible for medical assistance under the state plan (those Medicaid patients not enrolled with in the managed care plan). As such, the managed care plan's prior authorization process should permit the dispensing of a 72 hour emergency supply that, at a minimum, is consistent with how the state determines that a 72 hour emergency supply is needed. We do not agree that the 72 hour emergency supply requirement, which is meant to address emergency situations only, will prevent managed care plans from using utilization management tools to manage their covered outpatient drug coverage in non-emergency situations.

Comment: A commenter was concerned that the proposed rule for coverage of drugs that are medically necessary and are reimbursed under the prior authorization process would provide a disincentive to cover anything other than drugs subject to a signed rebate agreement and are "required" under the statute. All other drugs would be left to be reimbursed under the state FFS requirements, providing a "back-up" situation. The commenter suggested that this would discourage managed care plans from covering drugs that could otherwise be excludable under section 1927(d)(2) of the Act, such as drugs for weight loss.

Response: Nothing in this final rule prevents states or managed care plans from either restricting coverage or covering in full the drugs listed at section 1927(d)(2) of the Act, including agents when used for weight loss (see section 1927(d)(2)(A) of the Act). However, if a state elects to provide coverage of one of the agents listed at section 1927(d) of the Act and include such drugs under the managed care contract, the managed care plans must provide coverage consistent with the state's approved state plan for such drugs.

Comment: Several commenters recommended that CMS apply protections for the six protected classes of drugs under the Medicare Part D program to Medicaid managed care, including the prohibition of onerous prior authorization requirements. Commenters believe that the Part D protections are designed to mitigate the risks and complications associated with an interruption of therapy for certain vulnerable populations and should also apply to Medicaid managed care plans. Specifically, commenters recommended that enrollees that are currently taking

immune suppressants (for prophylaxis of organ transplant rejection), antidepressants, antipsychotics, anticonvulsants, antiretrovirals, or antineoplastic classes of drugs should not be subject to either prior authorization or step therapy requirements.

Response: We do not believe it is necessary to require the Part D protections for the six protected classes of drugs on Medicaid managed care plans because the state, and the managed care plan when applicable, must ensure access to covered outpatient drugs consistent with the formulary and prior authorization requirements at section 1927 of the Act. Unlike Part D formulary requirements, the formulary requirements at section 1927(d)(4)(C) of the Act include a provision for treatment of specific diseases or conditions for an identified population. This section of the statute specifies that a drug can only be excluded from a formulary because, based on the drug's labeling, it does not have a significant, clinically meaningful therapeutic advantage in terms of safety, effectiveness, or clinical outcome of such treatment for such population over other drugs included in the formulary and that there is a written explanation of the basis for the exclusion. We believe this formulary requirement ensures that vulnerable Medicaid populations that take drugs within the six protected drug classes will have access to these drugs including those vulnerable individuals enrolled in managed care plans. We note that if a covered outpatient drug is subject to prior authorization requirements, section 1927(d)(5) of the Act requires states to provide a response within 24 hours of the prior authorization request and dispensing of at least a 72 hour supply of a covered outpatient drug in emergency situations. Furthermore, section 1927(d)(4)(D) of the Act permits coverage of a drug excluded from the formulary, but does not allow for selected drugs (such as agents used to promote smoking cessation, barbiturates, or benzodiazepines) or classes of such drugs, or their medical uses, to be excluded from coverage, as stated in section 1927(d)(7) of the Act.

After consideration of the public comments, we will finalize § 438.3(s) as proposed except for the following modifications:

- Revision to the introduction language of section 438.3(s) to make a minor correction to address a grammatical issue; and
- In response to comments about states that may currently have processes in place to receive drug claims data

directly from covered entities so that states can exclude the 340B utilization data from their state files before invoicing manufacturers for rebates, we have revised § 438.3(s)(3) to indicate that MCOs, PIHPs, or PAHPs must have procedures to exclude utilization data for covered outpatient drugs that are subject to discounts under the 340B drug pricing program from the reports required under paragraph (s)(2) of this section when states do not require submission of Medicaid managed care drug claims data from covered entities directly.

r. Requirements for MCOs, PIHPs, or PAHPs Responsible for Coordinating Benefits for Dually Eligible Individuals (§ 438.3(t))

In § 438.3(t), we proposed a new contract provision for MCO, PIHP, or PAHP contracts that cover Medicare-Medicaid dually eligible enrollees and delegate the state's responsibility for coordination of benefits to the managed care plan. Under our proposal, in states that use the automated crossover process for FFS claims, the contract would need to provide that the MCO, PIHP, or PAHP sign a Coordination of Benefits Agreement and participate in the automated crossover process administered by Medicare.

We received the following comments in response to our proposal to add § 438.3(t).

Comment: Most commenters supported the proposed rule. Several commenters suggested providing states with flexibility for alternative arrangements. One raised concern about ensuring access to Medicare eligibility files. One commenter requested confirmation that managed care plans would be exempt from crossover fees, similar to the exemption for states. Another requested controls to prevent duplicate discounts. One commenter expressed concerns that that delegated claims could result in delays in payment.

Response: We appreciate the comments in support of the rule. We are finalizing the rule as proposed, with the following clarifications. Delegating coverage of Medicare cost-sharing to managed care plans remains optional for states under the rule. For states that do delegate cost-sharing coverage, we will provide states and managed care plans with technical assistance as needed to enable the managed care plans to enter into Coordination of Benefits Agreements (COBA) to receive Medicare crossover claims. We understand that managed care plans will need some time to enter into COBAs. (Note that managed care plans will receive COBA

crossover claims from Medicare FFS claims only). We expect to accommodate situations where a managed care plan may need additional data to set up and process a crossover claim. Currently, CMS provides additional data as necessary to managed care plans that have an existing COBA. Medicaid managed care plans will be exempt from crossover fees to the same extent that states are. CMS will provide states and managed care plans with technical assistance to prevent inappropriate discounts and delays in payment of claims.

After consideration of the public comments, we are finalizing § 438.3(t) as proposed.

s. Payments to MCOs and PIHPs for Enrollees That Are a Patient in an Institution for Mental Disease (§ 438.3(u) Redesignated at § 438.6(e))

In the proposed rule, we discussed our longstanding policy that managed care plans generally have had flexibility under risk contracts to offer alternative services or services in alternative settings in lieu of covered services or settings if such alternative services or settings are medically appropriate, cost-effective, and are on an optional basis for both the managed care plan and the enrollee. We noted, however, that legal issues are presented if the services offered in lieu of state plan services are furnished in an Institution for Mental Disease (IMD) setting, given the fact that, under subparagraph (B) following section 1905(a)(29) of the Act, Medicaid beneficiaries between ages 21 and 64 are not eligible for medical assistance (and thus FFP) while they are patients in an IMD. Under this broad exclusion, no FFP is available for the cost of services provided either inside or outside the IMD while the individual is a patient in the facility.

Since the capitation payments are made to the MCO or PIHP for assuming the risk of covering Medicaid-covered services during the month for which the capitation payment is made, there would be no such risk assumed in the case of an enrollee who is a patient in an IMD for the entire month, as the enrollee could not, by definition, be entitled to any Medicaid covered benefits during that month. Thus, it would not be appropriate for an MCO or PIHP to receive FFP for a capitation payment for a month for which an enrollee is a patient in an IMD the entire month.

To ensure that the use of IMD settings in lieu of covered settings for this care is sufficiently limited so as to not contravene subparagraph (B) following section 1905(a)(29) of the Act, we

proposed to permit FFP for a full monthly capitation payment on behalf of an enrollee aged 21 to 64 who is a patient in an IMD for part of that month to cases in which: (1) The enrollee elects such services in an IMD as an alternative to otherwise covered settings for such services; (2) the IMD is a hospital providing psychiatric or substance use disorder (SUD) inpatient care or a sub-acute facility providing psychiatric or SUD crisis residential services; and (3) the stay in the IMD is for no more than 15 days in that month.

In the proposed rule (80 FR 31116), we discussed that managed care programs may achieve efficiency and savings compared to Medicaid FFS programs by managing care through numerous means, including networks of providers, care coordination and case management. We also acknowledged that inherent in transferring the risk for Medicaid coverage during a period means that capitation payments may be made for months during which no Medicaid services are used by a particular beneficiary who is enrolled with the managed care plan, even though the managed care plan is at risk for covering such costs if they are incurred. Thus, we believed it would be appropriate to permit states to make a monthly capitation payment that covers the risk of services that are eligible for FFP rendered during that month when the enrollee is not a patient in an IMD, even though the enrollee may also be a patient in an IMD during a portion of that same period. A corollary of our proposal was that capitation payments eligible for FFP may not be made if the specified conditions outlined in this section are not met and that, if a beneficiary were disenrolled for the month from the MCO or PIHP, a state would have to ensure that covered Medicaid services (that is, services under the Medicaid state plan that are medically necessary during any period when the beneficiary is not a patient of an IMD and that are incurred during the month when the beneficiary is not enrolled in the MCO or PIHP) are provided on a FFS basis or make other arrangements to assure compliance. In addition, a state could refrain from seeking FFP for payments made for services provided to beneficiaries who are patients in an IMD for a longer period during the month as the Medicaid exclusion does not apply where the state pays the full amount for services with state-only funds.

We proposed that services rendered to a patient in an IMD may be considered “in lieu of services” covered under the state plan. As noted in section I.B.2.e, “in lieu of services” are alternative

services or services in a setting that are not covered under the state plan but are medically appropriate, cost effective substitutes for state plan services included within the contract (for example, a service provided in an ambulatory surgical center or sub-acute care facilities, rather than an inpatient hospital). However, an MCO, PIHP or PAHP may not require an enrollee to use an “in lieu of” arrangement as a substitute for a state plan covered service or setting, but may offer and cover such services or settings as a means of ensuring that appropriate care is provided in a cost efficient manner. Accordingly, the contract may not explicitly require the MCO or PIHP to use IMD facilities, and must make clear that the managed care plan may not make the enrollee receive services at an IMD facility versus the setting covered under state plan. However, the contract could include, in its list of available Medicaid-covered services to be provided under the contract, services such as inpatient psychiatric hospital services. The MCO or PIHP could then purchase these services from an IMD rather than an inpatient hospital if it so chooses to make the covered services available.

We proposed to limit payment of capitation rates for enrollees that are provided services while in an IMD (to stays of no more than 15 days per month and so long as the IMD is a certain type of facility) for two reasons. First, our proposal sought to address the specific concerns about ensuring access to and availability of inpatient psychiatric and SUD services that are covered by Medicaid; these concerns have focused on short-term stays. The expansion of the Medicaid program coupled with the overall increase in health care coverage in managed care plans in the Marketplace led us to expect greater demand on the limited inpatient resources available to provide mental health and SUD services. Specifically, we provided a number of statistics in the proposed rule, at 80 FR 31117, regarding the anticipated need for mental health and SUD services. We noted that states and other stakeholders have raised concerns that access to and availability of short-term inpatient psychiatric and SUD services have been compromised and that delays in the provision of care may occur. Managed care plans have an obligation to ensure access to and availability of services under Medicaid regulations for services not prohibited by statute and covered under the contract. To meet that obligation, managed care plans have used alternate settings, including short

term crisis residential services, to provide appropriate medical services in lieu of Medicaid-covered settings.

The second reason we proposed to limit the payment of capitation rates for enrollees that are provided services while in an IMD is that we believe that subparagraph (B) following section 1905(a)(29) of the Act is applicable to the managed care context. Managed care plans should not be used to pay—under the Medicaid program—for services for which coverage and payment are prohibited by the Medicaid statute. If an enrollee were a patient in an IMD for an extended period of time, the likelihood that the enrollee would otherwise be incurring authorized Medicaid-covered expense or receiving Medicaid-covered services—and with it, the risk on the managed care plan of having to furnish covered services that is compensated by the capitation payment—would not exist during that extended period when the enrollee is a patient in the IMD. We noted that permitting capitation payments when an enrollee has a short-term stay in an IMD is a means of securing compliance with the statute by delineating parameters for these capitation payments, which we would otherwise exclude or prohibit to achieve compliance with the statutory IMD exclusion.

Therefore, we proposed that for a month in which an enrollee is an IMD patient, FFP in capitation payments will only be provided if the enrollee receives inpatient services in an IMD for a period of no more than 15 days. This 15-day parameter is supported by evidence of lengths of stay in an IMD based on data from the Medicaid Emergency Psychiatric Demonstration. This preliminary evidence suggests that the average length of stay is 8.2 days.⁴ We proposed to define a short-term stay as no more than 15 days within the month covered by the capitation payment to account for the variability in the length of stay often experienced by individuals who need acute inpatient psychiatric or SUD services. We would expect practice patterns for the same services, whether delivered in an inpatient hospital or an IMD facility would be similar and that such patterns would be monitored by the state. We noted that an enrollee could have a length of stay longer than 15 days that covers two consecutive months where the length of stay within each month is less than 15 days, and, under this rule, the MCO or PIHP would be eligible to receive a capitation payment for that enrollee for both months. We requested comment on this

⁴ http://innovation.cms.gov/Files/reports/MEPD_RTC.pdf, page 12.

provision, general approach and methodology, or any other comments. We also requested comment on the proposed definition of a short-term acute stay in this context, including the cost of IMD services in FFS or managed care, the wisdom of reflecting a number as either a hard cap on the amount of time for which FFP would be available via the capitation payment, or as an articulation of the average length of stay across a managed care plan's enrollees that would legitimize FFP. We also requested comment on ways to operationalize use of an average length of stay in terms of capitation payment development and oversight. Finally, we requested comment on the percentage of enrollees that have a length of stay of less than 15 days for inpatient or sub-acute psychiatric services.

For purposes of rate setting, we explained the state and its actuary may use the utilization of services provided to an enrollee while they have a short term stay as a patient in an IMD to determine an estimate of the utilization of state plan services, that is, inpatient psychiatric services or SUD services, covered for the enrolled population in future rate setting periods. However, we provided that the costs associated with the services to patients in an IMD may not be used when pricing covered inpatient psychiatric services; rather, the IMD utilization must be priced consistent with the cost of the same services through providers included under the state plan. We noted that this guidance for accounting for service utilization to patients in an IMD differs from rate setting guidance issued in December 2009 for in lieu of services in the context of home and community based services, *see CMS, Providing Long-Term Services and Supports in a Managed Care Delivery System: Enrollment Authorities and Rate Setting Techniques* (December 2009), at page 15, available at <http://www.pasrassist.org/sites/default/files/attachments/10-07-23/ManagedLTSS.pdf>.⁵ In the context of services rendered to patients in an IMD, we provided that such proxy pricing is not consistent with the statutory prohibition on FFP for services when the enrollees is a patient in an IMD.

We received the following comments on proposed § 438.3(u).

Comment: Many commenters supported proposed § 438.3(u) to permit managed care plans to receive a Medicaid capitation payment for

enrollees with a short-term stay in an IMD during the month covered by that capitation payment. Commenters also supported the proposal to permit managed care plans to cover short-term inpatient care in facilities providing psychiatric or substance use disorder services, notwithstanding the IMD exclusion. Commenters stated that the proposed rule would support individuals with mental health or substance use disorder conditions who need access to inpatient care. Commenters also stated that this provision is an important step to address access issues for short-term inpatient stays and provides Medicaid managed care plans increased flexibility to ensure access to alternative care settings. Many commenters recommended that CMS repeal the IMD exclusion in entirety.

Response: We appreciate the commenters' support for this provision. As we discussed in the preamble to the proposed rule (80 FR 31116–31118) and in response to comments herein on this provision, we maintain that the recognition of a managed care plan's ability to cover short-term inpatient stays of no more than 15 days in an IMD as an alternative setting in lieu of settings for inpatient services covered under the state plan serves an integral role in ensuring access to mental health and substance use disorder services in those states with otherwise limited inpatient bed capacity. Further, the prohibition on FFP for services rendered to an individual aged 21–64 who is a patient in an IMD is statutory, and therefore cannot be eliminated without Congressional action.

Comment: We received several comments on the authority underlying this provision. Some commenters contended that CMS lacks statutory authority to issue proposed § 438.3(u) because the statutory provision prohibiting FFP for services provided to individuals 21–64 in IMDs is a broad exclusion and is applicable to the managed care context. Commenters stated that while section 1915(b)(3) of the Act permits states to offer Medicaid beneficiaries additional services not covered under the state plan through savings generated under a managed care program, the capitation payments for such additional services include FFP and cannot pay for services for individuals 21–64 who are patients in an IMD. Additionally, commenters noted that Title XIX statutory authorities for states to implement a managed care delivery system identify the particular statutory provisions that may be waived (that is, statewideness per section 1902(a)(1) of the Act,

comparability of services per section 1902(a)(10)(B) of the Act; and freedom of choice per section 1902(a)(23)(A) of the Act) and the IMD provision is not specified under those authorities. Therefore, these commenters recommended that CMS not finalize this proposal.

Other commenters highlighted that CMS has in the past permitted managed care plans to provide medically appropriate, cost-effective substitutes in lieu of state plan services included under the managed care plan contract. Commenters stated that this in lieu of policy originates from section 1915(a) of the Act which specifies that a state shall not be deemed to be out of compliance solely by reason of the fact that the State has entered into a contract with an organization which has agreed to provide care and services in addition to those offered under the State plan to individuals eligible for medical assistance. Commenters also stated that CMS has ample statutory authority beyond section 1915 of the Act to both permit managed care plans to offer coverage for services in addition to what is covered in a state plan and to allow for payment by the managed care plan for services rendered in an IMD in lieu of state plan services. Several commenters were supportive of the discussion of the legal authority for Medicaid managed care plans to provide additional services not covered under the state plan (80 FR 31116–31117). In addition, a commenter explained that the inclusion of mental health coverage in the benchmark benefit standard under the Affordable Care Act and the parity requirements under EHB/MHPAEA also lend support to for this proposed provision.

Response: We appreciate the comments received in support of and in opposition to our described authority for this particular proposal to authorize under 42 CFR part 438, under conditions, payment of the capitation rate for a month when the enrollee is a patient of an IMD for no more than 15 days. We agree that subparagraph (B) following section 1905(a)(29) of the Act applies in the managed care context, which is why we do not permit FFP in capitation payments for a month in which the enrollee is an IMD patient for more than 15 days within the month. We believe this provision remains consistent with subparagraph (B) following section 1905(a)(29) of the Act for the following reasons. By establishing the length of stay in an IMD that is less than the period covered by the monthly capitation payment the enrollee has a period of time during that month in which he or she is not a

⁵ In that guidance, we provided that the state may modify the rate setting process to account for the expected cost as well as utilization of in lieu of services as a proxy for the cost of approved state plan services in a contract.

patient in an IMD (thus could receive Medicaid-covered services for which FFP is available), and, because the MCO or PIHP would bear the risk of paying for covered services during the period when the enrollee is not a patient in an IMD within the month covered by the capitation payment, it is appropriate for a capitation payment to be made. The final part of the analysis is that the MCO's or PIHP's use of the IMD is in accordance with a managed care plan's ability to provide in lieu of services. The waivers of comparability of services (section 1902(a)(10)(B) of the Act) and statewideness (section 1902(a)(1) of the Act) accompany all authorities under which a managed care delivery system may be authorized. The waiver of comparability of services permits the managed care plan to provide services that are different in amount, duration, or scope than those under the state plan; thus, managed care plans may provide services that are a substitute for, although not identical to, state plan services. The waiver of statewideness permits the provision of different or substitute services to some beneficiaries but not all within the state Medicaid program; consistent with this waiver, services provided by the managed care plan in lieu of state plan services are not available to beneficiaries not enrolled in the managed care delivery system.⁶ As part of a risk contract and in accordance with the requirement (at section 1903(m)(2)(A)(iii) of the Act) that capitation rates be actuarially sound and based on services covered under the state plan (as specified at § 438.3(c) and § 438.4 of this final rule), we have historically provided managed care plans the flexibility to use the capitation payment to provide substitute services or settings, including when there is no comparable service under the state plan or when the additional service or setting is in lieu of services or settings that are covered under the state plan. We have required that such services be medically appropriate and cost effective alternatives, which the enrollee agrees to receive in lieu of state plan services. So long as these substitute services or settings are medically appropriate, they provide a cost-effective means to secure the goal of the Medicaid program to diagnose, treat or ameliorate health or medical conditions.

To clarify, the state may pay for services provided to individuals eligible under the state plan that are enrolled in a managed care program who are

⁶ We note that the waiver of comparability also supports a managed care plan's provision of services in addition to those in the state plan through savings.

patients in an IMD for a longer term than 15 days within the period covered by the capitation payment, either directly or through a separate arrangement *without FFP*. This provision does not prohibit the provision of services in an IMD by the state under non-Medicaid programs beyond the specified short term stay; however, FFP would not be available for a capitation payment in any month in which the individual is a patient in an IMD for longer than 15 days. Moreover, since services for enrollees with longer stays would not be covered under the Medicaid program, any capitated payment for such individuals with longer stays would not be covered under the Medicaid program, any capitated payment for such individuals would need to be under a separate contract (since the costs for such individuals would have to be accounted for separately in setting the capitation rate and the capitation rate would be paid with state-only funds).

Comment: Several commenters pointed out that the preamble discussed the provision of both psychiatric and SUD services. They recommended that CMS revise § 483.3(u) to be inclusive of both psychiatric and SUD inpatient or sub-acute residential crisis services to be consistent with the preamble in the proposed rule.

Response: We appreciate this request for clarification of the regulatory text and will finalize, consistent with the description of our proposal, this provision with references to psychiatric and substance use disorder treatment provided in both inpatient and sub-acute facilities. An additional technical correction to the regulatory text is necessary for consistency with the proposed rule; specifically, the proposal and final rule are limited to enrollees aged 21 to 64. We will finalize this provision with a reference to enrollees aged 21 to 64.

Comment: Several commenters noted that the proposed rule cites the decrease in psychiatric hospital beds across the country as part of the rationale for changing the interpretation of the IMD payment exclusion to increase access to inpatient treatment. Commenters stated that the decrease in psychiatric hospital beds reflects a deliberate public policy shift away from the historic overreliance on psychiatric institutions and an increased investment in community mental health services that reduce the need for psychiatric hospitalization. Commenters noted that states have shifted resources away from psychiatric hospitals and toward community-based services. Other commenters stated that IMDs do not have the expertise,

appropriate professional staff, or other capacity to provide short-term crisis services to people with serious mental illness. Commenters stated that most individuals would not benefit from a short-term stay in an IMD; rather, most individuals would be better served in the community. Commenters recommended that CMS not finalize this proposal so as not to incentivize increased admissions to psychiatric hospitals at the expense of developing appropriate community-based services.

Response: While we agree that most beneficiaries would be well served in the community, others may need more intensive services such as acute inpatient psychiatric care offered by general hospitals and inpatient psychiatric hospitals. As part of the continuum of care for behavioral health conditions, some short-term psychiatric services delivered in inpatient settings, including those delivered in facilities that meet the definition of an IMD, may be medically necessary depending on the needs of the individual. For example, services provided in acute and sub-acute levels of care may be appropriate for individuals experiencing a psychiatric episode that requires emergency care. We do not intend to incentivize admissions to inpatient psychiatric settings for services that are not medically necessary and appropriate, nor incentivize lengths of stay in inpatient psychiatric settings that are not medically necessary and appropriate. We take seriously our commitment to community integration approaches and adherence to *Olmstead* provisions requiring treatment in the least restrictive setting available.

However, we balance those points with the recognition that short-term inpatient stays may be necessary for individuals with the most acute behavioral health needs and are concerned that access to them may not currently be sufficient. We remind states and managed care plans of their obligations under the ADA and the *Olmstead* decision to provide services in the least restrictive setting possible and to promote community integration. Nothing in this final rule excuses failure to comply with these responsibilities.

Comment: A few commenters recommended that CMS provide a non-exclusive list of the characteristics that would enable a facility to qualify as a "sub-acute facility." Commenters stated that, at a minimum, community mental health centers with inpatient beds should qualify as sub-acute facilities. Commenters also recommended that CMS provide a non-exclusive list of the characteristics of "crisis residential services." Commenters recommended

that CMS clarify whether the availability of reimbursement is limited to crisis residential services. A few commenters also recommended that CMS annually publish a list of all IMD facilities within a state.

Response: We recognize that states may have various definitions of sub-acute facilities and crisis residential centers. Further, these definitions may not have consistent characteristics across states. We are considering releasing sub-regulatory guidance that would provide information to states regarding the characteristics of sub-acute and crisis services that divert individuals from acute stays in inpatient hospitals for psychiatric and substance use disorders. However, we decline at this time to publish an annual list of IMD facilities within a state, as the value of doing so is not immediately clear.

Comment: Several commenters recommended that CMS clearly establish and define in lieu of services in the final regulation. Commenters also recommended that CMS include explicit language in the final rule stating that managed care plans can provide covered behavioral health benefits in facilities that are considered IMDs as long as the requirements for in lieu of services are met, including that the enrollee has agreed to the substitution and the service is cost-effective. Several commenters also recommended that CMS specify that to be an in lieu of service and to receive the capitated payment, the managed care plan must provide the enrollee meaningful choice between the IMD service and a community-based crisis service. Commenters also recommended that CMS specify that managed care plans can continue to receive payment for covered medical services provided to enrollees while they are patients in IMD facilities. One commenter recommended that CMS clarify whether states may contractually require managed care plans to make in lieu of services available to enrollees.

Response: We appreciate commenters' recommendations to codify our longstanding in lieu of services policy in regulation text as generally applied, as well as in the IMD context. We agree that such clarity is appropriate and that defining the standards and parameters for "in lieu of services" will aid states and managed care plans. We will finalize § 438.3(e)(2) to address in lieu of services as explained more fully below.

First, we will finalize the substance of proposed § 438.3(u), relating to capitation payments for enrollees with a short term stay in an IMD, at § 438.6(e)

in this final rule. The proposed rule's designation of this section under § 438.3 "Standard Contract Provisions" could suggest that all states must provide access to psychiatric or SUD services through IMDs and that was not our intent. By moving this provision to § 438.6 "Special Contract Provisions Related to Payment", it is clearer that it is at the state's option to authorize use by managed care plans of IMDs as an in lieu of setting and the requirements therein must be followed to make a capitation payment for such enrollees. We are finalizing this rule largely as proposed, with little substantive change. Provision of the capitation payment for enrollees who are short-term patients in an IMD under this rule must also comply with the requirements we are finalizing for managed care plan coverage of in lieu of services with one difference related to rate setting that is addressed below. We clarify here that the capitation payment that is made for enrollees that fall under this provision represents the full capitation for that enrollee's rate cell and in response to these comments have added regulation text addressing the in lieu of services policy generally in this final rule.

Second, we have modified § 438.3(e), which explains additional services (not covered under the state plan) that may be covered by an MCO, PIHP, or PAHP on a voluntary basis, to include a new paragraph (e)(2) that sets forth the criteria for a separate category of additional services or settings provided in lieu of state plan services as follows: the state determines that the alternative service or setting is a medically appropriate and cost effective substitute for the covered service or setting under the state plan; the enrollee is not be required by the MCO, PIHP, or PAHP to use the alternative service or setting; the approved in lieu of services are identified in the MCO, PIHP, or PAHP contract, and will be provided at the option of the MCO, PIHP, or PAHP; and the utilization and cost of in lieu of services would be taken into account in developing the component of the capitation rates that represents the covered state plan services. We also note that the regulatory standard for rate setting is different when using an IMD as an in lieu of setting and that distinction is provided in revised § 438.6(e).

As provided in response to commenters that were concerned that the IMD provision would counter efforts for community integration, we highlight that the in lieu of service or setting must be medically appropriate. While we agree that most beneficiaries would be well served in the community, others

may need more intensive services such as acute inpatient psychiatric care offered by general hospitals and inpatient psychiatric hospitals. As part of the continuum of care for behavioral health conditions, some short-term psychiatric services delivered in inpatient settings, including those delivered in facilities that meet the definition of an IMD, may be medically necessary depending on the needs of the individual. These requirements for in lieu of services at § 438.3(e)(2) must be satisfied in addition to the specific standards contained in the IMD provision at § 438.6(e). Specifically, the IMD must be a facility that is a hospital providing psychiatric or substance use disorder inpatient care or a sub-acute facility providing psychiatric or SUD crisis residential services and the stay in the IMD is for no more than 15 days during the period covered by the monthly capitation payment. Further, the enrollee cannot be required to use the alternate setting or service; the enrollee must be allowed to opt for provision (and coverage) of the service and setting authorized in the state plan. Authorizing "in lieu of" services and settings under this final rule is not intended to limit enrollee choices or to require enrollees to receive inappropriate services. We emphasize that this is a basic element for in lieu of service to meet the provisions of this rule.

Third, in § 438.6(e), we add a cross-reference to the provisions of § 438.3(e)(2) to ensure compliance with the in lieu of services requirements, and add with additional regulation text to supersede the rate development component in § 438.3(e)(2)(iv). Specifically, we finalize regulation text for how to reflect services rendered in an IMD covered under this rule in the capitation rates in the manner we proposed (80 FR 31118); the state may use the utilization of services provided to an enrollee in an IMD but must price utilization at the cost of the same services through providers included under the state plan.

Comment: A few commenters recommended that CMS clarify that, where state law requires the state and not the managed care plan to pay for care at an IMD, the managed care plan would not receive a capitation payment and not be expected to pay for an enrollee's care at such a facility.

Response: Discussions related to the effect of state law are outside the scope of this final rule. We restate, however, that making use of the flexibility provided under §§ 438.6(e) and 438.3(e)(2) is optional and a state may elect to contract with an MCO or PIHP

without authorizing IMD—or any other service(s)—as an in lieu of service on the terms identified in this rule. In such cases involving IMD, the payment of the capitation rate for a month in which an enrollee is a patient of an IMD for any period of time is not consistent with this rule, and therefore not eligible for FFP.

Comment: Several commenters specified that states using existing in lieu of authority to cover IMD services should be permitted to continue using the authority as currently authorized in approved contracts and waivers, that is, without the limitations discussed in the proposed rule. Several commenters also stated opposition to any actual or implied proposed limitation on the use of in lieu of services if those services have been determined, as demonstrated to CMS by the state and their actuary, to be a cost-effective substitute service that the member agrees to and the managed care plan willingly provides. Commenters stated that eliminating or limiting current in lieu of service flexibility would result in program disruptions, increased costs to states and the federal government, and potentially decreased access to necessary behavioral health services.

Response: We acknowledge that current state practices vary regarding the use of IMDs as an in lieu of setting for covered inpatient mental health or substance use disorder services. This provision, as finalized, represents the only permissible approach for states to apply the in lieu of services approach for enrollees in an IMD given the statutory prohibition on FFP. States must be in compliance with these provisions for contracts starting on or after July 1, 2017.

Comment: Many commenters were concerned about the length of stay of 15 days or less for inpatient and sub-acute crisis residential psychiatric and substance use disorder care proposed in § 438.3(u) for which capitated payments to managed care plans would be permitted. These commenters expressed concern that the selection of a 15-day length of stay limit appeared arbitrary, not aligned with federal Medicare definitions of short-term hospitalization, solely based on data from the Medicaid Emergency Psychiatric Demonstration which is limited to severe psychiatric conditions and not reflective of managed care, or otherwise not clinically appropriate. Many of these commenters recommended alternative length of stay limitations for this provision, including 15 days with a 7-day extension option based on medical necessity, 21 days, 25 days to align with the average length of stay in under Medicare for long-term care hospitals,

and 30 days. In addition, many of these commenters requested CMS further explain the basis for proposing a 15-day length of stay limitation.

Response: In order for a capitation payment to be made by the state to the MCO or PIHP for an enrollee in an IMD, this provision has to define a reasonable short-term length of stay in an IMD for individuals with an inpatient level of care need for psychiatric or SUD services. This is because there must be some period of time within the month covered by the capitation payment that the enrollee is not a patient in an IMD and may receive other Medicaid covered services. As explained in the preamble of the proposed rule, the selection of a 15-day length of stay was based on data from several sources. For instance, initial results from the Medicaid Emergency Psychiatric Demonstration evaluation provides data reflecting certain psychiatric stays in IMDs in the Medicaid population. The evidence from the Demonstration suggests that the average length of stay was 8.2 days.⁷ In addition, the proposed 15-day length of stay is supported by Market Scan Medicaid 2013 inpatient records data for inpatient behavioral health hospital stays, which encompass both inpatient mental health stays and inpatient substance use disorder stays. This evidence suggests that the average length of mental health inpatient stays was 10.2 days, and that over 90 percent of mental health inpatient stays were 15 days or shorter. This evidence also suggests that the average length of substance use disorder inpatient stays was 5.9 days, and that over 90 percent of inpatient substance use disorder stays were 10 days or shorter. In addition, claims data from 2012 show that FFS Medicare beneficiaries had an average length of stay of 12.8 days in inpatient psychiatric facilities, according to analysis by the Medicare Payment Advisory Commission. Based on this analysis, we are finalizing the 15-day per month, per admission timeframe.

Comment: Many commenters were concerned that the length of stay of 15 days or less for inpatient and sub-acute crisis residential care proposed in this provision is not appropriate for substance use disorder care in particular. Some commenters recommended that the proposed 15-day length of stay limit be extended (for example, to 30 days) for substance use disorder exclusively. Other commenters recommended that CMS include

residential substance use disorder care in the provision.

Response: As explained in response to a previous comment, the proposed 15-day length of stay limitation for inpatient substance use disorder care is supported by recent Medicaid managed care inpatient substance use disorder stay hospital records data. We agree it is important to address the needs of individuals with substance use disorder who require longer lengths of stay in short-term, non-hospital based residential treatment settings. To that end, we recently issued a State Medicaid Director letter (SMDL) (#15–003) regarding opportunities to design service delivery systems for individuals with substance use disorder. See <https://www.medicaid.gov/federal-policy-guidance/downloads/SMD15003.pdf>. The letter outlined a new opportunity for demonstration projects approved under section 1115(a) of the Act, to ensure that a continuum of care is available to individuals with substance use disorder. In the letter, CMS describes the ability to receive FFP for short-term inpatient and residential substance use disorder treatment, including in facilities that meet the definition of an IMD, provided that such coverage complements broader substance use disorder system reforms and specific program requirements are met. The letter defines short-term inpatient stays as 15 days or less and occurring in a medically managed setting (ASAM Level 4.0), and defines short-term residential stays as an average of 30 days and occurring in a clinically managed or medically monitored setting (ASAM Levels 3.1, 3.3, 3.5 and 3.7). Through this section 1115(a) demonstration opportunity, state Medicaid programs can cover short-term residential substance use disorder treatment beyond a 15-day length of stay.

Comment: Some commenters raised concern that the proposed IMD provision that would permit the payment of capitation payments for enrollees with a short term stay of no more than 15 days within the month would violate MHPAEA as a treatment limitation. Other commenters asked if MHPAEA requires the use of IMDs as a setting to provide mental health or SUD services.

Response: First, this provision is a payment limitation on the MCO's or PIHP's ability to receive a capitation payment that is eligible for FFP for an enrollee with a short term stay in an IMD rather than a treatment limitation for mental health or SUD services. As stated previously, under the in lieu of approach authorized under this

⁷ CMS, "Report to Congress on the Evaluation of the Medicaid Emergency Psychiatric Demonstration" (December 1, 2013), at pg. 11, available at https://innovation.cms.gov/Files/reports/MEPD_RTC.pdf.

proposal, the alternative setting (for example, an IMD) for the short term stay of no more than 15 days within the month must be a medically appropriate substitute for covered inpatient stays under the state plan. If such an alternative is not appropriate for the needs of the enrollee, the MCO or PIHP must admit the enrollee to a general hospital instead of the IMD and/or provide the other covered services that are medically necessary and appropriate. We also point out that MHPAEA does not require an IMD to be used as a setting for covered mental health or SUD services. Rather, the provisions of MHPAEA require inpatient services for mental health or SUD services to be provided at a level consistent with coverage of medical or surgical benefits, but the location or setting for those services is not dictated under that federal law. In order for an MCO or PIHP to receive a capitation payment that is eligible for FFP for an enrollee with a short term stay in an IMD, the provisions at § 438.6(e) apply. Specifically, the requirements for in lieu of services at § 438.3(e)(2)(i) through (iii) must be met and, for purposes of rate setting as specified at § 438.6(e), the state may use the utilization of services provided to an enrollee under this section when developing the inpatient psychiatric or substance use disorder component of the capitation rate, but must price utilization at the cost of the same services through providers included under the state plan.

Comment: Some commenters raised concern that the proposed IMD provision could require the managed care plan to pay for as many as 30 consecutive days at an IMD if the stay spans two months. Commenters recommended that CMS clarify that the managed care plan shall not be required to pay for care at an IMD beyond the 15th day. One commenter recommended that CMS clarify whether a stay that begins in one month and ends in the following month is viewed as a single episode or for the purposes of monthly capitation payments may be viewed as the number of inpatient days within each capitation month. Commenters also recommended that CMS limit the managed care plan's covered benefit to 60 days per calendar year.

Response: The appropriate application of the in lieu of services policy for use of an IMD requires the MCO or PIHP to determine if the enrollee has an inpatient level of care need that necessitates treatment for no more than 15 days. If the managed care plan (or physician) believes that a stay of longer than 15 days is necessary or

anticipated for an enrollee, the use of this specific in lieu of service is likely not appropriate if Medicaid coverage is going to be continued because of the prohibition in subsection (B) following section 1902(a)(29) of the Act. As we explained in connection with this proposal (80 FR 31118), it is possible that an MCO or PIHP could receive two capitation payments for consecutive months if the length of stay could extend beyond 15 days, with no more than 15 days occurring during each month. For the purpose of determining whether a capitation payment may be made for an enrollee, the focus is the number of inpatient days within the period covered by the monthly capitation payment. We decline to accept the recommendation that the managed care plan's covered benefit for stays in an IMD be limited to 60 days per calendar year. We restate that managed care plans are not required to use flexibility described here. As we proposed (80 FR 31117), the contract may not require the managed care plan to use IMDs; the contract may only authorize in lieu of services that the MCO or PIHP may make available to enrollees FFP for capitation payments to managed care plans that provide coverage of services for enrollees aged 21 to 64 that are a patient in an IMD is available only as described in this final rule.

Comment: A few commenters stated that the preamble indicates that a state will be required to monitor beneficiary IMD lengths of stay on a monthly basis, and if such a stay lasts 15 days or longer in a month, to seek recoupment of its total capitation payment made to the managed care plan for that month. Commenters noted that requiring states to recoup capitation payments made to MCOs and PIHPs for an enrollee with an IMD stay that exceeds 15 days will require significant retroactive adjustments and create major financial uncertainty. Commenters also stated that such an approach would disrupt program operations. As an alternative to this approach, commenters recommended that CMS require states to have reporting requirements and appropriate compliance actions in their managed care plan contracts to enforce the IMD provision. Commenters also recommended that CMS could require a hard limit on the number of IMD days included in the state's monthly capitation payment but allow individuals to continue to be enrolled in care coordination in the event that an individual's stay exceeds 15 days.

Response: We acknowledge that this provision requires states to monitor the MCO's or PIHP's use of IMDs as an in

lieu of service to ensure that capitation payments were appropriately made and that claims for FFP associated with those capitation payments are filed only when consistent with this rule.

However, to ensure that the operation of this provision remains consistent with paragraph (B) following section 1905(a)(29) of the Act, such oversight is necessary on the part of the state, and the MCO or PIHP must use sound judgment when offering the IMD as an alternative setting for enrollees with an inpatient level of care need for psychiatric or SUD treatment. The provisions in § 438.6(e) specify the federal requirements to permit capitation payments that are eligible for FFP to be made in this context. States have the flexibility under this rule and applicable state law to design contract terms to ensure compliance by MCOs or PIHPs with the parameters of this final rule for using IMDs as an in lieu of service. As stated above in response to comments, the capitation payment that is made for enrollees that fall under this provision represents the full capitation rate for that enrollee's rate cell. If an enrollee has a length of stay for more than 15 days within the period covered by the monthly capitation payment, no capitation payment may be made for that enrollee under a Medicaid managed care program regulated under 42 CFR part 438. We note, however, that states may also pay independently for services provided to patients in IMDs. We emphasize that the statutory exclusion was designed to assure that states, rather than the federal government, continue to have principal responsibility for funding inpatient psychiatric services.

Comment: A few commenters recommended that CMS exclude residential addiction treatment programs from the definition of IMD. Other commenters recommended that CMS exclude substance use disorders from the definition of "mental disease" for the purposes of determining if a treatment facility is an IMD. A few commenters recommended that CMS clarify that the IMD provision is not applicable to inpatient psychiatric hospital services for individuals under age 21 as defined in § 440.160.

Response: Under section 1905(i) of the Act, an Institution for Mental Diseases is defined as a hospital, nursing facility, or other institution of more than 16 beds that is primarily engaged in providing diagnosis, treatment, or care of persons with mental diseases, including medical attention, nursing care, and related services. The regulation at § 435.1010 repeats this definition with an additional provision that an IMD is

identified by its “overall character” as a facility established and maintained primarily for the care and treatment of individuals with mental diseases, regardless of its licensure.

We consider facilities treating substance use disorder (including addiction) to be within the definition of an “institution for mental disease,” provided the other relevant criteria are met as set forth in the applicable law and guidance (for example, subsection C of Section 4390 of the State Medicaid Manual, a body of sub-regulatory guidance designed to provide states with policies, procedures and instructions for administering their Medicaid programs). The additional criteria, which are not intended to be exhaustive, include whether the facility is licensed as a psychiatric facility; the facility is accredited as a psychiatric facility; the facility is under the jurisdiction of the state’s mental health authority; the facility specializes in providing psychiatric/psychological care and treatment; and the current need for institutionalization for more than 50 percent of all the patients in the facility results from mental diseases. To the extent that the substance use disorder treatment services delivered are covered by the Medicaid program, the services are considered medical treatment of a mental disease. Facilities with more than 16 beds primarily engaged in providing this type of treatment would most likely meet the definition of an IMD. CMS is available to provide additional clarification on these points. We also note here that Medicaid-covered services provided in facilities meeting qualifications of the inpatient psychiatric benefit for individuals under the age of 21 are eligible for reimbursement under section 1905(a)(16) of the Act. These services are an exception to the IMD exclusion, regardless of the bed size of the facility.

Comment: Several commenters cited that lack of Medicaid coverage for acute short-term treatment services provided in facilities that are IMDs creates a significant barrier to accessing necessary care for individuals.

Response: We understand that there are access issues for short-term inpatient psychiatric and SUD treatment. We attempt to address the access issues noted above through several strategies. In addition to proposing § 438.6(e), we recently released an SMDL #15–003 that would allow states to request a section 1115(a) demonstration to receive federal matching funding for expenditures for individuals residing in IMDs to treat SUD. See <http://www.medicaid.gov/federal-policy-guidance/downloads/SMD15003.pdf>.

Comment: Other commenters stated that the IMD exclusion presents a parity issue for Medicaid beneficiaries. Several of these commenters recommended that CMS should clarify how parity and the IMD exclusion co-exist and explicitly state that services typically provided in IMDs remain subject to parity. Other commenters suggested that the proposed 15-day length of stay limit is inconsistent with parity standards and that that outpatient and inpatient services should be provided to people living with mental illness or substance use disorders in an equitable and non-discriminatory manner. One commenter suggested the 15-day length of stay limit imposes a quantitative treatment limitation on inpatient behavioral health services that the State would be required to include in its analysis of compliance with proposed § 440.395.

Response: We note that parity issues are not within the scope of this regulation and point commenters to the March 30, 2016 final rule (81 FR 18390) for a discussion of parity standards as applied to Medicaid, Medicaid ABPs, and CHIP managed care. Paragraph (B) following section 1905(a)(29) of the Act provides that FFP is not available for any medical assistance under Title XIX for services provided to an individual ages 21 to 64 who is a patient in an IMD facility. Under this broad exclusion, no FFP is available for the cost of services provided either inside or outside the IMD while the individual is a patient in the facility. States have the option, using state programs other than the Medicaid program, of providing inpatient psychiatric and SUD services in IMDs. This rule permits payment of capitation rates under the Medicaid program to MCOs and PIHPs for a month for an enrollee when only part of that period is spent by the enrollee as a patient in an IMD because the IMD is used as a substitute setting for otherwise covered services.

We also note that the IMD exclusion is not a non-quantitative treatment limit. Treatment and the provision of covered services maybe furnished in a different setting consistent with applicable parity standards. Further, the IMD exclusion is not a mandatory standard for provider admission to participate in a network. In addition, the 15-day length of stay standard in this rule is not a quantitative treatment limitation on treatment. It is a rule related to the payment of FFP for capitation rates to MCOs and PIHPs using substitute service settings; medically necessary treatment of enrollees in a non-IMD setting (for example, in a psychiatric ward of a general hospital) may

continue for greater than 15 days and be eligible for FFP.

Comment: Some commenters stated that the proposed length of stay of 15 days or less for inpatient hospital facilities or sub-acute facilities providing crisis residential services may result in increased readmissions to those facilities. Specifically, these commenters suggested that the 15-day length of stay limitation could result in disruptions in treatment by creating a financial incentive to discharge individuals before it is medically appropriate to do so and readmit those individuals in the following month to ensure managed care plans’ continued eligibility for the receipt of capitation payments.

Response: We share this concern about providing quality care and preventing unnecessary readmissions. States may consider incorporating provisions into their managed care contracts designed to address potentially undesirable financial incentives, such as prohibitions on paying for preventable readmissions or readmissions occurring within a specified timeframe. In addition, states and managed care plans should work to ensure successful discharges from inpatient and sub-acute facilities, including successful transitions to outpatient care. States and managed care plans may use quality measures to track readmissions, discharges and transitions. To that end, we may release subregulatory guidance recommending specific measures for this purpose.

Comment: Several commenters recommended that CMS require IMDs receiving federal Medicaid reimbursement to provide data on specific quality measures concerning inpatient care and linkages with community services following discharge. Commenters recommended measures such as: documentation of follow-up mental health services in the community within 14 days of discharge from the hospital, hospital readmission rates following discharge at specified intervals, arrests following discharge, patient experiences and satisfaction during hospitalization, and use of seclusion and restraints during hospitalization. One commenter recommended that CMS review the outcomes of this provision after a period of 3 years to determine whether Medicaid costs were reduced and if individuals were enabled to stabilize their mental illnesses or substance use disorders following a hospitalization and return to independent living in the community. One commenter recommended that CMS carefully monitor the use of the 15 day per month

allowance to prevent periodic inpatient care being overused or used as a substitute for high quality accessible community, home, and work based behavioral health services.

Response: The final rule does not regulate IMDs and CMS has not identified authority in this rule to regulate IMDs. As discussed in the proposed rule (80 FR 31117), this provision is intended to provide states with flexibility to address concerns about ensuring access to and availability of short-term inpatient psychiatric and SUD services in Medicaid programs. We encourage states to identify and track relevant measures including behavioral health measures but requiring states to collect specific performance measures related to IMDs is not within the scope of this regulation. Should we elect to identify national performance measures under the authority of § 438.330(a)(2) of this final rule, we will take these recommendations into consideration during the public notice and comment process. We also note that we have required states, through our section 1115(a) demonstration authority, to collect and analyze measures that other states may want to use for beneficiaries with behavioral health needs as part of their evaluation of these services. Evaluation of the use of in lieu of services in this context or more broadly could be part of a state's quality strategy for the managed care program under § 438.340, although we decline to require such evaluation in regulation.

Comment: A few commenters recommended that CMS allow the actual costs of the IMD, in the absence of inpatient hospital costs, as a substitute in the encounter data used to set rates. One commenter stated that using 15 days to project rates is too high. The commenter recommended that CMS require states to set rates based on 10 days and allow for the additional 5 days as an outlier until each state can analyze its data and confirm an average length of stay. A few commenters stated concerns regarding the refusal to allow states to utilize the IMD costs as a proxy in setting actuarially sound rates and recommended that CMS allow such an approach. A few commenters recommended that CMS clarify that the IMD provision is subject to the actuarial soundness requirements and rate development standards included in the proposed regulation.

Response: Consistent with our proposal (80 FR 31118), the utilization of services used for rate setting (that is, both historical and projected utilization) should include the provision of covered services when such services are

provided to an enrollee who is a patient in an IMD consistent with this rule (meaning that the terms of § 438.6(e) are all met); however the cost of such services should be priced at the cost of covered inpatient settings to remain consistent with the statutory prohibition of FFP. States and their actuaries may rely on actual utilization in an IMD of inpatient psychiatric or substance use disorder stays when setting the capitation rates, so long as the utilization in an IMD does not exceed 15 days per month per enrollee. This provision does not require states and their actuaries to apply a blanket utilization assumption of 15 days. Utilization of inpatient psychiatric and SUD services rendered outside of the IMD are also taken into account when developing that component of the capitation rate. We emphasize that the requirements for the development and documentation of actuarially sound capitation rates in §§ 438.4–438.7 apply to this provision; however, § 438.6(e) sets forth the specific requirements for pricing the utilization of services rendered in an IMD.

Comment: One commenter recommended that CMS include a community transition unit at § 438.3(u). The commenter also recommended that CMS invest in a short-term community living skills training program to ensure success of community transitions for longer-term institutionalized consumers with learned dependency habits.

Response: While we are unclear on the commenter's definition of community transition units, we recognize that inpatient diversion services play an important role in the treatment of individuals with mental health and substance use disorder service needs. However, this provision is solely intended to address the use of in lieu of services for short term care (including sub-acute crisis services) for individuals with inpatient level of care needs. We acknowledge the importance of implementing services and supports for individuals transitioning into community settings, but the explicit inclusion of community transition units would be outside the scope of this provision. CMS is considering releasing subregulatory guidance that provides greater clarity regarding sub-acute crisis services.

Comment: One commenter recommended that CMS clarify whether the flexibility offered at § 438.3(u) applies to Medicaid managed care plans that are not capitated. One commenter recommended that CMS clarify whether § 438.3(u) would also apply to a Provider Led Entity in its role as a manager of Medicaid services. One

commenter recommended that CMS allow states to extend this arrangement to the managed care enrollees who receive behavioral health services through a FFS carve-out.

Response: We interpret the commenter to question whether the provision at § 438.3(u) would apply to non-risk PIHPs as by definition, MCOs must be under comprehensive risk contracts, and non-risk PIHPs receive a monthly capitation payment that is reconciled to state plan payment rates under § 438.812. Section 438.6(e) is limited to risk-based MCOs and PIHPs; it is not applicable to FFS Medicaid delivery systems or non-risk delivery systems. Thus, this section is inapplicable to non-risk PIHPs that provide mental health or substance use disorder services. The use of in lieu of services only applies to risk contracts.

Comment: A few commenters recommended that CMS eliminate the state option to allow behavioral health services to be carved out of Medicaid managed care benefits, as this is a barrier to treating the whole person and to achieving the goal of better care, healthier people, and lower costs. A few commenters stated that these carve-out arrangements create barriers to the integration of behavioral and physical health care and inhibit the sharing of information across care settings.

Response: This comment is outside the scope of the proposed rule. However, while we concur with the commenters that integrated care eliminates many of the challenges posed by carving out services from a managed care program, we decline to prohibit such arrangements out of deference to the state's ability to design its Medicaid program.

After consideration of public comments, we are finalizing the regulation text for this provision at § 438.6(e) substantially as proposed, with the following modifications:

- Clarified that § 438.6(e) applies to both psychiatric and substance use disorder services;
- Specified that the provision was limited to enrollees aged 21–64;
- Incorporated requirements for in lieu of services in § 438.3(e)(2)(i) through (iii);
- Described the rate setting requirements for in lieu of services in an IMD consistent with our proposal (80 FR 31118).

t. Recordkeeping Requirements (Proposed as § 438.3(v), Finalized as § 438.3(u))

In paragraph (v), we proposed minimum recordkeeping requirements for MCOs, PIHPs, PAHPs, and

subcontractors, as applicable, of at least 6 years for data, documentation and information specified in this part. Specifically, we proposed that MCOs, PIHPs, PAHPs, and subcontractors retain enrollee grievance and appeal records as specified in § 438.416, base data as specified in § 438.5(c), MLR reports as specified in § 438.8(k), and the documentation specified in §§ 438.604, 438.606, 438.608, and 438.610. We made this proposal under our authority in section 1902(a)(4) of the Act to mandate methods of administration that are necessary for the efficient operation of the state plan. We requested comment on the proposed length of record retention; specifically, whether 6 years is consistent with existing state requirements on managed care plans for record retention and whether we should adopt a different timeframe. We noted that MA requires MA organizations to retain records for a period of 10 years at § 422.504(d).

We received the following comments in response to proposed § 438.3(v).

Comment: Several commenters supported the proposed recordkeeping requirement of 6 years at § 438.3(v). One commenter stated that 6 years is not a standard accounting practice and recommended that CMS adopt 7 years as the recordkeeping requirement. One commenter stated that CMS should align the recordkeeping requirement with § 438.230(c)(3)(iii) regarding the audit and inspection timeframe of 10 years. Further, one commenter stated that under the False Claims Act at 31 U.S.C. 3731(b)(2), claims may be brought up to “10 years after the date on which the violation is committed.” The commenter recommended that CMS require managed care plans and subcontractors to retain documentation for a period of 10 years for consistency with the False Claims Act as well as MA’s record retention requirement.

Response: We agree with commenters that the recordkeeping requirement at § 438.3(v) should align with § 438.230(c)(3)(iii) regarding the audit and inspection timeframe of 10 years. Further, since the 10 year timeframe would align with both the False Claims Act at 31 U.S.C. 3731(b)(2) and MA, we believe it is appropriate to align § 438.3(v) with the 10 year requirement. We are finalizing the regulatory text to adopt this recommendation.

After consideration of the public comments, we are modifying the regulatory text to revise the 6 year recordkeeping requirement to 10 years and redesignating this paragraph at (u) to account for the move of proposed § 438.3(u) relating to capitation

payments for enrollees with a short term stay in an IMD to § 438.6(e).

3. Setting Actuarially Sound Capitation Rates for Medicaid Managed Care Programs (§§ 438.2, 438.4, 438.5, 438.6, and 438.7)

Building on a decade of experience with states, we proposed to improve the effectiveness of the regulatory structure to better assure the fiscal integrity, transparency and beneficiary access to care under the Medicaid program and to promote innovation and improvement in the delivery of services through a comprehensive review of Medicaid managed care capitation rates. The overarching goal behind our proposed revisions to the rate setting framework (proposed in §§ 438.4 through 438.7) was to reach the appropriate balance of regulation and transparency that accommodates the federal interests as payer and regulator, the state interests as payer and contracting entity, the actuary’s interest in preserving professional judgment and autonomy, and the overarching programmatic goals—shared by states and the federal government—of promoting beneficiary access to quality care, efficient expenditure of funds and innovation in the delivery of care. We also noted that requiring more consistent and transparent documentation of the rate setting process would allow us to conduct more efficient reviews of the rate certification submissions.

Section 1903(m)(2)(A)(iii) of the Act permits federal matching dollars for state expenditures to a risk bearing entity for Medicaid services when such services are provided for the benefit of individuals eligible for benefits under this title in accordance with a contract between the state and the entity under which the prepaid payments to the entity are made on an actuarially sound basis and under which the Secretary must provide prior approval for contracts [meeting certain value thresholds].

We relied on the following principles of actuarial soundness to inform the modernized rate setting framework in this final rule. First, capitation rates should be sufficient and appropriate for the anticipated service utilization of the populations and services covered under the contract and provide appropriate compensation to the managed care plans for reasonable non-benefit costs. Built into that principle is the concept that an actuarially sound rate should result in appropriate payments for both payers (the state and the federal government) and that the rate should promote program goals such as quality of care, improved health, community

integration of enrollees and cost containment, where feasible. Second, an actuarial rate certification underlying the capitation rates should provide sufficient detail, documentation, and transparency of the rate setting components set forth in this regulation to enable another actuary to assess the reasonableness of the methodology and the assumptions supporting the development of the final capitation rate. Third, a transparent and uniformly applied rate review and approval process based on actuarial practices should ensure that both the state and the federal government act effectively as fiscal stewards and in the interests of beneficiary access to care.

a. Definitions (§ 438.2)

We proposed to define “actuary” to incorporate standards for an actuary who is able to provide the certification under current law at § 438.6(c); that is, that the individual meets the qualification standards set by the American Academy of Actuaries as an actuary and follows the practice standards established by the Actuarial Standards Board. We also proposed that where the regulation text refers to the development and certification of the capitation rates, and not the review or approval of those rates by CMS, the term actuary refers to the qualified individual acting on behalf of the state. We explained that an actuary who is either a member of the state’s staff or a contractor of the state could fulfill this role so long as the qualification and practice standards are also met. We did not receive comments on the proposed definition for “actuary” and will finalize the definition as proposed without modification.

We proposed to modify the existing definition of “capitation payment” by removing references to “medical” services in recognition of the fact that states are contracting with MCOs, PIHPs, and PAHPs for LTSS, which are not adequately captured in the existing definition of capitation payments that refers only to medical services.

We received the following comments in response to the proposed modification to the definition of “capitation payment.”

Comment: One commenter agreed with the removal of “medical” to modify “services” in the definition of a capitation payment but suggested that CMS insert “health care” before “services” to be more reflective of the type and range of services that are offered without becoming too broad. One commenter requested confirmation that the definition is consistent with sections 2.3 (definition of capitation

rate) and 3.2.2 (structure of Medicaid managed care capitation rates) of the ASOP No. 49 and section AA.4 of the CMS Rate Setting Checklist.

Response: We appreciate the commenter's suggestion but decline to add "health care" as that term would have a similar effect to retaining the term "medical" as a modifier of "services. For example, residential or employment supports may be provided through a managed LTSS program and, thereby included in capitation payments, and those services do not fall within a generally accepted understanding of the term "health care." The proposed definition of a capitation payment links services to the state plan, which would also include services authorized under a waiver authority (for example, section 1915(c) of the Act), and is sufficient to address the scope of services represented in a capitation payment.

The proposed rule made a minor modification to the definition of a capitation payment and the definition is consistent with sections 2.3 and 3.2.2 of ASOP 49. We note that section 3.2.2 of the ASOP No. 49 refers primarily to the development of rate cells and explains that capitation payments are made according to rate cell. In addition, to the extent any inconsistencies Section AA.4 of the CMS Ratesetting Checklist also addresses rate cells, we refer commenter to our response to comments on the definition of a "rate cell." Ultimately, the definitions are consistent. As stated in other forums, the CMS Ratesetting Checklist is an internal tool for CMS' use when reviewing rate certifications. The applicability or need to update that tool based on changes in these regulations is outside the scope of this rule. States, their actuaries, and managed care plans should rely on the regulatory requirements related to rate setting in §§ 438.4–438.7 when developing capitation rates and sub-regulatory rate development guidance published by CMS (for example, 2016 Medicaid Managed Care Rate Development Guide).

After consideration of the public comments, we are finalizing the definition of "capitation payment" as proposed without modification.

We proposed to define a "material adjustment" as one that, in the objective exercise of an actuary's judgment, has a significant impact on the development of the capitation rate. We noted that material adjustments may be large in magnitude, or be developed or applied in a complex manner. The actuary developing the rates should use reasonable actuarial judgment based on generally accepted actuarial principles

when assessing the materiality of an adjustment. We did not receive comments on the definition for "material adjustment" and will finalize as proposed without modification.

We also proposed to add a definition for "rate cells." The use of rate cells is intended to group people with more similar characteristics and expected health care costs together to set capitation rates more accurately. The rate cells should be developed in a manner to ensure that an enrollee is assigned to one and only one rate cell. That is, each enrollee should be categorized in one of the rate cells and no enrollee should be categorized in more than one rate cell.

We received the following comments in response to our proposal to define "rate cells."

Comment: We received several comments on the proposed definition of a "rate cell" in § 438.2. One commenter suggested that the definition of a rate cell be broadened to accommodate a wider set of payment structures and that the proposed definition that an enrollee could only be in one rate cell did not recognize existing practices. For example, in some states an enrollee can be in multiple rate cells because states have different contracts covering different benefits. Some commenters provided that a state may pay the medical acute benefit as one rate cell and the LTSS as an add-on rate cell and suggested that the definition be modified to provide that an enrollee would only be in one rate cell for each unique set of benefits. Another commenter noted that the definition of rate cell does not explicitly mention eligibility category and requested clarification as to whether eligibility category was still required in the development of rate cells.

Response: To address the commenters who raised the issue that enrollees may be in more than one rate cell in states that have separate managed care contracts for different benefits, we have modified the language that no enrollee should be categorized in more than one rate cell "under the contract." For those states that would categorize an enrollee under two rate cells—one for acute medical services and one for LTSS—under the same contract, we have modified the definition to acknowledge that enrollees may be in different rate cells for each unique set of mutually exclusive benefits under the contract. We have added "eligibility category" to the list of potential criteria for grouping enrollees under a rate cell and restate that the list of characteristics represent the range of permissive groupings and does not require that each characteristic

be applied to the development of rate cells for populations under the contract.

Comment: One commenter requested that CMS clarify its expectation for development of an amount paid outside the capitated rate, for example delivery kick payments. The commenter requested clarification that these types of payments that are outside the capitation rate will continue to be allowed.

Response: Kick payments are permissible under this final rule as such payments are capitation payments in addition to the base capitation payment per rate cell and are subject to the rate development and rate certification documentation requirements in this rule.

After consideration of the public comments, we are finalizing the definition of "rate cell" to recognize that enrollees may be in different rate cells for each set of mutually exclusive benefits under the contract and to include eligibility category to the criteria for creating rate cells.

Comment: One commenter suggested that CMS add a definition for a "rating period" in § 438.2 similar to the reference to a rating period in the definition of a "MLR reporting year" at § 438.8(b). The commenter stated that the addition of a definition for "rating period" would avoid confusion in the regulations between the period for which capitation rates are being developed and the historical data period(s) supplying the base data in the rate development process.

Response: We concur with the commenter that the inclusion of a definition for "rating period" would improve readability as the term appears in both § 438.5(c)(1) relating to base data for rate setting purposes and in the definition of MLR reporting year in § 438.8(b). Therefore, we will finalize § 438.2 to include a definition for "rating period" as "a period of 12 months selected by the State for which the actuarially sound capitation rates are developed and documented in the rate certification submitted to CMS as required by § 438.7(a)."

b. Actuarial Soundness Standards (§ 438.4)

Consistent with the principles of actuarial soundness described herein, we proposed to add a new § 438.4 that built upon the definition of actuarially sound capitation rates currently at § 438.6(c)(i) and established standards for states and their actuaries. In § 438.4(a), we proposed to define actuarially sound capitation rates as rates that are projected to provide for all reasonable, appropriate, and attainable

costs under the terms of the contract and for the time period and population covered under the contract. We explained that the rate development process should be conducted and rates developed in accordance with the proposed standards for approval of rates in § 438.4(b). We provided that under this provision, costs that are not reasonable, appropriate, or attainable should not be included in the development of capitated rates, (*see* 80 FR 31119).

We received the following comments on proposed § 438.4(a).

Comment: One commenter requested that CMS clarify that actuarial soundness applies not to individual components of rates (for example, the non-benefit component), but to the total capitation rate per rate cell. One commenter stated that it was unclear to what CMS would classify as reasonable, appropriate, and attainable costs.

Response: Generally accepted actuarial principles and practices apply to each rate development standard specified in § 438.5 used in the rate setting process, resulting in the actuary certifying that the capitation rate per rate cell under the contract is actuarially sound as defined in § 438.4(a). The total capitation rate per rate cell must be projected to provide for all reasonable, appropriate, and attainable costs, while individual components of the rate cell must be developed in accordance with § 438.5. It is unclear what additional clarification the commenter requests regarding “reasonable, appropriate, and attainable costs,” as actuaries have conducted their work based on this definition for a considerable length of time. It is difficult for us to provide an exhaustive list of “reasonable, appropriate, and attainable costs” as that determination is based on the obligations on the managed care plan under the particular contract and the actuary’s professional judgment using generally accepted actuarial principles and practices.

Comment: A commenter requested clarification as to whether the actuarial soundness and rate development standards in §§ 438.4 and 438.5, respectively, apply to Financial Alignment Demonstrations under section 1115A authority.

Response: Yes, upon the effective and applicable compliance dates of this final rule, these requirements apply to the Medicaid portion of the capitation rate paid under section 1115A Financial Alignment demonstrations. Section III.A.2 of the Memorandum of Understanding (MOU) for Financial Alignment Demonstrations specifies that Medicaid managed care

requirements under Title XIX and 42 CFR part 438 apply unless explicitly waived. Our consistent policy for Financial Alignment Demonstrations is to maintain the actuarial soundness requirements.

After consideration of the public comments, we are finalizing § 438.4(a) as proposed.

In § 438.4(b), we proposed to set forth the standards that capitation rates must meet and that we would apply in the review and approval of actuarially sound capitation rates. In § 438.4(b)(1), we proposed to redesignate the standard currently in § 438.6(c)(1)(i)(A) that capitation rates have been developed in accordance with generally accepted actuarial principles and practices. We also proposed in § 438.4(b)(1) that capitation rates must meet the standards described in proposed § 438.5 dedicated to rate development standards. We acknowledged that states may desire to establish minimum provider payment rates in the contract with the managed care plan. Because actuarially sound capitation rates must be based on the reasonable, appropriate, and attainable costs under the contract, minimum provider payment expectations included in the contract would necessarily be built into the relevant service components of the rate. However, we proposed in paragraph (b)(1) to prohibit different capitation rates based on the FFP associated with a particular population. We explained at 80 FR 31120 that different capitation rates based on the FFP associated with a particular population represented cost-shifting from the state to the federal government and were not based on generally accepted actuarial principles and practices.

We received the following comments on the introductory language in § 438.4(b) and paragraph (b)(1).

Comment: One commenter suggested that § 438.4(b) should be revised to delete “do all of the following:” so that paragraphs (b)(1) through (b)(8) read properly as complete sentences.

Response: We appreciate the commenter’s technical suggestion and have deleted that phrase from paragraph (b) for that reason. We note that each provision in paragraphs (b)(1) through (b)(8) must be met in order for CMS to approve capitation rates for MCOs, PIHPs, and PAHPs.

Comment: Several commenters requested clarification that capitation rates, with different FFP, may still vary by projected risk, and associated cost differences. Commenters requested clarification that capitation rates may likely vary by population for numerous reasons, but agreed that FFP is not a

permissible justification. Other commenters stated that the regulatory text did not take into account the fact that states receive 100 percent FFP for services and pay a special rate for services rendered to Indians by an Indian Health Care Provider.

Response: We agree that additional guidance and clarification is appropriate for § 438.4(b)(1). The practice intended to be prohibited in paragraph (b)(1) was variance in capitation rates per rate cell that was due to the different rates of FFP associated with the covered populations. For example, we have seen rate certifications that set minimum provider payment requirements or establish risk margins for the managed care plans only for covered populations eligible for higher percentages of FFP. Such practices, when not supported by the application of valid rate development standards, are not permissible under this rule. The provision would not prohibit the state from having different capitation rates per rate cell based on the projected risk of populations under the contract or based on different payment rates to providers that are required by federal law (for example, section 1932(h) of the Act). We will finalize § 438.4(b)(1) to provide that any differences among capitation rates according to covered populations must be based on valid rate development standards and not be based on the FFP associated with the covered populations.

After consideration of the public comments, we are finalizing the introductory text of § 438.4(b) without the phrase “do all of the following” and are finalizing § 438.4(b)(1) with additional text to provide that any proposed differences among capitation rates must be based on valid rating factors and not on network provider reimbursement requirements that apply only to covered populations eligible for higher percentages of FFP.

In § 438.4(b)(2), we proposed to redesignate the provision currently at § 438.6(c)(1)(i)(B). We restated the standard, but the substance is the same: the capitation rates must be appropriate for the population(s) to be covered and the services provided under the managed care contract.

We received the following comments on § 438.4(b)(2).

Comment: Many commenters supported § 438.4(b)(2) but some were concerned that the standard would not account for non-clinical services rendered under the contract or patient complexity and socio-demographic considerations. Others wanted assurance that the capitation rates

would account for the value of new and innovative therapies.

Response: The requirement in § 438.4(b)(2) is that the capitation rates are appropriate for the populations covered and services rendered under the contract. Because capitation rates are based on state plan services, and developed and certified at the rate cell level, and that unit of measure groups populations according to similar characteristics, this broad requirement would accommodate non-clinical services received by enrollees under MLTSS programs, enrollees with chronic conditions, or other enrollees that receive non-clinical services. Medical management, assessment, and other coordination activities required under the contract would be reflected in audited financial reports, which is a required source of base data in § 438.5(c)(1). If new therapies are covered under the state plan, and therefore, the contract, those costs would be taken into account in the rate development process. Patient complexity based on sociodemographic considerations may be addressed as part of the risk adjustment methodology.

After consideration of the public comments, we are finalizing § 438.4(b)(2) as proposed.

In § 438.4(b)(3), we proposed that capitation rates be adequate to meet the requirements on MCOs, PIHPs, and PAHPs in §§ 438.206, 438.207, and 438.208, which contain the requirements for MCOs, PIHPs, and PAHPs to ensure availability and timely access to services, adequate networks, and coordination and continuity of care, respectively. We noted that the definition of actuarially sound capitation rates in proposed § 438.4(a) provides that the rates must provide for all reasonable, appropriate, and attainable costs that are required under the contract. The maintenance of an adequate network that provides timely access to services and ensures coordination and continuity of care is an obligation on the managed care plans for ensuring access to services under the contract. In the event concerns in these areas arise, the review of the rate certification would explore whether the capitation payments, and the provider rates on which the capitation payments are based, are sufficient to support the MCO's, PIHP's, or PAHP's obligations.

We received the following comments on § 438.4(b)(3).

Comment: Many commenters supported § 438.4(b)(3) and requested that states be required to demonstrate that the capitation rates support provider payment levels that reflect a living wage. Other commenters

requested that CMS require states, on a periodic basis, to study and report on how capitation rates and the subsequent managed care plan reimbursement to providers affect patient access and provider network development. Some commenters stated that the evaluation of access should not be based on capitation rates alone. Other commenters recommended that CMS review the provider reimbursement levels of the managed care plans in its review and approval of the rate certifications.

Other commenters were opposed to proposed § 438.4(b)(3) and stated that the actuary should not be responsible for evaluating network adequacy. Commenters provided that it is the state's responsibility to assess and ensure managed care plan compliance with §§ 438.206, 438.207, and 438.208 and that the actuary should be able to rely on the state's assessment. Several commenters requested additional guidance as to how this assessment would be conducted.

Response: We maintain that the development of actuarially sound capitation rates includes an evaluation as to whether the capitation rates are adequate to meet the requirements on MCOs, PIHPs, and PAHPs in §§ 438.206, 438.207, and 438.208, as those are obligations specified under the managed care contract. The underlying base data, cost and utilization assumptions, as well as the consideration of the MCO's, PIHP's, or PAHP's MLR experience, inform the evaluation as to whether the capitation rates are sufficient to maintain provider networks that ensure the availability of services and support coordination and continuity of care.

In response to commenters that requested an additional evaluation of network adequacy or that suggested that review of capitation rates alone was not a sufficient evaluation of network adequacy, there are several other requirements regarding network adequacy that are in this part of note. Specifically, § 438.207(d) requires the state to provide documentation to CMS, at specified times, that managed care plans meet the requirements in that section and § 438.206, which incorporates compliance with the network adequacy standards established by the state under § 438.68. In addition, the annual program report in § 438.66 that is publicly available requires the state to report on the availability and accessibility of services in managed care plan networks. Finally, the mandatory EQR-related activity in § 438.358(b)(1)(iv) requires validation of MCO, PIHP, and PAHP network adequacy during the preceding 12 months for compliance with § 438.68.

After consideration of the public comments, we are finalizing § 438.4(b)(3) as proposed.

In § 438.4(b)(4), we proposed that capitation rates be specific to the payment attributable to each rate cell under the contract. We explained that the rates must appropriately account for the expected benefit costs for enrollees in each rate cell, and for a reasonable amount of the non-benefit costs of the plan. We further explained that payments from any rate cell must not be expected to cross-subsidize or be cross-subsidized by payments for any other rate cell. In accordance with the existing rule in § 438.6(c)(2)(i), we proposed that all payments under risk contracts be actuarially sound and that the rate for each rate cell be developed and assessed according to generally accepted actuarial principles and practices. See 67 FR 40989, 40998 (discussion of existing rule). We proposed to make this a more explicit standard in the new regulation text in paragraph (b)(4) to eliminate any potential ambiguity and to be consistent with our goal to make the rate setting and rate approval process more transparent. Some states use rate ranges as a tool that allows the submission of one actuarial certification but permits further negotiation with each of the MCOs, PIHPs, and PAHPs within the rate range. We noted that, historically, we have considered any capitation rate paid to a managed care plan that was within the certified range to be actuarially sound regardless of where it fell in the range. Thus, states have not had to submit additional documentation to CMS as long as the final payment rate was within the certified rate range. Additionally, we noted that states have used rate ranges to increase or decrease rates paid to the managed care plans without providing further notification to CMS or the public of the change or certification that the change was based on actual experience incurred by the MCOs, PIHPs, or PAHPs that differed in a material way from the actuarial assumptions and methodologies initially used to develop the capitation rates. We proposed to alter past practices moving forward such that:

- Each individual rate paid to each MCO, PIHP, or PAHP be certified as actuarially sound with enough detail to understand the specific data, assumptions, and methodologies behind that rate.

- States may still use rate ranges to gauge an appropriate range of payments on which to base negotiations, but states would have to ultimately provide certification to CMS of a specific rate for each rate cell, rather than a rate range.

We received the following comments in response to proposed § 438.4(b)(4).

Comment: Some commenters were supportive of the prohibition of rate ranges in § 438.4(b)(4) as an approach that would enhance the transparency and integrity of the rate setting process. Several commenters were opposed to the proposed elimination of rate ranges as it would reduce state flexibility to modify capitation rates during the course of the contract period and would result in an administratively burdensome rate setting process. Some commenters stated that the prohibition may result in the unintended consequence of diminishing a state's ability to implement capitation rate adjustments that support critical funding to providers that serve the Medicaid population or to implement programmatic changes and adjust capitation rates accordingly without the administrative burden associated with the submission a revised rate certification for CMS' review and approval. As an alternative, commenters suggested that CMS permit the certification of rate ranges within a specified range, such as plus or minus 3 to 5 percent from the midpoint. If CMS adopted this provision as proposed, some commenters requested that the requirement be phased in over 3 to 5 years.

Response: We agree with commenters who supported restrictions in the use of rate ranges as a way to further enhance the integrity and transparency of the rate setting process, and to align Medicaid policy more closely with actuarial practices used in setting rates for non-Medicaid health plans. We note that the current use of rate ranges is unique to Medicaid managed care. Other health insurance products that are subject to rate review (for example, QHPs or MA plans) submit and justify a specific premium rate. Although the use of both a specific rate and a rate range is mentioned in section 3.2.1 of the Actuarial Standards Board's ASOP 49, this ASOP was developed to reflect the current practice and regulations. Requirements under law or regulation take precedent over the ASOP.

We believe that once a managed care plan has entered into a contract with the state, any increase in funding for the contract should correspond with something of value in exchange for the increased capitation payments. Our proposal also was based on the concern that some states have used rate ranges to increase capitation rates paid to managed care plans without changing any obligations within the contract or certifying that the increase was based on managed care plans' actual expenses

during the contract period in a way that differed materially from the actuarial assumptions and methodologies initially used to develop the capitation rates. While we appreciate states' need for flexibility, we think there is an important balance to strike between administrative burden related to submitting revised rate certifications for small programmatic changes and upholding the principle that in the contracting process, managed care plans are agreeing to meet obligations under the contract for a fixed amount. Therefore, in this final rule, we will not permit states to certify to a rate range in the rate certification required in § 438.7(a). We do, however, provide some administrative relief as described below with respect to small changes in the capitation rates.

We recognize that the use of rate ranges can provide states greater flexibility to effectuate programmatic changes and adjust capitation rates accordingly without the administrative burden associated with a submission of a revised rate certification for our review and approval. In response to comments about the administrative burden associated with small programmatic changes, we will permit states flexibilities moving forward. First, states may increase or decrease the capitation rate certified per rate cell as required under § 438.4(b)(4) by 1.5 percent, which results in a 3 percent range, without submitting a revised rate certification for CMS review and approval based on our general determination that fluctuation of plus or minus 1.5 percent does not change the actuarial soundness of a capitation rate. We have selected 1.5 percent as the permissible modification because that percentage is generally not more than the risk margin incorporated into most states' rate development process. Some commenters suggested that there should be the flexibility to raise or lower capitation rates 3 to 5 percent without a rate certification. We do not believe that 3 to 5 percent (resulting in a 6 to 10 percent rate range) is a reasonable amount. At 5 percent, the top of the range is almost 11 percent more than the bottom of the range. It is difficult to imagine that both of these capitation rates are actuarially sound, especially when the risk margin is almost always less than 3 percent. Therefore, we are providing the flexibility to raise or lower the certified capitation rate without a revised rate certification, but at the smaller amount of one percent. If the state needs to make an adjustment to the capitation rate per rate cell that exceeds the 1.5 percent rate range, the

state will need to submit a new rate certification supporting that change to CMS for review and approval. We believe that it is reasonable for the capitation rate to be modified a *de minimis* amount and still remain actuarially sound.

The ability for the state to adjust the actuarially sound capitation rate during the rating period within a 1.5 percent range will be finalized at a new paragraph (c)(3) in § 438.7, which governs the requirements for the rate certification. Because the initial rate certification, and any subsequent rate certification, must certify to a capitation rate per rate cell, the proposed regulatory text at § 438.4(b)(4) will be finalized without modification. If a state modifies the capitation rate paid under the contract within that 1.5 percent range from the capitation rate certified in the rate certification, the state will need to ensure that the payment rate in the contract is updated with CMS, as required in § 438.3(c), to reflect the appropriate capitation rate for purposes of claiming FFP. We believe that it is reasonable for the capitation rate to be modified a *de minimis* amount and still remain actuarially sound. We remind commenters that application of a risk adjustment methodology that was approved in the rate certification (§ 438.7(b)(5) and the discussion of risk adjustment in section I.B.3.e) does not require a revised rate certification for our review and approval. However, the payment term in the contract will have to be updated for the same reasons as discussed when adjusting the capitation rates within the one percent rate range.

We believe that this approach, which requires states to certify a specific rate but allows states to increase or decrease the capitation rate certified per rate cell by 1.5 percent, provides the most clarity on the particular assumptions, data, and methodologies used to set capitation rates, and facilitates CMS' review process of rate certifications in accordance with the requirements for actuarial sound capitation rates. The approach also provides states flexibility to make small changes while easing the administrative burden of rate review for both states and CMS. There are other mechanisms in the regulation for states to modify capitation rates when there is a more significant contract change or other valid rationale for an adjustment to the assumptions, data, or methodologies used to develop the capitation rates as specified in §§ 438.5(f) and 438.7(b)(4). In addition, states have other options—such as setting minimum provider payment requirements for a class of providers at § 438.6(c)(1)(iii)—to ensure access to

specified providers. As noted in the compliance date section at the beginning of this final rule, states must come into compliance with this requirement for contracts starting on or after July 1, 2018.

Comment: A few commenters requested clarification on the requirement that payments from any rate cell must not cross-subsidize or be cross-subsidized by payments for any other rate cell under the contract. A commenter requested clarification if this requirement would prohibit blended rate structures. One commenter was concerned that this requirement would limit managed care plans from enhancing the delivery of community-based services.

Response: The prohibition on cross-subsidization among rate cells under the contract is to ensure prudent fiscal management and that the capitation rate for each rate cell is independently actuarially sound. This provision does not require there to be different assumptions for each rate cell and does not prevent the use of the same assumptions across all rate cells (such as trend or age, gender or regional rating). This provision would not prohibit the use of blended rate structures. Blended rate structures are typically used for a rate cell covering individuals that have an institutional level of care and may receive institutional or home and community based services. To address comments specific to the delivery of community-based services, the development of an actuarially sound capitation rate for a rate cell that covers enrollees receiving LTSS under the contract must account for the home and community based services under the contract. We do not believe that the prohibition on cross-subsidization would inhibit the managed care plan's ability to provide home and community based services. The prohibition on cross-subsidization is tied to the FMAP associated with individuals covered under the contract and is not a barrier to incentivizing the delivery of home and community based services. However, for clarity, we believe that the two requirements proposed in § 438.4(b)(4) should be stated separately in the final rule. Therefore, we will finalize the requirement that payments from any rate cell must not cross-subsidize or be cross-subsidized by payments for any other rate cell as a new paragraph § 438.4(b)(5). All subsequent paragraphs in § 438.4(b) will be renumbered accordingly.

After consideration of public comments, we are finalizing § 438.4(b)(4) as proposed but will

finalize § 438.7(c) with an additional paragraph (3) to indicate that states may adjust the capitation rate within a 1.5 percent range without submitting a revised rate certification for CMS' review and approval. This provision also indicates that the payment term of the contract must be updated to reflect such adjustment of the capitation rate to be compliant with § 438.3(c). The requirement that payments from any rate cell must not cross-subsidize or be cross-subsidized by payments for any other rate cell will be finalized as § 438.4(b)(5).

In proposed § 438.4(b)(5), we proposed to redesignate the standard in current § 438.6(c)(1)(i)(C) that an actuary certify that the rate methodology and the final capitation rates are consistent with the standards of this part and generally applicable standards of actuarial practice. We provided that this would require that all components and adjustments of the rate be certified by the actuary. We also restated that for this standard to be met, the individual providing the certification must be within our proposed definition of "actuary" in § 438.2. Proposed § 438.4(b)(5) also incorporated the requirements at § 438.3(c) and (e) to reiterate that the development of actuarially sound capitation rates is based on services covered under the state plan and additional services for compliance with parity standards (§ 438.3(c)) and is not based on additional services that the managed care plan voluntarily provides (§ 438.3(e)(1)).

We received the following comments in response to proposed § 438.4(b)(5).

Comment: We received one comment requesting that CMS clarify that the state's actuary is not certifying the assumptions underlying the rates. Otherwise, this requirement violates ASOP 49 which specifies "the actuary is not certifying that the underlying assumptions supporting the certification are appropriate for an individual MCO."

Response: The requirement in § 438.4(b)(5) is consistent with section 3.1 of ASOP No. 49. An actuary may still certify capitation rates that differ by managed care plan, in which case we would assume that the actuary is certifying the capitation rate per rate cell for each managed care plan. An actuary may still need to consider differences among managed care plans when certifying capitation rates and to determine if one set of capitation rates is appropriate for multiple managed care plans within the state. For example, if a state has two managed care plans and one managed care plan costs twice as much of the other (for any number of

reasons), we would be concerned about the actuarial soundness of those capitation rates if the actuary certified the capitation rates for the lowest cost managed care plan or the average of the two managed care plans.

Comment: One commenter noted that the definition of actuary in § 438.2 suggests that the actuary certifying to the capitation rates in the rate certification submitted to CMS for review and approval is the actuary acting on behalf of the state rather than the managed care plan.

Response: The commenter is correct that the rate certification must be provided by an actuary who is working on behalf of the state. We will not accept a rate certification certified by a managed care plan's actuary.

Comment: One commenter stated that the requirement that the final capitation rates be certified by an actuary is unnecessarily restrictive.

Response: We disagree. Actuarially sound capitation rates are statutory condition for FFP at section 1903(m)(2)(A)(iii) of the Act. The process for developing the capitation rates must be certified by an actuary to ensure the integrity of the rate setting process. This is a longstanding requirement of the statute and regulations governing managed care plans under 42 CFR part 438 and we do not believe it is wise to eliminate it.

Comment: One commenter questioned if it was appropriate for the actuary preparing the rate certification to assume that the CMS reviewer is another actuary.

Response: Yes, the requirements in the rate certification in § 438.7 require a level of detail and documentation so that another actuary can understand and evaluate the application of the rate standards in accordance with generally accepted actuarial principles and practices. Federal review of Medicaid managed care capitation rates will be conducted by actuaries.

After consideration of the public comments, we are finalizing § 438.4(b)(5) as proposed with the following technical modifications: (1) to redesignate this provision as § 438.4(b)(6); and (2) to refine the reference to § 438.3(c) to § 438.3(c)(1)(ii) (pertaining to the types of services that the final capitation rates must be based upon) as the other requirements in § 438.3(c) are not subject to the actuary's certification.

As proposed, § 438.4(b)(6) incorporated the special contract provisions related to payment proposed in § 438.6 if such provisions were applied under the contract. In § 438.6, we proposed to address requirements

for risk-sharing mechanisms, incentive arrangements, withhold arrangements, and delivery system and provider payment initiatives under MCO, PIHP, or PAHP contracts. Comments received on § 438.6 and considerations for rate setting are addressed in response to comments received on § 438.6 generally.

We received no comments on § 438.4(b)(6) itself (that is, separate from comments about § 438.6) and we will finalize § 438.4(b)(6) as proposed but will redesignate the provision as § 438.4(b)(7). We discuss § 438.6 in section I.B.3.d.

Section 438.4(b)(7) incorporated the documentation standards for the rate certification proposed in § 438.7. We explained that for us to assess the actuarial soundness of capitation rates, the data, methodologies, and assumptions applied by the actuary must be sufficiently and transparently documented. We also explained that clear documentation would support the goal of instituting a meaningful and uniformly applied rate review and approval process and would streamline the process for both states and CMS.

We received no comments on § 438.4(b)(7) itself (that is, separate from comments about § 438.7) and we will finalize § 438.4(b)(7) as proposed but will redesignate the provision as paragraph § 438.4(b)(8). We discuss § 438.7 in section I.B.3.e.

In § 438.4(b)(8), we proposed to include a new standard that actuarially sound capitation rates for MCOs, PIHPs, and PAHPs must be developed so that MCOs, PIHPs, and PAHPs can reasonably achieve a minimum MLR of at least 85 percent, and if higher, a MLR that provides for reasonable administrative costs when using the calculation defined in proposed § 438.8. We explained that states could establish standards that use or require a higher MLR target—for rate development purposes, as a minimum MLR requirement for managed care plans to meet, or both—but that the MLR must be calculated in accordance with § 438.8. We noted that this minimum 85 percent standard, which is consistent with MLR standards for both private large group plans and MA organizations, balances the goal of ensuring enrollees are provided appropriate services while also ensuring a cost effective delivery system. As a result of this standard, the MLR reports from MCOs, PIHPs, and PAHPs would be integral sources of data for rate setting. For instance, states that discover, through the MLR reporting under proposed § 438.8(k), that an MCO, PIHP, or PAHP has not met an MLR standard of at least 85 percent would need to take this into account and

include adjustments in future year rate development. All such adjustments would need to comply with all standards for adjustments in § 438.5(f) and § 438.7(b)(4).

We received the following comments in response to our proposal at § 438.4(b)(8).

Comment: Several commenters were supportive of 85 percent as the MLR standard for rate setting purposes while others provided that states should be able to set their own MLR threshold. Other commenters requested that CMS establish an upper limit on the MLR.

Response: In the interest of establishing a national floor for Medicaid managed care plan MLRs, we will not permit states to establish an MLR that is less than 85 percent. We decline to establish an upper limit on the MLR that may be imposed by the state as appropriate higher MLR standards may depend on the particular managed care program. Therefore, we will finalize the language in § 438.4(b)(8) specifying that an MLR threshold higher than 85 percent must result in capitation rates that are adequate for reasonable, appropriate, and attainable administrative costs in accordance with § 438.5(e) (a conforming change, discussed in the comments and responses to § 438.5(e), is made to the regulatory text of § 438.5(e) for consistency with the definition of actuarially sound capitation rates under § 438.4(a)). For consistency with the language used in § 438.5(e), we will strike “necessary” and insert “adequate,” and replace “administrative costs” with “non-claim costs” so that the phrase reads “capitation rates are adequate for reasonable, appropriate, and attainable non-claim costs” in the final rule at § 438.4(b)(8).

Comment: One commenter requested that we clarify that the actuary should be able to take into consideration the MLR for all managed care plans’ experience in a geographic rating area.

Response: Recognizing that many states do not set capitation rates on an individual managed care plan level, it is permissible for the actuary to consider the MLR experience of managed care plans in the same rating area in the aggregate when developing the capitation rates for all such managed care plans.

Comment: A commenter noted that since the first reporting year would coincide with the first contract year subject to the provisions of the final rule, past MLR experience data would not be available to apply the requirement in § 438.4(b)(8).

Response: Section 438.4(b)(8) requires that capitation rates be developed in a

way that the MCO, PIHP or PAHP would reasonably achieve a MLR, as calculated under § 438.8, of at least 85 percent for the rate year. The actual MLR experience is not required to create this projection for the first year.

However, once the MLR reports are received by the state from the managed care plans—see § 438.8(k)(2)—§ 438.74(a) requires the state to submit a summary description of the reports with the rate certification. The reported MLR experience, once available, would inform the projection required in § 438.4(b)(8) for later rating periods.

Comment: A commenter requested clarification that capitation rates must be actuarially sound if the state establishes an MLR threshold above 85 percent.

Response: We clarify that capitation rates that are subject to an MLR threshold above 85 percent must meet the requirements for actuarially sound capitation rates established in this part.

Comment: One commenter requested we clarify that the consideration of the MLR in the rate setting process should not create a requirement to raise or lower capitation rates.

Response: We disagree with the commenter. The consideration of a projected MLR—based on the assumptions underlying the rate setting process—may result in increases or decreases to the capitation rate to reach a projected MLR of at least 85 percent. The consideration of the actual MLR experience of the contracted managed care plans may necessitate a modification to capitation rates for future rating periods. To suggest otherwise in regulation would diminish the utility of requiring managed care plans to calculate and report an MLR and require states to take that experience into account in the rate setting process.

After consideration of the public comments, we are finalizing § 438.4(b)(8) with a modification to use the standard “appropriate and reasonable” to modify “non-benefit costs”, which was inserted in place of “administrative costs”, for consistency with § 438.5(e). We will also redesignate this provision as paragraph § 438.4(b)(9).

c. Rate Development Standards (§ 438.5)

We proposed § 438.5 as a list of required steps and standards for the development of actuarially sound capitation rates. We discuss each paragraph of § 438.5 below in more detail; we received the following comments on proposed § 438.5 generally.

Comment: We received many comments of support for the proposed provisions in § 438.5. Commenters believed that the proposed provisions added much needed specificity to the processes and procedures that will bring consistency, accountability, and transparency to rate setting. A few commenters stated that proposed § 438.5 was too prescriptive and could restrict the normal actuarial functions and payment innovation. One commenter believed that CMS should align its rate development standards with NAIC.

Response: We appreciate commenters support for the rate development standards in proposed § 438.5. We disagree that the standards set forth are too prescriptive as the standards are derived from generally accepted actuarial principles and practices, support payment innovation (for example, § 438.6(c)(1)), and provide clarity as to our expectations for the development and documentation (as specified in § 438.7) of actuarially sound capitation rates. We decline to align with rate development standards published by the NAIC as we maintain that there are unique considerations for the development of capitation rates in the Medicaid program and that it is appropriate for us to set forth Medicaid-specific standards for the development of actuarially sound capitation rates that are eligible for FFP.

Comment: Several commenters requested that the regulatory text throughout §§ 438.5 and 438.7 use “appropriate” rather than “sufficient” or “adequate” out of concern that the latter two terms were too subjective.

Response: We disagree with commenters that the terms “sufficient” or “adequate” are too subjective and that the term “appropriate” should be used in their place. According to the Merriam-Webster dictionary (accessed online), the simple definition of “adequate” is sufficient for a specific requirement or of a quality that is good or acceptable. At the same source, the word “appropriate” is defined as especially suitable or compatible or fitting, which implies association to a particular situation. Due to these distinctions, we maintain that the use of “appropriate” in § 438.5 related to rate standards is accurate as it describes the rate development standards for a particular Medicaid program. However, § 438.7 describes the level of documentation in the rate certification to support the rate development standards which is not associated with the characteristics of a particular Medicaid program. For that reason, § 438.7 will be finalized with use of the

adverb “adequately” in place of “sufficient” so that the phrase reads adequately described with enough detail.

In § 438.5(a), we proposed to establish definitions for certain terms used in the standards for rate development and documentation in the rate certification in § 438.7(b). We proposed to add definitions for “budget neutral,” “prospective risk adjustment,” “retroactive risk adjustment,” and “risk adjustment.”

We proposed to define “budget neutral” in accordance with the generally accepted usage of the term as applied to risk sharing mechanisms, as meaning no aggregate gain or loss across the total payments made to all managed care plans under contract with the state.

We received the following comments on the proposed definition for “budget neutral.”

Comment: We received a couple of comments on the definition of “budget neutral” in § 438.5(a). The commenter believed that to be consistent with the prospective nature of the rate development process, CMS should include “. . . and does not create an expected net aggregate gain or loss across all payments” to the definition for “budget neutral.”

Response: The “budget neutral” requirement in § 438.5(g) and as defined at § 438.5(a) only applies to the application of risk adjustment. The distinction between prospective and retrospective risk adjustment is based on the data source used to develop the risk adjustment model. The application of the risk adjustment methodology cannot result in a net aggregate gain or loss across all payments. If a state uses prospective risk adjustment—that is, they are applying risk adjustment to the capitation rates initially paid and do not reconcile based on actual enrollment or experience—the application of the risk adjustment methodology is expected, but not certain, to be budget neutral and is consistent with the regulatory requirement. We would not require a state conduct a reconciliation under a prospective risk adjustment approach.

However, we do believe that additional clarification to the definition for “budget neutral” is warranted in respect to the payments for which there can be no net aggregate gain or loss. The payments are the capitation payments subject to risk adjustment made to all managed care plans under contract for the particular managed care program. This clarification to reference “managed care program” in the regulatory text is to recognize that states may have more than one Medicaid managed care program—for example physical health

and behavior health—and a risk adjustment applied to behavioral health contracts would not impact the physical health program.

After consideration of public comments, we are finalizing the definition of “budget neutral” with modifications to clarify the payments considered when determining that no net gain or loss results from the application of the risk adjustment methodology.

We proposed to define “risk adjustment” as a methodology to account for health status of enrollees covered under the managed care contract. We proposed that the definitions for “prospective risk adjustment” and “retrospective risk adjustment” clarify when the risk adjustment methodology is applied to the capitation rates under the contract.

We received the following comment on the proposed definition for “risk adjustment.”

Comment: We received one comment on the proposed definition for “risk adjustment” at § 438.5(a). The commenter suggested that for consistency with ASOP No. 49, the definition of “risk adjustment” should be revised to clarify that the health status of enrollees is determined via relative risk factors.

Response: We agree with the commenter about the appropriate definition for “risk adjustment” and will finalize the definition for “risk adjustment” in § 438.5(a) with a reference to relative risk factors.

After consideration of public comments, we are finalizing the definition of “risk adjustment” with additional text that specifies that risk adjustment determines the health status of enrollees via relative risk factors. In addition, we will finalize § 438.5(a) with a technical edit to the introductory text at § 438.5(a) to specify that the defined terms apply to § 438.5 and § 438.7(b).

We did not receive comments on proposed definitions for “prospective risk adjustment” or “retrospective risk adjustment” and will finalize those definitions without modification.

In § 438.5(b), we set forth the steps a state, acting through its actuary, would have to follow when establishing Medicaid managed care capitation rates. The proposed standards were based on furthering the goals of transparency, fiscal stewardship, and beneficiary access to care. We explained that setting clear standards and expectations for rate development would support managed care systems that can operate efficiently, effectively, and with a high degree of fiscal integrity.

We based these steps on our understanding of how actuaries approach rate setting with modifications to accommodate what actuarial soundness should include in the context of Medicaid managed care. We solicited comment on whether additional or alternative steps were more appropriate to meet the stated goals for establishing standards for rate setting. While we do not require for these steps to be followed in the order listed in this final rule, we proposed that the rate setting process include each step and follow the standards for each step. States would have to explain why any one of the steps was not followed or was not applicable. The six steps included:

- Collect or develop appropriate base data from historical experience;
- Develop and apply appropriate and reasonable trends to project benefit costs in the rating period, including trends in utilization and prices of benefits;
- Develop appropriate and reasonable projected costs for non-benefit costs in the rating period as part of the capitation rate;
- Make appropriate and reasonable adjustments to the historical data, projected trends, or other rate components as necessary to establish actuarially sound rates;
- Consider historical and projected MLR of the MCO, PIHP, or PAHP; and
- For programs that use a risk adjustment process, select an appropriate risk adjustment methodology, apply it in a budget neutral manner, and calculate adjustments to plan payments as necessary.

We discuss each step within § 438.5(b) below and received the following comments on proposed § 438.5(b) generally.

Comment: We received one comment on the order of the steps proposed in § 438.5(b). The commenter believed that the order in which they are presented may not align with all the variations that exist today. For example, Step 4 (adjustments for benefit, program and other changes) may be performed before trend. The commenter requested that CMS clarify in the regulation text if CMS anticipates requiring a specific order of adjustments or if states and actuaries will have flexibility with the capitation rate setting order of adjustments.

Response: At 80 FR 31121 and as restated above, we do not intend for the steps in § 438.5(b) to be followed in the order as presented in the regulation; however, the state would need to apply each step or explain why a particular step was not applicable. For clarity on that point, we will finalize introductory

text at § 438.5(b) that acknowledges that the order of the steps in the regulation text is not required; specifically, we will finalize regulation text that requires the steps to be followed “in an appropriate order.” The actuary may use his or her judgment as to the order that is appropriate for the particular rate setting, but must complete each step or explain why the step is not applicable.

After consideration of public comments, we are finalizing the introductory text in § 438.5(b) with changes to clarify that the steps in paragraph (b) have to be performed in an appropriate order.

We did not receive comments on proposed § 438.5(b)(1), pertaining to the identification and development of the base utilization and price data as specified in paragraph (c) of this section, and will finalize without modification.

We received the following comment on proposed § 438.5(b)(2) that cross-referenced the requirements for trend in paragraph (d) of this section.

Comment: We received one comment requesting clarification if proposed § 438.5(b)(2) means that a state would have to develop separate trend for cost and utilization and then apply them to their respective components of the base rate.

Response: We appreciate the commenter raising this point for clarification. The provision at § 438.5(b)(2) would not require the development of separate trends for cost and utilization and it would be permissible for the actuary to apply a trend that captures both cost and utilization. Note that this is consistent with section 3.2.9 of ASOP No. 49, which provides that the actuary should include appropriate adjustments for trend and may consider a number of elements in establishing trends in utilization, unit costs, or in total.” See http://www.actuarialstandardsboard.org/wp-content/uploads/2015/03/asop049_179.pdf. This provision acknowledges that the development of trend factors may encompass a number of considerations related to the actual experience of the Medicaid managed care program and that cost and utilization must be considered. Note that § 438.7(b)(2) sets forth the documentation requirements for each trend.

After consideration of public comments, we are finalizing § 438.5(b)(2) as proposed without modification.

We received the following comments on proposed § 438.5(b)(3) that cross-referenced the requirements for the non-

benefit component of the capitation rate in paragraph (e) of this section.

Comment: We received a few comments on the wording of proposed § 438.5(b)(3). The commenters stated concern regarding the word “or” since all of the components listed must be included in capitation rates. The commenter recommended changing “. . . cost of capital; or other operational costs . . .” to “cost of capital; and other operational costs.”

Response: We agree with the commenter and have also made a corresponding change to § 438.5(e).

Comment: One commenter believed that the term “risk margin” is a more appropriate term than “profit margin” in proposed § 438.5(b)(3). The commenter also requested clarification as to whether § 438.5(b)(3) would require the state to include an explicit provision for each of the non-benefit items listed in the section or if it would be acceptable to combine several of the items into a single rating factor. For example, the provision for contribution to reserves, profit margin, and cost of capital could be included in risk margin.

Response: We agree with the commenter’s suggestion that “risk margin” is a more appropriate term than “profit margin” because profit could be a subset of the risk margin for the non-benefit component of the capitation rate. We will finalize § 438.5(b)(3) using the term “risk margin.” To address the commenter’s question about the level of documentation required for the development of the non-benefit component, § 438.7(b)(3) provides that the development of the non-benefit component of the capitation rate must be adequately described with enough detail so that CMS or an actuary applying generally accepted actuarial principles and practices can identify each type of non-benefit expense and evaluate the reasonableness of the cost assumptions underlying each expense. Sections 438.5(b)(3) and (e) list the following types of non-benefit expenses: Administration; taxes, licensing and regulatory fees; contribution to reserves; risk margin; cost of capital; and other operational costs. While the documentation of the non-benefit component cannot combine all of these items into a single rating factor, it would be permissible for the actuary to document the non-benefit costs in groupings, for example: Administration; taxes, licensing and regulatory fees; contribution to reserves, risk margin, cost of capital, and other operational costs.

After consideration of public comments, we are finalizing

§ 438.5(b)(3) with modifications. The revisions are: (1) To use “risk margin” rather than “profit margin”; and (2) to use “and other operational costs” to clarify that all listed categories of non-benefit costs must be included in the development of actuarially sound capitation rates.

We received the following comment on proposed § 438.5(b)(4) that cross-referenced the requirements for adjustments in paragraph (f) of this section.

Comment: We received a few comments on proposed §§ 438.5(b)(4) and 438.7(b)(4) (as the latter describes the documentation necessary for adjustments in the rate certification), requesting confirmation that all adjustments including, but not limited to, those in ASOP No. 49 and the CMS Rate Setting Checklist continue to be valid under the proposed rule as part of generally accepted actuarial principles and practices.

Response: We maintain that the requirements for developing and documenting adjustments are consistent with the practice standards in ASOP No. 49. We restate that every component of the rate setting process is based on generally accepted actuarial principles and practices. As stated in other forums, the CMS Ratesetting Checklist is an internal tool for CMS’ use when reviewing rate certifications. The applicability or need to update that tool based on changes in these regulations is outside the scope of this rule. States, their actuaries, and managed care plans should rely on the regulatory requirements related to rate setting in §§ 438.4–438.7, and consistent with all other provisions in this part, when developing capitation rates and other formal rate development guidance published by CMS (for example, 2016 Medicaid Managed Care Rate Development Guide available at <https://www.medicaid.gov/medicaid-chip-program-information/by-topics/delivery-systems/managed-care/downloads/2016-medicaid-rate-guide.pdf>).

After consideration of public comments, we are finalizing § 438.5(b)(4) as proposed.

We received the following comments on proposed § 438.5(b)(5) that incorporated the requirement to take a managed care plan’s past MLR into account.

Comment: We received a few comments requesting clarification on how proposed § 438.5(b)(5) can be met. Commenters stated that it is common practice to review the historical and emerging financial experience of both the individual managed care plan and

for the program as a whole, but rarely, if ever, is a specific adjustment made in the capitation rate setting process to adjust for the MLR observed or emerging. Commenters provided that historical MLR data will not reflect more recent changes to programs and capitation rates that would bring expected experience in line with capitation rate development assumptions. One commenter believed that CMS will not need to consider historical MLR experience because of the use of the historical cost experience trended forward to develop revenue requirements and that 2 years to correct any issues seems reasonable for corrections.

Response: The requirement in § 438.5(b)(5) is that the managed care plans’ MLR experience is one of the many considerations taken into account in the development of actuarially sound capitation rates. An MLR below 85 percent, or that is substantially higher than expected, will likely be part of our review and we would expect the actuary to explain how the MLR experience was taken into account in the development of the capitation rates. In addition, there is specific information from the MLR reports, such as activities that improve health care quality, that could be important for future rate setting purposes and which would not be reflected in base data sources based on service delivery.

Comment: One commenter noted that proposed § 438.5(b)(5) referred to “§ 438.4(b)(7)” when the intended cite should be § 438.4(b)(8).

Response: We appreciate the commenter bringing this error to our attention. Section 438.4(b)(8) is the correct cross-reference and we will make that correction in the final rule.

After consideration of public comments, we are finalizing § 438.5(b)(5) with a modification to correct the cross-reference to § 438.4(b)(9) for consistency with redesignation of paragraphs in § 438.4(b) discussed above.

We received the following comments on proposed § 438.5(b)(6) that cross-referenced the requirements for risk adjustment in paragraph (g) of this section.

Comment: We received a few comments requesting that proposed § 438.5(b)(6) be revised to reflect that step 6 relating to risk adjustment is only applicable if the state is choosing to risk adjust the rates. The commenters believed this would make the provision more accurate since risk adjustment is not required.

Response: We agree with the commenters’ suggestion and have

modified § 438.5(b)(6) to clarify that this step is applicable if a risk adjustment methodology is applied.

After consideration of public comments, we are finalizing § 438.5(b)(6) to limit application of the budget neutral requirement for risk adjustment to the managed care programs within a state to which risk adjustment is applied.

In § 438.5(c), we proposed standards for selection of appropriate base data. In paragraph (c)(1), we proposed that, for purposes of rate setting, states provide to the actuary Medicaid-specific data such as validated encounter data, FFS data (if applicable), and audited financial reports for the 3 most recent years completed prior to the rating period under development. In § 438.5(c)(2), we proposed that the actuary exercise professional judgment to determine which data is appropriate after examination of all data sources provided by the state, setting a minimum parameter that such data be derived from the Medicaid population or derived from a similar population and adjusted as necessary to make the utilization and cost data comparable to the Medicaid population for which the rates are being developed. We proposed that the data that the actuary uses must be from the 3 most recent years that have been completed prior to the rating period for which rates are being developed. For example, for rate setting activities in 2016 for CY 2017, the data used must at least include data from calendar year 2013 and later. We noted that while claims may not be finalized for 2015, we would expect the actuary to make appropriate and reasonable judgments as to whether 2013 or 2014 data, which would be complete, must account for a greater percentage of the base data set. We used a calendar year for ease of reference in the example, but a calendar year is interchangeable with the state’s contracting cycle period (for example, state fiscal year). We also noted that there may be reasons why older data would be necessary to inform certain trends or historical experience containing data anomalies, but the primary source of utilization and price data should be no older than the most recently completed 3 years. Noting that states may not be able to meet the standard in proposed paragraph (c)(2) for reasons such as a need to transition into these new standards or for an unforeseen circumstance where data meeting the proposed standard is not available, we proposed an exception in the regulation to accommodate such circumstances. We proposed, in § 438.5(c)(3)(i) and (ii), that the state may request an exception to the

provision in paragraph (c)(2) that the basis of the data be no older than from the 3 most recent and complete years prior to the rating period provided that the state submits a description of why an exception is needed and a corrective action plan with the exception request that details how the problems will be resolved in no more than 2 years after the rating period in which the deficiency was discovered, as proposed in § 438.5(c)(3)(ii). We stated that 2 years was enough time for states to work with their contracted managed care plans or repair internal systems to correct any issues that impede the collection and analysis of recent data. We requested comment on this proposed standard and our assumption about the length of time to address data concerns that would prevent a state from complying with our proposed standard.

We received the following comments in response to proposed § 438.5(c).

Comment: We received many comments on the proposed provision § 438.5(c)(1) requiring the use of data from “at least the last 3 most recent and complete years.” Many commenters believed that generally accepted actuarial principles and practices typically would allow for use of only 1 to 2 years of data and that time periods greater than that may add prohibitive cost. Commenters recommended that, rather than the requirements we proposed, the base data should be determined via actuarial judgment, consistent with ASOP No. 49, in consultation with the state. We received one comment recommending that CMS limit the base data for developing the managed care plans’ capitation rates to the most recent and complete 3 years prior to the rating period as older data may incorporate assumptions and experience that are no longer applicable.

Response: The requirement in § 438.5(c)(1) is that the state provide the actuary with the listed sources of base data for at least the 3 most recent and complete years prior to the rating period. As discussed at 80 FR 31121, we provided that the actuary would exercise professional judgment to determine which data is appropriate after examination of all data sources provided by the state. At § 438.5(c)(2), the actuary must use the most appropriate base data from that provided by the state and the basis of the data must be no older than from the 3 most recent and complete rating periods. The actuary would not be required to use base data from the rating period 3 years prior to the rating period for which capitation rates are being developed; however, base data from that

rating period may be necessary to inform certain trends or historical experience containing data anomalies.

Comment: We received many comments on the proposed provision in § 438.5(c)(1) requiring the use of audited financial reports. Commenters recommended that the base data requirements in § 438.5(c) be expanded to include unaudited managed care plan experience reports. Some commenters stated that there should be options for using alternative CEO/CFO certified reports, or utilization of reports done on a statutory accounting basis because requiring GAAP audited financial reports will increase costs for managed care plans, which will result in higher costs for states and CMS, but may have only limited additional value. Commenters stated that states would be unable to take advantage of unaudited, but more recent, restated financial data typically collected by states 3 months after the close of each calendar year and that using the most recent data increases the relevance and reliability of assumptions underlying final payment rates.

Response: We maintain that audited financial reports are an important source of base data for the purposes of rate setting and this final rule includes the annual submission of audited financial reports as a standard contract provision at § 438.3(m). The requirement at § 438.5(c)(1) would not prohibit the actuary from also relying on more recent unaudited financial reports if such information is useful in the rate setting process, but such data does not supplant the inclusion of audited financial reports. We view § 438.5(c)(1) as setting the minimum scope of base data that must be provided to the state’s actuaries engaged in rate setting; it does not prohibit the provision or use of additional data (subject to paragraphs (c)(2) and (c)(3)).

Comment: We received a few comments on the use of FFS data as proposed in § 438.5(c)(1). Commenters believed that CMS should modify this section to not only allow that base data may vary from the traditional FFS type model, but that promotes the use of alternative payment methods which may not fall into the proposed base data requirements. Another commenter stated that as managed care grows, FFS data becomes less available and less reliable as a benchmark for establishing capitation rates and may not truly reflect the health status of, and spending for, individuals in managed care plans.

Other commenters requested that CMS require states to consider market rates in MA, CHIP, and the private

market when developing the capitation rates.

Response: We agree that FFS may not be the most reliable or relevant source of base data, especially for mature managed care programs. Note that at § 438.5(c)(1) modifies FFS data with “as appropriate” to recognize that such data may not be a reasonable data source in all circumstances; however, such data would likely be relevant when a new population transitions to a managed care program. We believe that encounter data and audited financial reports would be appropriate sources of base data under managed care contracts that use value-based purchasing.

Regarding the commenters that requested that CMS require states to consider market rates in other coverage options when developing capitation rates, it would not be appropriate for us to do so. The relevant base data must be based on the Medicaid population, or if such data is not available, the base data must be derived from a similar population and adjusted to make the utilization and price data comparable to data from the Medicaid population.

Comment: We received many comments on the exceptions process proposed in § 438.5(c)(3). Several commenters believed that changes should be made to proposed § 438.5(c)(2) (as discussed above) to prevent states from needing exceptions. One commenter requested that the exception and explanation be contained within the actuarial certification documentation if the actuary is the originator of the exception request. The commenter stated that it will often be the opinion and request of the actuary to modify the base data used in the capitation rate development process. We received one comment recommending that proposed § 438.5(c)(3) be eliminated and that no exceptions be permitted.

Response: We maintain that it is appropriate to permit an exceptions process to the base data requirement. The request for an exception with a supporting explanation may be contained within the rate certification if the actuary is the originator of the exception request.

Comment: We received several comments on proposed § 438.5(c)(3)(ii) stating that 2 years is not sufficient time for corrective action. One commenter believed that 2 years is generally insufficient for new populations and that the requirement should be revised to a 3-year term with an opportunity for extensions on a case-by-case basis. One commenter recommended that more detail be added to § 438.5(c)(3)(ii) to reflect the review, approval, and

monitoring processes for the corrective action plans.

Response: We disagree that a 2 year corrective action plan is insufficient time to remedy base data issues. It is not clear why commenters suggested that compliance with the base data requirements for new populations would require more time. Section 438.5(c)(1) requires states to use validated encounter data, FFS data (as appropriate), and audited financial reports. Managed care plans are required to submit encounter data in accordance with § 438.242 and FFP is conditioned on the state's submission of validated encounter data in § 438.818. Audited financial reports must be submitted by the managed care plans on an annual basis per § 438.3(m). The regulations would permit the state to rely on FFS data or data for similar populations that is adjusted to reflect the Medicaid population when new populations are added to a managed care program. We will consider providing additional detail on the review and approval of the exceptions process to the base data requirements in subregulatory guidance.

After consideration of public comments, we are finalizing § 438.5(c) as proposed.

Section 438.5(d) addressed standards for trend factors in setting rates. Specifically, we proposed that trend factors be reasonable and developed in accordance with generally accepted actuarial principles and practices. We also stipulated that trend factors be developed based on actual experience from the same or similar populations. We proposed specific standards for the documentation of trend factors in proposed § 438.7(b)(2). We requested comment on whether we should establish additional parameters and standards in this area.

Comment: We received a number of comments on proposed § 438.5(d). Most of the commenters recommended that CMS not limit or restrict the data and information sources used in trend development. The commenters acknowledged that actual experience from the Medicaid, or a similar population, should be the primary source of trend data and information, but that generally accepted actuarial practices and principles do not limit or restrict the data and information sources used in trend development. Prospective trends may, and often do, differ materially from historical experience trends, whether or not it is from the Medicaid population or a similar population. Commenters recommended that CMS include language in the final rule referencing other appropriate and

relevant data, other information sources, and professional judgment to aid in the development of prospective trends to be consistent with current practices and principles. Another commenter suggested that some flexibility should be provided for trend when new, innovative payment models are being implemented. Additionally, if trend is always tied to actual experience, it provides an incentive over the long-run to use more services, or services at a higher cost to push trend higher.

Response: The trend should be a projection of future costs for the covered population and services. It should be based on what the actuary expects for that covered population and historical experience is an important consideration. That said, we agree that it is not the only source the actuary may consider and there are instances when historical experience may not be relevant or the sole source for the development of trend. As proposed, § 438.5(d) provided that trend must be developed from the Medicaid population or a similar population. We did not intend this requirement to prohibit the actuary from using national projections for other payer trends in addition to sources derived from the Medicaid population or similar populations.

However, general trends unassociated with the Medicaid population or similar populations cannot be the sole or primary source of information to develop the trends. To clarify this distinction, address the comment, and to better reflect our intent that other sources of data may be used to set trend, we will finalize § 438.5(d) with additional text. Trend must be developed primarily from actual experience of the Medicaid population or from a similar population. The trend should be a projection of future costs for the covered population and services. It should be based on what the actuary expects for that population, and historical experience is an important consideration. Actual experience must be one consideration for developing trend and the actuary must compare the experience to projected trends.

After consideration of public comments, we are finalizing § 438.5(d) with modification to provide that trend must be developed primarily from actual experience of the Medicaid population or from a similar population.

Paragraph (e) established standards for developing the non-benefit component of the capitation rate, which included expenses related to administration, taxes, licensing and regulatory fees, reserve contributions, profit margin, cost of capital, and other

operational costs. We explained in preamble that the only non-benefit costs that may be recognized and used for this purpose are those associated with the MCO's, PIHP's, or PAHP's provision of state plan services to Medicaid enrollees; the proposed regulation text provided for the development of non-benefit costs "consistent with § 438.3(c)," thus incorporating the authority to include costs related to administration of additional benefits necessary for compliance with mental health parity standards reflected in subpart K of part 438.

We received the following comments on the non-benefit component rate standard proposed § 438.5(e).

Comment: Several commenters recommended that CMS consider revising the final rule regarding the non-benefit components of the rate to state that such rate component should be "reasonable, appropriate, and attainable" consistent with the definition of actuarially sound capitation rates.

Response: We agree with commenters that the non-benefit expenses in § 438.5(e) should be modified by "reasonable, appropriate, and attainable" rather than "appropriate and reasonable" for consistency with the definition of actuarially sound capitation rates in § 438.4(a). The definition of actuarially sound capitation rates explains that such capitation rates are a projection of all "reasonable, appropriate, and attainable" costs that are required under the terms of the contract and for the operation of the MCO, PIHP or PAHP for the time period and populations covered under the contract, and such costs are comprised of benefit and non-benefit components. Therefore, it is appropriate to use "reasonable, appropriate, and attainable" in § 438.5(e).

Comment: Several commenters requested clarification that the non-benefit component of the capitation rate is not required to be completed at the rate cell level; rather, it would be appropriate to develop these costs across the managed care program.

Response: We clarify here that the development of the non-benefit component may be developed at the aggregate level and incorporated at the rate cell level.

Comment: One commenter requested that CMS clarify if medical management could be included in the non-benefit component proposed in § 438.5(e) while another requested if corporate overhead could be included. Another commenter recommended that there be consistency for accounting and the rate setting

process, and that “non-benefit, health care related expenses” be allowed separate from administration, taxes, licensing and regulatory fees to account for services for integrated mental health treatment plans (required under mental health parity), and activities that support health care quality and care coordination.

Response: Each of the expenses highlighted by commenters would fall under the “other operational costs” category for the non-benefit component of the capitation rate.

Comment: Several commenters requested that CMS clarify that the Health Insurance Provider Fee established by section 9010 of the Affordable Care Act would be included in this definition and to address the non-deductibility of that fee. Commenters recommended that the final rule specify that these components should be included in rates in a timely manner to when Medicaid managed care plans incur these costs.

Response: The Health Insurance Providers Fee established by section 9010 of the Affordable Care Act is a regulatory fee that should be accounted for in the non-benefit component of the capitation rate as provided at § 438.5(e). Our previous guidance on the Health Insurer Fee issued in October 2014 acknowledged that the non-deductibility of the fee may be taken into account when developing the non-benefit component of the capitation rate. See <http://www.medicaid.gov/Federal-Policy-Guidance/Downloads/FAQ-10-06-2014.pdf>. That guidance also explained that the state could take the Health Insurer Providers Fee into account during the data or fee year. We decline to set forth explicit rules for the Health Insurance Providers Fee in this regulation as the existing guidance remains available.

Comment: We received a few comments on proposed § 438.5(e) in relation to MLR in § 438.8. When § 438.5(e) is viewed in conjunction with the MLR requirement, commenters stated that CMS’ intent was not clear. The commenters believed that § 438.5(e) was consistent with CMS’ 2016 Rate Setting Guidance, which recommends developing PMPM cost estimates for many of these components. However, if the development of the non-benefit component of the capitation rate is based on reasonable, appropriate, and attainable expenses and the managed care plans have an MLR of less than 85 percent, commenters questioned whether the rate standards or the MLR standards would control. The commenters requested that CMS clarify

the relationship between these requirements.

Response: We interpret the commenters’ concern to be that the requirement that the non-benefit component of the capitation rate is developed based on reasonable, appropriate, and attainable expenses consistent with § 438.5(e) may still result in a managed care plan with an MLR experience of less than 85 percent. In other words, we believe that the commenter is asking whether the actuarial soundness of the capitation rate could be impacted or called into question if a managed care plan’s MLR experience was less than 85 percent. In our view, actuarial soundness is a prospective process that anticipates the reasonable, appropriate, and attainable costs under the managed care contract for the rating period whereas MLR is a retrospective tool to assess whether capitation rates were appropriately set and to inform the rate setting process going forward. As provided in § 438.5(b)(5), the MLR experience of contracted managed care plans is one consideration among many in the development of actuarially sound capitation rates.

After consideration of public comments, we are finalizing § 438.5(e) with a revision to require that non-benefit costs must be reasonable, appropriate, and attainable for consistency with the definition of actuarially sound capitation rates § 438.4(a). As noted above, we are also finalizing § 438.5(e) with three changes: (1) Using “and other operational costs” to clarify that all listed categories of non-benefit costs must be included in the development of actuarially sound capitation rates; (2) using “risk margin” instead of “profit margin”; and (3) specifying that the non-benefit expenses must be associated with the provision of services identified in § 438.3(c)(1)(ii) to the populations covered under the contract in place of the cross-reference to § 438.3(c) for increased clarity in the regulatory text.

In paragraph (f), we proposed to address adjustments and explained that adjustments are important for rate development and may be applied at almost any point in the rate development process. We noted that most adjustments applied to Medicaid capitation rate development would reasonably support the development of accurate data sets for purposes of rate setting, address appropriate programmatic changes, the health status of the enrolled population, or reflect non-benefit costs. For additional discussion on acuity adjustments to account for the health status of the

enrolled population, refer to the content on risk adjustment in section I.B.3.e of the proposed rule (80 FR 31126). We considered identifying specific adjustments we find permissible in the regulations instead of requiring additional justification, but we noted that such an approach might foreclose the use of reasonable adjustments.

We received the following comment on proposed § 438.5(f) relating to adjustments.

Comment: The commenter believed that while acuity adjustments are invaluable for managed care plans, the acuity adjustments specified in this proposal would not allow for different types of adjustments. The commenter encouraged CMS to adopt flexibility in its definition of acuity adjustments to account for additional challenges, including risk exposure from the movement of complex populations to managed care, or the impact of high cost drug utilization.

Response: The discussion of acuity adjustments in relation to risk adjustment was to clarify which approaches would fall under the respective rate development standards. Acuity adjustments fall under the categories of permissible adjustments specified in § 438.5(f). In addition, we maintain that the standard in paragraph (f)—adjustments developed in accordance with generally accepted actuarial principles and practices that address the development of an accurate base data set, address appropriate programmatic changes, and reflect the health status of the enrolled population—is sufficiently broad to permit the actuary to apply adjustments to address complex populations or the impact of high cost drug utilization in the development of actuarially sound capitation rates.

After consideration of public comments, we are finalizing § 438.5(f) with a modification to insert the word “reflect” before “the health status of the enrolled population” to improve clarity of the regulatory text.

In paragraph (g), we proposed to set forth standards for risk adjustment. In general, risk adjustment is a methodology to account for the health status of enrollees when predicting or explaining costs of services covered under the contract for defined populations or for evaluating retrospectively the experience of MCOs, PIHPs, or PAHPs contracted with the state.

We noted that states currently apply the concept of “risk adjustment” in multiple ways and for multiple purposes. In some cases, states may use risk adjustment as the process of

determining and adjusting for the differing risk between managed care plans. In other cases, states may use risk adjustment as the process of determining the relative risk of the total enrolled population compared to a standard population (for example, the enrolled population from a prior rating period). We noted that for purposes of this regulation, we consider the first case to be the concept of risk adjustment as described in § 438.5(a) and § 438.5(g). We consider the second case to be an acuity adjustment subject to the standards for adjustments in § 438.5(f). Risk adjustment may be conducted in one of two ways. First, a state may use historical data to adjust future capitation payments. This is risk adjustment conducted on a prospective basis. Second, a state may perform a reconciliation and redistribution of funds based on the actual experience in the rating period. This is risk adjustment conducted on a retrospective basis. In § 438.5(g), we proposed that risk adjustment, whether prospective or retrospective in nature, be budget neutral. This is a proposed redesignation and renaming of the standard that such mechanisms be cost neutral in the current § 438.6(c)(1)(iii). The proposed documentation standards in the certification would depend on the type of risk adjustment chosen and were discussed in proposed § 438.7(b)(4).

We received the following comments in response to proposed § 438.5(g).

Comment: Several commenters recommend that CMS require the development of risk adjustment methodologies that incorporate disparities and social determinants of health that contribute to patient complexity and disease severity. Commenters believed that providers that see a disproportionate share of complex/high cost patients are disadvantaged and undervalued when underlying, non-clinical risk factors that impact patient outcomes are not captured.

Response: Disparities and social determinants of health that contribute to patient complexity and disease severity would be appropriate considerations in developing the risk adjustment methodology. We maintain that the reference to generally accepted actuarial principles and practices in § 438.5(g) is sufficient to address the application of such considerations in the risk adjustment methodology.

After consideration of the public comments, we are finalizing § 438.5(g) as proposed.

d. Special Contract Provisions Related to Payment (§ 438.6)

We proposed, at § 438.6, contract standards related to payments to MCOs, PIHPs, and PAHPs, specifically, risk-sharing mechanisms, incentive arrangements, and withhold arrangements. This section built upon and proposed minor modifications to the special contract provisions that are currently codified at § 438.6(c)(5). We proposed, at paragraph (a), three definitions applicable to this section. The definition for an “incentive arrangement” was unchanged from the definition that is currently at § 438.6(c)(1)(iv).

We proposed a definition for “risk corridor” with a slight modification from the existing definition at § 438.6(c)(1)(v). The current definition specifies that the state and the contractor share in both profits and losses outside a predetermined threshold amount. Experience has shown that states employ risk corridors that may apply to only profits or losses. We therefore proposed to revise the definition to provide flexibility that reflects that practice.

We also proposed to add a definition for “withhold arrangements,” which would be defined as a payment mechanism under which a portion of the capitation rate is paid after the MCO, PIHP, or PAHP meets targets specified in the contract.

We received the following comments on proposals in § 438.6(a).

Comment: Several commenters were opposed to the proposed change in § 438.6(a) to define risk corridors as having one-sided risk while others supported the proposed revision. Commenters stated that the rationale stated in the proposed rule at 80 FR 31114, which cited current state practice of one-sided risk corridors, did not substantiate the change. Commenters stated that the purpose of a risk corridor is to protect both the state and the managed care plan from excessive losses or profits resulting from the uncertainty of projecting payments and expenditures and that the proposed definition was inconsistent with the purpose of a risk corridor as well as with the application of risk corridors in the small and group markets. Commenters recommended that we retain the existing definition of a risk corridor that would account for upside and downside risk.

Response: We agree with the commenters that a risk corridor should account for upside and downside risk and that our rationale for proposing the change to the definition was insufficient

to justify a modification to how risk corridors should operate under Medicaid managed care programs. In the proposed definition, we referred to a “contractor”, which is not a defined term in this part, and will insert MCO, PIHP, and PAHP in its place. We will finalize the definition of a risk corridor in § 438.6(a) as a risk sharing mechanism in which states and MCO, PIHPs, or PAHPs may share in profits and losses under the contract outside of a predetermined threshold amount.

Comment: Several commenters requested clarification in the regulation that risk sharing arrangements are incentive arrangements and that incentive payments to FQHCs are to be held outside of the reconciliation process to reimburse FQHCs at the amounts required under the State plan.

Response: The risk sharing arrangements, incentive arrangements, and withhold arrangements described in § 438.6(a) and (b) are between the state and the MCO, PIHP or PAHP. These arrangements—and the requirements of § 438.6(a) and (b)—do not regulate arrangements between the managed care plans and network providers. (See § 438.3(i) for the regulation governing physician incentive plans, which are a type of incentive arrangement between managed care plans and providers). To directly address the commenters’ request, FQHCs and RHCs are required by statute to be reimbursed according to methodologies approved under the State plan. In the event a particular financial incentive arrangement related to meeting specified performance metrics for these providers is part of the provider agreement with the managed care plan, those financial incentives must be in addition to the required reimbursement levels specified in the State plan.

After consideration of public comments, we are finalizing paragraph (a) and its definitions with modifications. The definition of a risk corridor in § 438.6(a) as a risk sharing mechanism that accounts for both profits and losses between the state and the MCO, PIHP, or PAHP. Section 438.6(a) also maintained the existing definition for incentive arrangements and proposed a definition for withhold arrangements. While we did not receive comments on those proposed definitions, we believe clarification is necessary as to the scope of these contractual arrangements. These arrangements are the methods by which the state may institute financial rewards on the MCO, PIHP, or PAHP for meeting performance targets specified in the contract. These arrangements, and the

associated regulatory framework in § 438.6(b)(1) and (2), do not apply to financial arrangements between managed care plans and network providers to incent network provider behavior. We will finalize the definition of incentive arrangements in § 438.6(a) with a technical correction to replace the term “contractor” with “MCO, PIHP, or PAHP” for consistency with the definition for withhold arrangements and to remove any ambiguity as to the entity that may be subject to such arrangements under the contract.

In addition, we believe it is important to distinguish in the final rule between a withhold arrangement, subject to the requirements at § 438.6(b)(3), and a penalty that a state would impose on a managed care plan through the contract. A withhold arrangement is tied to meeting performance targets specified in the contract that are designed to drive managed care plan performance in ways distinct from the general operational requirements under the contract. For example, states may use withhold arrangements (or incentive arrangements) for specified quality outcomes or for meeting a percentage of network providers that are paid in accordance with a value-based purchasing model. A penalty, on the other hand, is an amount of the capitation payment that is withheld unless the managed care plan satisfies an operational requirement under the contract and is not subject to the requirements at § 438.6(b)(3). For example, a state may withhold a percentage of the capitation payment to penalize a managed care plan that does not submit timely enrollee encounter data. To clarify this distinction in the final rule, we are finalizing the definition for a withhold arrangement with additional text to distinguish it from a penalty, which is assessed for non-compliance with general operational contract requirements. We note that this does not provide federal authority for penalties (other than sanctions authorized under section 1932(e) of the Act) and that penalties are subject to state authority under state law.

In paragraph (b), we established the basic standards for programs that apply risk corridors or similar risk sharing arrangements, incentive arrangements, and withhold arrangements. In § 438.6(b)(1), we proposed to redesignate the existing standard (in current § 438.6(c)(2)) that the contract include a description of any risk sharing mechanisms, such as reinsurance, risk corridors, or stop-loss limits, applied to the MCO, PIHP, or PAHP. The proposed regulation text included a non-

exhaustive list of examples and we stated our intent to interpret and apply this regulation to any mechanism or arrangement that had the effect of sharing risk between the MCO, PIHP, or PAHP and the state. Given the new standards related to using, calculating, and reporting MLRs, we noted that states should consider the impact on the MLR when developing any risk sharing mechanisms. We did not receive comments on paragraph (b)(1) and will finalize as proposed with a modification to include the standard that was in the 2002 rule at § 438.6(c)(5)(i) that was inadvertently omitted in the proposed rule specifying that risk-sharing mechanisms must be computed on an actuarially sound basis.

In § 438.6(b)(2), we proposed to redesignate the existing standards for incentive arrangements currently stated in § 438.6(c)(5)(iii), but with a slight modification. We proposed to add a new standard in § 438.6(b)(2)(v) that incentive arrangements would have to be designed to support program initiatives tied to meaningful quality goals and performance measure outcomes. We also clarified that not conditioning the incentive payment on IGTs means that the managed care plan’s receipt of the incentive is solely based on satisfactory performance and is not conditioned on the managed care plan’s compliance with an IGT agreement. We requested comment as to whether the existing upper limit (5 percent) on the amount attributable to incentive arrangements is perceived as a barrier to designing performance initiatives and achieving desired outcomes and whether CMS must continue to set forth expectations for incentive arrangements between the state and managed care plans.

We received the following comments on proposed § 438.3(b)(2) relating to incentive arrangements for managed care plans.

Comment: One commenter requested clarification that amounts earned by a managed care plan under an incentive arrangement are a separate funding stream in addition to the monthly capitation payment.

Response: We confirm the commenter’s understanding and believe that the nature of incentive arrangements is clearly defined in § 438.6(a).

Comment: A few commenters asked if pay-for-performance arrangements would constitute an incentive arrangement and thereby be subject to the requirements in § 438.6(b)(2). If pay-for-performance arrangements fell under the requirements for incentive arrangements in § 438.6(b)(2),

commenters were concerned about the provisions in § 438.6(b)(2)(i) and (ii) that limit such arrangements to a fixed period of time and specify that these arrangements are not subject to automatic renewal.

Response: We believe that pay-for-performance programs, if applied to the performance of managed care plans, may be an incentive arrangement or withhold arrangement under the regulations in § 438.6(b)(2) or (b)(3). The distinction depends on whether the financial reward to the managed care plan is in addition to the amounts received under the capitation payment or are based on payment of amounts withheld from the actuarially sound capitation payment. We address comments related to the requirements in § 438.6(b)(2)(i) and (ii) below.

Comment: Many commenters supported the retention of the limit on total compensation—capitation plus incentive arrangements—in § 438.6(b)(2) to 105 percent of the approved capitation payments attributable to the enrollees or services covered by the incentive arrangements, while other commenters recommended that the limit be increased to incentivize performance by managed care plans.

Response: We believe that the limit on the amount of the incentive arrangement is appropriate to both incentivize performance by managed care plans, as well as cap federal expenditures for such arrangements as the amounts are in addition to the actuarially sound capitation rate. Since the 2002 regulations, this limitation has been in place to determine that the additional payments under an incentive arrangement remain actuarially sound. The proposed rule at § 438.6(b)(2) and 80 FR 31123 set forth the modifications to the existing requirements for incentive arrangements, which did not include removing the tie to actuarial soundness, and inadvertently did not retain that language in the regulatory text. We will finalize this paragraph to include the link to actuarial soundness.

Comment: Several commenters were opposed to the provisions in § 438.6(b)(2)(i) and (ii) that incentive arrangements be for a fixed period of and not subject to automatic renewal. Commenters stated that managed care plans will only invest in efforts to gain incentives if they will be extended over several years and have confidence that the incentive payments will continue.

Response: Since similar requirements would apply to withhold arrangements in § 438.6(b)(3)(i) and (ii), we address these limitations and requirements in both contexts. The requirements that the incentive or withhold arrangements be

for a fixed period of time and not subject to automatic renewal are in place to ensure that the state evaluates managed care plan performance during the rating period for the contract in which the arrangement was in place and determines whether revised or new performance or quality measures or targets are appropriate for future contract years. These provisions ensure that these arrangements are dynamic and drive continual performance or quality improvement rather than reward performance over several contract periods that should become the minimum expectation over time. Therefore, we will retain these requirements for incentive and withhold arrangements; we clarify that performance is measured during the rating period under the contract in which the incentive or withhold arrangement is applied in paragraphs (b)(2)(i) and (b)(3)(i). A state could design a plan of performance for a managed care plan that would span more than one contract year, but the period of measure for specific performance measures within the broader plan for performance must be at the rating period level. This is because the payment of the incentive or withhold is based on the capitation rates for the rating period.

Comment: Several commenters requested clarification on the provision in § 438.6(b)(2)(iv) that incentive arrangements not be conditioned on Intergovernmental Transfers (IGTs). Commenters interpreted this provision as foreclosing IGTs as a financing mechanism for the non-federal share under managed care program, particularly in relation to public hospitals.

Response: At 80 FR 31123, we clarified that not conditioning the incentive payment on IGTs meant that the managed care plan's receipt of the incentive is solely based on satisfactory performance and not conditioned on the managed care plan's compliance with an IGT agreement. The provision in the proposed rule at § 438.6(b)(2)(iv) has existed since the final rule was issued in 2002 at § 438.6(c)(5)(iii)(D). In the 2002 final rule, we explained that the purpose of the prohibition was "to prevent incentive arrangements in managed care contracts from being used as a funding mechanism between state agencies or state and county agencies." See 67 FR 41004. We proposed to keep this provision in the managed care regulations, at 80 FR 31123, and restate here that a managed care plan's receipt of an incentive payment or amounts earned back under a withhold arrangement cannot be conditioned on

the managed care plan providing an IGT to the state. To clarify this requirement, we will finalize this language in § 438.6(b)(2)(iv) and (b)(3)(iv) (and will also use parallel language at § 438.6(c)(2)(i)(E) for permissible approaches to provider payments) to specify that the incentive or withhold arrangement does not condition managed care plan participation on the managed care plan entering into or adhering to intergovernmental transfer agreements.

Comment: Several commenters were supportive of the proposed addition of § 438.6(b)(2)(v), which would require incentive arrangements (and withhold arrangements in § 438.6(b)(3)(v)) to be designed to support program goals and performance measure outcomes. Some commenters recommended that the incentive or withhold arrangements be evaluated as part of the quality strategy in § 438.340. Other commenters supported this provision so long as the goals or measures are attainable considering the populations served, the goals or measures provided prospectively to managed care plans prior to initiation of the measurement period, and the goals or measures are not subject to change mid-year.

Response: We appreciate commenters support for the element in § 438.6(b)(2)(v) and (b)(3)(v). We agree with commenters that measures in place for managed care plans to achieve the incentive arrangement or earn withhold amounts should be reasonably attainable and that such goals or measures should be provided to managed care plans prospectively. As incentive or withhold arrangements are included in the contract between the state and the managed care plan, the process of negotiating the contract will address those concerns, as well as the concern that the goals or measures be in place for the duration of the contract period. While the requirement that the incentive or withhold arrangement be designed to support programmatic goals would suggest that the state link these arrangements to the quality strategy, we concur that an explicit reference is warranted. Therefore, we will add a reference to the quality strategy at § 438.340, which is also consistent with the approach for payment and delivery system reform initiatives in § 438.6(c)(2)(i)(C), to both § 438.6(b)(2)(v) and (b)(3)(v).

Comment: One commenter requested that CMS modify § 438.6(b)(2)(v) so that not all of the elements must be in place for incentive arrangements.

Response: Proposed § 438.6(b)(2)(v) provided that incentive arrangements must be "necessary for the specified

activities, targets, performance measures, and quality-based outcomes that support program initiatives." We agree with the commenter that, as written, the provision would require that an incentive arrangement address each of the elements to comply with paragraph (b)(2)(v). This was not our intention; rather, the text should be read as a list of different approaches to measuring the performance of the managed care plans subject to the incentive arrangement. Therefore, we will replace "and" with "or" in that paragraph. As this is also a requirement for withhold arrangements in § 438.6(b)(3)(v), we will modify that text as well. We do emphasize, however, that each element in paragraphs (b)(2)(i) through (v) must be met for an incentive arrangement (or, in connection with paragraph (b)(3)(i) through (v), a withhold arrangement) to be compliant with this final rule.

After consideration of public comments, we are finalizing § 438.6(b)(2) with the following modifications: (1) In paragraph (b)(2), to reinsert the longstanding requirement that payments under incentive arrangements may not exceed 105 percent of the approved capitation rate "since such total payments will not be considered to be actuarially sound; (2) in paragraph (b)(2)(i), to add text to clarify that the arrangement is for a fixed period of time and performance is measured during the rating period under the contract in which the arrangement is applied; (3) in paragraph (b)(2)(iv), to add text to clarify how participation cannot be conditioned on entering into or complying with an IGT; and (4) in paragraph (b)(2)(v), to insert "or" in place of "and" to insert a reference to the state's quality strategy at § 438.340. We are finalizing identical technical modifications in paragraphs § 438.6(b)(3)(i), (iv) and (v).

In paragraph (b)(3), we proposed that the capitation rate under the contract with the MCO, PIHP, or PAHP, minus any portion of the withhold amount that is not reasonably achievable, must be certified as actuarially sound. As an example, if the contract permits the state to hold back 3 percent of the final capitation rate under the contract, or 3 percent from a particular rate cell of the capitation rate under the contract, the actuary must determine the portion of the withhold that is reasonably achievable. We requested comment on how an actuary would conduct such an assessment to inform future guidance in this area. If the actuary determines that only two thirds of the withhold is reasonably achievable (that is, 2 percent of the final contract capitation rate), the

capitation rate, minus the portion that is not reasonably achievable (that is, 1 percent of the final capitation rate), must be actuarially sound. The total amount of the withhold, achievable or not, must be reasonable and take into account an MCO's, PIHP's, or PAHP's capital reserves and financial operating needs for expected medical and administrative costs. We provided that when determining the reasonableness of the amount of the withhold, the actuary should also consider the cash flow requirements and financial operating needs of the MCOs, PIHPs, and PAHPs, taking into account such factors as the size and characteristics of the populations covered under the contract. In addition, we explained that the reasonableness of the amount of the withhold should also reflect an MCO's, PIHP's, or PAHP's capital reserves as measured by risk-based capital levels or other appropriate measures (for example, months of claims reserve) and ability of those reserves to address expected financial needs. The data, assumptions, and methodologies used to determine the portion of the withhold that is reasonably achievable must be included in the documentation for rate certification specified under § 438.7(b). We noted that the proposed terms for the design of the withhold arrangement mirror the terms for incentive arrangements minus the upper limit, as the rate received by the MCO, PIHP, or PAHP absent the portion of withhold amount that is not reasonably achievable must be certified as actuarially sound.

The proposed rule was designed to ensure that any withhold arrangements meet the following goals: (1) The withhold arrangement does not provide an opportunity for MCOs, PIHPs, or PAHPs to receive more than the actuarially certified capitation rate; (2) the withhold arrangement provides MCOs, PIHPs, and PAHPs an opportunity to reasonably achieve an amount of the withhold, such that if the state had set the capitation rate at the actual amount paid after accounting for the effect of the withhold, it would be certifiable as actuarially sound; and (3) the actuarial soundness of the capitation rates after consideration of the withhold arrangement is assessed at an aggregate level, across all contracted MCOs, PIHPs, or PAHPs, rather than at the level of an individual managed care plan. A withhold arrangement is applied at the contract level rather than at the rate cell level as there is not a practical way to accomplish the latter. For example, a withhold arrangement may be described as 2 percent under the

contract, which would encompass all rate cells under the contract, rather than calculating and deducting the amount to be withheld per individual rate cell to reach 2 percent under the withhold arrangement. We welcomed comment on appropriate approaches to evaluating the reasonableness of these arrangements and the extent to which the withholds are reasonably achievable and solicited comment on whether our proposed regulation text sufficiently accomplished our stated goals.

We received the following comments in response to proposals at § 438.3(b)(3) relating to withhold arrangements for managed care plans.

Comment: Several commenters supported the inclusion of withhold arrangements at § 438.6(a) and (b)(3), while some commenters recommended that CMS only permit incentive arrangements. A few commenters questioned the utility of withhold arrangements to drive managed care plan performance when the capitation payment received by the managed care plan is actuarially sound.

Response: From our experience in reviewing managed care contracts and rate certifications, it is clear that withhold arrangements represent the predominant approach to incentivizing managed care plan performance. For that reason we decline to prohibit such arrangements and maintain that regulation is appropriate in this area. We maintain, and state practice supports this conclusion, that withhold arrangements can incentivize managed care plan performance even though the monthly capitation payment received by the managed care plan absent the amount of the withhold is actuarially sound.

Comment: A commenter suggested that states should have the flexibility to reward high performing managed care plans with a bonus payment in addition to the receipt of the withhold amount and that such funds would come from managed care plans that did not meet the metrics under the withhold arrangement. The commenter stated that this approach should be permissible and would be budget neutral.

Response: Such an arrangement would have to meet the requirements for both withhold and incentive arrangements under § 438.6(b)(2) and (b)(3), respectively. Incentive and withhold arrangements are specific to a MCO's, PIHP's, or PAHP's performance according to the specific metrics under the contract. The commenter stated that any bonus payments could be made from unearned amounts from withhold arrangements under the contract from managed care plans that did not fully

meet the specified metrics of the withhold arrangement. Unearned amounts under a withhold arrangement do not create a residual pool of money to be distributed to other managed care plans operating within a state. If the state wanted to provide a bonus payment in addition to the amount paid under a withhold arrangement, that bonus payment would have to meet the requirements of an incentive arrangement at § 438.6(b)(2).

Comment: A commenter requested that CMS clarify how an unearned portion of the withhold should be treated by states.

Response: The withhold amount is not paid to the managed care plans until the conditions for payment are met by the managed care plan. Therefore, the state claims FFP for the amount of the withhold through the CMS-64 only if a managed care plan has satisfied the conditions for payment under the withhold arrangement and the amount has been paid to the managed care plan. If a managed care plan does not earn some or all of the withhold amount, no federal or state dollars are expended for those amounts.

Comment: In response to the request for comment as to how an actuary would evaluate the amount of the withhold that was reasonably achievable, a commenter provided the following steps: review the language and criteria for earning the withhold for prior contract years; review the language and criteria for earning back the withhold for the rate period; assess differences between the prior year and the rate period; review the amounts earned by the managed care plans in prior years; and based on the above, extrapolate and use actuarial judgment to determine the achievable amount.

Response: We believe that in many circumstances the approach described would be a reasonable methodology. However, it is not the only viable and reasonable approach. We do not believe that it is necessary to have a prior year of experience for the specific MCO, PIHP or PAHP to make such an assessment. Other data sources may also be appropriate. For example, the experience from other health insurance coverage may be an appropriate data source.

Comment: We received several comments on the proposed "reasonably achievable" standard for withhold arrangements at § 438.6(b)(3). Many commenters stated that the "reasonably achievable" standard was vague and too subjective. A few commenters recommended that CMS clarify that the actuary may rely on the state's assessment of what portion of the

withhold is or is not reasonably achievable, as it is outside the scope of the actuary's expertise to independently assess the reasonableness of the withhold amount in relation to performance expectations for each managed care plan. Other commenters suggested a modified standard in § 438.6(b)(3) that the capitation rate minus any portion of the withhold that is not reasonably achievable by a managed care plan given the non-benefit load must be actuarially sound. Another commenter requested that CMS clarify that the need to take into account the managed care plan's financial operating needs be done at the broader level of the managed care program, rather than at the level of individual managed care plans, as a state should not have to forego applying a withhold arrangement for the managed care program overall if a particular managed care plan was not operating as efficiently in the financial sense as other managed care plans in the program.

Many commenters suggested alternatives to the "reasonably achievable" standard for withhold arrangements. Several commenters recommended that a limitation of 5 percent similar to incentive arrangements at § 438.6(b)(2) be placed on withhold arrangement, because without such a limitation, the capitation rates actually received by managed care plans if they do not earn back the withhold amount would not be actuarially sound. Another commenter suggested that the amount of the withhold be considered exempt from the actuarial soundness requirement so long as the amount met a CMS defined limit, similar to the 5 percent cap used for incentive arrangements. Other commenters suggested that CMS limit the withhold arrangement to no more than the profit percentage assumed in the rate setting process. Some commenters suggested that the entire amount of the withhold be excluded from the actuarially sound capitation rate to ensure that the amount received by the managed care plans remained actuarially sound absent receipt of funds for meeting specified performance metrics.

Response: We thank the commenters for their feedback in this area. We disagree that the "reasonably achievable" standard is vague or unnecessarily subjective. A withhold is intended to incentivize a managed care plan to achieve, or partially achieve, articulated performance metrics. Depending on the selected performance metrics and the structure of the withhold, it may be easy or difficult to achieve some, or all, of the withhold. To

not consider the amount of the withhold toward the assessment of actuarially sound capitation rates would significantly limit states' ability to use withholds because the withhold would not count toward an actuarially sound capitation rate (and thus not be eligible for FFP) even as managed care plans earn some or all of the withhold.

Similarly, we considered counting all of the withhold amount toward the assessment of actuarially sound capitation rates. However, this approach created a risk that a managed care plan would not actually be paid an actuarially sound capitation rate because managed care plans frequently do not earn the full withhold amount. If the capitation rates were determined to be actuarially sound on the assumption that the managed care plans would earn all of the withhold, then it is possible that the capitation rates would not remain actuarially sound if a managed care plan did not meet the performance metrics. This situation would put the enrollee at risk.

This provision is intended to strike a balance between the approach of counting all of the withhold toward actuarially sound capitation rates and the approach of counting none of the withhold toward actuarially sound capitation rates. We agree that determining the amount of the withhold that is reasonably achievable requires the actuary to exercise judgment. There may be a number of methods that could be used to make the determination. Historical experience may be relied upon as many states track managed care plans' performance on various quality measures over a number of years. It may also be possible to look at the experience in other states and estimate how that experience is applicable. It is also possible that there may be managed care plan industry metrics or metrics from other health insurance coverage types that could be used as a comparison. If neither the state, nor actuary, can provide any evidence or information that managed care plans can expect to earn some or all of withhold, the appropriate course would be to take the most cautious approach and assume that none of the withhold is reasonably achievable.

States use a variety of withhold arrangements today. Setting arbitrary limits for withhold such as the expected profit margin could interfere with states' current approaches. Therefore, we decline to use these approaches to limit the amount of the withhold.

Comment: Several commenters offered suggestions on how states should operationalize the "reasonably achievable" standard for withhold

arrangements. For example, commenters recommended that states be required to have one full year of managed care plan reporting on the specific performance metrics prior to implementing any withholds. During the one year reporting period, the state would function as if the withhold was in place so that the managed care plans would anticipate the financial impact of nonperformance and have time to develop improvement strategies prior to incurring financial consequences.

Other commenters supported the provision in § 438.7(b)(6), and at 80 FR 31259, that a description of withhold arrangements (and other special contract provisions described in § 438.6) be included in the rate certification, but requested that states should have to share the information supporting the withhold amount with managed care plans. Another commenter asked for clarification under § 438.7(b)(6) as to the scope of the data, assumptions, and methodologies used to determine the portion of the withhold that is reasonably achievable to be documented in the rate certification. The commenter questioned if the intention was for the state to include something other than the metrics, methods and assumptions for those metrics, and if so, raised concern about the administrative burden the level of documentation would create.

Response: As provided in response to a previous comment, there may be a number of methods that could be used to make the determination that a portion (or all) of a withhold amount is reasonably achievable. There may be historical experience that can be used. For example, many states track managed care plans' performance on various quality measures over a number of years. It may also be possible to look at the experience in other states and estimate how that experience is applicable. It is also possible that there may be managed care plan industry metrics or metrics from other health insurance coverage types that could be used as a comparison. If neither the state, nor actuary, can provide any evidence or information that managed care plans can expect to earn some or all of withhold, the appropriate course would be to take the most cautious approach and assume that none of the withhold is reasonably achievable.

Given the states have many different performance metrics, there may be a variety of appropriate assumptions, data, and methodologies for assessing the amount of the withhold that is reasonably achievable. We clarify that the scope of the assumptions, data, and methodologies for determining the

amount of the withhold should include the basis for determining that some or all of the withhold is achievable and that information would be included in the rate certification. Such documentation would include any data, historical experience, other states' experiences, industry data, or other relevant information.

After consideration of public comments, we are finalizing § 438.6(b)(3)(i), (iv) and (v) with the same modifications noted above for § 438.6(b)(2)(i), (iv) and (v).

We proposed to redesignate the standard at the existing § 438.6(c)(5)(v), related to adjustments to actuarially sound capitation rates to account for graduate medical education (GME) payments authorized under the state plan, at § 438.6(b)(4) without any changes to the substantive standard.

We received the following comments on proposed § 438.6(b)(4).

Comment: Several commenters objected to the requirement at § 438.6(b)(4) that if the state directly makes payments to network providers for graduate medical education (GME) costs under an approved State plan, the actuarially sound capitation payments must be adjusted to account for those GME payments.

Response: This provision was redesignated in the proposed rule from the current regulation at § 438.6(c)(5)(v) and is linked to the provision in § 438.60 that permits states to make GME payments directly to network providers. Based on the comments received, it is clear that states were not consistently applying this provision. We agree that for states that make direct GME payments to providers, it is not necessary for the state to develop actuarially sound capitation rates prior to excluding GME payments.

After consideration of public comments, we are not finalizing proposed § 438.6(b)(4) (which has the effect of removing the provision currently codified at § 438.6(c)(5)(v)) in this final rule but clarify here that if states require managed care plans to provide GME payments to providers, such costs must be included in the development of actuarially sound capitation rates. We will also remove the reference to § 438.6(c)(5)(v) in § 438.60 to be consistent with our decision not to finalize § 438.6(b)(4).

We proposed to add a new provision to § 438.6(c) to codify what we believe was a longstanding policy on the extent to which a state may direct the MCO's, PIHP's or PAHP's expenditures under a risk contract. Existing standards in § 438.6(c)(4) (proposed to be redesignated as § 438.3(c)) limit the

capitation rate paid to MCOs, PIHPs, or PAHPs to the cost of state plan services covered under the contract and associated administrative costs to provide those services to Medicaid eligible individuals. Furthermore, under existing standards at § 438.60, the state must ensure that additional payments are not made to a provider for a service covered under the contract other than payment to the MCO, PIHP or PAHP with specific exceptions. Current CMS policy has interpreted these regulations to mean that the contract with the MCO, PIHP or PAHP defines the comprehensive cost for the delivery of services under the contract, and that the MCO, PIHP or PAHP, as risk-bearing organizations, maintain the ability to fully utilize the payment under that contract for the delivery of services. Therefore, in § 438.6(c)(1), we proposed the general rule that the state may not direct the MCO's, PIHP's, or PAHP's expenditures under the contract, subject to specific exceptions proposed in paragraphs (c)(1)(i) through (iii).

In the proposed rule, we noted the federal and state interest in strengthening delivery systems to improve access, quality, and efficiency throughout the health care system and in the Medicaid program. In support of this interest, we encouraged states that elect to use managed care plans in Medicaid to leverage them to assist the states in achieving their overall objectives for delivery system and payment reform and performance improvements. Consistent with this interest, we established a goal of empowering states to be able, at their discretion, to incentivize and retain certain types of providers to participate in the delivery of care to Medicaid beneficiaries under a managed care arrangement. We proposed in paragraphs (c)(1)(i) through (c)(1)(iii) the ways that a state may set parameters on how expenditures under the contract are made by the MCO, PIHP, or PAHP, other mechanisms would be prohibited.

Paragraph (c)(1)(i) proposed that states may specify in the contract that managed care plans adopt value-based purchasing models for provider reimbursement. In this approach, the contract between the state and the managed care plan would set forth methodologies or approaches to provider reimbursement that prioritize achieving improvements in access, quality, and/or health outcomes rather than merely financing the provision of services. Implementing this flexibility in regulation would assure that these regulations promote paying for quality or health outcomes rather than the volume of services, which is consistent

with broader HHS goals, as discussed in more detail in the proposed rule at 80 FR 31124.

In paragraph (c)(1)(ii), we proposed that states have the flexibility to require managed care plan participation in broad-ranging delivery system reform or performance improvement initiatives. This approach would permit states to specify in the contract that MCOs, PIHPs, or PAHPs participate in multi-payer or Medicaid-specific initiatives, such as patient-centered medical homes, efforts to reduce the number of low birth weight babies, broad-based provider health information exchange projects, and other specific delivery system reform projects to improve access to services, among others. We acknowledge that, despite the discussion at 80 FR 31124 about the ability to engage managed care plans in Medicaid-specific initiatives, we unintentionally omitted these initiatives from the proposed regulatory text at § 438.6(c)(1)(ii). Under our proposal, states could use the managed care plan payments as a tool to incentivize providers to participate in particular initiatives that operate according to state-established and uniform conditions for participation and eligibility for additional payments. The capitation rates to the managed care plans would reflect an amount for incentive payments to providers for meeting performance targets but the managed care plans would retain control over the amount and frequency of payments. We noted that this approach balances the need to have a managed care plan participate in a multi-payer or community-wide initiative, while giving the managed care plan a measure of control to participate as an equal collaborator with other payers and participants. We also clarified that because funds associated with delivery system reform or performance initiatives are part of the capitation payment, any unspent funds remain with the MCO, PIHP, or PAHP. We also stated our belief that the overall regulatory approach to identify mechanisms that permit states to direct MCO, PHIP, or PAHP expenditures was designed to ensure that payments associated with a reform initiative are also tied to the relative value of the initiative as demonstrated through the utilization of services or quality outcomes. As an example of a delivery system reform initiative, we provided that states could make available incentive payments for the use of technology that supports interoperable health information exchange by network providers that were not eligible for EHR

incentive payments under the HITECH Act (for example, long-term/post-acute care, behavioral health, and home and community based providers).

We proposed in paragraph (c)(1)(iii) to permit states to require certain payment levels for MCOs, PIHPs and PAHPs to support two state practices critical to ensuring timely access to high-quality, integrated care, specifically: (1) setting minimum reimbursement standards or fee schedules for providers that deliver a particular covered service; and (2) raising provider rates in an effort to enhance the accessibility or quality of covered services. For example, some states have opted to voluntarily pay primary care providers at Medicare reimbursement rates beyond CYs 2013–2014, which was the time period required for such payment levels under section 1202 of the Affordable Care Act. Because actuarially sound capitation rates are based on all reasonable, appropriate and attainable costs (see section I.B.3.b. of the final rule), the contractual expectation that primary care providers would be paid at least according to Medicare reimbursement levels must be accounted for in pricing the primary care component of the capitation rate. These amounts would be subject to the same actuarial adjustments as the service component of the rate and would be built into the final contract rate certified by the actuary. Under the contract, the state would direct the MCO, PIHP, or PAHP to adopt a fee schedule created by the state for services rendered by that class of providers. As proposed, paragraph (c)(1)(iii)(A) would permit states to direct payment levels for all providers of a particular service as contemplated in this scenario.

In paragraph (c)(1)(iii)(B), we noted the state could specify a uniform dollar or percentage increase for all providers that provide a particular service under the contract. This option would have the state treat all providers of the services equally and would not permit the state to direct the MCO, PIHP, or PAHP to reimburse specific providers specific amounts at specified intervals. We noted that this option would help ensure that additional funding is directed toward enhancing services and ensuring access rather than benefitting particular providers. It would also support the standard that total reimbursement to a provider is based on utilization and the quality of services delivered. Finally, we also noted that this option would be consistent with and build upon the existing standard that the capitation rate reflects the costs of services under the contract. Under both approaches in (c)(1)(iii), the MCO,

PIHP or PAHP could negotiate higher payment amounts to network providers under their specific network provider agreements.

Sections 438.6(c)(2)(i) and (ii) set forth proposed approval criteria for approaches under paragraphs (c)(1)(i) through (iii) to ensure that the arrangement is consistent with the specific provisions of this section. To ensure that state direction of expenditures promotes delivery system or provider payment initiatives, we expected that states would, as part of the federal approval process, demonstrate that such arrangements are based on utilization and the delivery of high-quality services, as specified in paragraph (c)(2)(i)(A). Our review would also ensure that state directed expenditures support the delivery of covered services. Consequently, we expected that states would demonstrate that all providers of the service are being treated equally, including both public and private providers, as specified in paragraph (c)(2)(i)(B). In proposed paragraph (c)(2)(i)(C) and (D), we linked approval of the arrangement to supporting at least one of the objectives in the comprehensive quality strategy in § 438.340 and that the state would implement an evaluation plan to measure how the arrangement supports that objective. This would enable us and states to demonstrate that these arrangements are effective in achieving their goals. In proposed paragraph (c)(2)(i)(E), to promote the extent to which these arrangements support proactive efforts to improve care delivery and reduce costs, we would prohibit conditioning provider participation in these arrangements on intergovernmental transfer agreements. Finally, in proposed paragraph (c)(2)(i)(F), because we sought to evaluate and measure the impact of these reforms, such agreements would not be renewed automatically.

Under proposed paragraph (c)(2)(ii), we specified that any contract arrangement that directs expenditures made by the MCO, PIHP, or PAHP under paragraphs (c)(1)(i) or (c)(1)(ii) for delivery system or provider payment initiatives would use a common set of performance measures across all payers and providers. Having a set of common performance measures would be critical to evaluate the degree to which multi-payer efforts or Medicaid-specific initiatives achieve the stated goals of the collaboration. We sought comment on the proposed general standard, and the three exceptions, providing a state the ability to direct MCO's, PIHP's, or PAHP's expenditures. Specifically, we sought comment on the extent to which

the three exceptions were adequate to support efforts to improve population health and better care at lower cost, while maintaining MCO's, PIHP's or PAHP's ability to fully utilize the payment under that contract for the delivery of services to which that value was assigned.

We received the following comments in response to proposed § 438.6(c).

Comment: Many commenters supported proposed § 438.6(c)(1)(i) and (ii) as broad approaches to support value-based purchasing and delivery system reform. Specifically, commenters supported mechanisms to advance patient-centered quality outcomes, value-based purchasing models, multi-payer delivery system reforms, performance improvement initiatives, and other promising delivery system reforms that could improve care for Medicaid enrollees. A few commenters that supported § 438.6(c)(1) recommended that CMS include regulatory text for specific models of care. A few commenters recommended that CMS provide regulatory support for Medicaid Accountable Care Organizations (ACOs) and other community-based health care models, health homes, patient-centered medical homes, bundled payments, and episodes of care. Other commenters recommended that CMS include specific financial incentives to encourage states to begin implementing value-based purchasing and begin transitioning their health care delivery systems from volume to value. A few commenters recommended against CMS pursuing value-based purchasing. One commenter stated that according to a recent Congressional testimony by MedPAC, there is little to no evidence that value-based purchasing programs actually produce savings. One commenter recommended that CMS implement value-based purchasing gradually to ensure that such delivery system models actually produce results and savings.

Response: As proposed and finalized here, § 438.3(c)(1)(i) is intended to permit states to require their MCOs, PIHPs or PAHPs to use value-based purchasing methods for provider reimbursement as an exception to the general rule specified in paragraph (c)(1) regarding state direction of managed care plan expenditures under the contract. It is not a requirement that states do so although we encourage states to engage their managed care plans, the provider community, and other stakeholders to consider arrangements that would be appropriate for their Medicaid programs. We recognize that the evaluation of the

efficacy of value-based purchasing methods is ongoing and that several models are either in place or under consideration by states. Value-based purchasing is also a priority for the Department as discussed at 80 FR 31124. We decline to implement specific financial incentives for states to undertake value-based purchasing initiatives as such financial incentives would require specific federal statutory funding authority. States have the flexibility to use incentive or withhold arrangements as specified in § 438.6(b)(2) and (3) to encourage managed care plans to adopt such payment models.

Comment: Several commenters recommended that CMS include specific protections under § 438.6(c)(1)(i) for patients with special health care needs or high cost conditions for states and managed care plans to monitor how new payment models ensure access to quality care. A few commenters recommended that CMS add protections for vulnerable populations accessing innovative therapies that might initially drive costs up but could ultimately improve a patient's outcomes in the long-term. A few commenters recommended that CMS include regulatory language that would protect dual eligible enrollees, frail seniors, enrollees with behavioral health needs, enrollees with disabilities under the age of 65, and enrollees receiving LTSS from inadvertently being impacted by value-based purchasing models.

Response: States have the flexibility to determine which services would be reimbursed through value-based purchasing models as such models may not be appropriate for all services and populations covered under the contract. Regardless of the reimbursement models used by the contracted managed care plans, all enrollee protections for access and availability of care in part 438 apply. Therefore, we do not believe it is necessary to specify additional protections in relation to value-based purchasing models.

Comment: Several commenters recommended that CMS include specific stakeholder engagement and public notice requirements at § 438.6(c) before states implement delivery system reform initiatives under § 438.6(c)(1)(ii). Several commenters recommended that CMS include specific transparency requirements and seek stakeholder feedback on value-based payment arrangements that the state intends to include in managed care plan contracts under § 438.6(c)(1)(i).

Response: We decline to add such requirements to § 438.6(c); we believe

that these concerns are adequately addressed by other disclosure and stakeholder involvement requirements. Public notice requirements apply to waiver and state plan authorities for managed care programs. In addition, such delivery reform initiatives would be appropriately discussed at the state's Medical Care Advisory Committee (MCAC), which is required under § 431.12, or at a Member Advisory Committee, which is required under § 438.110, if such initiatives involved the MLTSS program. In addition, such performance or quality measures would be included in the state's annual program report at § 438.66(e)(2)(vii), which is made available on the state's Web site and shared with the MCAC at § 438.66(e)(3).

We received the following comments in response to the example of incentive payments to network providers for EHR adoption that are not eligible for incentives under the HITECH Act.

Comment: Many commenters supported regulatory flexibility for states to make available incentive payments for the use of technology that supports interoperable health information exchange by network providers that were not eligible for EHR incentive payments under the HITECH Act. Commenters stated that by allowing and offering EHR incentives to a wider range of health care programs and providers, CMS enables the delivery of coordinated care and seamless information sharing across the health care continuum. Several commenters recommended that CMS provide guidance to states and other contracting entities suggesting that state-based EHR incentive programs must leverage ONC certification criteria for data exchange so that the same standards and methods of data transfer are used for state-incented EHR programs as are used for the Meaningful Use program. Commenters recommended that CMS clarify and finalize this provision to ensure states can efficiently and effectively take advantage of these incentive payments.

Response: We appreciate commenters support for the example (at 80 FR 31124) of how proposed § 438.6(c)(1)(iii) would permit states to incent EHR adoption by providers that were not eligible for incentives under the HITECH Act. The discussion in the preamble provided suggestions for states to consider for broad ranging delivery system reform or performance improvement initiatives and did not result in a new regulatory framework for states that desired to establish a state-incented EHR program for providers. That being said, states that desired to

create such an initiative would benefit from taking the existing ONC certification criteria for data exchange into account to support an EHR system that was consistent with systems for providers covered under the HITECH Act.

Comment: A few commenters recommended that CMS include requirements at § 438.6(c) to support team-based care in any delivery system reform initiative under § 438.6(c)(1)(ii). Specifically, commenters recommended that CMS include language that would support advanced practice registered nurses (APRNs) and certified registered nurse anesthetists (CRNAs) in state delivery system reform efforts. A few commenters recommended that CMS specify managed care plan provider reimbursement levels for community pharmacists in regulation.

Response: Each state's Medicaid managed care program is unique and the states are best positioned, in collaboration with managed care plans and stakeholders, to design delivery system reform efforts. Therefore, we decline to specify particular initiatives through regulation.

Comment: A few commenters stated concern that the regulatory language at paragraphs § 438.6(c)(1)(i) through (iii) could be misinterpreted as a complete list of the permissible limitations states can impose on managed care plan expenditures. Commenters stated that this overlooks the fact that the state's contract must direct the managed care plans expenditures to the extent that such expenditures are mandated under the statute and related regulations. Commenters provided that one example of this type of requirement is payment levels for federally-qualified health centers. Commenters recommended that CMS modify the text in paragraph (c)(1) to acknowledge payments that may be required under statute.

Response: We have modified the statement of the general rule at § 438.6(c)(1) to include exceptions for specific provisions of Title XIX, or a regulation implementing a Title XIX provision related to payments to providers that is applicable to managed care programs.

Comment: We received comments both for and against our proposal at § 438.6(c)(1)(iii) regarding state establishment of minimum reimbursement requirements for network providers. Several commenters did not support proposed § 438.6(c)(1)(iii)(A) and (B) regarding a minimum fee schedule for all providers that provide a particular service under the managed care contract or a uniform dollar or percentage increase for all

providers that provide a particular service under the managed care contract. Commenters stated that the proposed regulatory language conflicts with the overarching construct of managed care under which the payer does not dictate how managed care plans must use the capitated payment to fulfill the requirements specified in the contract. Commenters stated that minimum fee schedule requirements interfered with managed care plan provider rate negotiations and that provisions requiring minimum payment rates for providers could stifle innovation by inserting the state into managed care plan-provider relationships. Commenters recommended that CMS withdraw these requirements as they remove the managed care plan's ability to effectively manage utilization costs and raise concerns about the ability of managed care plans to measure quality improvements in providing services through the issuance of uniform rates. Other commenters were concerned that these proposed provisions would eliminate providers' abilities to negotiate higher provider payment rates with managed care plans if states are allowed to set standard fee schedules.

Several commenters supported proposed § 438.6(c)(1)(iii)(A) and (B) but recommended that CMS include additional requirements. Some commenters requested clarification as to the parameters for a minimum fee schedule. Several commenters recommended that CMS set a national floor for minimum provider fee schedules for all managed care plans at the Medicare reimbursement rate to improve access to care for all Medicaid managed care enrollees. One commenter recommended that CMS require states to include the methods and procedures related to rates that the state mandates that a managed care plan pay to a provider in the state's Medicaid state plan, and that CMS review and approve such methods and rates to ensure adequate access to care. A few commenters recommended that CMS require any minimum fee schedule to reflect an adequate living wage for health care providers sufficient to live in the communities they serve. One commenter recommended that CMS expand the requirement to allow states to establish both minimum and maximum fee schedules for all providers that provide a particular service under the managed care contract.

Response: As proposed and finalized here, § 438.6(c)(1)(iii)(A) and (B) is intended to permit—not mandate—states to require their contracted

managed care plans reimburse providers that provide a particular service in accordance with a minimum fee schedule or at a uniform dollar or percentage increase as an exception to the general rule specified in paragraph (c)(1) regarding state direction of managed care plan expenditures under the contract. It is not a requirement that states do so. We restate that these provisions would permit the state to specify a minimum payment threshold and would not prohibit the managed care plans from negotiating higher provider rates. To clarify the parameters for the state in setting a fee schedule for particular network providers under the contract, we will add a new paragraph (c)(1)(iii)(C) to specify that states could include a maximum fee schedule in the managed care plan contract, so long as the managed care plan retains the ability to reasonably manage risk and have discretion in accomplishing the goals of the contract. An example of a maximum fee schedule that would satisfy this requirement is that the managed care plan could pay no more than a specified percentage of a benchmark rate, such as Medicare or commercial rates. The use of minimum or maximum fee schedule or uniform increases ensures that provider payment initiatives are tied to the utilization and delivery of particular services under the contract. In the event the state used these provisions under the contract, the minimum payment expectations would be taken into account in the rate development process. However, for consistency with changes in the final rule at § 438.6(c)(2)(i)(B), described in response to comments on that provision below, we will finalize § 438.6(c)(1)(iii)(A) and (B) without the proposed requirement that the minimum fee schedule or uniform dollar or percentage increase in provider payments apply to *all* providers that provide a particular service under the contract.

We cannot establish a national floor for network provider payments without explicit statutory authority. We decline to specify that any minimum fee schedule reflect a living wage for the providers subject to such a fee schedule. In addition, we decline to incorporate such minimum provider payment amounts in the State plan as the State plan only governs FFS provider payments.

Comment: A few commenters did not support the proposed regulatory language at § 438.6(c)(2). Commenters stated that the regulatory language unfairly restricted the state's policy making authority, was unduly burdensome, and did not provide any meaningful evaluation criteria to

enhance CMS's approval beyond the approval process for the plan as a whole. Commenters recommended that as an alternative to the pre-approval process, CMS require states to sufficiently document and support directed payment programs within the rate development and contract approval process.

Response: We disagree with commenters that the provisions in § 438.6(c)(2) are unduly burdensome and inhibit state policy goals. This section does not require an approval separate from the contract and rate certification because approval of these initiatives would be part of this review. In light of comments received on specific provisions within § 438.6(c)(2), we are finalizing that section with some modifications as described below.

Comment: Many commenters recommended that CMS include requirements at § 438.6(c)(2) to ensure that states have conducted readiness reviews to ensure providers are ready for delivery system reform and have the ability to successfully participate in delivery system reform initiatives before implementation. Commenters also recommended that CMS include requirements that protect providers at risk for managed care plan performance for quality and efficiency objectives that rest solely within the control of managed care plan administrators. Commenters recommended that CMS prohibit plans from passing risk to providers resulting from state withhold and incentive arrangements. One commenter recommended that CMS clarify that managed care plans are only required to make a best effort to encourage providers to participate in delivery system reform.

Response: We appreciate that success of value-based purchasing models or other delivery system reforms are predicated on the readiness of affected parties—namely, managed care plans and affected providers—to undertake the operational and other considerations to implement and sustain these approaches. Section 438.6(d)(4) sets forth the broad categories of a managed care plan's operations that are subject to evaluation during a readiness review. While we believe that operations, service delivery, and financial management are sufficiently broad to capture value-based purchasing or other delivery system reforms under the contract, we acknowledged in the proposed rule, at 80 FR 31158, that states have the flexibility to evaluate additional aspects of the managed care plan during the readiness review. Considering the resources necessary to implement, oversee, and achieve

meaningful delivery system reform, we encourage states to assess the readiness of managed care plans to partner in those efforts.

Comment: Several commenters recommended that CMS include requirements that states may not require FQHCs to assume risk for services beyond primary and preventive care as a prerequisite for obtaining a managed care provider agreement. Commenters provided that FQHCs are prohibited from using section 330 funding for any services outside their scope, which is typically limited to primary and preventive care and requested a new paragraph in § 438.6(c)(2)(i) to acknowledge that FQHCs cannot be required to assume risk for additional services as a condition for obtaining a managed care provider agreement.

Response: The determination to apply value-based purchasing models, delivery system reform initiatives, or performance improvement initiatives to a particular provider type must take into account statutorily mandated payment levels or methodologies, as well as additional considerations such as conditions for grant funding from other federal agencies. We recognize that provider types in addition to FQHCs may have similar concerns; therefore, it would not be appropriate to specify one provider type, as the commenter recommended, to the exclusion of others in the regulation. However, depending on a provider's particular treatment under Title XIX, we clarify here that value-based purchasing methodologies or other performance initiatives may not interfere with federal statutory mandates, including payment methodologies.

Comment: Several commenters did not support proposed § 438.6(c)(2)(i)(B) which requires states to direct expenditures equally for all public and private providers providing the same service under the contract. Commenters recommended that states be permitted to direct payments to certain provider types within a service classification without having to include all providers of that same service under a singular payment initiative. Commenters also recommended that states not be held to unreasonable uniformity requirements when pursuing next generation, value-based payment initiatives, because these programs are designed to target only certain providers within a category. Many commenters recommended that CMS clarify and allow states to direct payment amounts for certain services to providers of differing types, specialties, and settings.

Response: We agree with commenters that the proposal at § 438.6(c)(2)(i)(B),

which would have required states to direct expenditures under the approach selected at § 438.6(c)(1)(i) through (iii) to all public and private providers providing the same service under the contract, was unnecessarily restrictive and could have inhibited a state's policy goals for the Medicaid program. Therefore, we will finalize this section to specify that the expenditures are directed equally, and using the same terms of performance, for a class of providers providing the service under the contract. This modification will permit states to limit a fee schedule, value-based purchasing arrangement, or delivery system reform or performance improvement initiative to public hospitals, teaching hospitals, or other classification of providers. Similarly, we have modified § 438.6(c)(2)(ii)(A) to remove the requirement that participation in value-based purchasing initiatives, delivery system reform, or performance improvement initiatives be made available to both public and private providers subject to the initiative and are replacing it with a requirement that such initiatives be available to a class of providers.

Comment: Several commenters did not support proposed § 438.6(c)(2)(i)(E) which would prohibit states from conditioning provider participation in a delivery system reform initiative based on intergovernmental transfer agreements. Some commenters requested that CMS permit flexibility on proposed limits or restrictions regarding intergovernmental transfers while others stated that the proposal should be withdrawn entirely. Other commenters requested further clarification on the extent to which the prohibition against conditioning provider participation on intergovernmental transfer arrangements would restrict increased capitation payment programs where the non-federal share component is based entirely on voluntary local contributions.

Response: Section 438.6(c)(2)(i)(E) means that the network provider's participation in a contract arrangement under paragraphs (c)(1)(i) through (c)(1)(iii) cannot be conditioned on the network provider entering into or adhering to an IGT agreement. The approaches in § 438.6(c)(1)(i) through (iii) are permissible ways under the managed care contract to set minimum payment requirements or reimbursement models or to incent quality outcomes. These approaches recognize the role of the provider in the delivery of services rather than as a source of the non-federal share. Therefore, it is imperative that provider eligibility to receive payments under

these provisions can only be conditioned on the delivery of services in the instances of minimum provider fee schedules or value based purchasing models or the achievement of specified performance measures. We will finalize § 438.6(c)(2)(i)(E) to clarify that the network provider's participation in the contract arrangements at paragraphs (c)(1)(i) through (iii) is not conditioned on the network provider entering or adhering to an IGT agreement; this change is discussed in more detail in connection with § 438.6(b)(2)(i) through (v) and (b)(3)(i) through (v) above.

Comment: One commenter recommended that CMS revise proposed § 438.6(c)(2)(i)(F) from "not to be renewed automatically" to "may not be renewed automatically" so that the phrase makes a complete sentence when paired with the lead-in phrase.

Response: We appreciate the commenters suggestion and will finalize § 438.6(c)(2)(i)(F) with that change.

Comment: Many commenters stated concerns regarding proposed § 438.6(c)(2)(ii)(A) and (B) regarding performance measures. Several commenters recommended that CMS provide flexibility when it comes to managed care plan requirements of performance measurement for providers. Commenters stated that there is too much variation in provider setting, specialty, and patient population characteristics to require all providers to focus on the same performance measures. One commenter recommended that CMS require the quality performance measures utilized in the Medicaid quality rating system (QRS) to provide the foundation for the performance measurement approach used to define health outcomes. Other commenters recommended that CMS prescribe specific performance measures in tracking value, such as those related to preventable admissions, spending per patient, emergency room visits, and adverse inpatient events. Commenters also recommended the utilization of patient reported measures (PRM), which can support understanding of how patients do over time and to assess care performance. Some commenters recommended specific performance measures for MLTSS programs. One commenter recommended that managed care plan contracts include performance incentives and penalties tied to achieving change in the integration and coordination of services across systems and improving population health.

Response: We appreciate commenters' suggestions for the types of performance measures that should be part of a state's delivery system reform efforts; however, we decline to specify particular

measures or approaches in regulation to provide states with appropriate flexibility to target initiatives that meet the needs of their specific Medicaid programs.

Comment: Many commenters disagreed with proposed § 438.6(c)(2)(ii)(D) which prohibits the state from recouping any unspent funds allocated for delivery system or provider payment initiatives from the managed care plan. Commenters recommended that the final rule permit states to share in the savings with managed care plans, with the terms for doing so specified in the negotiated agreement. Several commenters recommended that unspent funds be reinvested with high-quality providers or returned to the state Medicaid program to reinvest in other delivery system reform initiatives.

Response: Managed care plans receive risk-based capitation payments to carry out the obligations under the contract. Section 438.6(c) establishes parameters by which the state can direct expenditures under the contract. As funds associated with delivery system reform or performance initiatives are part of the risk-based capitation payment, any unspent funds remain with the MCO, PIHP, or PAHP.

Comment: Several commenters recommended that CMS provide a clear regulatory path for value-based or delivery system reform payments to be considered in rate setting. Commenters recommended that CMS provide a linkage between proposed §§ 438.5 and 438.6(c) to clarify that payments made under a value-based purchasing model, where improvements in population health driven by managed care plans and their providers reduced the volume of encounters, can be considered as an allowable component of rate development. Some commenters stated that implementing delivery system reforms has administrative cost implications, including data analysis, program design and monitoring, and contract development activities. Commenters stated that these costs need to be considered in actuarial soundness analyses and included in the administrative component of the capitation rate. Commenters also recommended that managed care plans not be penalized in any MLR calculations as a result of having to spend additional administrative dollars to undertake these activities.

Response: Section 438.7(b)(6) requires that the rate certification describe any special contract providers related to payment in § 438.6(c). In addition, § 438.5(e) pertaining to the non-benefit component of the capitation rate development includes other operational

costs, which could accommodate administrative expenses incurred in the operation of delivery reform efforts under the contract. The MLR calculation standards finalized in this rule for the numerator at § 438.8(e)(3)(i), relating to activities that improve health care quality, encompass value-based purchasing or other delivery system reforms; therefore, we do not believe that there is a concern about penalizing managed care plans in the MLR calculation in this context. Section § 438.8(e)(3)(i) incorporates 45 CFR 158.150(b) and that provision sets forth criteria for activities that improve health care quality in a manner that would accommodate such approaches. Therefore, we do not believe additional specificity is necessary in regulation.

Comment: Many commenters disagreed with proposed § 438.6(c)(1) and specified that limiting state direction of payments under the managed care plan contract has never been a longstanding policy of CMS before this proposed rule. Several commenters stated that there is no federal statute prohibiting a state from directing the expenditures of an MCO, PIHP, or PAHP and recommended that CMS remove the language at § 438.6(c)(1). Many commenters recommended that CMS allow flexibility for delivery system reform programs to reflect state and local realities, allowing states and managed care plans to design quality and value-based purchasing efforts to target providers and direct payments to drive overall improvement in care delivery and access to care. Other commenters stated that CMS' characterization in the proposed rule was inaccurate given that CMS has approved managed care plan arrangements that involve requirements for managed care plans to make minimum payments for designated providers.

Many commenters stated specific concerns regarding proposed § 438.6(c)(1) and stated that the regulatory language creates inequality in the use of supplemental payments in managed care compared to FFS programs. Commenters stated that by making it more difficult for states to use supplemental payments in managed care, it would dis-incentivize the use of the managed care delivery model. Commenters stated that the proposed regulatory language would limit the full functionality of Medicaid managed care in driving quality and value for Medicaid beneficiaries. Commenters stated that CMS' regulatory approach would inhibit state flexibility to produce the next generation of transformative innovations and that the

proposed new restrictions could create the potential for a major destabilization of state health care delivery systems. Commenters recommended that rather than restricting the use of supplemental payments in broad and inappropriate ways, CMS should pursue alternative approaches to promote transparency around these payments. Commenters stated that such an approach would help the agency achieve its policy goals while ensuring the policy is not a barrier to the use of Medicaid managed care or other innovation.

Many commenters recommended that CMS modify the proposed language to provide additional flexibility for states to direct expenditures to promote access to services for safety-net providers and tailor payment models, for specific class of provider type. Commenters recommended that CMS include a fourth exception (to be codified at a new § 438.6(c)(1)(iv)) to allow states to direct managed care payments to promote access to and retain certain types of safety-net providers, including public hospitals and public health systems to ensure that Medicaid can retain essential community providers. Many commenters stated that the proposed language would destabilize their safety-net provider systems and block states from targeting additional Medicaid support to providers with the largest Medicaid patient populations and acknowledging the role and extra burden these safety-net providers bear and their inability to subsidize low reimbursement rates.

Response: We agree with commenters that it is critical for states to have flexibility in using their Medicaid managed care programs to drive value for beneficiaries through improved quality, better care coordination, and reduced costs. We also agree with commenters that the regulatory approach should not serve as a barrier to innovation and to transformative payment approaches. However, we believe that the statutory requirement that capitation payments to managed care plans be actuarially sound requires that payments under the managed care contract align with the provision of services to beneficiaries covered under the contract. Aligning provider payments with the provision of services through managed care contracts is also necessary to support improved care delivery and transformative innovation. In our review of managed care capitation rates, we have found pass-through payments being directed to specific providers that are generally not directly linked to delivered services or the outcomes of those services. These pass-through payments are not

consistent with actuarially sound rates and do not tie provider payments with the provision of services.

For purposes of this final rule, we define pass-through payments at § 438.6(a) as any amount required by the state to be added to the contracted payment rates between the MCO, PIHP, or PAHP and hospitals, physicians, or nursing facilities that is not for the following purposes: A specific service or benefit covered under the contract and provided to a specific enrollee; a provider payment methodology permitted under § 438.6(c)(1)(i) through (c)(1)(iii) for services and enrollees covered under the contract; a subcapitated payment arrangement for a specific set of services and enrollees covered under the contract; GME payments; or FQHC or RHC wrap around payments. This definition is consistent with the definition for pass-through payments in CMS' 2016 Medicaid Managed Care Rate Guidance.

Accordingly, our final rule phases out the ability of states to use pass-through payments by allowing states to direct MCO, PIHP and PAHP expenditures only based on the utilization, delivery of services to enrollees covered under the contract, or the quality and outcomes of services. However, because we recognize that pass-through payments are often an important revenue source for safety-net providers and some commenters requested a delayed implementation of the provision at § 438.6(c), the final rule will allow transition periods for pass-through payments to hospitals, physicians and nursing facilities to enable affected providers, states, and managed care plans to transition pass-through payments into payments tied to services covered under the contract, value-based payment structures, or delivery system reform initiatives without undermining access for the beneficiaries they serve.

To clearly address the issues raised by commenters, it is helpful to clarify the statutory and regulatory differences between provider payments under FFS and managed care programs. In the case of FFS, section 1902(a)(30)(A) of the Act requires that payment for care and services under an approved state plan be consistent with efficiency, economy, and quality of care. Regulations implementing section 1902(a)(30)(A) of the Act permit states considerable flexibility in structuring FFS rates, but impose aggregate upper payment limits (UPLs) on rates for certain types of services or provider types. For institutional providers, these UPLs are generally based on Medicare payment methodologies. Additionally, these UPLs determine the maximum amount

of federal funding, or FFP, that is available for services through these institutional providers. Many states have used the flexibility under FFS to structure rates to include both base payment rates and supplemental rates, with the supplemental rates in some cases reflecting individual provider circumstances, such as the volume of uncompensated care. Since aggregate supplemental payments, when added to the aggregate base payments, cannot exceed the UPL, the supplemental payments are sometimes tied directly to the UPL calculation.

To draw down the federal share of an expenditure for a provider payment, including expenditures for supplemental payments, states must document an expenditure that includes a non-federal share. Supplemental payments are typically funded by intergovernmental transfers (IGTs) from local governments, by certified public expenditures (CPEs) from public providers, or by provider taxes, all of which are permissible sources of the nonfederal share of Medicaid spending. As states have faced budget pressures, states have sought various approaches to maintain existing Medicaid coverage and to avoid reducing benefits for beneficiaries. One approach used to address these challenges has been to increase supplemental payments funded through IGTs, CPEs and provider taxes. Over time, these supplemental payments have become an important and significant revenue stream to certain provider types.

The increase in supplemental payments is frequently associated with lower base payment rates to providers. In fact, in some situations supplemental payment revenues exceed revenues from the Medicaid base rates.⁸ Paying lower base rates raises questions about whether provider rates are sufficient to ensure quality of and access to care, and whether adding or increasing supplemental payments to these lower base rates is sufficient to maintain access and quality across all providers. Moreover, in some cases these supplemental payment mechanisms are contingent on some providers' ability and willingness to provide the nonfederal share through intergovernmental transfers or certified public expenditures rather than on the providers' provision of services or the efficiency or quality of those services. In reviewing supplemental payments, we often find it difficult to demonstrate

their linkage to services, utilization, quality, or outcomes.

In contrast to FFS, section 1903(m)(2)(A)(iii) of the Act provides the requirements for the payment for care and services under managed care. Section 1903(m)(2)(A)(iii) of the Act requires contracts between states and MCOs to provide capitation payments for services and associated administrative costs that are actuarially sound. The underlying concept of managed care and actuarial soundness is that the state is transferring the risk of providing services to the MCO and is paying the MCO an amount that is reasonable, appropriate, and attainable compared to the costs associated with providing the services in a free market. Inherent in the transfer of risk to the MCO is the concept that the MCO has both the ability and the responsibility to utilize the funding under that contract to manage the contractual requirements for the delivery of services. Further, unlike FFS, which uses maximum aggregate caps to limit the amount of FFP available, managed care limits the amount of FFP to the actuarially sound capitation rate paid to the managed care plan, which is based on the amount of funding that is reasonable and appropriate for the managed care plan to deliver the services covered under the contract. We also note here that the actuarial soundness requirements apply statutorily to MCOs under section 1903(m)(2)(A)(ii) of the Act and were extended to PIHPs and PAHPs under our authority in section 1902(a)(4) of the Act in the 2002 final rule.

Because the capitation payment that states make to a managed care plan is expected to cover all reasonable, appropriate, and attainable costs associated with providing the services under the contract, the statutory provision for managed care payment does not anticipate a supplemental payment mechanism. Managed care plans are expected to utilize capitation payments made under a contract to cover all reasonable, appropriate and attainable costs associated with providing the services under the contract. We do not believe that section 1903(m)(2)(A)(ii) of the Act permits managed care payments that are not directly related to the delivery of services under the contract, because it requires actuarially sound payments for the provision of services and associated administrative obligations under the managed care contract.

We disagree with the assertion of commenters that limiting state direction of payments under the managed care plan contract has not been a federal policy before the proposed rule. As

⁸ MACPAC. "MACfacts Key Findings on Medicaid and CHIP: Medical UPL Supplemental Payments" (Nov 2012), available at https://www.macpac.gov/wp-content/uploads/2015/01/MACFacts-UPL-Payments_2012-11.pdf.

discussed at 80 FR 31123, § 438.6(c)(4) (redesignated at § 438.3(c) in this final rule) limits the capitation rate paid to MCOs, PIHPs, or PAHPs to the cost of state plan services covered under the contract and associated administrative costs to provide those services to Medicaid eligible individuals. Furthermore, under § 438.60, the state must ensure that additional payments are not made to a provider for a service covered under the contract other than payment to the MCO, PIHP or PAHP with specific exceptions. We have interpreted these regulations to mean that the contract with the MCO, PIHP or PAHP defines the comprehensive cost for the delivery of services under the contract, and that MCOs, PIHPs or PAHPs, as risk-bearing organizations, maintain the ability and responsibility to fully utilize the payment under that contract for the delivery of services.

Current managed care regulations at § 438.60 expressly prohibit the state from making a payment to a provider for services available under the contract between the state and the managed care plan. As a matter of policy, we have interpreted § 438.60 to mean that states are also prohibited from making a supplemental payment to a provider through a managed care plan, which is referred to as a “pass-through” payment, as discussed earlier.

The rationale for this policy interpretation is that the payment to the managed care plan is for the provision of services under the contract, in which the managed care plan is responsible for negotiating contracts with providers. If the state is making a pass-through payment by requiring a managed care plan to pay network providers in a manner that is not related to the delivery of services, this situation is no different than the state making a payment outside of the contract directly to providers. Put another way, the pass-through payment requirements do not align payment to the managed care plan or providers with the provision of services.

Despite CMS’ interpretation of § 438.60, a number of states have integrated some form of pass-through payments into their managed care contracts for hospitals, nursing facilities, and physicians. In general, the size and number of the pass-through payments for hospitals has been more significant than for nursing facilities and physicians. There are multiple reasons that states have implemented pass-through payments into their managed care contracts. Commonly, states that have moved from FFS to managed care have sought to ensure a consistent payment stream for certain

critical safety-net hospitals and providers and to avoid disrupting existing IGT, CPE, and provider tax mechanisms associated with the supplemental payments.

The amount of the pass-through payment often represent a significant portion of the overall capitation rate under the contract. We have seen supplemental payments that have represented 25 percent, or more, of the overall contract and 50 percent of individual rate cells. The rationale for these pass-through payments in the development of the capitation rates is often not transparent and it is not clear what the relationship of these pass-through payments is to the requirement for actuarially sound rates. Additionally, not directly connecting provider payments to the delivery of services also compromises the ability of managed care plans to manage their contractual responsibilities for the delivery of services.

We are concerned that pass-through payments may limit a managed care plan’s ability to effectively use value-based purchasing strategies and implement quality initiatives. As in FFS, the existence of pass-through payments may affect the amount that a managed care plan is willing or able to pay for the delivery of services through its base rates or fee schedule. In addition, pass-through payments make it more difficult to implement quality initiatives or to direct beneficiaries’ utilization of services to higher quality providers because a portion of the capitation rate under the contract is independent of the services delivered. Put another way, when the fee schedule for services is set below the normal market, or negotiated, rate to account for pass-through payments, moving utilization to higher quality providers can be difficult because there may not be adequate funding available to incentivize the provider to accept the increased utilization. In addition, when pass-through payments guarantee a portion of a provider’s payment and divorces the payment from service delivery, it is more challenging for managed care plans to negotiate provider contracts with incentives focused on outcomes and managing individuals’ overall care.

We understand that many states are interested in directing efforts through contracts with MCOs, PIHPs, or PAHPs to improve and integrate care, enhance quality, and reduce costs. Some states have also had an interest in using their Medicaid program, which is often one of the largest payers in a state, to promote market-wide delivery and payment changes in collaboration with other

insurers in the state. We have clarified elsewhere in our response to comments that § 438.6(c) provides explicit mechanisms to support innovative efforts to transform care delivery and payment. Section 438.6(c)(1)(i) allows states to contractually require managed care plans to adopt value-based purchasing approaches for provider reimbursement. In addition, section 438.6(c)(1)(ii) allows states to require managed care plan participation in multi-payer, market-wide delivery system reform, or Medicaid-specific delivery system reform or performance improvement initiatives. Finally, § 438.6(c)(1)(iii) allows states to specify minimum and maximum provider fee schedules. The provisions of § 438.6(c) provide significant flexibility for states to use their Medicaid managed care program to implement initiatives to improve and integrate care, enhance quality, and reduce costs. However, § 438.6(c)(2)(i)(A) and (B) maintains our approach in the proposed rule to require that the payment arrangements be based on the utilization, delivery of services, and performance under the contract. As a whole, § 438.6(c) maintains the MCO’s, PIHP’s, or PAHP’s ability to fully utilize the payment under that contract for the delivery and quality of services by limiting states’ ability to require payments that are not directly associated with services delivered to enrollees covered under the contract.

While we do not believe that pass-through payments are consistent with actuarially sound rates and do not align provider payments with the provision of services, we also acknowledge pass-through payments have served as critical source of support for safety net providers who provide care to Medicaid beneficiaries. We also share commenters concerns that an abrupt end to pass-through payments could create significant disruptions for some safety-net providers who serve Medicaid managed care enrollees. As such, we are retaining our proposal to transition pass-through payments into value-based payment structures, delivery system reform initiatives, or payments tied to services under the contract as provided in § 438.6(c)(1)(i) through (iii).

We recognize the challenges associated with transitioning pass-through payments into payments for the delivery of services covered under the contract to enrollees or value-based payment structures for such services. The transition from one payment structure to another requires robust provider and stakeholder engagement, agreement on approaches to care delivery and payment, establishing systems for measuring outcomes and

quality, planning, and evaluating the potential impact of change on Medicaid financing mechanisms. Many states and state Medicaid programs are actively working through many of these issues as part of efforts to move toward value-based purchasing, but the process often takes substantial time and attention. We recognize that implementing value-based payment structures, other delivery system reform initiatives and working through these transition issues, including ensuring adequate base rates, is central to both delivery system reform and to strengthening access, quality and efficiency in the Medicaid program. Ensuring that actuarially sound capitation rates include adequate provider payments is one of the reasons that § 438.4(b)(3) requires an evaluation of the adequacy of the capitation rates to meet the requirements on MCOs, PIHPs, and PAHPs in §§ 438.206, 438.207, and 438.208 for the availability of services and support coordination and continuity of care. We also note that § 438.6(c)(2)(i)(B), which permits any of the approaches in § 438.6(c)(1)(i) through (iii) to be directed toward specific classes of providers, is a tool through which states and managed care plans can support payment rates that are directly tied to services.

In an effort to provide a smooth transition for network providers, to support access for the beneficiaries they serve, and to provide states and managed care plans with adequate time to design and implement payment systems that link provider reimbursement with services covered under the contract or associated quality outcomes, we will finalize this rule with a new § 438.6(d) that provides for transition periods related to pass-through payments for specified providers. The rule provides a 10-year transition period for hospitals, subject to limitations on the amount of pass-through payments in § 438.6(d)(2) through (3). After July 1, 2027, states will not be permitted to require pass-through payments for hospitals under a MCO, PIHP, or PAHP contract. The rule also provides a 5-year transition period for pass-through payments to physicians and nursing facilities. After July 1, 2022, states will not be permitted to require pass-through payments for physicians and nursing facilities under a MCO, PIHP, or PAHP contract. After July 1, 2022, for physicians and nursing facilities, and after July 1, 2027 for hospitals, only the approaches in § 438.6(c)(1)(i) through (iii) will be permitted mechanisms for states to direct the MCO's, PIHP's or PAHP's expenditures under the contract. This

transition period provides states, network providers, and managed care plans time and flexibility to integrate pass-through payment arrangements into different payment structures, including enhanced fee schedules or the other approaches consistent with § 438.6(c)(1)(i) through (c)(1)(iii) under actuarially sound capitation rates.

Section 438.6(d) sets forth the time frames and requirements for transitioning pass-through payments to payment structures linked to delivered services for hospitals, physicians, and nursing facilities. We have created transition periods for the payment structures for the three provider types acknowledged in § 438.6(d), because these are the primary provider types to which states make UPL and other supplemental payments under state plan authority, which states have typically sought to continue making as pass-through payments under managed care programs.

It is important to note that § 438.6(d) provides different periods for hospitals versus nursing facilities and physicians. States are also required to phase down hospital pass-through payments, but do not have the same requirement for physicians and nursing facilities. This distinction in the treatment of hospitals versus physicians and nursing facilities under § 438.6(d) is based on the difference in number and dollar amount of pass-through payments to these different provider types under managed care today. Pass-through payments to hospitals are significantly larger than the pass-through payments to physicians and nursing facilities. We recognize that states and hospitals may use a variety of payment approaches to link payments to services and outcomes. Understanding that it will take significant time to design and implement alternative approaches consistent with the final rule and the amount of funding involved, we provided a longer time period to transition pass-through payments to hospitals. We also provide for a phased transition with annual milestones. Having these milestones is particularly important for hospital payments where states may use multiple approaches to achieving the goal of complying with the final rule.

We believe that states will be able to more easily transition pass-through payments to physicians and nursing facilities to payment structures linked to services covered under the contract. Consequently, we have provided a shorter time period for eliminating pass-through payments to physicians and nursing facilities, but have also not required a prescribed phase down for

these payments, although states have the option to phase down these payments if they prefer. The distinction between hospitals and nursing facilities and physicians is also based on the comments from stakeholders during the public comment period to the proposed rule. We received many comments on the disruptive nature to hospitals and beneficiary access if such pass-through arrangements were abruptly eliminated. Similar concerns were not raised with respect to payments to physicians and nursing facilities.

To determine the total amount of pass-through payments to hospitals that may be included in the MCO, PIHP or PAHP contracts in any given contract year under the final rule, a state must calculate a base amount and then reduce the base amount by the schedule provided in § 438.6(d)(3). The base amount is defined at § 438.6(a) as the amount available for pass-through payments to hospitals in a given contract year subject to the schedule for the reduction of the base amount in paragraph (d)(3). For contracts beginning on or after July 1, 2017, a state would be able to make pass-through payments for hospitals under the contract up to the full "base amount" as defined in § 438.6(a).

The portion of the base amount calculated in § 438.6(d)(2)(i) is analogous to performing UPL calculations under a FFS delivery system, using payments from managed care plans for Medicaid managed care hospital services in place of the state's payments for FFS hospital services under the state plan. The portion of the base amount calculated in § 438.6(d)(2)(ii) takes into account hospital services and populations included in managed care during the rating period that includes pass-through payments which were in FFS 2 years prior. This timeframe and use of 2-year old data is in place so that the state has complete utilization data for the service type that would be subject to pass-through payments. We point out that the base amount includes both inpatient and outpatient hospital services. Therefore, the calculation of the base amount in § 438.6(d)(2) is calculated using a four-step process:

- *Step One:* Identify the hospital services that will be provided for the populations under managed care contracts in the time period for which the base amount of pass-through payments is being calculated.
- *Step Two:* For the hospital services identified in Step One that were provided to the relevant populations under managed care contracts for the 12-month period immediately 2 years

prior to the time period for which the base amount for pass-through payments is being calculated, compare reasonable estimates of the aggregate difference between: (a) The amount Medicare would have paid for those hospital services as utilized under the MCO, PIHP, or PAHP contracts 2 years prior; and (b) the amount MCOs, PIHPs, or PAHPs paid (not including pass through payments) for those hospital services utilized under the MCO, PIHP, or PAHP contracts for the 12-month period immediately 2 years prior.

- *Step Three:* For the hospital services identified in Step One that were provided to the relevant populations under FFS during the 2 years immediately prior to the time period for which the base amount is being calculated, compare actual or reasonable estimates of the aggregate difference between: (a) The amount Medicare FFS would have paid for those hospital services as utilized under FFS two years prior; and (b) the amount the state paid under FFS (not including supplemental payments) for those hospital services utilized 2 years prior. This step is in place to acknowledge situations where hospital services may not have been covered for some populations during the period for which the base amount of pass-through payments is calculated.

- *Step Four:* Sum the reasonable estimates of the aggregate differences calculated in Step Two and Step Three.

As an example, for contracts starting on July 1, 2017, the base amount is derived for the hospital services and the populations that will be included in the July 1, 2017 managed care contracts. For those hospital services and populations, the difference between what Medicare FFS would have paid for the hospital services utilized in 2015 (under Medicaid managed care and/or Medicaid FFS, as appropriate) and the actual Medicaid payments for the hospital services utilized in 2015 (under managed care and/or FFS, as appropriate) represents the base amount. This method for establishing the base amount, which uses the aggregate difference between Medicaid and Medicare reimbursement for actual hospital utilization, is directly analogous to the calculations of a hospital UPL payment under Medicaid FFS and is, therefore, a familiar exercise for many states.

Building on the similarity to the FFS hospital UPL calculations, in § 438.6(d)(2)(iv), we permit states to make reasonable estimates of the aggregate differences in Steps Two and Three in accordance with the hospital upper payment limit requirements

under 42 CFR part 447 and described in CMS' hospital UPL guidance, available at <https://www.medicaid.gov/medicaid-chip-program-information/by-topics/financing-and-reimbursement/accountability-guidance.html>.

Section 438.6(d)(2)(iii) establishes that the base amount is calculated by the state on an annual basis and is recalculated annually. This annual recalculation is done to account for various factors which impact hospital service utilization over time such as changes in enrollment, fee schedules, and service mix.

The schedule for the phased reduction of the base amount of pass-through payments to hospitals is specified at § 438.6(d)(3). As mentioned above, for contracts beginning on or after July 1, 2017, the state may require pass-through payments to hospitals under the contract up to the base amount. For subsequent contract years (contracts beginning on or after July 1, 2018 through contracts beginning on or after July 1, 2026), the available amount of pass-through payments decreases by 10 percentage points per year. To illustrate, for contracts beginning on or after July 1, 2018, 90 percent of the base amount is available to be included as pass-through payments under the contract. Per this schedule, contracts beginning on or after July 1, 2026, can include 10 percent of the base amount as pass-through payments. For contracts starting on or after July 1, 2027, no pass-through payments are permitted. In addition, this schedule applies regardless of when a state elects to include pass-through payments. If a state elected to include pass-through payments starting for contracts on or after July 1, 2018, rather than 2017, the amount available for pass-through payments is 90 percent of the base amount. We note that nothing in this paragraph would prohibit a state from eliminating pass-through payments to hospitals before contracts starting on or after July 1, 2027. However, we provided for a phased reduction in the percentage of the base amount that can be used for pass-through payments, anticipating that a phased transition would support the development of stronger payment approaches while mitigating any disruption to states and providers.

Section 438.6(d)(4) specifies that the calculation of the base amount must be included in the rate certification required under § 438.7. The documentation must include the following: A description of the data, methodologies, and assumptions used to calculate the base amount; each calculated component of the base

amount in § 438.6(d)(2)(i) through (ii); and the calculation of the applicable percentage of the base amount available for pass-through payments under the schedule in paragraph (d)(3). These additional documentation requirements only apply when the contract with the state requires MCOs, PIHPs or PAHPs to make pass-through payments and the state is relying on § 438.6(d) rather than an exception identified in § 438.6(c) to direct the MCO's, PIHP's or PAHP's expenditures.

At § 438.6(d)(5), for contracts starting on or after July 1, 2017, pass-through payments would be permitted for physicians and nursing facilities at any amount; this means that pass-through payments for physicians and nursing facilities are not subject to the base amount calculation at paragraph (d)(2) or the schedule for pass-through payments at paragraph (d)(3) that are applicable to hospitals. However, the transition period for pass-through payments to physicians and nursing facilities is shorter than that provided for hospitals. Pass-through payments for physicians and nursing facilities are permitted for a total of 5 years ending with contracts that begin on or after July 1, 2022. This transition period for pass-through payments to physicians and nursing facilities is in place to provide states maximum flexibility over the 5 year period that such payments may be made under managed care contracts. Again, the rationale for the shorter transition timeframe is based on our understanding that these payments are generally smaller than the pass-through payments attributable to hospitals and, therefore, the process of tying the payments more directly to services will be less disruptive. States could elect to take an approach that incrementally phases down the amount of pass-through payments to these provider types or to eliminate pass-through payments immediately or a period less than 5 years.

Therefore, after consideration of the public comments, we are finalizing the proposals at § 438.6(c) with the following modifications:

- Clarified the statutory and regulatory requirements under Title XIX, as applicable to managed care programs, that would be exceptions to the general rule at § 438.6(c)(1).
- Modified §§ 438.3(c)(1)(iii)(A) and (B) to remove the proposed requirement that a minimum fee schedule or uniform dollar or percentage increase in provider payments apply to all providers that provide a particular service under the contract and made a technical modification to insert "network" before "providers" in each of these paragraphs.

- Added a new § 438.6(c)(1)(iii)(C) to specify that states can include a maximum fee schedule in managed care plan contracts, so long as the managed care plan retains the ability to reasonably manage risk and have discretion in accomplishing the goals of the contract.

- Clarified § 438.6(c)(2) that expenditures under § 438.6(c)(1)(i) through (iii) must be developed in accordance with §§ 438.4, 438.5, and generally accepted principles and practices.

- Changed §§ 438.6(c)(2)(i)(B) and 438.6(c)(2)(ii)(A) to permit states to direct expenditures or make participation in value-based purchasing, delivery system reform, or performance improvement initiatives to a class of providers rather than to all public and private providers under the contract.

- Revised § 438.6(c)(2)(i)(E) to clarify that the network provider's participation in a contract arrangement under paragraphs (c)(1)(i) through (c)(1)(iii) is not conditioned on the network provider entering or adhering to an IGT agreement.

In addition, we are finalizing § 438.6 with a new paragraph (d) to define pass-through payments, to permit pass-through payments to hospitals subject to a specific calculation and schedule so that the availability of pass-through payments for hospitals under managed care contracts ceases for contracts starting on or after July 1, 2027. This new paragraph permits pass-through payments for physicians and nursing facilities for contracts starting on or after July 1, 2017 through contracts starting on or after July 1, 2021.

At 80 FR 31125, we stated our belief that the regulations in part 438 were not a barrier to the operation of programs that promote wellness among beneficiaries by Medicaid managed care plans. We advised states and managed care plans that undertake efforts to reward beneficiary health care decisions and behaviors through inexpensive gifts or services to consult OIG guidance for compliance with section 1128A(a)(5) of the Act. See, for example, OIG, *Special Advisory Bulletin: Offering Gifts and Other Inducements to Beneficiaries* (August 2002), available at <http://oig.hhs.gov/fraud/docs/alertsandbulletins/SABGiftsandInducements.pdf>.

We received the following comments on the preamble discussion on wellness initiatives.

Comment: Several commenters supported the preamble language in the proposed rule at 80 FR 31125 to promote wellness among beneficiaries by managed care plans and recommended that CMS add regulatory

language to support wellness initiatives. Commenters also recommended that CMS clarify section 1128A(a)(5) of the Act and the OIG guidance bulletin by discussing more completely the scope and applicability related to wellness incentives. Several commenters recommended that CMS develop a more flexible policy for the promotion of Medicaid wellness programs by aligning its rewards and incentives policy for Medicaid managed care with that of MA at § 422.134 in the interest of treating enrollees of both programs similarly and ensuring that the incentives are sufficient in the Medicaid population to motivate healthy behavior.

Response: The discussion of enrollee wellness incentives offered by managed care plans at 80 FR 31125 clarified that part 438 did not prohibit such arrangements but that such arrangements should be developed in consultation with the OIG's Special Advisory Bulletin or through an opinion from the OIG. In light of the ongoing evaluation of the Medicaid Incentives for the Prevention of Chronic Diseases (MIPCD) program authorized under section 4108 of the Affordable Care Act, we believe it is prudent to consider additional guidance in this area that is informed by the lessons learned under that program. We are not adopting a final rule that would incorporate reward and incentive authority for Medicaid managed care that is similar to authority for MA organizations under § 422.134.

e. Rate Certification Submission (§ 438.7)

In new § 438.7, we proposed the content of the rate certification that is submitted by the state for CMS review and approval. This section is distinguished from the rate development standards in § 438.5 in that it focuses on documentation of rate development as opposed to the actual steps taken by states and actuaries to develop capitation rates. This section includes a new proposal that states receive CMS' approval of the rate certification in addition to the contract, as provided in § 438.3(a). The rate certification is part of the procedural mechanism for CMS to ensure that the capitated rates payable to MCOs, PIHPs, and PAHPs are actuarially sound as specified in section 1903(m)(2)(A)(iii) of the Act. We proposed that rate certifications in § 438.7(a) follow the same procedures as for contract submissions through a cross-reference to § 438.3(a). Our proposal therefore included the regulatory flexibility to set forth timeframes and more detailed processes for the submission of the rate certification review and approval

process in subregulatory guidance, which is in addition to the specific proposed standard that states seeking contract and rate approval prior to an anticipated effective date should submit such contracts and rate certifications to us no later than 90 days before anticipated effective date. We believe that review and approval of the rate certification separate from the approval of a contract is an integral step to work with states to ensure appropriate rates under these programs and to modernize our oversight of Medicaid managed care rate setting practices. In addition, we provided that this approach will streamline the approval process as the rate certification supports the payment terms in the contract. We explained that section 1903(m)(2)(A)(iii) authorizes us to stipulate review and approval of both the contract and the rate certification for MCOs as the contract must include the payment rates, which are developed via the rate certification. Consistent with existing standards for our review and approval for PIHP and PAHP contract in § 438.6(a) (redesignated as § 438.3(a) in this final rule), we proposed to extend the review and approval standards for the rate certification for PIHPs and PAHPs under our authority under section 1902(a)(4) of the Act. Under our proposal, the rate certification would describe and provide the necessary documentation and evidence that the rates were developed consistent with generally accepted actuarial principles and practices and applicable regulatory standards. In the event that the certification and the contract are submitted to us at different times, we noted in the proposed rule that we would approve the rate certification prior to approval of the contract but that FFP for the program would be contingent upon approval of the contract. Our statutory authority to oversee the Medicaid program and to ensure that capitation rates are actuarially sound, which in turn helps states and managed care plans to improve access to and quality of care for Medicaid beneficiaries, would be met by review of the documentation we proposed to require.

We received the following comments on proposed § 438.7 generally.

Comment: We received many comments of support for the proposed provisions in § 438.7. Commenters supported the increased oversight and transparency of the rate certification process, the amount and scope of documentation required to be submitted, and the active review and approval role of CMS. We also received one comment stating that the proposed rule is far too prescriptive in the level

of detail required for CMS review and approval of rates. This commenter believed that CMS should respect the work of the actuaries rather than checking each and every calculation they perform.

Response: We appreciate commenters' support for the provisions of § 438.7 and disagree that the requirements for the documentation in the rate certification submitted for CMS' review is overly prescriptive. In our view, the requirements proposed and finalized at § 438.7 reflect a level of detail and documentation in the rate certification that is supported by generally accepted actuarial standards and practices. It is not CMS' intent to check or verify every calculation that is performed to develop the rate certification; rather, the standards in § 438.7 support a level of documentation and detail that enable CMS to understand the actions that were taken by the actuary when developing the capitation rates.

Comment: Consistent with comments on the use of the terms "sufficient" or "adequate" in § 438.5, we also received comments about the subjectivity of the term "adequate" to describe the level of documentation throughout § 438.7

Response: According to the Merriam-Webster dictionary (accessed online), the simple definition of "adequate" is sufficient for a specific requirement or of a quality that is good or acceptable. Section 438.7 describes the level of documentation in the rate certification to support the rate development standards which is not associated with the characteristics of a particular Medicaid program. For that reason, § 438.7 will be finalized with use of the adverb "adequately" throughout so that it is clear that information must be adequately documented with enough detail.

We received the following comments on proposed § 438.7(a).

Comment: We received many comments on proposed § 438.7(a) regarding the submission of the certification 90 days in advance of the rates' effective date. A few commenters supported this provision while most believed 90 days was too long. Commenters suggested 30–45 days as a more appropriate time frame.

Commenters believed that such an early submission would result in states using data that is less timely, which raises concerns with accuracy of developed rates. Commenters explained that actuaries at the state level generally take 60 days or more to conduct their analysis and establish rates. For states to meet the proposed 90 day state submission deadline, the data used for rates will be almost 6 months old by the

time of the contract effective date, at a minimum. The commenters stated that the 90 day time frame would limit the State's ability to capture the latest policy and budget changes in the rate development process.

Response: As described in response to similar comments to § 438.3(a), we disagree with commenters that requested a 45 day timeframe for the submission of rate certifications to mitigate concerns of the actuary relying on older data for rate setting purposes to meet the 90 day timeframe. Section 438.5(c)(2) would require states and their actuaries to use appropriate base data with the basis of the data being no older than the 3 most recent and complete years prior to the rating period. The additional claims data that would be used in a rate development process that would accommodate a 45 day timeframe for submission to CMS, rather than a 90 day timeframe, is not actuarially significant.

Comment: We received many comments on the release of the information in the state's submission to the managed care plans and the public. Commenters believed § 438.7(a) should be revised to require states to share the information, methodologies, assumptions, procedures and data used in the development of the capitation rates. Some commenters believed this should be done at the same time as the submission is made to CMS, while others suggested release before submitting to CMS or after CMS approval but before implementation.

Response: As provided in response to comments on § 438.3(a), we acknowledge the valuable input that providers and other stakeholders have to offer to inform the development of a state's managed care program and there are public notice and engagement requirements to facilitate that process. However, the direct parties to the contracting process are the state and the managed care plans. We do not believe it would be reasonable to institute a federal requirement that would permit public comment or review of the rate certification. Similarly, we decline to require states to share the information, methodologies, assumptions, procedures and data used in the development of the capitation rates. Such requests could be made by the managed care plans of the states during the contract negotiation phase.

Comment: We received several comments requesting that CMS add a provision to § 438.7(a) for an appeal process of the actuarial soundness of capitation rates for managed care plans to utilize. One commenter believed managed care plans should be able to

appeal an agency determination of actuarial soundness based on additional information that was not reflected in the development of the capitation rates.

Another commenter suggested a process for managed care plans to bring concerns about the actuarial soundness of the methodology and its implementation to CMS for review and possible adjustment.

Response: The actuarial soundness requirement in section 1903(m)(2)(A)(iii) of the Act is met by our determination that capitation are actuarially sound and eligible for FFP; it is not a mechanism for CMS to be an arbiter of payment disputes between the state and managed care plans. Managed care plans have the option of not contracting with states if they believe the capitation rates are too low to reflect the populations, services, and other obligations under the contract. To help ensure that the rate setting process results in actuarially sound capitation rates, managed care plans have every incentive to provide complete and accurate base data to the state. That being said, we are available to meet with managed care plans informally during the review of capitation rates to hear and consider their concerns. Further, our approval of the capitation rates is a final administrative action.

Comment: We received a few comments requesting that CMS guarantee the confidentiality of any proprietary managed care plan data that states submit to CMS.

Response: To the extent applicable, the Freedom of Information Act (FOIA) and the Trade Secrets Act protect the confidentiality of proprietary information submitted to the federal government. However, applicable confidentiality requirements do not restrict the authority of the Office of the Inspector General to access records under the Inspector General Act of 1978,

Comment: We received one comment requesting clarification on whether a community rating model is still an available rating model.

Response: We interpret this comment to mean that the community rating model would not differentiate capitation rates by age or potentially other factors. The concept is not necessarily relevant in Medicaid where enrollees typically do not pay a premium. It is not clear what advantage a state would have in using community rating when the amount the state pays is presumably the same whether age or community rating is used.

After consideration of public comments, we are finalizing § 438.7(a) as proposed.

Section 438.7(b) sets forth the content that must be in the rate certification to initiate the CMS review process. In paragraph (b)(1), the certification would describe the base data. The rate certification would describe how the actuary used professional judgment to determine which data was appropriate after examination of all data sources and the data sources used, as well as reasons if the other data sources provided to the actuary were not used in the rate development process.

We did not receive comments on § 438.7(b)(1) and will finalize as proposed.

In paragraph (b)(2), we proposed specific documentation standards for trend. We proposed that the rate certification be detailed enough so that CMS or an actuary can understand and evaluate the development and reasonableness of the trend and any meaningful differences among trend factors applied across rate cells, populations, or services. Comments relating to trend were addressed in response to comments received on § 438.5(d), we did not receive comments specific to § 438.7(b)(2). We are finalizing § 438.7(b)(2) as proposed.

In paragraph (b)(3), we proposed that the basis for determining the non-benefit component of the rate must be included in the actuarial certification with enough detail so we or an actuary can understand each type of non-benefit expense and evaluate the reasonableness of each cost assumption underlying each non-benefit expense.

We received the following comments on proposed § 438.7(b)(3).

Comment: We received a few comments on proposed § 438.7(b)(3). One commenter requested clarification on whether documentation is needed on each element if a state breaks down the general administrative component into assumptions regarding marketing, medical management, rent, corporate overhead, cost of equipment, depreciation, etc. but excludes certain expenses such as lobbying, political contributions, and management cost in excess of actual cost. Another commenter suggested that § 438.7(b)(3) be revised to indicate that the non-benefit component may be developed in as much detail as identified in the proposed rule or in an aggregated way such that the total administrative and underwriting gain components are reasonable, appropriate, and attainable.

Response: We addressed a similar comment in response to § 438.5(b)(3) and (e). Section 438.7(b)(3) provides that the development of the non-benefit component of the capitation rate must be adequately described so that CMS or

an actuary applying generally accepted actuarial principles and practices can identify each type of non-benefit expense and evaluate the reasonableness of the cost assumptions underlying each expense. Sections 438.5(b)(3) and (e), as finalized, list the following types of non-benefit expenses: Administration; taxes, licensing and regulatory fees; contribution to reserves; risk margin; cost of capital; and other operational costs. While the documentation of the non-benefit component cannot combine all of these items into a single rating factor, it would be permissible for the actuary to document the non-benefit costs according to the following groupings: administration; taxes, licensing and regulatory fees; contribution to reserves, risk margin, cost of capital, and other operational costs. Section 438.7(b)(3) has been modified to clarify the documentation requirements for non-benefit costs by cross-referencing § 438.5(e).

After consideration of public comments, we are finalizing § 438.7(b)(3) with the clarification that non-benefit costs may not be documented as a single rating factor but may be documented according to the types of non-benefit costs listed in the section.

In paragraphs (b)(4)(i) through (iii), we proposed standards for transparency in the rate certification on how the material adjustments were developed and the reasonableness of the adjustment for the population, the cost impacts of each material adjustment and where in the rate development process the adjustment was applied. We understand there may be multiple adjustments applied in the rate setting process, ranging from minor adjustments (which on their own do not impact the overall rate by a material amount), to material adjustments (which may be much greater in scope and magnitude). Therefore, we proposed that states only provide information on the development of and cost impact for each of the material adjustments. Adjustments that do not meet this threshold (“non-material adjustments”), may be aggregated and only the cost impact of that aggregated bundle would need to be shown in the certification as set forth in paragraph (b)(4)(ii). In § 438.7(b)(4)(iv), we proposed that the actuarial certification include a list of all the non-material adjustments used in rate development, but that specifics of each non-material adjustment would not need to be identified. We noted that as we gain experience in reviewing adjustments consistent with these standards and further consult with

states, we may issue guidance on what we believe to be material and non-material adjustments, but until that time, we would expect the actuary to exercise reasonable judgment and good faith when characterizing or treating an adjustment as material or non-material.

We received the following comments in response to proposed § 438.7(b)(4).

Comment: We received one comment stating that, absent a formal CMS definition of materiality, § 438.7(b)(4) should permit materiality to be determined by each certifying actuary and documented in the certification. For proposed § 438.7(b)(4)(iv), a commenter requested clarification on what is meant by “a list of all non-material adjustments used in the rate development process” and clarification on the benefit of listing adjustments that were not deemed material. The commenter questioned if this was intended to address only those adjustments that were included in the development of the capitation rates or all of the adjustments that were considered in the rate development process.

Response: As we stated in the proposed rule, at 80 FR 31126, and restated above, as we gain experience in reviewing adjustments consistent with these standards and further consult with states, we may issue guidance on what we believe to be material and non-material adjustments. Until that time, we expect the actuary to exercise reasonable judgment and good faith when characterizing or treating an adjustment as material or non-material. Regarding the commenter’s question on the intent of § 438.7(b)(4)(iv), the list of all non-material adjustments encompasses non-material adjustments actually applied in the rate development process. The distinction between non-material and material adjustments and the requirement that both be documented in the rate certification permits us, in our review and approval of the rate certification, to document changes in the state’s Medicaid program, knowing that the actuary addressed them and deemed them non-material (for example, if a new small benefit was added to the contract). Note that we may determine in the review of the rate certification that something the actuary deemed non-material is actually material and seek to discuss it with the state.

Comment: One commenter believed that when a state applies an efficiency factor to the proposed rate, the state’s rate certification submission should include documentation supporting the assumptions behind the efficiency factor and that they should be determined by

the actuary to be reasonably achievable, fully transparent, and required milestones be disclosed on a prospective basis.

Response: We concur with the commenter and believe the statement is consistent with the final rule.

After consideration of public comments, we are finalizing § 438.7(b)(4) as proposed.

In paragraph (b)(5), we proposed to establish documentation standards in the certification for prospective and retrospective risk adjustment. In paragraph (b)(5)(i), we proposed that the rate certification should include sufficient detail of the prospective risk adjustment methodology for our review because the methodology is an integral part of the rate development process. To evaluate the appropriateness of the prospective risk adjustment methodology, we proposed that the following specific pieces of information be included in the rate certification: The model selected and data used by the state; the method for calculating the relative risk factors and the reasonableness and appropriateness of the method in measuring the risk of the respective populations; the magnitude of the adjustment on the capitation rate for each MCO, PIHP, or PAHP; and an assessment of the predictive value of the methodology compared to prior rating periods, and any concerns the actuary may have with the risk adjustment process.

Retrospective risk adjustment methodologies are calculated and applied after the rates are certified; however, we proposed in § 438.7(b)(5)(ii) that the certification must document who is calculating the risk adjustment; the timing and frequency of the risk adjustment; the model and the data to be used and any adjustments to them; and any concerns the actuary may have with the risk adjustment process. For either approach to risk adjustment, our proposal required adjustment to be budget neutral under § 438.5(b)(6).

We proposed that use of the risk adjustment model as a method to retrospectively increase or decrease the total payments across all Medicaid managed care plans based on the overall health status or risk of the population would not be permitted. Such retrospective increases or decreases in the total payments would not meet the standard in § 438.5(g) that the risk adjustment methodology be developed in a budget neutral manner. We believe that an adjustment applied to the total payments across all managed care plans to account for significant uncertainty about the health status or risk of a

population is an acuity adjustment, which is a permissible adjustment under § 438.5(f), but would need to be documented under paragraph (b)(4) of this section regarding adjustments. While retrospective acuity adjustments may be permissible, they are intended solely as a mechanism to account for differences between assumed and actual health status when there is significant uncertainty about the health status or risk of a population, such as: (1) New populations coming into the Medicaid program; or (2) a Medicaid population that is moving from FFS to managed care when enrollment is voluntary and there may be concerns about adverse selection. In the latter case, there may be significant uncertainty about the health status of which individuals would remain in FFS versus move to managed care; although this uncertainty is expected to decrease as the program matures.

We received the following comments in response to proposed § 438.7(b)(5).

Comment: We received one comment recommending that CMS not require recertification of the capitation rates through submission of revised rate certification when capitation rates change (after the base rates have been certified) as a result of the application of risk adjustment. The commenter contends that recertification on each risk adjustment would represent a significant, and costly change from current practice. Another commenter believed that requiring recertification would represent a significant change from current practice in that the rate certification is for the base capitation rates and the documentation of risk adjustment certifies that it is being applied on a budget neutral basis. Another commenter requested clarification on whether it will now be a requirement that the actuary include this as a part of the actuarial certification documentation even though risk adjustment can be calculated and applied to the certified base rates by the state or outside vendors.

Response: We appreciate the opportunity to clarify these issues. First, the state would not need to submit a revised rate certification for the capitation rates that have been modified through the risk adjustment methodology if the risk adjustment methodology was approved in the initial rate certification. The state would need to submit an update to the capitation rates under the contract consistent with § 438.3(c) to ensure that CMS has the appropriate capitation rates for purposes of reconciling the CMS-64. That process would not necessarily require a formal

contract amendment and we encourage states to include the payment terms in the contract (as required in § 438.3(c)) as an appendix to the contract for ease of updating the information. We will finalize § 438.7(b)(5) with a new paragraph (iii) to clarify that a new rate certification is not required for the capitation rates to which the risk adjustment methodology was applied. Second, § 438.7(b)(5) requires the rate certification to adequately describe the risk adjustment methodology with enough detail in §§ 438.7(b)(5)(i) or 438.7(b)(5)(ii) for CMS to review and approve the methodology.

Comment: We received a few comments on proposed § 438.7(b)(5) stating that CMS should review the adequacy of the risk adjustment methodology, including a review of information such as the documented R-squared value for the proposed methodology. Any state-specific adjustments to an established methodology (that is, credibility factors) should be thoroughly explained and subject to the transparency requirements. Another commenter requested clarification as to whether the documentation required for prospective risk adjustment includes the magnitude of the adjustment per managed care plan. The commenter stated that this information is not available at the same time as the rate development report and would delay submission of the rate development package if risk score results (not just the methodology) need to be completed.

Response: The risk adjustment methodology, whether prospective or retrospective, must be documented in the rate certification submitted for our review and approval as specified in § 438.7(b)(5). The level of documentation required by the rule includes adjustments to the model (see § 438.7(b)(5)(i)(B) and (b)(5)(ii)(B)). In regard to the second comment, § 438.7(b)(5)(i)(D) specifies that the magnitude of the adjustment on the capitation rate is to be documented per MCO, PIHP, or PAHP. We do not understand the commenter's concern that this requirement would delay submission of the rate certification. If the risk adjustment is applied prospectively, the results, including both the methodology and risk scores, should be known prior to the start of the contract. If the risk adjustment is applied retrospectively, the state would report this along with the changes to the capitation rates.

Comment: We received one comment requesting clarification on the assessment of the predictive value of the risk adjustment methodology compared

to prior rating periods required in proposed § 438.7(b)(5)(i)(E). The commenter believed that for most programs, this will be additional administrative effort going forward and that this issue may be better addressed via reliance upon ASOP No. 45, which specifically covers the topic of risk adjustment, and the CMS Ratesetting Checklist AA.5.4 which indicates use of “generally accepted diagnosis groupers.”

Response: In a prospective risk adjustment model—where enrollee and/or managed care plan data from a prior year is used—it is important to establish how well these models perform. Therefore, we are finalizing as proposed the requirement at § 438.7(b)(5)(i)(E) that the rate certification include an assessment of the predictive values of the methodology compared to prior rating periods.

Comment: We received one comment on proposed § 438.7(b)(5)(i)(F) which requests identifying any concerns the actuary has with the risk adjustment process. The commenter stated that actuaries do not choose or develop the individual risk adjustment factors in many of the states in which capitation rates are set. The actual derivation, cost weights, etc. are typically considered proprietary by either an outside vendor or perhaps even a state. To include “concerns” from the certifying actuary that does not have that detailed knowledge about the risk adjustment process or a way to validate it without undue cost burden is a challenge to request. The commenter suggested that § 438.7(b)(5)(i)(F) be revised to “Where the certifying actuary is responsible for the development of the risk adjustment process, provide any concerns the actuary has with the risk adjustment process.”

Response: The actuary does not necessarily have to evaluate the risk adjustment methodology under this final rule, but if the actuary does, then the actuary will need to specify if there is a concern. However, we note that it would be of concern to us if the risk adjustment is conducted by someone not qualified to do so.

After consideration of public comments, we are adding a new paragraph (iii) to § 438.7(b)(5) to clarify that a revised rate certification is not required for capitation rates that change due to application of an approved risk adjustment methodology. Consistent with other technical corrections to § 438.7 discussed above, the phrase “sufficient detail” was struck and replaced with “enough detail.”

In § 438.7(b)(6), we proposed that the rate certification include a description

of any of the special contract provisions related to payment in § 438.6, such as risk sharing mechanisms and incentive or withhold arrangements. We did not receive comments on § 438.7(b)(6) and are finalizing that provision as proposed.

In paragraph (c), we proposed the rate certification standards for rates paid under risk contracts. In paragraph (c)(1), we acknowledge that states may pay different capitation rates to different managed care plans; for example, some states already account for differences in final capitation rates paid to contracted managed care plans through risk adjustment. States that choose to pay different rates to managed care plans (for factors such as differing administrative assumptions, service area adjustments or other non-risk adjustment methodologies) will need to provide documentation for the different assumptions used in the development of each of the individual rates paid to each plan. While such variations are permissible, we reminded states as reflected and strengthened in this final rule, that all payment rates must be actuarially sound under existing law.

We received the following comments on § 438.7(c)(1).

Comment: We received several comments on the certification of the final rate paid as proposed in § 438.7(c)(1). A few commenters requested clarification on whether a capitation rate is considered to be “independently developed” if it is a rate that is selected from within an actuarially sound rate range that may be used to select or negotiate rates for multiple managed care plans. One commenter requested clarification on whether CMS will require actuarial certification of both the rate range(s) used in the RFP and a second certification for the actual rate. Another commenter requested clarification on whether CMS requires an explanation of why a particular rate within the range is selected, even if the selection is based on negotiation with the managed care plan. Under § 438.7(c)(1), the actuary is required to certify the final capitation rate paid under each risk contract, not the average rate. The entire development of the capitation rates does not necessarily need to be different for each managed care plan operating in the state, as some components of rate development may be the same for all managed care plans in a given managed care program.

Response: We clarify here that the actuary must certify to actuarially sound capitation rates per rate cell, but the actuary may provide a rate range to the state for purposes of contract

negotiation. This is consistent with and permissible under the “independently developed” requirement in § 438.7(c)(1). The rate certification submitted under § 438.7(a) is to the actuarially sound capitation rates per rate cell; this final rule does not require development or submission to CMS of a rate certification for a rate range that may be used in a RFP to contract with managed care plans. The rate certification required under § 438.7 does not need to include an explanation of how the capitation rate was selected from a rate range used during contract negotiations because the rate certification must address the specific capitation rate assigned to each rate cell.

Comment: We received one comment requesting clarification as to what may be conflicting requirements in §§ 438.5(b)(5), 438.7(c)(1) and ASOP No. 49. The commenter requested that CMS confirm that the application of the MLR results for an individual MCO, PIHP, or PAHP—as required by § 438.5(b)(5)—to an average capitation rate for a specific population in a specific geographical service area would not trigger the requirement under § 438.7(c)(1) that rates must be “independently developed.” The commenter also stated that in addition to the MLR, the actuary may also apply other managed care plan specific factors to a single, average capitation rate established for a specific population in a specific geographic area, such as risk adjustment and components of the rate that are competitively bid (such as administrative costs). The commenter requested that CMS confirm that the application of these factors to an average rate would not trigger the requirement under § 438.7(c)(1) that rates be independently developed for each managed care plan.

Response: We do not find the commenter’s scenarios to be in conflict with § 438.7(c)(1). Section 438.7(c)(1) requires the actuary to certify the final rate paid under each risk contract regardless of the MLR results. Under § 438.5(b)(5), the actuary must consider the managed care plan’s past MLR when setting the final capitation rates paid under each risk contract. The actuary must consider whether or not § 438.7(c)(1) requires them to independently develop capitation rates for each MCO, PIHP, or PAHP. This does not mean that the entire development of the rates necessarily needs to be different for each MCO, PIHP, or PAHP, as some components of rate development may be the same for all MCOs, PIHPs, or PAHPs in a given program. The actuary may consider whether or not an average rate would be appropriate for all MCOs, PIHPs, or

PAHPs in a given program, so long as the rate certification is provided for each final capitation rate.

After consideration of public comment, we are finalizing the introductory text in § 438.7(c) as proposed with two technical modifications: (1) To insert “per rate cell” preceding “under each risk contract”; and (2) to insert the word “capitation” after “specific.” We are finalizing § 438.7(c)(1) as proposed by replacing “the” following the phrase “so long as” with the word “each”; and to insert the word “capitation” before “rate.”

In § 438.7(c)(2), we proposed to establish parameters for retroactive adjustments to capitation rates paid under the risk contract. Specifically, we proposed that the state submit a revised rate certification (and contract amendment) that describes the specific rationale, data, assumptions, and methodologies of the adjustment in sufficient detail to understand and evaluate the proffered retroactive adjustments to the payment rate. All such adjustments are also subject to federal timely filing standards for FFP.

Comment: One comment recommended that if the state determines a retroactive rate adjustment is necessary, CMS should require the state to provide supporting information to justify the need for a rate adjustment.

Response: That is the requirement at § 438.7(c)(2).

After consideration of public comments, we are finalizing § 438.7(c)(2) as proposed with a technical correction to insert “claim” so that the regulatory reference is to “Federal timely claim filing requirements” and to insert “enough” in place of “sufficient.” As discussed in section I.B.3.b of this final rule, we will finalize § 438.7(c) with a new paragraph (3) to reflect the state’s ability to modify the certified capitation rate per rate within a 1.5 percent range without submitting a revised rate certification. This provision also specifies that the payment term under the contract must be updated as required under § 438.3(c).

In paragraph (d), we proposed to require states to include additional information in the rate certification if pertinent to our approval of the contract rates and to identify whether that additional information, which may supplement the rate certification, is proffered by the state, the actuary, or another party. This proposal was to set forth our expectations and set parameters for consistent and transparent documentation of the rate setting process so that we conduct more efficient reviews of the rate certification

submissions and to expedite the approval process.

We received the following comments on proposed § 438.7(d).

Comment: We received one comment on proposed 438.7(d) requesting additional detail on what additional information CMS could reasonably require, given that the documentation requirements in § 438.7 as a whole would appear to cover all information necessary for approval.

Response: Section 438.7(d) permits CMS to request additional information, such as data books, rate setting information from past rating periods, or other relevant information, to inform the review of the rate certification and make the determination that the capitation rates are actuarially sound.

After consideration of public comments, we are finalizing § 438.7(d) as proposed.

We proposed to remove the standard currently at § 438.6(c)(4)(iii) that states document the projected expenditures under the proposed contract compared to the prior year’s contract, or with FFS if the managed care program is new. We do not believe that this information is integral to the review of the rate certification or contract; further, such information can be reasonably calculated by CMS if necessary. We did not receive comments on this proposal and will finalize this rule without the requirement that states document the projected expenditures under the contract compared with the prior year’s contract or with FFS.

4. Other Payment and Accountability Improvements

a. Prohibition of Additional Payments for Services Covered Under MCO, PIHP, or PAHP Contracts (§ 438.60)

We proposed a new heading for § 438.60 and to make minor revisions to the regulatory text to clarify the intent of the prohibition of additional payments to network providers that are contracted with an MCO, PIHP or PAHP. The original heading of § 438.60 was “Limit on payments to other providers;” we believe that heading was potentially ambiguous or confusing when paired with the regulatory text as it could be read to treat an MCO, PIHP, or PAHP as a provider. We proposed to revise the section heading as “Prohibition of additional payments for services covered under MCO, PIHP, or PAHP contracts” to make clear that the capitation payments are to be inclusive of all service and associated administrative costs under such contracts. In addition, we proposed to refine overly broad references to Title

XIX of the Act and this title of the CFR to clarify that such payments are permitted only when statute and regulation specifically stipulate that the state make those payments directly to a provider. We explained that the exception to this standard has always been limited to cases where other law (statutory or regulatory) explicitly directs the state to make the additional payment to the health care provider and propose to strengthen the language accordingly. Finally, we proposed to update the cross-reference for GME payments from its current location at § 438.6(c)(5)(v) to § 438.6(b)(4) to reflect the proposed restructuring of § 438.6.

We received the following comments in response to our proposal to revise § 438.60.

Comment: Several commenters objected to the requirement at § 438.6(b)(4) that if the state directly makes payments to network providers for graduate medical education (GME) costs under an approved State plan, the actuarially sound capitation payments must be adjusted to account for those GME payments. A cross-reference to § 438.6(b)(4) is in § 438.60, which conditioned the state’s direct payment of GME payments to providers covered under the managed care contract on compliance with the adjustment to capitation rates to account for such payments.

Response: Section 438.6(b)(4) pertaining to the adjustment to the capitation rates to account for GME payments was redesignated in the proposed rule from § 438.6(c)(5)(v) and is linked to the provision in § 438.60 that permits states to make GME payments directly to network providers. Based on the comments received, it is clear that states were not consistently applying this provision. We agree that for states that make direct GME payments to providers, it is not necessary for the state to develop actuarially sound capitation rates prior to excluding GME payments or to include GME payments that are made directly by the state to eligible providers in the development of the capitation rates. Therefore, we are finalizing § 438.60 without the cross-reference to § 438.6(b)(4) and have deleted that provision from § 438.6(b). State payment of GME directly to network providers is an exception to the general prohibition in § 438.60 for state payments to network providers for services covered under the MCO, PIHP, or PAHP contract. In addition, we will clarify at § 438.60 that GME payments made directly by the state to eligible network providers must be consistent with the state plan.

Comment: We received several comments on the intersection between § 438.60 and supplemental or pass-through payments to network providers.

Response: The discussion of supplemental or pass-through payments is provided in section I.B.3.d of this rule that involves special contract provisions related to payment and proposed § 438.6(c).

After consideration of the public comments, we are finalizing § 438.60 with two modifications: (1) without the cross-reference to § 438.6(b)(4) or the requirement to adjust capitation payments when the state directly makes GME payments to eligible network providers; and (2) with the addition of a requirement that the state payment of GME be consistent with the state plan.

b. Subcontractual Relationships and Delegation (§ 438.230)

We proposed to replace the current standards in § 438.230 with clearer standards for MCOs, PIHPs, or PAHPs that enter into subcontractual relationships and delegate responsibilities under the contract with the state. These proposed standards were modeled on the MA standards relating to MA organization relationships with first tier, downstream, and related entities at § 422.504(i).

In paragraph (a), we proposed to more clearly state when § 438.230 would apply by adding language specifying that the standards of this section would apply to all contracts and written arrangements that a MCO, PIHP, or PAHP has with any individual or entity that relates directly or indirectly to the performance of the MCO's, PIHP's, or PAHP's obligations under the contract with the state.

In new paragraph (b)(1), we proposed that regardless of any relationship that a MCO, PIHP, or PAHP may have, it alone is accountable for complying with all terms of the contract with the state. While this is not a new standard, we explained that this revision to the text more clearly stated our intent. We proposed in new paragraph (b)(2) to specify that all contracts and written arrangements comply with the provisions of paragraph (c).

Existing paragraphs (b)(2)(i) (requiring the contract to specify the delegated activities, obligations, and responsibilities) and (b)(2)(ii) (providing for revocation of any delegation) would be redesignated as (c)(1)(i) and (c)(1)(iii) but would otherwise remain substantially the same with revisions for clarity. In paragraph (c)(1)(ii), we proposed to add that the individual or entity accepting the delegation agrees to

perform the activities in compliance with the MCO's, PIHP's, or PAHP's contract with the state. In paragraph (c)(2), we proposed a general standard that the entity or individual performing the delegated activities must comply with all applicable Medicaid laws, regulations, subregulatory guidance, and contract provisions. Lastly, in paragraphs (c)(3)(i) through (iv), we proposed that the entity or individual performing the delegated activities must agree to grant the state, CMS, HHS OIG, or the Comptroller General the right to audit, evaluate, and inspect any books, contracts, computer or other electronic systems that pertain to services performed or determinations of amounts payable; make available for audit, evaluation, or inspection, its premises, physical facilities, equipment and records; preserve the rights under (c)(3)(i) for 10 years from completion; and grant the state, CMS, HHS OIG, or the Comptroller General the right to audit, evaluate, and inspect at any time if the reasonable possibility of fraud is determined to exist by any of these entities.

We received the following comments in response to our proposal to revise § 438.230.

Comment: Many commenters supported proposed § 438.230 and stated that the provisions will strengthen program integrity efforts for subcontractors of managed care plans. A few commenters recommended additional clarification at § 438.230(a) and (b). A few commenters recommended that CMS add language to clarify that such requirements only apply to applicable services and activities that are delegated to meet the obligations under the managed care plan's contract with the state. One commenter recommended that CMS clarify whether the intent and scope of § 438.230(a) and (b) are related to program integrity standards or specific vendor IT requirements. A few commenters recommended that CMS either define "relates indirectly" or remove the language from the regulatory text, as it is unclear as written. One commenter stated that the language "relates indirectly to the performance" indicates that cafeteria vendors or real estate contractors would also need to meet the requirements specified at § 438.230.

Response: We thank commenters for their support and agree that the provisions at § 438.230 will strengthen program integrity efforts for subcontractors of managed care plans. Section 438.230 applies to all contracts and written agreements between managed care plans and individuals or

entities that directly or indirectly relate to the performance of the managed care plan's obligations under its contract with the state. In other words, if managed care plans subcontract or delegate any of their obligations, services, or activities under their contract with the state, § 438.230 applies. In reviewing these public comments and considering a managed care plan's subcontracted or delegated obligations, services, or activities, we realized that PCCM entities should have been included throughout § 438.230, as PCCM entities may contract with a fiscal intermediary or other administrative organization to conduct requirements under their contract with the state. Therefore, we will modify the regulatory text throughout § 438.230 to add and include PCCM entities in this regulation. We note that it is unlikely that cafeteria vendors or real estate contractors would directly or indirectly relate to the performance of the managed care plan's obligations under its contract with the state. We therefore decline to revise the proposed regulatory language, as we believe our intent is clear that the focus is on the obligations of the managed care plan under the contract with the state and when those obligations are subcontracted or delegated. We also clarify for the commenter that the intent and scope of § 438.230(a) and (b) are related to program integrity standards and not specific vendor IT requirements; however, we clarify that this regulation would apply to all IT subcontractors if they are performing work that is governed by the managed care plan's contract with the state or these regulations.

Comment: A few commenters recommended that CMS impose requirements for related entities who share common ownership, board membership, or subsidiary status. One commenter recommended that CMS clarify whether states need to review ownership and control disclosures for all subcontractors of managed care plans, or only those subcontractors that perform services and activities applicable to the requirements under the contract with the state. One commenter recommended that CMS exempt managed care plans' network providers, as these requirements are unworkable for network providers. One commenter recommended that CMS exempt small vendors who are performing services and activities for a minimal amount of money.

Response: We decline to add specific requirements for ownership and control disclosures at § 438.230(a) and (b), as these requirements are found at

§ 438.602(c) § 438.608(c) of this part. We clarify for commenters that states must review ownership and control disclosures for all subcontractors of managed care plans that perform services and activities applicable to the requirements under the contract with the state. We decline to add an exemption for small vendors who are performing services and activities on behalf of the managed care plan for a minimal amount of money, as these recommendations are inconsistent with our general approach to strengthen program integrity efforts for all subcontractors of managed care plans. It is critical for CMS and states to continue strengthening program integrity activities that protect beneficiaries and promote better stewardship of state and federal funds and resources.

However, in light of public comments received on this provision and others, we believe it is important to distinguish network providers from subcontractors as the responsibilities on both, as well as the responsibilities on managed care plans in relation to both, are different throughout this part. Therefore, we will finalize this rule with a new definition for “subcontractor” in § 438.2 as an individual or entity that has a contract with an MCO, PIHP, PAHP, or PCCM entity that relates directly or indirectly to the performance of the MCO’s, PIHP’s, PAHP’s, or PCCM entity’s obligations under its contract with the State. A network provider is not a subcontractor by virtue of the network provider agreement. Similarly, we will finalize the definition of a “network provider” at § 438.2 to clarify that a network provider is not a subcontractor when acting as a network provider; the network provider agreement with the managed care plan does not create a subcontractor relationship for purposes of this rule. Since the definition of a subcontractor includes “an individual or entity” we will finalize § 438.230(a), (b)(1) and (2), (c)(1) introductory text, (c)(1)(ii) and (iii), (c)(2), (c)(3) introductory text, and (c)(3)(i) through (iv) with “subcontractor” in place of “individual or entity.”

Comment: A few commenters recommended that CMS fix the typographical error at § 438.230(b)(2) to include commas between “MCO’s PIHP’s or PAHP’s.”

Response: We are modifying the regulatory text at § 438.230(b)(2) to include commas in the referenced phrase.

Comment: A few commenters recommended that CMS add standards at § 438.230(c)(1) to require managed care plans to submit a list of all subcontractors to the state for review.

One commenter recommended that CMS define “not performed satisfactorily” at § 438.230(c)(1)(iii).

Response: We decline to add standards at § 438.230(c)(1) to require managed care plans to submit a list of all subcontractors to the state for review. Consistent with the requirements at § 438.230, states and managed care plans must ensure that the contract between them addresses certain requirements that must be present in any contract or written arrangement between the plan and the plan’s subcontractor or delegate. It would not be appropriate to broaden this requirement to require, as a matter of federal law, the managed care plan to seek state approval of all subcontracting or delegation arrangements. States that wish to have this additional level of information and involvement in the arrangements the managed care plan has with subcontractors or delegates may impose such requirements consistent with state law. We also decline to define “not performed satisfactorily” at § 438.230(c)(1)(iii), as this standard should be established and defined under the contract between the state and managed care plan.

Comment: Several commenters recommended that CMS revise the requirements at § 438.230(c)(2). A few commenters recommended that CMS add the term “relevant” before “laws and regulations.” A few commenters recommended that CMS clarify that the term “applicable” only applies to “laws and regulations.” A few commenters recommended that CMS add the phrase “to the extent applicable” before “laws and regulations.” A few commenters recommended that CMS remove “subregulatory guidance” or clarify that only “relevant subregulatory guidance” applies.

Response: We are modifying the regulatory text at § 438.230(c)(2) to clarify for commenters that the individual or entity agrees to comply with all applicable Medicaid laws and regulations, including applicable subregulatory guidance and contract provisions. We believe this modification will clarify our intent for subcontractors.

Comment: Several commenters recommended that CMS revise the requirements at § 438.230(c)(3). One commenter recommended that CMS add oversight requirements for states. A few commenters recommended that CMS define “reasonable possibility of fraud” at § 438.230(c)(3)(i). One commenter recommended that CMS remove “reasonable possibility of fraud” as all contracts already contain audit rights for state and federal government officials.

One commenter recommended that CMS add “or similar risk” after “reasonable possibility of fraud” at § 438.230(c)(3)(i) to be consistent with § 438.230(c)(3)(iv). A few commenters recommended that CMS add “waste or abuse” after “reasonable possibility of fraud” to be consistent with industry standards. One commenter recommended that CMS clarify that § 438.230(c)(3) only applies to delegated services and activities under the managed care plan’s contract with the state. Finally, several commenters recommended that CMS revise the right to audit requirement and timeframe of 10 years at § 438.230(c)(3)(iii) to be consistent with the recordkeeping requirement and timeframe of 6 years at § 438.3(v). A few commenters recommended that the right to audit requirement and timeframe of 10 years be reduced to 5 years to relieve recordkeeping burden.

Response: We clarify for commenters that § 438.230(c) applies to all contracts and written agreements between managed care plans and individuals or entities that directly or indirectly relate to the performance of the managed care plan’s obligations under its contract with the state. In other words, if managed care plans subcontract or delegate any of their obligations, services, or activities under their contract with the state, § 438.230(a) through (c) applies. We appreciate the recommendation to add oversight requirements for states, but note that such requirements are found throughout part 438, and specifically at § 438.3 for standard contract requirements and subpart H of this part for program integrity safeguards. For consistency with the inspection and audit provisions at § 438.3(h), we have deleted from § 438.230(c)(3)(i) the language conditioning the inspection or audit rights of subcontractors to instances where the reasonable possibility of fraud exists. Due to changes in § 438.3(u) relating to record keeping requirements to change the retention period from 6 years to 10 years, we are retaining the 10 year audit period in paragraph (c)(3)(iii), which is consistent with § 438.3(h) as finalized in this rule.

After consideration of the public comments, we are modifying the regulatory text at § 438.230(b)(2) to include commas as necessary. As we will finalize this rule with a definition for “subcontractor,” that term replaces references to “individual or entity” throughout § 438.230. We are also modifying the regulatory text at § 438.230(c)(2) to clarify for commenters that the subcontractor agrees to comply

with all applicable Medicaid laws and regulations, including applicable sub-regulatory guidance and contract provisions. For consistency with the inspection and audit provisions at § 438.3(h), we are deleting the regulatory language conditioning the inspection or audit rights of subcontractors to instances where the reasonable possibility of fraud exists from § 438.230(c)(3)(i). To clarify the contract that is referenced in § 438.230(c)(3)(i), we have inserted “MCO’s, PIHP’s, or PAHP’s” before “contract.” In addition, we will finalize paragraphs (c)(3)(i) and (c)(3)(ii) to include the same list of items that are subject to audit, evaluation, and inspection. Finally, we will add and include PCCM entities throughout § 438.230 as they may contract with a fiscal intermediary or other administrative organization to conduct requirements under the contract with the state. We are finalizing all other sections as proposed.

c. Program Integrity (§§ 438.600, 438.602, 438.604, 438.606, 438.608, and 438.610)

We proposed several changes to the program integrity provisions in subpart H that were intended to address two types of program integrity risks that were of particular concern: fraud committed by Medicaid managed care plans and fraud by network providers. The provisions of the proposed rule were intended to address both of these types of risk, as well as tighten standards for MCO, PIHP, PAHP, PCCM, and PCCM entity submission of certified data, information, and documentation that is critical to program integrity oversight by state and federal agencies. At 80 FR 31127–31128, we discussed a number of laws that passed since 2002 that impacted program integrity as well as relevant OIG reports that identified potential program integrity vulnerabilities in Medicaid managed care programs. We proposed to modify the title of subpart H to “Additional Program Integrity Safeguards” from the current title “Certifications and Program Integrity” to recognize that various program integrity standards, such as those relating to audited financial data, MLR, and subcontractual relationships, among others, were proposed to be added throughout this part. In addition, we proposed to add entirely new provisions and amend existing provisions to address program integrity risks that are addressed in detail below.

(1) Statutory Basis (§ 438.600)

In § 438.600, we proposed to add to the existing list of statutory provisions

related to program integrity that support our proposed changes to this subpart. Our proposal included the following statutory provisions: sections 1128, 1128J(d), 1902(a)(4), 1902(a)(19), 1902(a)(27), 1902(a)(68), 1902(a)(77), 1902(a)(80), 1902(kk)(7), 1903(i), 1903(m), and 1932(d)(1) of the Act. In the description of section 1932(d)(1) of the Act in § 438.600, we proposed to remove the term “excluded” and replace it with “debarred” to reflect the statutory standard. As a general matter, we relied on section 1902(a)(4) of the Act when standards in this subpart were proposed to extend beyond MCOs to PIHPs, PAHPs, PCCMs, and PCCM entities.

We received the following comments in response to our proposal to revise § 438.600.

Comment: A few commenters objected to the deletion of the basic rule in the existing § 438.602 that would require MCO, PIHP, PAHP and PCCM compliance with the certification, program integrity and prohibited affiliation requirements of this subpart as a condition for payment as the proposed rule modified that section to include state responsibilities for program integrity. A commenter also requested that the general rule be a condition for state and federal funds.

Response: We appreciate commenters raising this point as the deletion of the general rule was not intended. Therefore, we have modified the title and text of § 438.600 to include both the statutory basis and basic rule, as was provided under § 438.602 prior to the proposed rule, with the addition of PCCM entities and specific references to §§ 438.604, 438.606, 438.608 and 438.610. The statutory basis has been redesignated as paragraph (a) with each statutory provision in numerical order and the basic rule is designated as paragraph (b). As part 438 sets forth the requirements for the expenditure of federal funds for a Medicaid managed care program, we decline to extend the basic rule to be a condition on the expenditure of state funds under the contract.

Comment: One commenter requested that CMS provide a definition of the term “debarred” as it appears in § 438.600(a)(12).

Response: The term “debarred” is used in statute at section 1932(d)(1) of the Act and has been and continues to be used in § 438.610. It is one means by which an individual or entity is excluded from participation in the Medicaid program. We do not believe a separate regulatory definition is necessary for the term.

After consideration of the public comments, we are finalizing § 438.600 with a statement of the basic rule and have redesignated the paragraphs accordingly. We have also made a technical correction to § 438.600(a)(6) to specify that section 1902(a)(68) of the Act applies to entities that receive or make annual payments of at least \$5 million for consistency with the statutory language, as the proposed rule only specified entities that receive such amounts on an annual basis.

(2) State Responsibilities (§ 438.602)

We proposed to replace § 438.602 in its entirety. The intent of the revisions to § 438.602 was to contain all state responsibilities associated with program integrity in one section. Proposed paragraph (a) set forth the state’s monitoring standards for contractor compliance with provisions in this subpart and § 438.230 (subcontractual relationships and delegation) and § 438.808 (excluded entities). We did not receive comments on the proposed revisions to § 438.602(a) and will finalize that provision as proposed.

In § 438.602(b), we proposed that states must enroll all network providers of MCOs, PIHPs, and PAHPs that are not otherwise enrolled with the state to provide services to FFS Medicaid beneficiaries. Such enrollment would include all applicable screening and disclosure standards under part 455, subparts B and E and ensure that all providers that order, refer or furnish services under the state plan or waiver are appropriately screened and enrolled. We also proposed that this standard would apply to PCCMs and PCCM entities, to the extent that the PCCM is not otherwise enrolled with the state to provide services to FFS Medicaid beneficiaries. In addition, we provided that the proposed extension of the screening and enrollment requirement to network providers would not obligate the network provider to also render services to FFS beneficiaries.

We requested comment on this approach; in particular, we sought feedback on any barriers to rapid network development that this approach might create by limiting the ability of MCOs, PIHPs, or PAHPs to contract with providers until the results of the state’s screening and enrollment process are complete. We also explained that this proposal did not alter the MCO’s, PIHP’s, or PAHP’s responsibility under § 438.214(c) to operate a provider selection process that does not discriminate against providers that serve high-risk populations or that specialize in costly treatments or the state’s responsibility to monitor the

implementation of provider selection policies in § 438.214(a).

We received the following comments in response to our proposal at § 438.602(b).

Comment: Several commenters requested clarification on § 438.602(b) that would extend the screening and enrollment disclosures of part 455, subparts B and E to network providers that order, refer or furnish services covered under the managed care contract. Many commenters cited the administrative burden for network providers to complete the enrollment process as applied to FFS providers, the administrative and financial burden on the state to conduct the process, and potential adverse impacts on network development. Some commenters suggested that imposing this requirement would deter provider participation in managed care networks. Commenters also cited that managed care plans have provider credentialing processes in their contracts and such processes should be used rather than requiring network providers to enroll with the State Medicaid agency. A number of commenters requested clarification as to the meaning of “enrollment” in this context and how network providers attest that they are participating in the Medicaid program if they do not sign a similar agreement with the state.

In light of these concerns, some commenters requested that CMS remove this provision altogether while others requested clarification in the final rule that states would be permitted to delegate the screening and enrollment processes to managed care plans or another third party. Other commenters suggested the imposition of timeframes for the state to complete the screening and enrollment process to mitigate delays in network development. Another suggestion to mitigate delays in network development was to permit managed care plans to enter into provisional provider agreements pending the outcome of the screening and enrollment process. If a provider failed the screen, the managed care plan would be obligated to terminate the provider agreement immediately or within 30 days and provide notice to impacted enrollees. Some commenters suggested that the screening and enrollment provisions only apply to new providers that negotiate provider agreements with managed care plans after this provision would become effective.

Other commenters were supportive of the provision as a way to reduce administrative costs by centralizing the screening, enrollment, and revalidation

of network provider eligibility but encouraged CMS to provide guidance on how the state could reduce administrative and financial burden. Some commenters requested that CMS require states to share a list of screened providers with the managed care plans on at a least a monthly basis. Many commenters questioned the date that states would have to be in compliance with the screening and enrollment provision for network providers.

Response: After reviewing the comments received on § 438.602(b), it may be helpful to clarify the meaning of terms used in this provision in relation to similar activities elsewhere in this part. First, screening is governed by 42 CFR part 455, subparts B and E, which requires that Medicaid providers that order, refer or provide services under the state plan undergo certain screening procedures according to the applicable risk level for their provider type. In addition, providers must disclose information on ownership and control. The verification of a provider’s licensure under these screening requirements overlaps with the credentialing standards in § 438.214 discussed below. Generally speaking, as the screening process is tied to enrollment, § 455.414 requires states to revalidate the enrollment of providers at least every 5 years.

Second, the credentialing process involves the activities taken by the state or the managed care plan to verify the education, training, liability record, and practice history of providers. This step represents the level of scrutiny necessary to ensure that the provider is qualified to perform the services that they seek to be paid to perform. There is undoubtedly some overlap between the screening and credentialing processes. Section 438.214 requires the managed care plan to follow the state’s credentialing and recredentialing policies. Under managed care programs, managed care plans primarily conduct the credentialing process as part of executing network provider agreements with providers to become part of the managed care plan’s network.

Finally, the screening, disclosures, and credentialing processes described above are the precursor to a provider being “enrolled” as a Medicaid provider with the State Medicaid agency. Under FFS programs, upon enrollment, the provider is loaded into the claim adjudication system as an approved provider and able to receive payment through Electronic Funds Transfer (EFT). We recognize that the proposed rule could have been clearer in describing what “enrollment” means for network providers; however,

§ 438.602(b) makes clear that the “enrollment” of network providers will not obligate those providers to participate in the FFS delivery system. Section 1902(a)(27) of the Act requires the state plan to provide for agreements with every person or institution providing services under the State plan under which such person or institution agrees to keep such records as are necessary fully to disclose the extent of the services provided under the State plan, and to furnish the State agency or the Secretary with such information, regarding any payments claimed by such person or institution for providing services under the State plan. Execution of the provider agreement with the state and satisfaction of the applicable screening requirements results in the provider being enrolled as required under 42 CFR part 455. In the regulations implementing a provision in section 6402 of the Affordable Care Act, requiring inclusion of a National Provider Identifier (NPI) on all applications to enroll in Medicare or Medicaid, we noted that there is no Federally required enrollment application, although all Medicaid providers are required to enter into a provider agreement with the State as a condition of participating in the program under section 1902(a)(27) of the Act. *See* 77 FR 25284, 25285 (April 27, 2012). Accordingly, CMS interpreted the statutory reference to an “enrollment application” to refer to the provider agreement with the state in the Medicaid context. To streamline the execution of the provider agreements required for enrollment of network providers, states may, if they wish, establish a separate category of provider agreement just for network providers, but we note that the required screening must still be conducted for such providers. In addition, managed care plans may make the state’s provider agreement form available to their network providers to expedite the process. We reiterate that the network provider’s execution of the provider agreement with the state does not obligate that provider to participate in the FFS delivery system.

We recognize the changes in administrative procedures and resources that may be necessary to carry out the screening and enrollment of network providers but believe that the additional burden imposed by such changes is outweighed by the benefit of the additional safeguards these activities bring to ensure the quality of and access to care for Medicaid beneficiaries, as well as to support effective stewardship of public resources. We also note that a

number of states already conduct these activities in relation to network providers. In addition, we would anticipate that a significant number of current network providers will not need to be screened due to existing participation in Medicaid or Medicare FFS (because states, per existing regulation, can rely on Medicare screening for Medicaid purposes).

We acknowledge here that states may require a third party, such as contracted managed care plans or a fiscal intermediary, to conduct the functions in § 438.602(b) but we do so with some cautionary statements. We recognize existing arrangements in many states that extended the provisions of part 455, subparts B and E to network providers before this final rule, as well as the desire of other states, that have not already extended these requirements to network providers, to rely on their contracted managed care plans or a fiscal intermediary to facilitate compliance with these provisions of the final rule. We are concerned about quality control, consistency among the managed care plans or a fiscal intermediary in conducting these activities, and duplicative efforts with respect to network providers that participate in several managed care plans. We are also concerned about the ability of managed care plans or a fiscal intermediary to conduct all of the functions required in subpart E of 42 CFR part 455, including on-site visits and fingerprint-based criminal background checks for high-risk providers. As with any state function that is contracted out for performance, the state must maintain oversight of the activity. Some state functions, such as entering into provider agreements under § 431.107, cannot be contracted out for performance. The state is not required to contract with a third party for the activities in § 438.602(b).

To mitigate concerns about delays in network development, we are adding a new paragraph (b)(2) that the MCO, PIHP, or PAHP may execute network provider agreements pending the outcome of the screening process of up to 120 days, but upon notification from the state that a provider's enrollment has been denied or terminated, or the expiration of the one 120 day period without enrollment of the provider, the managed care plan must terminate such network provider immediately and notify affected enrollees that the provider is no longer participating in the network. States must be in compliance with these provisions by the rating period for managed care contracts starting on or after July 1, 2018, for all network providers. The 120 day

timeframe is intended to encourage the state's expedient completion of the screening and enrollment process.

Comment: A few commenters requested that CMS clarify in regulation that managed care plans would be insulated from any penalties if they detrimentally relied on the state's screening for a network provider that is later found to have been excluded or sanctioned.

Response: We appreciate the commenters' concerns but the creations of a blanket protection for managed care plans that detrimentally relied on the state's screen of a network provider would be contrary to some of the prohibited affiliation requirements at § 438.610 that do not premise liability on a "knowing" requirement. We refer commenters to the discussion of comments received on § 438.610 below.

Comment: Several commenters were concerned about the potential application of the screening and enrollment provisions to providers of self-directed services under section 1915(k) of the Act and requested that such providers be exempt from these requirements.

Response: We decline to adopt the commenters' recommendation. The requirements at 42 CFR part 455, subparts B and E are applicable to all provider types eligible to enroll as participating providers in the state's Medicaid program as it is integral to the integrity of the Medicaid program that all providers that order, refer or furnish services to Medicaid beneficiaries are appropriately screened and enrolled. For provider types that exist in both Medicare and Medicaid, states must use the same (or higher) level of screening assigned by Medicare. For Medicaid-only provider types such as those participating under a section 1915(k) waiver program, the state must assign the provider types to a risk level and conduct the level of screening associated with that risk level as described at § 455.450.

Comment: Some commenters requested that CMS permit an exemption from the screening and enrollment provisions for out-of-network providers under single case agreements or for providers rendering emergency services.

Response: Out-of-network providers under single case agreements are not network providers and, therefore, are not subject to § 438.602(b). Emergency room physicians are only subject to § 438.602(b) to the extent that they meet the definition of a network provider in § 438.2.

Commenter: A few commenters requested clarification that a managed

care plan could deny a provider participation in the network that passed the screening and enrollment requirements but failed the managed care plan's credentialing process. In addition, some commenters requested clarification that the managed care plan can terminate a provider agreement independent of the outcome of the state's screening and enrollment process.

Response: This provision does not prevent the managed care plan from declining to enter into a network provider agreement with a provider that was otherwise screened and enrolled but did not meet the managed care plan's credentialing criteria. Similarly, this provision does not change the managed care plan's ability to terminate a provider agreement without cause.

After consideration of public comments, we are finalizing § 438.602(b) as proposed and with a new paragraph (b)(2) to explain that managed care plans may execute network provider agreements pending the outcome of the screening process but upon notification from the state that a network provider cannot be enrolled, must terminate such agreement and notify affected enrollees.

In paragraph (c), we proposed that the state must review the ownership and control disclosures submitted by the MCO, PIHP, PAHP, PCCM, or PCCM entity, and any subcontractors, in accordance with 42 CFR part 455, subpart B.

We received the following comments in response to our proposal at § 438.602(c).

Comment: A few commenters requested that the state be permitted to delegate the requirements in § 438.602(c), particularly for subcontractors. Many commenters suggested that it would be prudent and administratively efficient, for states to have a common entry point to streamline acceptance and review of the required information on disclosures. Another commenter asked that subcontractors not be included in § 438.602(c) or, alternatively, be limited to subcontractors delegated for direct medical services or claims payment.

Response: Section 438.602(c) governs the review of ownership and control disclosures required of managed care plans and subcontractors. We agree that a centralized portal would streamline the disclosure process and we encourage states to consider such approaches. Subcontractors, as they take on responsibility from the managed care plan, are appropriately subject to these requirements.

After consideration of public comments, we are finalizing § 438.602(c) with a technical modification to refer to § 438.608(c) rather than subpart B of part 455 of this chapter, as § 438.608(c) incorporates the disclosure requirements in § 455.104.

In paragraph (d), we proposed that states must conduct federal database checks, consistent with the standards in § 455.436, to confirm the identity of, and determine the exclusion and debarment status of, the MCO, PIHP, PAHP, PCCM, or PCCM entity, any subcontractor, any person with an ownership or control interest, or any agent or managing employee at the time of entering into the contract and no less frequently than monthly thereafter. If a state determines that a party subject to the federal database checks has been excluded from Medicaid participation, it must promptly notify the MCO, PIHP, PAHP, PCCM, or PCCM entity and take action consistent with § 438.610(c).

We received the following comments in response to our proposal at § 438.602(d).

Comment: Several commenters requested that the rule be modified to allow use of the National Practitioner Data Bank (NPDB) to check for exclusion information. Other commenters recommended that the National Provider Identifier (NPI) should be a required element in the applicable federal databases.

Response: Section 438.602(d) incorporates the federal databases that must be routinely checked consistent with § 455.436. The NPDB is not among the specified databases, and checking the NPDB is not a substitute for checking the databases specified in § 455.436. Use of the NPI in all applicable federal databases is outside the scope of this final rule. As indicated in the discussion above regarding § 438.602(b) and the required screening of network providers, states may require a third party, including managed care plans, to check the federal databases for network providers, to the extent managed care plans can access the required databases. In contrast, states may not permit managed care plans to conduct the database checks required pursuant to § 438.602(d) for contracted managed care plans or their subcontractors. After consideration of public comments, we are finalizing § 438.602(d) as proposed with a technical correction to add the National Plan and Provider Enumeration System (NPPES) in the list of databases in § 455.436.

In paragraph (e), we proposed that the state must periodically, but no less frequently than once every 3 years,

conduct, or contract for the conduct of, an independent audit of the accuracy, truthfulness, and completeness of the encounter and financial data submitted by, or on behalf of, each MCO, PIHP, and PAHP.

We received the following comments in response to our proposal at § 438.602(e).

Comment: One commenter requested that the audit of encounter data and financial reports occur annually rather than once every 3 years because of the importance of this information to the rate setting process. Another commenter requested that we expand the periodic audit requirement to other aspects of the managed care program in this part. Another commenter requested clarification that the EQR optional activity at § 438.358(c)(1) could satisfy this requirement.

Response: While we agree that encounter data and financial reports are integral to the rate setting process and are required sources of base data at § 438.5(c), there are other requirements relating to the accuracy of encounter data (§ 438.242 and § 438.818) and financial reports (§ 438.3(m)) that impose more frequent validation or audit requirements. The optional EQR activity at § 438.358(c)(1) would satisfy the periodic audit requirement for encounter data but there is not a similar activity for the EQR to similarly audit financial reports. The evaluation of other elements of the managed care program are addressed elsewhere in this part and § 438.602(e) is limited to the auditing requirements for program integrity related provisions and we decline to add additional program elements to this audit requirement.

After consideration of public comments, we are finalizing § 438.602(e) as proposed.

In paragraph (f), we proposed to incorporate the requirement for states to receive and investigate information from whistleblowers. We did not receive comments on § 438.602(f) and will finalize as proposed.

In paragraph (g), we proposed that each state must post on its Web site or otherwise make available, the MCO, PIHP, PAHP, or PCCM entity contract, the data submitted to the state under § 438.604, and the results of any audits conducted under paragraph (e) of this section. We proposed to add PCCM entity contracts to this standard as we proposed in § 438.3(r) that such contracts be submitted for our review and approval.

We received the following comments in response to our proposal at § 438.602(g).

Comment: Many commenters supported the transparency requirements at § 438.602(g) and recommended that states be required to put all the specified information on their Web sites. On the other hand, several commenters, while supporting overall efforts at transparency, stated that the list of information that would be on the Web site or made available upon request was overly burdensome and may cause concerns about the confidentiality of proprietary and enrollee information as well as general privacy concerns for the individuals that submit ownership and control disclosures. Commenters provided that the reporting requirements, as proposed, would not create meaningful transparency for the public as an insurmountable quantity of information keeps individuals from accessing the most pertinent and useful information.

Response: We agree that the proposed rule was overly broad in the types of information that would need to be on the state's Web site or made available upon request. Accordingly, we are modifying § 438.602(g) to narrow the information that must be made publicly available on the state's Web site as follows: the MCO, PIHP, PAHP or PCCM entity contract; data required by § 438.604(a)(5); the name and title of individuals included in § 438.604(a)(6); and the results of any audits under paragraph (e). We will not finalize the requirement that certain other types of information must be available upon request as any such requests would be handled through the state's relevant sunshine or freedom of information laws. We also added "as required in § 438.10(c)(3)" after "Web site" for clarity.

After consideration of public comments, we are finalizing § 438.602(g) with modification of the types of information that must be provided on the state's Web site.

In paragraph (h), we proposed that states have conflict of interest safeguards in place consistent with § 438.58. We did not receive comments on § 438.602(h) and are finalizing as proposed.

In paragraph (i), we proposed that the state must ensure, consistent with section 1902(a)(80) of the Act, that the MCO, PIHP, PAHP, PCCM, or PCCM entity is not located outside of the United States and that no payments are made for services or items to any entity or financial institution outside of the U.S. We interpreted this payment prohibition to mean that no such payments made by an MCO, PIHP, or PAHP to an entity or financial institution located outside of the U.S.

are considered in the development of actuarially sound capitation rates.

We received the following comments in response to our proposal at § 438.602(i).

Comment: One commenter requested confirmation as part of the final rule that the SMDL #10–026, issued in December 2010, remains in effect and that the guidance and final rule would permit managed care plans to undertake the same administrative tasks permitted by CMS. Another commenter requested clarification on the proposed requirement that no claims paid by a managed care plan to a subcontractor located outside the United States are to be considered in the development of actuarially sound capitation rates. For example, a managed care plan may subcontract with a vendor that employs an overseas company for IT or other operational services. The commenter stated that, in this case, the prohibition on services provided under the state plan should not apply to downstream contracts for administrative services. In addition, at least one state contract requires a managed care plan to cover emergency admissions in border countries. In this case, the managed care plan should not be penalized if coverage is required under the contract. Finally, managed care plans should be allowed to utilize out-of-country services in some limited circumstances; for example, a U.S. licensed and credentialed physician who happens to be out of the country but is an employee of a U.S.-based telemedicine company.

Response: The SMDL #10–026 that provided guidance on section 1902(a)(80) of the Act remains in effect; the SMDL is available at <http://www.medicaid.gov/Federal-Policy-Guidance/downloads/SMD10026.pdf>. The intent of § 438.602(i) was to extend that statutory limitation to medical assistance provided by contracted managed care plans. As was provided in the SMDL 10–026, the phrase “items or services provided under the State plan or under a waiver” refers to medical assistance for which the state claims federal funding under section 1902(a) of the Act. Tasks that support the administration of the Medicaid state plan that may require payments to financial institutions located outside of the U.S. are not prohibited under this statute. For example, payments for outsourcing information processing, call centers related to enrollment, or claims adjudication are not prohibited under this statute. The SMDL 10–026 clearly specifies that section 1902(a)(80) of the Act prohibits payments to telemedicine providers located outside of the U.S. Section 1902(a)(80) of the Act does not

permit FFP for emergency services rendered outside of the U.S.

After consideration of public comments, we are finalizing § 438.602(i) as proposed.

(3) Data, Information, and Documentation That Must be Submitted (§ 438.604) and Source, Content, and Timing of Certification (§ 438.606)

We proposed to modify existing standards regarding submission and certification of data by managed care plans, PCCMs and PCCM entities to the state which currently exist in §§ 438.604 and 438.606. We proposed to revise § 438.604(a) and (b) to specify the data, information and documentation that must be submitted by each MCO, PIHP, PAHP, PCCM, or PCCM entity to the state, including encounter data and other data generated by the managed care plan for purposes of rate setting; data on which the state determined that the entity met the MLR standards; data to ensure solvency standards are met; data to ensure availability and accessibility of services; disclosure information as described at 42 CFR part 455, subpart B; the annual report on recoveries of overpayments as proposed in § 438.608(d)(3); and any other data related to the performance of the entity’s obligations as specified by the state or the Secretary.

Comments received on proposed § 438.604 were primarily related to the transparency requirements in § 438.602(g). Those comments were addressed in response to comments on § 438.602(g) above. Therefore, we are finalizing § 438.604 as proposed.

Section § 438.606 stipulated that MCOs, PIHPs, PAHPs, PCCMs, and PCCM entities must certify the data, information and documentation specified in § 438.604. We proposed to expand the certification requirement to documentation and information, as well as data and proposed to cross-reference the submission standards in § 438.604 to identify the scope of the certification requirement. In § 438.606(a), we proposed to eliminate the option for a MCO’s, PIHP’s, PAHP’s, PCCM’s, or PCCM entity’s executive leadership to delegate the certification.

We received the following comments in response to § 438.606(a).

Comment: Several commenters stated that not permitting certification by an individual with delegated authority from the CEO or CFO would be administratively burdensome, particularly for the certification of data, information, and documentation that is provided in the regular course of business.

Response: Although we stated in the proposed rule that we believed that in these critical program areas, the CEO or CFO must be personally responsible for the accuracy, completeness, and truthfulness of the reported data, documentation or information, upon further consideration, we agree with commenters that the proposed requirement was overly restrictive and potentially disruptive to a managed care plan’s daily operations. An individual that has the authority to sign on a CEO’s or CFO’s behalf, and who reports directly to those individuals, binds the CEO or CFO to the attestations made through the signature, which arrives at the desired result of the certification process.

After consideration of public comments, we are modifying § 438.606(a) to permit an individual who reports directly to the managed care plan’s CEO or CFO with delegated authority to sign for the CEO or CFO, so that the CEO or CFO remains ultimately responsible for the certification, to be the source of the certification required in this section. We are also modifying this paragraph with grammatical changes to insert semi-colons where appropriate.

In § 438.606(b), we proposed to include documentation or information after the existing reference to data for consistency with the addition of such terms in § 438.604 and § 438.606 and to specify that the certification attests that the MCO, PIHP, PAHP, PCCM, or PCCM entity has conducted a reasonably diligent review of the data, documentation, and information in § 438.604(a) and (b), and that such data, documentation, and information is accurate, complete, and truthful. We proposed this modification to the certification to clarify that the attesting individual has an affirmative obligation to ensure that a reasonably diligent review has been conducted and that the information being certified is accurate, complete, and truthful. We requested comment on the proposed certification language.

We received the following comments on § 438.606(b).

Comment: Several commenters requested clarification as to what the revised certification standard would require and stated that CMS has long recognized that the “best information, knowledge, and belief” as a reasonable and appropriate standard for certifications. A commenter noted that none of the certification requirements in the MA and Part D programs, including for reporting overpayments, specify that the certification is based on a “reasonably diligent” review, as

provided at § 438.606(b). Commenters stated that adding this new standard for Medicaid data submissions would create an inappropriate degree of ambiguity for those certifying data to CMS and diverge from the standards in place for MA and Part D programs.

Response: We agree with commenters that the existing certification language for data submissions under MA and Part D does not explicitly reference a “reasonable diligence” standard under the MA and Part D overpayment regulation at § 422.326. To be consistent across programs, we will maintain the existing “best information, knowledge, and belief” language for certifications by managed care plans in § 438.606. However, we restate here our well-established expectation that any certifications by a managed care plan cannot be based on a blind or careless acceptance of information, including data critical to payment determinations, but must be informed. For indications of our historical views on the matter, we urge the commenters to look at our comments regarding the certifications in 2001 to the part 438 rule (66 FR 6228, 6357 (Jan. 19, 2001)) and in 2000 to the similar rule for Medicare Part C (65 FR 40170, 40268 (June 29, 2000)). We note that the emphasis on program and payment integrity throughout part 438 aligns with our expectations for certifications to be based on a reasonably diligent review of the accuracy, completeness, and truthfulness of the data, documentation, and information. As one example, under § 438.608(a), we require states, through their contracts with each MCO, PIHP, or PAHP, to ensure the managed care plans and their subcontractors maintain a compliance program that has procedures for routine monitoring and auditing of compliance risks and requires the entities to have arrangements or procedures for prompt reporting of all overpayments identified or recovered.

After consideration of public comments, we are finalizing § 438.606(b) to include the best information, knowledge, and belief language for certifications by managed care plans.

In paragraph (c), we proposed to maintain the existing standard that the certification is provided concurrently with the submission of the data, documentation or information specified in § 438.604. We did not receive comments on § 438.606(c) and are finalizing as proposed.

(4) Program Integrity Requirements Under the Contract (§ 438.608)

Current § 438.608 specifies the elements that must be included in a MCO’s and PIHP’s program integrity/compliance program and administrative procedures to detect and prevent fraud, waste and abuse. We proposed to expand those standards to PAHPs and subcontractors to the extent that the subcontractor is delegated responsibility by the MCO, PIHP, or PAHP for coverage of services and payment of claims under the contract between the state and the MCO, PIHP, or PAHP.

We received the following general comments on § 438.608(a).

Comment: A commenter recommended removing the language requiring subcontractors of MCOs, PIHPs, and PAHPs to be subject to provisions of § 438.608 and instead require MCOs, PIHPs, and PAHPs to maintain effective and reasonable oversight of subcontractors.

Response: We disagree. It is imperative that subcontractors that take on responsibilities of the MCO, PIHP, and PAHP under the contract and have the same program integrity structure as the MCOs, PIHP, or PAHP. At § 438.230(b)(1), the final rule requires MCOs, PIHPs, and PAHPs to oversee the activity of subcontractors and specifies that the MCO, PIHP, and PAHP retains ultimate responsibility for the obligations under the contract. This regulatory structure is important to the integrity of the Medicaid program, especially in states that rely on heavily sub-delegated arrangements.

Comment: One commenter provided that the state should be required to issue guidance related to all program integrity activities undertaken by managed care plans, the managed care plans should be required to demonstrate validity and accuracy of any planned program integrity project based on sampling or data mining before it is implemented, and the state should coordinate program integrity activities by the managed care plans on issues likely to be in common.

Response: We appreciate the commenter’s recommendations but decline to require such activities in the regulation. Section 438.66 includes program integrity as an area for ongoing monitoring by the state and the ability of the managed care plan to comply with the program integrity requirements is a required element of the readiness review.

Comment: Some commenters requested that CMS engage a stakeholder workgroup before expanding program integrity requirements.

Response: The requirements in subpart H in this final rule were informed by the public comments received and we will finalize these provisions, with some modifications, as described herein. We will not create a stakeholder workgroup before finalizing these provisions.

Comment: A commenter asked how these rules would impact those provider organizations that are looking to become stand-alone, risk-bearing managed care plans or are adopting different partnership models with managed care plans.

Response: If the provider organization or collaborative model would meet the definition of an MCO, PIHP, or PAHP, the requirements of this part would apply.

We proposed the following changes to § 438.608:

- Establishment of written policies, procedures, and standards of conduct that articulate the organization’s commitment to comply with all applicable requirements and standards under the contract, and all applicable Federal and state requirements (proposed to redesignate § 438.608(b)(1) as § 438.608(a)(1)(i)). We did not receive comments on § 438.608(a)(1)(i) and will finalize the provision as proposed.
- Direct reporting by the Compliance Officer to both the CEO and board of directors of the MCO, PIHP, or PAHP, which is consistent with MA requirements at § 422.503(b)(4)(vi)(B)(2); the designation of compliance officer that is accountable to senior management is at current § 438.608(b)(2) (proposed § 438.608(a)(1)(ii)). We received the following comments on proposed § 438.608(a)(1)(ii).

Comment: A few commenters were supportive of the proposed change to align with the MA standard for Compliance Officers, while a few others thought that the requirements were too prescriptive. A commenter recommended that a Compliance Officer should be able to report to another executive level position for supervisory purposes as long as the job description clearly provides for direct reporting in terms of compliance activities to the CEO and board of directors on a regular basis.

Response: We appreciate the supportive comments and agree that it is appropriate to align with MA. The commenters’ recommendation that the Compliance Officer be able to report to another executive level position for supervisory purposes as described the summary of comments is permissible under this provision.

After consideration of public comments, we are finalizing § 438.608(a)(1)(ii) as proposed.

- Establishment of a Regulatory Compliance Committee on the Board of Directors and at the senior management level charged with oversight of the compliance program for consistency with MA requirements at § 422.502(b)(4)(vi)(B). We received the following comments on proposed § 438.608(a)(1)(iii).

Comment: A commenter requested clarification that the managed care plan has the authority to determine the composition of the Regulatory Compliance Committee; for example, the number of board meetings, frequency of meetings, etc.

Response: The federal standard permits the managed care plans such discretion. States may add additional requirements through the contract.

After consideration of public comments, we are finalizing § 438.608(a)(1)(iii) as proposed.

- Establishment of a system for training and education for the Compliance Officer, the organization's senior management, and the organization's employees for the federal and state standards and requirements under the contract for consistency with MA organization requirements at § 422.503(b)(4)(vi)(C). We did not receive comments on proposed § 438.608(a)(1)(iv) and are finalizing as proposed.

- Establishment of a system for effective communication between the compliance officer and the organization's employees (proposed to redesignate § 438.608(a)(4) as § 438.608(a)(1)(v)). We did not receive comments on § 438.608(a)(1)(v) and are finalizing as proposed.

- Enforcement of standards through well-publicized disciplinary guidelines (proposed to redesignate § 438.608(b)(5) as § 438.608(a)(1)(vi)). We did not receive comments on § 438.608(a)(1)(vi) and are finalizing as proposed.

- Establishment and implementation of procedures and a system with dedicated staff for routine internal monitoring and auditing of compliance risks, prompt response to compliance issues as they are raised, investigation of potential compliance problems as identified in the course of self-evaluation and audits, correction of such problems promptly and thoroughly (or coordination of suspected criminal acts with law enforcement agencies) to reduce the potential for recurrence, and ongoing compliance with the requirements under the contract; the provision for internal monitoring and auditing and prompt response to

detected offenses is at current § 438.608(b)(6) and (7) (proposed § 438.608(a)(1)(vii)).

We received the comments on § 438.608(a)(1)(vii):

Comment: A few commenters requested clarification as to the measure of "prompt" as related to responding to compliance issues.

Response: We decline to set forth a specific definition for "prompt" in the regulation and note that the use of "prompt" was in § 438.608(b)(7) in the 2002 final rule—pertaining to the response of the managed care plan to detected offenses and for the development of corrective action initiatives—and that section informed the development of § 438.608(a)(1)(vii). We defer to states to set forth specific parameters for a measure of "promptness" in the managed care contracts. This response applies to comments similarly requesting clarification on the use of "prompt" elsewhere in this subpart.

Comment: A few commenters requested clarification of "dedicated staff" in this paragraph.

Response: The term "dedicated staff" means that the job description includes the activities in § 438.608.

After consideration of public comments, we are finalizing § 438.608(a)(1)(vii) as proposed.

- Mandatory reporting to the state or law enforcement of improper payments identified or recovered, specifying the improper payments due to potential fraud. We received the following comments on proposed § 438.608(a)(2).

Comment: One commenter requested that CMS give states the explicit authority to articulate additional expectations for defining and reporting on fraud and improper payments. State should be permitted, but not required, to define improper payments in the context of state program integrity efforts. Another commenter suggested that states should be able to specify additional staffing requirements for the managed care plan.

Response: As stated in response to comments for other provisions in this final rule, states have the flexibility to establish standards that are more restrictive than the requirements of this part through the contract.

Comment: Many commenters requested clarification on the definition of "potential fraud" used in this provision and others in this subpart. Another commenter suggested that the reporting requirement only apply to "actual fraud."

Response: Fraud is defined in § 455.2 and for purposes of identifying improper payments identified or

recovered relating to "potential fraud" in this section, that is conduct that the managed care plan believes to be fraud as defined in § 455.2. We note that a managed care plans cannot, themselves, determine whether something meets the legal definition of fraud. That determination must be made by law enforcement and the courts. Thus, we disagree that the reporting requirement should be limited to actual fraud.

For clarity in this part, we will add a definition for "fraud" in § 438.2 that incorporates the definition found in § 455.2.

Upon review of this provision, as proposed, we identified two areas within the provision that require modification to clarify the regulatory standard. First, the use of the term "improper payments" in the proposed provision could have been interpreted to incorporate Payment Error Rate Measurement (PERM) requirements, and that was not our intention. Our intention for § 438.608(a)(2) is that managed care plans promptly report overpayments to the state that are identified or recovered and, in that reporting, to specify the overpayments due to potential fraud. Second, overpayments must be reported to the state and it is not necessary that the managed care plan instead, or in addition to, report this information to law enforcement as proposed. Note that § 438.608(a)(7) separately requires managed care plans to refer any potential fraud, waste, or abuse to the state Medicaid program integrity unit or any potential fraud directly to the state MFCU.

After consideration of public comments, we are finalizing § 438.608(a)(2) with the following modifications: (1) Replacing "improper payments" with "overpayments"; and (2) deletion of law enforcement. In addition, to clarify the definition of "fraud" applicable in this paragraph and elsewhere in this part, we will finalize the rule with a cross-reference in § 438.2 to the definition of "fraud" in § 455.2.

- Mandatory reporting to the state of information received by managed care plans about changes in an enrollee's circumstances that may affect the enrollee's eligibility. We received the following comments on proposed § 438.608(a)(3).

Comment: Several commenters objected to § 438.608(a)(3)(i) and (a)(3)(ii) because reporting on each piece of returned mail would be administratively burdensome and costly, and returned mail does not necessarily mean that the enrollee is no longer eligible for Medicaid. In addition,

the managed care plan would not likely be aware of changes in an enrollee's income. Another commenter suggested that the provision was of little value because the state's MMIS is the ultimate system of record.

Response: We agree with the commenters that the value of reporting returned mail is outweighed by the administrative burden and that managed care plans would have little to no expectation of receiving information on the enrollee's income that could be of value to the state, and thus, returned mail would not be sufficient to trigger the reporting requirements under § 438.608(a)(3)(i) or (ii). We believe that the managed care plans have more direct communication with enrollees than the state and can serve as valuable sources of information relevant to the enrollee's eligibility for Medicaid.

After consideration of public comments, we are finalizing § 438.608(a)(3) so that managed care plans would notify the state of changes in the enrollee's residence and death.

- Mandatory reporting to the state of information received by the managed care plan about changes in a provider's circumstances that may affect the provider's participation in the managed care program. Such changes in circumstances would include the termination of the network agreement with the managed care plan.

We received the following comment on proposed § 438.608(a)(4).

Comment: One commenter suggested that changes in provider eligibility reported to the state should mirror the existing Medicare requirement for provider reporting to the Medicare Administrative Contractors (MAC).

Response: Provider reporting to the MACs applies to providers that participate in Medicare Parts A and B. The intention of § 438.608(a)(4) is for managed care plans to alert the state of changes in a network provider's circumstances that may impact the network provider's participation in the state's Medicaid managed care program. States may incorporate additional reporting requirements for network providers through the managed care contracts.

After consideration of public comments, we are finalizing § 438.608(a)(4) as proposed.

- Verification by sampling or other methods, whether services that were represented to have been delivered by network providers were actually received. We received the following comments on proposed § 438.608(a)(5).

Comment: Some commenters requested that CMS or the states provide clear and consistent guidance to

managed care plans on the methods they can use to verify the delivery of services by network providers. Another commenter was opposed to any requirement for the use of Explanation of Benefits (EOBs) as a means to detect fraud and abuse given the extremely limited return; however, if verification is required, sampling that is limited in scope and easy to administer would be supported.

Response: We prefer to leave to state discretion the sampling method or other methods used to verify that services represented to have been delivered to enrollees were actually provided to the managed care contract.

After consideration of public comments, we are finalizing § 438.608(a)(5) as proposed.

- Establishment of written policies related to the Federal False Claims Act, including information about rights of employees to be protected as whistleblowers at proposed § 438.608(a)(6). We did not receive comments on § 438.608(a)(6) and will finalize with a minor grammatical change so that this provision reads correctly from the introductory language in paragraph (a).

- Mandatory referral of any potential fraud, waste, or abuse that the MCO, PIHP, or PAHP identifies to the State Medicaid program integrity unit or any potential fraud directly to the State Medicaid Fraud Control Unit (proposed § 438.608(a)(7)). We explained that states that have a MFCU may choose, as part of their contracts with MCOs, PIHPs, or PAHPs, to stipulate that suspected provider fraud be referred only to the MFCU, to both the MFCU and to the Medicaid program integrity unit, or only to the Medicaid program integrity unit. For those matters referred to the Medicaid program integrity unit, 42 CFR part 455 provides that the unit must conduct a preliminary investigation and cooperate with the MFCU in determining whether there is a credible allegation of fraud. For those MCOs, PIHPs, and PAHPs with their own Special Investigation Unit (SIU) to investigate suspected provider fraud, the program integrity unit should assess the adequacy of the preliminary investigation conducted by those units and seek to avoid the duplication and delay of their own preliminary investigation.

We received the following comments on § 438.608(a)(7).

Comment: A few commenters suggested that managed care plans should be required to refer fraud, waste and abuse to the Medicaid program integrity unit and states should have the option to also require simultaneous

reporting to the state's MFCU. Another commenter wanted CMS to require managed care plans to coordinate with the MFCU.

Response: Section 438.608(a)(7) requires managed care plans to refer any potential fraud, waste, or abuse to the state Medicaid program integrity unit or any potential fraud directly to the state MFCU. Section 455.21 specifies the level of cooperation between the state and the MFCU and does not require managed care plans to coordinate directly with the MFCUs. The contract would specify if the state wanted the managed care plan to refer potential fraud to the MFCU.

Comment: A few commenters requested clarification on the meaning of "abuse" in this paragraph.

Response: The definition of "abuse" in § 455.2 applies here and to any use of the term within this part. To clarify the meaning of "abuse" in this paragraph and elsewhere in this part, we will finalize the rule with a cross-reference in § 438.2 to the definition of "abuse" in § 455.2.

After consideration of public comments, we are finalizing § 438.608(a)(7) as proposed.

- Provision for the MCO's, PIHP's, or PAHP's suspension of payments to a network provider for which the state determines there is a credible allegation of fraud in accordance with § 455.23 (proposed § 438.608(a)(8)). Under § 455.23, which implements section 1903(i)(2)(C) of the Act, the state must suspend payments to an individual or entity against which there is a pending investigation or a credible allegation of fraud against the individual or entity, unless the state determines that there is good cause not to suspend such payments. Under our authority in sections 1903(i)(2)(C) and 1902(a)(4) of the Act, we proposed to require that the state make provision for the MCO, PIHP, or PAHP to suspend payment to a network provider when the state determines there is a credible allegation of fraud against that network provider, unless the state determines there is good cause for not suspending such payments pending the investigation. Under this provision, the responsibility of MCOs, PIHPs, and PAHPs is limited to promptly suspending payments at the direction of the state until notified by the state that the investigation has concluded.

We received the following comments on proposed § 438.608(a)(8).

Comment: Several commenters requested clarification as to what would constitute a credible allegation of fraud. Other commenters provided that states must ensure that managed care plans are

notified of credible allegations of fraud and the need to suspend payment in a timely manner. Another commenter requested that states be required to notify the managed care plan in writing. A commenter suggested that CMS address the impact of suspension of payments to a provider on access to care.

Response: “Credible allegation of fraud” is defined at § 455.2 for purposes of the payment suspension requirement. Section 455.23 specifies written notification requirements and timeframes for such notification applicable to the state when notifying FFS providers of a payment suspension. These same requirements are applicable for purposes of notifying the managed care plans that payments to a network provider should be suspended under § 438.608(a)(8). For additional information on § 455.23, consult the CPI–CMCS Informational Bulletin CPI–B 11–4, available at <https://downloads.cms.gov/cmsgov/archived-downloads/CMCSBulletins/downloads/payment-suspensions-info-bulletin-3-25-2011.pdf>. We acknowledge that suspension of payments may, in some instances, impact access to care, but note that, in certain circumstances, § 455.23(e) permits the state to determine that good cause exists not to suspend payments despite a credible allegation of fraud. Section 455.23(e)(4) expressly permits such a determination where beneficiary access to covered items or services would be jeopardized.

After consideration of public comments, we are finalizing § 438.608(a)(8) as proposed.

Section 438.608(b) incorporated the provider screening and enrollment standards in § 438.602(b). Comments on this proposal were addressed in response to comments on § 438.602(b). We are finalizing § 438.608(b) as proposed.

In paragraph (c) of § 438.608, we proposed additional expectations for performance by managed care plans that the state must include in their contracts, including:

- Requiring MCOs, PIHPs, and PAHPs to disclose in writing any prohibited affiliation outlined in § 438.610 (proposed paragraph (c)(1));
- Requiring written disclosures of information on control and ownership under § 455.104 (proposed paragraph (c)(2)); and
- Requiring MCOs, PIHPs, and PAHPs to report to the state within 60 calendar days of when they identify receipt of payments in excess of the capitation rate or other payments established in the contract (proposed paragraph (c)(3)).

We requested comment on whether we should establish timeframes for the written disclosures on control and ownership at proposed paragraph (c)(2).

We did not receive comments on § 438.608(c)(1) or (c)(2) and will finalize those provisions as proposed.

We received the following comments on proposed § 438.608(c)(3).

Comment: A commenter requested clarification that proposed paragraph (c)(3) that would require managed care plans to report to the state within 60 calendar days of when they identify receipt of payments in excess of the capitation rate or other payments established in the contract would not satisfy the managed care plans’ obligations under section 1128J(d) of the Act:

Response: The reporting obligation in this paragraph pertains to one type of overpayment—capitation payments or other payments (such as a kick payment or similar arrangement) that are due to calculation errors in excess of the amounts specified in the managed care contract—under section 1128J(d) of the Act.

Comment: Some commenters requested that CMS align with the MA approach for reporting of overpayments where a specific timeframe is not specified. A commenter stated that 60 days seemed too short considering the nature of payments. Another commenter stated that it needed to be clear that a determination that an overpayment exists before the obligation to report and refund is triggered in paragraph (c)(3).

Response: As discussed in response to the previous comment, the payments at issue in paragraph (c)(3) are a subset of the overpayments defined under section 1128J(d) of the Act. The overpayments at issue in this rule include those that occur when the managed care plan identified capitation payments or other payments in excess of the amounts specified in its contract with the state, (for example, when the state incorrectly calculates the capitation payments or other payments due to a managed care plan). We do not consider any comments received on the 60 day timeframe as responsive to the extent they were based on an assumption that the payments at issue in this section were overpayments made to providers.

After consideration of comments received, we are finalizing § 438.608(c)(3) as proposed.

In § 438.608(d)(1), we proposed that MCO, PIHP, and PAHP contracts specify that recoveries of overpayments made by the MCO, PIHP, or PAHP to providers that were excluded from Medicaid participation or that were due to fraud, waste or abuse were to be

retained by the MCO, PIHP, or PAHP.

We explained that because these overpayments represent state and federal Medicaid funds that were paid to the excluded or fraudulent providers by the MCO, PIHP, or PAHP, states are then expected to take such recoveries into account in the development of future actuarially sound capitation rates as proposed in § 438.608(d)(4). The proposal in § 438.608(d)(1) would not prohibit the federal government or states from retaining the appropriate share of recoveries of overpayments due to their own audits and investigation. We solicited comment on this proposal to allow MCOs, PIHPs, and PAHPs to retain overpayment recoveries of payments made to providers that were excluded from Medicaid participation or that were due to fraud, waste or abuse that were made by the managed care plan, while also allowing the federal government and states retain overpayment recoveries they make. We also requested comment on alternative approaches to determining when a recovery may be retained by an MCO, PIHP, or PAHP. Specifically, whether we should instead impose a timeframe between 6 months to 1 year for which the MCO, PIHP, or PAHP may act to initiate the recovery process and retain such recovered overpayments. We further proposed that, consistent with that contractual language, the state collect reports from each MCO, PIHP, or PAHP about recoveries of overpayments in proposed § 438.608(d)(3).

To aid in the creation and submission of such reports in proposed paragraph (d)(3), in paragraph (d)(2) we proposed a standard that the MCO, PIHP, or PAHP must have a mechanism in place for providers to report the receipt of overpayments and to return such overpayments to the MCO, PIHP, or PAHP within 60 calendar days after the overpayment was identified. For clarity, in proposed (d)(5) we define the term “overpayment.”

We received the following comments in response to our proposal to add § 438.608(d).

Comment: Some commenters were supportive of the proposal at § 438.608(d)(1) that managed care plans would be able to retain recoveries of overpayments that the plans identified while others expressed opposition to such a requirement. Some suggested that states should retain complete flexibility to devise ways to incentivize managed care plans to identify such overpayments that would differ from the proposed rule.

Some commenters recommended that the window for the managed care plan to identify, recover, and retain such

overpayments be limited to 6 months or one year from the point of identification by the managed care plan or from the initiation of the recovery. Another commenter suggested that no timeframe be imposed since the process to initiate, investigate and recover overpayments can be time-consuming and the managed care plan must honor a provider's due process and appeal rights.

Some commenters recommended that overpayments made to excluded providers, as proposed at § 438.608(d)(1)(i), should not be permitted to be retained as the managed care plan never should have made a payment to an excluded provider. A few commenters wanted it to be clarified that all overpayments identified by the MFCU or under a False Claims Act case should be fully retained by the state.

Response: We believe that the ability of managed care plans to retain overpayments that they identified and recovered is a reasonable mechanism to incentivize managed care plans to oversee the billing practices of network providers. The goal of the proposal was to incentivize managed care plans to undertake monitoring on a proactive basis to determine if fraud, waste or abuse exists within the provider network. Based on this goal, states should consider ways to properly incent proactive identification and recovery of overpayments by the contracted managed care plans. For example, timeframes for the managed care plan to retain recoveries should not be open ended, as such an approach may not properly incentivize managed care plans to take swift action when such overpayments are identified.

However, in light of comments received on this proposal and after further consideration, it is clear that a number of states have long-standing procedures in place for the treatment of overpayments recovered by managed care plans that differ from the approach in the proposed rule. It also became clear to us that implementing this provision as proposed may result in ambiguity as to when an overpayment was identified for purposes of entitlement to the recovery. Therefore, we will not finalize § 438.608(d) as proposed and instead finalize a requirement that permits states flexibility to set forth an approach to overpayment recoveries in the managed care plan contracts. As provided in a new paragraph § 438.608(d)(1)(i), the state will need to address in its contracts the retention policies for the treatment of recoveries of all overpayments from the MCO, PIHP, or PAHP, and in particular, the policy for

recoveries of overpayments due to fraud, waste, or abuse. A new paragraph (d)(1)(ii) provides that the contract must specify the process, timeframes, and documentation required of the managed care plans for reporting the recovery of all overpayments. Finally, a new paragraph (d)(1)(iii) requires that the contract specify the process, timeframes, and documentation required for the payment of recoveries of overpayments to the state if the managed care plan is not permitted to retain some or all of the recoveries. We believe that this revised approach respects current approaches that are working well within a Medicaid managed care program, but it also requires states to have policies in place for the treatment of managed care plan recoveries of overpayments.

States must ensure that contract provisions implementing § 438.608(d)(1) are consistent with other requirements under federal law and this part. For example, § 438.608(d)(2) requires network providers to return overpayments to MCOs, PIHPs, and PAHPs within 60 days once the overpayment is identified. We may provide additional guidance regarding § 438.608(d)(1) to ensure that states incorporate appropriate requirements into their overpayment retention contract provisions. Although states have the flexibility to implement overpayment retention contract provisions, the policies in the contract would not prohibit the federal government from retaining the appropriate share of recoveries of overpayments due to their own audits and investigations.

After consideration of public comments, we are finalizing § 438.608(d)(1) to require states to have policies in place for the treatment of overpayment recoveries and to specify that policies implemented pursuant to this provision do not apply to the retention of recoveries made under the False Claims Act or through other investigations.

Comment: A few commenters stated that the 60 day timeframe in § 438.608(d)(2) for network providers to return an overpayment to the managed care plan was unrealistic and potentially burdensome on small providers.

Response: Section 438.608(d)(2) incorporates the statutory timeframe for the return of overpayments under section 1128J(d) of the Act.

Comment: A commenter recommended that CMS implement the same look-back period of 5 years that the agency already has in place with the Zone Program Integrity Contractors (ZPICs) for the Medicare program.

Response: The link the commenter makes between this provision and the work of ZPICs is not clear; therefore, we consider this comment to be beyond the scope of this rule.

After consideration of public comments, we are finalizing § 438.608(d)(2) as proposed. We did not receive comments on paragraph (d)(3) and will finalize as proposed. We did not receive comments on paragraph (d)(4) but, for consistency with the final provisions in § 438.608(d)(1), we will finalize this paragraph as proposed and with an additional requirement that the information and documentation collected pursuant to paragraph (d)(1) must be used by the state for purposes of setting actuarially sound capitation rates.

We received the following comment on proposed § 438.608(d)(5).

Comment: A commenter stated that the definition of an overpayment in § 438.608(d)(5) was confusing and should be clarified or deleted.

Response: The definition of an "overpayment" in § 438.608(d) is modeled after the statutory language in section 1128J(d) of the Act and for consistency with the provision at § 438.608(c)(3), we will finalize the definition of overpayments to include any payments to a managed care plan by a state to which the managed care plan was not entitled under the Act.

After consideration of public comments, we will finalize the definition of an "overpayment," as proposed and with a modification to reflect a state's payments to managed care plans to which the plans are not entitled, in the general definition section at § 438.2, rather than in § 438.608(d), as the term appears in multiple sections of this part.

(5) Prohibited Affiliations (§ 438.610)

We proposed to revise the title of § 438.610 from "Prohibited affiliations with individuals debarred by federal agencies" to "Prohibited affiliations." This proposed change was in recognition of the addition of individuals or entities excluded from Medicaid participation under section 1128 of the Act. In paragraph (a), which provided the general standards under this section, we added PCCM and PCCM entities through our authority for the proper and efficient administration of the state plan in section 1902(a)(4) of the Act.

In paragraphs (a)(1) and (a)(2) that specify the types of knowing relationships in section 1932(d)(1)(C) of the Act, we proposed to clarify that these relationships may be with individuals or entities that meet those

criteria. The existing language referred only to individuals and the proposed edits were consistent with the definition of “persons” in the Federal Acquisition Regulation and the Nonprocurement Common Rule. In addition, we proposed to add paragraph (b) to include individuals or entities excluded from Medicaid participation under section 1128 or 1128A of the Act in the list of prohibited relationships by the MCO, PIHP, PAHP, PCCM, or PCCM entity, as specified in section 1902(p)(2) of the Act. We noted that, in the case of excluded individuals and entities, the prohibition applies whether or not the relationship is known to the MCO, PIHP, PAHP, PCCM, or PCCM entity.

We proposed to redesignate paragraph (b) that specified the relationships that are prohibited as paragraph (c) to accommodate the proposed inclusion of individuals or entities excluded from participation under section 1128 of the Act. In addition, we proposed to add subcontractors of the MCO, PIHP, PAHP, PCCM, or PCCM entity as described in § 438.230 to the types of prohibited relationships in paragraph (c)(3). In paragraph (c)(4), we proposed to add network providers to clarify that they fall under the employment or other consulting arrangement for items and services under the contract between the state and the managed care plan.

Due to the proposed restructuring of paragraphs within this section, we redesignated paragraph (c) as paragraph (d) without change, with the exception of the following modifications. In paragraph (d)(3), we proposed to clarify that the reasons for continuation of a managed care plan’s agreement with a prohibited individual or entity must be compelling despite the prohibited affiliation. In addition, we proposed a new paragraph (d)(4) to clarify that this section does not limit or affect any remedies available to the federal government under sections 1128, 1128A or 1128B of the Act. Finally, we proposed to redesignate paragraph (d) as paragraph (e) without change.

We received the following comments in response to our proposal to revise § 438.610.

Comment: A few commenters stated that managed care plans, PCCMs, and PCCM entities should only be responsible for prohibited affiliations that they know about. Another writer commented that managed care plans, PCCMs, and PCCM entities should be responsible for all affiliations whether known or not, because otherwise it would be unclear who was responsible for reimbursing payment.

Response: As described in the proposed rule at 80 FR 31131, § 438.610

addresses two different statutory requirements. Paragraphs (a)(1) and (a)(2) address section 1932(d)(1)(A) of the Act and that statutory provision includes a knowledge requirement. Paragraph (b) incorporates section 1902(p)(2) of the Act and that statutory provision does not have a knowledge requirement. Therefore, we do not have the ability to modify those requirements through regulation.

Comment: A commenter asked whether the state had to report to the Secretary if a prohibited provider affiliation became known after the provider had already been enrolled.

Response: Yes, the state reporting requirement is not limited to pre-enrollment knowledge of prohibited provider affiliations.

Comment: A commenter stated that CMS should clarify that any consequences noted in this section would apply in addition to consequences for failure to comply with a condition of payment.

Response: As proposed, § 438.610(d)(4) stated that nothing in this section must be construed to limit or otherwise effect any remedies available to the U.S. under sections 1128, 1128A, or 1128B of the Act, and thus makes it clear that this section does not supersede other remedies for inappropriate payment to prohibited affiliates.

After consideration of the public comments, we are finalizing § 438.610 as proposed.

d. Sanctions (§§ 438.700, 438.702, 438.704, 438.706, 438.708, 438.722, and 438.730)

Throughout subpart I pertaining to sanctions, we proposed to extend standards applicable to PCCMs to PCCM entities, as we proposed to recognize PCCM entities as a type of PCCM as defined in section 1905(t)(2) of the Act and referenced in section 1932(a)(1)(B)(ii) of the Act. The discussion of the proposed recognition and application of standards in this part to PCCM entities is described in section I.B.6.e. of this final rule. Therefore, we proposed to add PCCM entities to § 438.700(a), (c), and (d)(2); § 438.704(a); § 438.708; and § 438.722.

In § 438.700(a), we proposed to clarify that the intermediate sanctions specified in § 438.702 “may” be used by the state, rather than providing that these “must” be the sanctions that the state establishes. The current regulation could be interpreted to mean that the specific intermediate sanctions enumerated must be used by the state, even though section 1932(e)(1) of the Act only stipulates that intermediate

sanctions be in place for the specified violations, and that such intermediate sanctions may include those specified in section 1932(e)(2) of the Act and set forth in § 438.702. The standard in section 1932(e)(1) of the Act that is a condition for having or renewing a MCO contract is only that there be intermediate sanctions in place.

In § 438.700(c), we proposed to delete PIHPs and PAHPs from the state’s determination that unapproved or misleading marketing materials have been distributed as provided for in the last sentence of section 1932(e)(1) of the Act. In the 2002 final rule, we included PIHPs and PAHPs in the regulation text implementing this sentence but have determined that the statutory provision, by its terms, only applies to a “managed care entity.” While a PCCM may be both a managed care entity and a PAHP, if it is paid on a risk basis, it would only be subject to this provision based on its status as a “managed care entity” under section 1932 of the Act, rather than its status as a PAHP. In this paragraph, we proposed to add PCCM entities consistent with the discussion of PCCM entities in the opening paragraph of this section of this final rule, and with the fact that the definition of managed care entity includes a PCCM.

In § 438.702(a)(4), we proposed to delete the phrase “after the effective date of the sanction,” and insert “after the date the Secretary or the State notifies the MCO or PCCM of a determination of a violation of any standard under sections 1903(m) or 1932 of the Act.” The proposed language is identical to the statutory standard in section 1932(e)(2)(D) of the Act; we believed that the current language did not fully reflect the statutory directive.

In § 438.706, we proposed a change to correct an inconsistency. Currently, § 438.706 discusses special rules for temporary management and, in paragraph (a), we reference “onsite survey, enrollee complaints, financial audits, or any other means” as acceptable ways to determine if an MCO must be subjected to temporary management. However, this language is inconsistent with language at § 438.700(a) that references “onsite surveys, enrollee or other complaints, financial status, or any other source” as a means to determine impossible sanctions. We proposed to correct this inconsistency by revising § 438.706(a) to incorporate the language of § 438.700(a).

In § 438.724(a), we proposed to delete the reference to “Regional Office,” consistent with proposed changes in § 438.3(a) and § 438.7(a).

We also proposed changes to update terms. For instance, § 438.730 currently addresses sanctions imposed by CMS on MCOs and paragraphs (e)(1) and (e)(2) use the term “HMO.” The Balanced Budget Act of 1997 (BBA) replaced the term “Health Maintenance Organization (HMO)” with “Managed Care Organization (MCO).” We proposed to correct these obsolete references to HMO in paragraphs (e)(1) and (2) by replacing the term with “MCO.” In addition, current § 438.730 uses “State agency” or “agency,” which is inconsistent with references to the state in subpart H as well as our proposal to create a uniform definition for “state” in § 438.2. We therefore proposed revisions to address this.

We also proposed to correct several inaccurate cross-references to other provisions of the regulations text. In § 438.730(f)(1), the reference to “paragraph (b)” would be revised to reference “paragraph (c).” In § 438.730(f)(2)(i) and (ii), the reference to “(d)(2)(ii)” would be revised to reference “(d)(2)” and the reference to “(c)(1)(ii)” would be revised to reference “(d)(1)(ii).” Finally, in § 438.730(g)(1), the reference to “paragraph (c)(1)(i)” would be revised to reference “paragraph (c)(1).”

We received the following comments in response to our proposal to revise §§ 438.700, 438.702, 438.704, 438.706, 438.708, 438.722, and 438.730.

Comment: A few commenters objected to the proposed change in § 438.700(a) to permit states the option to establish intermediate sanctions for MCOs and requested clarification as to whether the intermediate sanctions in § 438.702 represent an exclusive list of sanctions for states to consider for conduct specified in § 438.700(b) through (d). A commenter also stated that the imposition of intermediate sanctions should be required. A commenter also noted that the proposed change to replace “must” with “may” in § 438.700(a) that was discussed in the preamble of the proposed rule at 80 FR 31132 did not appear in the regulatory text.

Response: The basis for imposition of sanctions in § 438.700 is based on section 1932(e)(1) of the Act that states that a state may not enter into or renew a contract under section 1903(m) unless the State has established intermediate sanctions, which may include any of the types (set forth in § 438.702). The plain language of section 1932(e)(1) of the Act requires states to have intermediate sanctions in place before entering into or renewing a contract with an MCO and we will retain the use of “must” in reference to states having intermediate

sanctions in place for MCOs. However, the statute does not require that the state have the specific intermediate sanctions that are listed in section 1932(e)(2) of the Act and repeated in regulation at § 438.702; the statute provides that a state’s intermediate sanctions “may include” sanctions of the type listed in section 1932(e)(2) of the Act. We direct the commenter to the parenthetical in § 438.702(a), which is new text proposed in our proposed rule and finalized here; that parenthetical does not appear in the current regulation text at § 438.700(a) and provides states with the flexibility as to the intermediate sanctions that are adopted. To be consistent with the statute, we will retain the parenthetical in § 438.700(a) that the intermediate sanctions that must be in place for a state to contract with MCOs (and may be in place for the state to contract with PCCMs or PCCM entities) may include those specified in § 438.702 to reflect the statutory requirement in section 1932(e)(1) of the Act.

Regarding comments whether the state has the option to impose intermediate sanctions upon a determination that an MCO, PCCM, or PCCM entity acted or failed to act as specified in § 438.700(b) through (d), section 1932(e)(1) and (2) of the Act clearly permits state flexibility as to the decision to impose a sanction and as to the appropriate sanction. The state, as the direct contractor with the MCO, PCCM, or PCCM entity, is in the best position to determine if the imposition of intermediate sanctions is warranted. If a state determines that the imposition of intermediate sanctions is appropriate, it may select from the options in § 438.702 or use others in place through the contract with the MCO, PCCM, or PCCM entity. We note that § 438.702(b) specifies that states retain the authority to impose additional sanctions for the areas of noncompliance in § 438.700, as well as additional areas of noncompliance. For the most part, the state has the discretion to choose which of these intermediate sanctions to use. However, the state is required to have authority to appoint temporary management under section 1932(e)(2)(B) of the Act, and to permit individuals to terminate without cause under section 1932(e)(2)(C) of the Act. This is because section 1932(e)(3) of the Act requires the state to impose at least those two sanctions if an MCO repeatedly fails to meet the requirements of section 1903(m) or 1932 of the Act. This requirement is specified at § 438.706(b).

Comment: A commenter suggested that since § 438.700(a) provides that a state may impose intermediate sanctions

if it makes any of the determinations specified in paragraphs (b) through (d), the use of “whether” in those paragraphs is confusing and does not clearly link a determination of wrongdoing with the option of imposing an intermediate sanction. The commenter suggested replacing “whether” with “that” in the relevant paragraphs of § 438.700.

Response: We agree with the commenter’s suggestion to clarify the language in § 438.700(b) through (d) by replacing “whether” with “that” to clarify the intent of the section.

Comment: A commenter asked for clarification if the proposed deletion of PIHPs and PAHPs from § 438.700(c) for violations of marketing rules in § 438.104 meant that such violations by PIHPs or PAHPs could be subject to intermediate sanctions.

Response: States may cover PIHPs and PAHPs under their own sanction laws and we encourage them to do so whenever they believe necessary.

Comment: A commenter supported the proposed change in § 438.702(a)(4) that the suspension of new enrollment applies “after the date the MCO is notified of a determination of violation” to match the statutory standard in section 1932(e)(2)(D) of the Act.

Response: We appreciate the commenter’s support for this proposed change and are finalizing without further modification.

Comment: A commenter asked for clarification as to the meaning of “each determination” in § 438.704 to determine the total amount of the civil monetary penalty. The commenter asked if the phrase should be interpreted to mean “each individual” case or if “several individual cases reviewed at the same time” would constitute a single determination.

Response: We appreciate the commenter’s request for clarification of “each determination” and conclude that the phrase, which is incorporated in regulation from section 1932(e)(2)(A) of the Act, means each individual case that supports the state’s finding of an MCO’s, PCCM’s, or PCCM entity’s act or failure to act under § 438.700(b) through (d).

Comment: One commenter stated that the amounts for civil monetary penalties in § 438.704 should be left to the states to determine and another commenter recommended that the amounts for civil monetary penalties be increased.

Response: The specific limits for civil monetary penalties in § 438.704(b) and (c) are set forth in section 1932(e)(2)(A) of the Act and cannot be altered without statutory modification. Under § 438.704(a), if a state imposes civil monetary penalties as provided under

§ 438.702(a)(1), the maximum amount of the civil monetary penalties per type of violation are set forth in paragraphs (b) and (c).

Comment: A commenter requested that CMS define the term “egregious” in § 438.706(a)(1) relating to the state’s discretionary imposition of temporary management of an MCO.

Response: We decline to explicitly define “egregious” in this context because it is a substantive determination by the state whether the MCO’s conduct merits the imposition of temporary management. We did identify a necessary technical correction in § 438.706(a). The reference to the intermediate sanction in § 438.702(a)(3) has been corrected to § 438.702(a)(2).

Comment: A commenter suggested that the notice process for temporary management of an MCO in § 438.706 was unnecessary because states generally have laws and regulatory processes for regulatory management of an MCO.

Response: The notice requirement in § 438.706(b) pertains to notifying enrollees of their right to terminate enrollment without cause as provided in § 438.702(a)(3) rather than a notification process to the MCO. We believe that such notification to enrollees is reasonable and necessary to provide enrollees with the opportunity to make decisions that are in their best interests.

Comment: A commenter suggested that the notice and appeal process for sanction or termination of an MCO in § 438.710 was duplicative of existing state laws and regulatory processes for such actions and should be modified or removed.

Response: The provision in § 438.710(a) for written notice of the imposition of an intermediate sanction to the affected entity containing the basis and nature of the sanction and any other appeal rights that the state elects to provide is based on section 1932(e)(5) of the Act and cannot be modified by regulation. We note that § 438.710(a)(2) provides states the discretion whether additional hearing or appeal rights are provided to the affected entity. The requirement in § 438.710(b) for a pre-termination hearing is similarly specified in statute at section 1932(e)(4) of the Act and cannot be modified by regulation.

Comment: One commenter believed that § 438.726, which requires the state plan to include a plan for monitoring violations that involve the actions and failures to implement the provisions of this part, was burdensome as it would require an amendment for every modification to an approach that should be dynamic.

Response: We disagree. The state plan page for § 438.726 requires high level information verifying that the state has a monitoring plan in place for the actions or inactions by MCOs, PCCMs and PCCM entities in § 438.700, specifying a threshold to be met before an MCO is considered to have repeatedly committed violations of section 1903(m) of the Act, and thus, be subject to the imposition of temporary management, and confirms compliance with § 438.726(b). Specific detail on the monitoring plan or detail on additional types of intermediate sanctions is not required and the state is under no obligation to update the state plan page to reflect such practices.

Comment: One commenter requested that CMS clarify in § 438.730 (that is, sanction of an MCO by CMS), which entity (the state or CMS) the MCO would submit a request for an extension in paragraph (c)(3) and which entity (the state or CMS) would make a determination as to the credibility of the MCO’s request for an extension in paragraph (c)(3)(i).

Response: We appreciate the commenter’s request for clarification. Paragraph (c) provides that the state’s determination becomes CMS’ determination under paragraph (b)(2) if the state takes the actions specified in that paragraph. Therefore, the MCO would submit the request for an extension to the state and the state would determine whether to grant the 15-day extension based on the state’s determination that the MCO provided a credible explanation for additional time. The extension would ultimately be granted by the state if CMS, upon receipt of the request for an extension before the expiration of the initial 15-day period, determines that the MCO’s conduct does not pose a threat to an enrollee’s health or safety. We believe this is clear from the regulatory text and will rely on this explanation as the requested clarification.

After consideration of the public comments, we are finalizing § 438.700 with the modifications to replace “whether” with “that” in paragraphs (b), (c) and (d) as described above but otherwise as proposed. We are finalizing, as proposed, §§ 438.702, 438.704, 438.706, 438.708, 438.710, 438.722, 438.724, 438.726 and 438.730; in § 438.704(b), § 438.706(a), and § 438.730(a) we are also finalizing minor technical corrections to cross-referenced cites.

e. Deferral and/or Disallowance of FFP for Non-Compliance With Federal Standards (§ 438.807)

We proposed to add a new § 438.807 to specify that we may defer and/or disallow FFP for expenditures under a MCO contract identified in section 1903(m)(2)(A) of the Act when the state’s contract, as submitted for our approval or as administered, is non-compliant with standards therein, with section 1932 of the Act, or with the provisions of 42 CFR part 438 implementing such standards. These standards include whether final capitation rates, as specified in the contract and detailed in the rate certification, are consistent with the standards of actuarial soundness proposed in §§ 438.4 through 438.7. The proposed process for issuance of a deferral or a disallowance is the same as the process identified in §§ 430.40 and 430.42, respectively.

Section 1903(m)(2)(A) of the Act specifies that if the requirements set forth in paragraphs (i) through (xiii) therein are not satisfied, no FFP is authorized for expenditures incurred by the state for services under a prepaid capitation or other risk-based contract under which the payment is for inpatient hospital services and any other service described in paragraphs (2), (3), (4), (5), or (7) of section 1905(a) of the Act, or for the provision of any three or more of the services described in such paragraphs. We have previously interpreted this to mean that if the state fails to comply with any of the listed conditions, there could be no FFP at all for payments under the contract, even for amounts associated with services for which there was full compliance with all requirements of section 1903(m)(2)(A) of the Act. This interpretation has resulted in a potential penalty that in some cases appears to be out of proportion to the nature of the violation, under which FFP would be withheld for payment amounts representing services which are in compliance.

We proposed to interpret section 1903(m)(2)(A) of the Act that the enumerated services are for purposes of defining the minimum scope of covered services under a comprehensive risk, or MCO, contract. We proposed that deferrals and/or disallowances of FFP can be targeted to all services under the MCO contract even if not listed explicitly in section 1903(m)(2)(A) of the Act, rather than FFP in the full payment amount made under the contract. Specifically, we proposed in § 438.807 to interpret section 1903(m)(2)(A) of the Act to condition

FFP in contract payment amounts on a service by service basis, so that, for example, if the violation involved the payment amount associated with coverage of inpatient hospital costs and that is the only portion of the payment amount that is not actuarially sound, then FFP in only that portion of the payment would be deferred or disallowed. We argued that this approach was supported as the language reads no payment shall be made under this title to a State with respect to expenditures incurred by it for payment for services provided by any entity as placing emphasis on “payment for services provided by any entity” without regard to what the services are, so long as the minimum scope of covered services for a MCO contract is satisfied. Under the proposal, we would have deferred and/or disallowed partial FFP under the contract associated with only a particular service category if a violation involves only that category of services and not the delivery of services generally.

We received the following comments in response to our proposal to add § 438.807.

Comment: Many commenters supported proposed § 438.807 and recommended additional clarification. One commenter recommended that CMS clarify whether it retains the authority to withhold all FFP due to non-compliance, or if CMS is only able to withhold FFP on a service by service basis. One commenter recommended that CMS use such authority to penalize managed care plans that do not meet the network adequacy and access to care standards.

One commenter stated that none of the requirements listed in section 1903(m)(2)(A) of the Act support CMS’ approach in § 438.807. The commenter stated that section 1903(m)(2)(A)(iii) of the Act contains the requirement that capitation rates be actuarially sound, and this concept does not allow CMS to isolate and remove portions of capitation rates to be paid for individual services, without affecting the certification of the rate as adequate to meet the needs of contracting plans. The commenter also stated that the remaining federal Medicaid managed care requirements in section 1903(m)(2)(A) of the Act are established as obligations imposed on states for inclusion in their contracts with Medicaid plans, not as requirements applicable to individual services. The commenter stated that it is unclear when and under what basis, CMS would be able to conclude that a violation involves only a particular category of service. Other commenters opposed to

§ 438.807 stated that CMS’ approach to defer or disallow FFP for targeted services is incongruent with the operation of Medicaid managed care programs and inconsistent with a comprehensive full-risk managed care contract and capitated payment model.

Response: After consideration of public comments and reconsideration of the statutory text, we have determined that section 1903(m)(2)(A) of the Act does not permit us the flexibility to take partial deferral or disallowance of FFP under the contract as proposed. Therefore, we will not finalize proposed § 438.807.

We are not finalizing § 438.807.

f. Exclusion of Entities (§ 438.808)

Current § 438.808 implements the requirements of section 1902(p)(2) of the Act with respect to MCOs. Section 1902(p) of the Act enforces exclusions from federal health care programs by prohibiting FFP for medical assistance to MCOs and entities furnishing services under a waiver approved under section 1915(b)(1) of the Act if the MCOs or entities that have a contractual or other relationships with excluded entities or individuals. We proposed to clarify that PIHPs, PAHPs, PCCMs or PCCM entities that have contracts with the state under a section 1915(b)(1) waiver would also be subject to § 438.808, which implements the requirements in section 1902(p)(2) of the Act for the types of organizations or entities with which the state must not contract in order for the state to receive federal payments for medical assistance. Section 1902(p)(2) of the Act similarly provides that an entity furnishing services under a waiver approved under section 1915(b)(1) of the Act must meet the exclusion parameters identified in section 1902(p)(2)(A), (B) and (C) of the Act in order for the state to receive FFP. The regulation, at § 438.808(b), lists the entities that must be excluded. There is no requirement in the statute that MCO contracts be tied to a specific managed care authority so we proposed that all MCO contracts under any authority be subject to this provision.

We received the following comments in response to our proposal to revise § 438.808.

Comment: One commenter supported the addition of PIHPs, PAHPs, PCCMs, and PCCM entities that operate under a waiver approved under section 1915(b)(1) of the Act.

Response: We appreciate the comment as the proposed change is consistent with section 1902(p)(2) of the Act.

Comment: One commenter pointed out that § 438.808(b)(2) does not

reference individuals or entities that are excluded from participation in any federal health care program under section 1128 or 1128A of the Act as set forth in § 438.610(b).

Response: We appreciate the commenter’s identification of this omission. Section 438.808 is based on section 1902(p)(2) of the Act and includes individuals or entities excluded from participation under sections 1128 or 1128A of the Act; therefore § 438.808(b)(2) and (b)(3)(i) and (ii) should also include a reference to § 438.610(b). The distinction between individuals or entities in § 438.610(a) and (b) is for purposes of distinguishing whether the “knowingly” standard applies.

After consideration of the public comments, we are finalizing this section as proposed with a modification to include appropriate references to § 438.610(b).

5. Beneficiary Protections

a. Enrollment (§ 438.54)

In this section, we addressed a gap in the current managed care regulations regarding the enrollment process. Other than the default enrollment standards currently in § 438.50(e) and (f) for MCOs and PCCMs, there have been no federal regulations governing enrollment of beneficiaries into Medicaid managed care programs. In the absence of specific federal regulatory provisions, states have used a number of different approaches to enrolling beneficiaries into voluntary and mandatory managed care programs. The variation in proposed processes revealed a need for guidance to ensure an appropriate, minimum level of beneficiary protection and consistency across programs. In this section, we proposed basic federal standards for enrollment while continuing to permit state flexibility in designing enrollment processes for Medicaid managed care programs.

Among states currently operating voluntary Medicaid managed care programs, which allow each beneficiary to choose to receive services through either a managed care or FFS delivery system, states have generally used a passive enrollment process to assign a beneficiary to a managed care plan immediately upon being determined eligible. Typically, the beneficiary is provided a period of time to elect to opt-out of enrollment from the state-assigned managed care plan and select a different managed care plan or elect to opt-out of managed care completely and, instead, receive services through a FFS delivery system. If the beneficiary does not make an affirmative choice, the

beneficiary remains enrolled in the state-assigned managed care plan during the period of Medicaid eligibility and enrollment. Our experience shows the rate of potential enrollees that opt-out is generally very low.

In a mandatory Medicaid managed care program, states require beneficiaries to receive Medicaid benefits from managed care plans. Under section 1932(a)(4)(A)(ii)(I) of the Act, beneficiaries in a mandatory managed care program have the right to change plans without cause within 90 days of enrolling in the plan and every 12 months; enrollees may also change plans for cause at any time. When the beneficiary does not actively select a managed care plan in the timeframe permitted by the state, states have generally used the default assignment process to assign individuals into plans. Section 1932(a)(4)(D) of the Act and current implementing regulations at § 438.50(f) outline the process that states must follow to implement default enrollment (also commonly known as auto-assignment) in a mandatory managed care program.

In both voluntary and mandatory managed care programs, we suggested that beneficiaries are best served when they affirmatively exercise their right to make a choice of delivery system or plan enrollment. We noted that this involves both an active exercise of choice and requisite time and information to make an informed choice. Further, given the sensitive nature of this transition from FFS to managed care or from one managed care system to a new managed care system and the often complex medical, physical and/or cognitive needs of Medicaid beneficiaries, we indicated that enrollment processes should be structured to ensure that the beneficiary has an opportunity to make an informed choice of a managed care plan and that state processes support a seamless transition for an enrollee into managed care.

Our goal of alignment prompted us to consider how enrollment is conducted in the private market and in other public programs. In the proposed rule, we noted that MA is a voluntary managed care program, in which beneficiaries actively select the MA organization during the annual open enrollment period with limited exceptions for passive enrollment. To promote integration of care for dually eligible (Medicare and Medicaid) beneficiaries in a section 1115A demonstration, CMS' Medicare-Medicaid Coordination Office (MMCO) is using a form of passive enrollment. That enrollment process generally

requires notifying dually eligible individuals that they can select a Medicare plan 2 months before they would be enrolled in the plan. If no active choice is made, enrollment into the plan identified through the passive process takes effect.

We also noted that enrollment into a QHP in either the FFM or SBM requires an active selection of a plan, and in some cases premium payment. The online application for the FFM at Healthcare.gov provides the option to select a QHP at the time of application. If a QHP is not selected at the time of application, the FFM single, streamlined application requires follow-up by the individual to complete enrollment into a QHP. A few states with mandatory Medicaid managed care programs require applicants to select a Medicaid managed care plan at the time of application. While this approach aligns the processes for Medicaid, CHIP and QHPs, it also eliminates the traditional approach of providing a post-eligibility determination choice period to select a managed care plan for Medicaid beneficiaries already eligible for FFS coverage.

We proposed a new § 438.54 to apply a consistent standard for all managed care enrollment processes. At the same time, we proposed to move and revise, as noted below, the existing provisions in § 438.50(e) and (f) to our new § 438.54. Under these proposed changes, states would implement enrollment processes subject to a set of enrollment standards that are consistent with section 1932(a)(4) of the Act and that promote high quality managed care programs. The goals of this approach were to promote accurate and timely information to beneficiaries about their managed care options; to enable and encourage active beneficiary choice periods for enrollment; and to ensure the state's ability to conduct intelligent default enrollments into a managed care plan when necessary.

Through the changes discussed below, we proposed to set broad parameters for a state's enrollment process rather than dictate specific elements. In paragraph § 438.54(a), we proposed to clarify that the provisions of this section apply to all authorities under which a state may enroll beneficiaries into a managed care delivery system to ensure a broad and consistent application. We noted that this includes voluntary managed care programs under section 1915(a) of the Act, as well as mandatory or voluntary programs under sections 1932(a), 1915(b) or 1115(a) of the Act.

We proposed in paragraph (b) that the state have an enrollment system for both

voluntary and mandatory managed care programs, and proposed definitions for those programs in, respectively, paragraphs (b)(1) and (b)(2). These proposals supported clarity and consistency.

Proposed paragraph (c) specified the standards for programs using a voluntary managed care program. In paragraph(c)(1), we proposed that the state may use either an enrollment system that provides the beneficiary time to make an affirmative election to receive services through a managed care or FFS delivery system or a passive enrollment process. We proposed to define a passive enrollment process as one in which the State selects a MCO, PIHP, PAHP, PCCM, or PCCM entity for a potential enrollee but provides a period of time for the potential enrollee to decline the managed care plan selection before enrollment became effective. Using either option, the state would have had to comply with the standards proposed in paragraphs (c)(2) through (c)(8).

In paragraph (d), we proposed to set forth standards for enrollment systems for mandatory managed care programs. In paragraph (d)(1), we proposed that such a system must meet certain standards, listed in proposed paragraphs (d)(2) through (d)(7). We discussed the remaining proposals for paragraphs (c) and (d) together below as these proposed standards were substantially similar.

In paragraph (c)(2) and (d)(2), we proposed a specific enrollment standard applicable to both voluntary and mandatory managed care programs that all states must provide a period of time of at least 14 calendar days of FFS coverage for potential enrollees to make an active choice of their managed care plan. We explained that the minimum 14-calendar day period would have had to occur between the date that the notice specified in paragraph (c)(3) and (d)(3) is sent and the date on which the enrollee becomes covered under the applicable managed care entity.

We proposed to clarify in paragraph (c)(2)(i), that if the state does not use a passive enrollment process and the potential enrollee does not make a choice, then the potential enrollee would have been enrolled into a managed care plan selected by the state's default process when the choice period has ended. We did not propose that states must use FFS as the default enrollment when using a voluntary managed care program; rather FFS enrollment could be limited to those beneficiaries that affirmatively selected FFS. In proposed paragraph (c)(2)(ii), we clarified that if the state used a passive

enrollment process and the potential enrollee does not make a choice, then the potential enrollee is enrolled into the managed care plan selected by the state's passive enrollment process when the choice period has ended. In the mandatory program, the minimum 14-day period would have to occur before any default enrollment process is used. We did not propose any passive enrollment mechanism for mandatory managed care programs because the default enrollment mechanism would provide the same measure of administrative flexibility.

We acknowledged that states may want to effectuate plan enrollment in mandatory programs as soon as possible after the eligibility determination. Our proposal would have required those states to provide a period of FFS coverage for beneficiaries between their date of eligibility and their date of managed care enrollment. To minimize any further delay in managed care enrollment, we proposed to allow states to operationalize the 14-day active choice period by advising beneficiaries of the managed care plan they would be enrolled into through the default process if they do not make an active choice of managed care plan in that 14-day period. According to this process, states would complete the default enrollment process outlined in § 438.54(d)(5) prior to beginning the notice and education process described in paragraph (d)(3) with beneficiaries, and ensure that adequate and appropriate information is provided to beneficiaries regarding the implications of not making an active managed care plan selection. This proposal would also have enabled beneficiaries to override default enrollments by exercising their ability to make an active choice of a managed care plan.

We requested comment on the impact of this new standard on managed care program costs and operations, as well as the operational flexibility we proposed to relieve beneficiaries of the burden of receiving too many mailings, which can create confusion, before making the default enrollment permitted in § 438.54. We also invited comment on whether a 14-day period is necessary, provides sufficient time for beneficiaries to make an election, or whether a longer minimum period, such as 30 days or 45 days, should be adopted.

All beneficiaries, regardless of whether enrollment is mandatory or voluntary, must be given the information, education, and opportunity to participate actively in their choice of managed care plan. Paragraphs (c)(3) and (d)(3) proposed that states develop informational notices to clearly explain

to the potential enrollee the implications of not actively making the decisions available to them and allowing the passive or default enrollment to take effect. Proposed paragraphs (c)(3)(i) and (d)(3)(i) provided that the notices comply with § 438.10 and proposed paragraphs (c)(3)(ii) and (d)(3)(ii) provided that the notices have a postmark or electronic date stamp that is at least 3 calendar days prior to the first day of the 14-day choice period. We believed these proposed provisions established reasonable time for either postal delivery or the potential enrollee to read the electronic communication and still have 14 days to make an active selection.

Priority for enrollment into a managed care plan is currently in § 438.50(e); however, for better organization, we proposed to delete the text from § 438.50 and proposed it as paragraphs (c)(4) and (d)(4). No other changes were proposed to this text regarding priority for enrollment.

We proposed in paragraphs (c)(5) and (d)(5) that states assign potential enrollees to a qualified MCO, PIHP, PAHP, PCCM, or PCCM entity. This concept is currently addressed in § 438.50(f)(2) but only to the extent of excluding those MCOs and PCCMs that are subject to the intermediate sanction in § 438.702(a)(4). In proposed (c)(5)(i) and (d)(5)(i), we proposed to exclude MCOs, PIHPs, PAHPs, PCCMs, or PCCM entities subject to sanction under § 438.702(a)(4) and to add paragraphs (c)(5)(ii) and (d)(5)(ii) to ensure that a MCO, PIHP, PAHP, PCCM, or PCCM entity has the capacity for new enrollments as a condition of being qualified to accept assigned enrollments.

In proposed paragraphs (c)(6) and (d)(6), we addressed standards that are currently reflected in § 438.50(f) which provides that states have a default enrollment process for assigning a MCO or PCCM when the potential enrollee does not make an active managed care plan selection. Section 1932(a)(4)(D) of the Act provides that a state conduct such enrollments in a manner that takes existing provider-individual relationships into consideration, and if that approach is not possible, to equitably distribute individuals among the participating managed care plans. While the 2002 final rule strictly interpreted the provisions of section 1932(a)(4)(D) of the Act regarding default enrollment to apply only to enrollment that occurred under state plan authority in section 1932(a) of the Act, we noted our belief that the enrollment processes currently specified

in § 438.50(e) and (f) should not be limited only to entities subject to section 1932(a)(4)(D) of the Act.

Allowing potential enrollees sufficient time to make informed decisions about their managed care plan is an important protection that should not exclude potential enrollees of PIHPs and PAHP, as well as those subject to voluntary programs that utilize a passive process. Therefore, we proposed to make these provisions applicable to all managed care authorities and to both passive and default enrollment processes. We proposed adding existing text from § 438.50(f)(2) through (f)(4) in paragraphs (c)(6) and (d)(6). While § 438.50(f) currently only applies to default enrollment in mandatory managed care programs, we stated that enrollees in voluntary programs that utilize a passive enrollment process should also benefit from being assigned to a plan based on existing provider relationships or other criteria relevant to beneficiary experience. Therefore, we proposed to add standards in paragraph (c)(6) for voluntary programs that mirrored the standards for mandatory programs using default enrollments.

In paragraphs (c)(7) and (d)(7), we proposed to include provisions from existing § 438.50(f)(2) that provide that if a state cannot preserve existing provider-beneficiary relationships and relationships with providers that traditionally serve Medicaid, then enrollees must be equitably distributed. Paragraphs (c)(7)(i) and (d)(7)(i) proposed a standard that states may not arbitrarily exclude a MCO, PIHP, PAHP, PCCM, or PCCM entity from the assignment process. We proposed interpreting "equitable distribution" in section 1932(a)(4)(D)(ii)(II) of the Act to mean not only that the criteria applied to make default enrollments are fair and reasonable for enrollees and plans, but that the pool of contractors eligible to receive default enrollments is not based on arbitrary criteria. We also proposed to allow the flexibility to use additional criteria related to the beneficiary when making default assignments, such as the geographic location of the beneficiary, enrollment preferences of family members, previous plan assignment of the beneficiary, quality assurance and improvement performance, procurement evaluation elements, and other reasonable criteria that support the goal of the Medicaid program, should be provided for in the regulation. We proposed that such criteria be part of an equitable distribution by ensuring fair treatment for enrollees and managed care plans.

For voluntary programs only that use passive enrollment, paragraph (c)(8)

proposed that states send confirmation notices to enrollees of their plan selection that contain information explaining the enrollee's right to disenroll from that MCO, PIHP, PAHP, PCCM, or PCCM entity within 90 days. We noted that many states use a voluntary model when first starting to introduce managed care, which means the beneficiaries are not as familiar with the limitations of managed care plan enrollment; we believed that the additional confirmation notice would help limit unintended plan selections before they take effect.

We received the following comments in response to our proposal to add a new § 438.54 with these provisions.

Comment: Many commenters supported the enrollment provisions proposed in § 438.54. Commenters supported having all enrollment information in one section and the increased information provided on topics previously not addressed in part 438, such as mandatory and voluntary enrollment.

Response: We thank the commenters for their support of the organization and clarity of the proposed § 438.54 and of the proposal to provide increased direction and details on critical enrollment processes and policies.

Comment: A few commenters recommended that when potential enrollees are provided the opportunity to make an active choice of a managed care plan (in both voluntary and mandatory programs) and do not make a choice, that the enrollees should be automatically placed in the FFS delivery system. We also received a few comments recommending that passive enrollment, default assignment, and mandatory enrollment be prohibited. These commenters believed that all potential enrollees should only be enrolled into a managed care plan after making an active choice.

Response: We decline to make these changes. Mandatory enrollment- for specified populations- and default enrollment are permitted statutorily in sections 1932(a)(1)(A), 1915(b), 1932(a)(4)(D) of the Act. Passive enrollment, while not statutorily defined, is an enrollment mechanism used to more quickly provide the additional benefits, provider network, and care coordination services generally only available through managed care. Passive enrollment processes have been used successfully in many states. Additionally, states using a passive enrollment process must still fulfill the intent of a voluntary program by offering enrollees time to elect to remain in managed care or to move to the state's FFS delivery model. In addition, if the

enrollee elects to remain in managed care, the enrollee has at least 90 days from the date of enrollment in the managed care plan, as provided in § 438.56(c)(2)(i), to decide whether to remain in the assigned plan or to select a different managed care plan. Enrollees can also avail themselves of the for-cause reasons specified in § 438.56 after the 90 day period has ended. We believe there are adequate protections in place in programs using passive enrollment to warrant their continuation.

Comment: A few commenters recommended that CMS mandate exemptions from mandatory managed care plan enrollment for enrollees in a current course of care and enrollees with complex conditions such as pregnancy. The commenters believed mandating these types of enrollees into managed care could be disruptive and harmful.

Response: We do not believe that mandating such an exemption from mandatory enrollment is necessary or within our authority. Section 1932(a) of the Act provides for the exclusion of certain populations (certain children with special health care needs, Medicare recipients, and Indians) from mandatory enrollment, unless permitted under another authority, as discussed in section I.A. of this rule. Beyond these exclusions, states have flexibility to design the parameters of their managed care programs for mandatory or voluntary enrollment and nothing in the final § 438.54 would diminish that flexibility. We believe that pregnant enrollees or enrollees with chronic and/or complex conditions benefit from the care coordination and additional benefits that may be provided through a managed care plan. The provisions of this final rule that establish requirements for care coordination and continuity of care were designed to promote a smooth transition into managed care for beneficiaries with complex health care needs. Currently, states have the ability to include this type of exemption into their programs and nothing in § 438.54 would diminish that flexibility.

Comment: We received many comments on the proposed 14 day FFS choice period in §§ 438.54(c)(2) and 438.54(d)(2). Many commenters supported this proposed provision as they believe that time to make an informed choice is important, particularly for potential enrollees with special health care needs or receiving LTSS. Most commenters who supported a choice period recommended that the period be 30 days or longer.

We also received many comments opposed to the 14 day FFS choice

period. These commenters believed that putting potential enrollees in FFS would be confusing for enrollees and providers; result in disruptions of care when FFS providers did not also participate in managed care plan networks; and delay enrollees' access to the increased benefits, provider network, case management and care coordination that come through managed care enrollment. Further, many commenters stated that the delay in enrollment under the proposal would negatively impact potential enrollees in need of care coordination, such as pregnant women, newborns, and individuals recently released from incarceration. Several commenters pointed out that due to low or no enrollment in their FFS programs over time, implementing a FFS period for all new potential enrollees would be difficult, if not impossible, for several states. Some commenters stated that these challenges would be particularly significant for states with State-based Marketplaces (SBMs) that were designed to determine eligibility for multiple products and facilitate up-front managed care plan selection. Commenters also believed that a mandated FFS choice period was unnecessary given the 90 day opportunity to change managed care plans without cause afforded all enrollees in § 438.56(c)(2)(i), the ability to disenroll for cause as specified in § 438.56(d)(2)(iv), and the accessibility of choice counseling and other information through the beneficiary support system proposed in § 438.71. Lastly, commenters recommended that CMS to leave the decision of whether to include a choice period to the states and not mandate a one-size-fits-all approach.

Response: We appreciate the range of comments received on this proposed provision. After careful consideration, we have decided not to finalize this provision in § 438.54 for voluntary or mandatory managed care programs. We agree that there should not be mandated barriers in place to timely access to the benefits of managed care, in particular, provider networks, care coordination and case management. The proposal for a 14 day FFS period prior to managed care enrollment did not adequately consider potential disruptions in care and delays in accessing care coordination for vulnerable populations such as pregnant women, newborns, and individuals released from incarceration. In addition, we acknowledge that the proposal was incompatible with the direction of state Medicaid programs to effectuate enrollment at the point of the eligibility

determination or soon thereafter. We understand the concerns regarding insufficient numbers of providers under FFS in many states and the significant difficulty and challenge for states to rebuild FFS programs to accommodate the proposed 14 day period. As many commenters stated, the 90 day without cause disenrollment window afforded to all enrollees in connection with their initial managed care enrollment, serves as a choice period. We believe that potential enrollees and enrollees will have easier access to information given the provisions in § 438.10 that require member handbooks, provider directories, and drug formularies be publicly available; such information will assist enrollees in making an active enrollment choice. We appreciate the commenters' recognition of the value of the new for-cause disenrollment reason in § 438.56(d)(2)(iv) related to residential, institutional, or employment supports for enrollees using LTSS; discussion of this provision can be found in section I.B.5.b. We also appreciate the support for the beneficiary support system proposed in § 438.71 and expect states to implement their beneficiary support systems so that they are easily accessible, well publicized, and that they fully educate potential enrollees and enrollees on their enrollment and disenrollment opportunities and limitations. Additional discussion of § 438.71 can be found in I.B.5.c. We clarify that nothing in the final § 438.54 prevents or discourages states from providing a choice period for some or all populations, if the state believes that this option is best suited to the state's programmatic circumstances and the needs of the beneficiaries. We believe that continuing the flexibility of allowing states to decide whether to include a choice period in their program is the best approach. The final regulation text at paragraphs (c)(1) and (2) and (d)(2) do not include the 14-day choice period; § 438.54, as finalized, will permit states to make passive enrollments effective upon eligibility determination, subject to the enrollees' right to opt-out or elect a different managed care plan. The elimination of the 14-day choice period also necessitated revisions to paragraph (d)(2) to clarify enrollment process options available to states with mandatory programs; specifically, paragraph (d)(2)(i) addresses states that choose to not use a passive enrollment process and paragraph (d)(2)(ii) addresses states that choose to use a passive enrollment process.

Comment: One commenter requested clarification on the permissibility of using a passive enrollment process as described in proposed § 438.54(c)(2)(ii) for a program with only one PCCM entity.

Response: We appreciate the opportunity to clarify that § 438.54(c)(2)(ii) is applicable to PCCM programs and remind the commenter that provisions for programs with single PCCM entities are included in proposed § 438.52, specifically, that choice is at the PCCM level as with PCCM programs.

Comment: We received many supportive comments about the informational notices proposed in §§ 438.54(c)(3) and 438.54(d)(3). Commenters recommended that the informational notices proposed in §§ 438.54(c)(3) and 438.54(d)(3) should be written at a 6th grade reading level to improve readability and add consistency among states; include the contact information for the state's beneficiary support system; be consumer tested; be developed by CMS rather than the state; and include detailed explanations of the implications of selecting a managed care plan given possible lock-in enrollment periods and limited for cause disenrollment provisions. We also received a few comments recommending that enrollment and disenrollment forms be included with the notice.

Response: We appreciate these comments and agree that adding the contact information for the beneficiary support system would be a useful addition. We also agree that the informational notices should contain a comprehensive explanation of any lock-in enrollment periods, as well as, the 90 day without cause disenrollment opportunity and all for cause disenrollment reasons in § 438.56. Since, in some cases, this notice will be the last one from the state to the enrollee until their eligibility redetermination or their annual right to change plans, it is critical that this notice be as complete, clear, factual, and easy to understand as possible. We are finalizing paragraphs (c)(3) and (d)(3) to reflect requirements for when the notice must be sent to the enrollee, contact information for the beneficiary support system, the length of the enrollment period, and disenrollment rights. In paragraphs (c)(3) and (d)(3) in this final rule, we specify new requirements for the notices which states a timeframe for sending the notices; the implications to the potential enrollee of exercising each of the options available; the managed care plans available for selection; the

process for making the selection know to the state; the length of the enrollment period and all disenrollment rights; and information on how to contact the beneficiary support system.

Given the tremendous variation among managed care programs, we believe each state, rather than CMS, is in the best position to draft these notices. We acknowledge that states and managed care plans appreciate the importance of producing easily understood materials and have traditionally utilized reading level tools and standards to facilitate the production of effective materials. We also believe that education and demographic differences across states necessitate flexibility and we encourage states to ensure that it, and its managed care plans, are producing materials in a grade level that is most appropriate for their population. We decline to revise the final rule to reflect these recommendations. Given that most enrollment and disenrollment is done electronically or by phone, we do not believe there is a need to mandate a requirement for including forms with the notice; however, states are free to do so if it supports their enrollment processes.

Comment: A few commenters recommended that passive and default enrollment be prohibited from managed care plans that do not cover some services due to moral or religious objections. We received a few comments requesting that CMS add states' ability to suspend passive and default enrollment for poorly performing plans. We received one comment that states should publish the logic or criteria used to make passive and/or default plan assignments.

Response: We thank commenters for their suggestions but decline to add them to § 438.54. These are all options available to the state but we do not agree that specifically addressing them in § 438.54 is necessary. For a managed care plan that does not provide a covered service based on moral or religious objections, there are notification requirements that it must comply with in § 438.10. This section also contains requirements for the state to provide information on how and where to obtain the otherwise covered service.

Comment: One commenter requested clarification on the meaning of "qualified" as used in proposed § 438.54(c)(5) and (d)(5).

Response: The criteria for "qualified" were proposed, and are finalized without substantive change, in § 438.54(c)(5)(i) and (ii) and (d)(5)(i) and (ii); we made one editorial change to

add the word “and” for additional clarity. The regulation text requires two criteria to be met for a MCO, PIHP, PAHP, PCCM or PCCM entity to be qualified: (1) Not being subject to the intermediate sanction described in § 438.702(a)(4) and (2) Having capacity to enroll beneficiaries. We believe both criteria are clear and require no further explanation.

Comment: A few commenters recommended that CMS clarify that specialists and hospitals should be considered when a state determines an “existing provider-beneficiary relationship” in proposed § 438.54(c)(6)(i) and § 438.54(d)(6)(i). Some other commenters recommended that states try to preserve as many existing provider-beneficiary relationships as possible for an enrollee that utilizes multiple services with different providers.

Response: We understand the commenters’ concerns but do not believe it is necessary to add reference to specialists or hospitals to the text proposed in § 438.54(c)(6)(i) and § 438.54(d)(6)(i) (to be finalized in paragraphs (c)(6)(i) and (d)(7)(i) respectively). As proposed the relevant text states an existing provider-beneficiary relationship is one in which the provider was the main source of Medicaid services for the beneficiary during the previous year. However, we agree that states should attempt to preserve as many existing provider-beneficiary relationships as possible for an enrollee and encourage states to review their passive and default algorithms to achieve that goal. To clarify this, we are finalizing paragraphs (c)(6)(i) and (d)(7)(i) to state in which the provider was a main source. This permits complete flexibility to include any provider who is a main source of Medicaid services.

Comment: One commenter recommended that states should be required to consult with their managed care plans when determining how to equitably distribute enrollees as proposed in §§ 438.54(c)(7)(i) and 438.54(d)(7)(i).

Response: States are free to consult with their contracted managed care plans as they deem appropriate for designing their method for equitably distributing enrollees. We do not agree that it should be a requirement and, therefore, we decline to revise §§ 438.54(c)(7)(i) and 438.54(d)(7)(i) (to be finalized as § 438.54(d)(8)(i)).

Comment: Some commenters suggested criteria that states should have to consider in their passive and default enrollment processes in addition to those proposed in §§ 438.54(c)(7)(ii)

and 438.54(d)(7)(ii). Suggestions included providers serving sub-populations; languages spoken; and coverage of needed medications. One commenter requested clarification on the inclusion of “accessibility of provider offices for people with disabilities (when appropriate)” proposed in the criteria for passive enrollment in § 438.54(c)(7)(ii) but not in the proposed criteria for default assignment in § 438.54(d)(7)(ii).

Response: The additional criteria suggested by commenters could add value to the passive and default enrollment processes and we encourage states to utilize additional criteria as they deem appropriate. We included other reasonable criteria that support the objectives of the managed care program to encourage the use of additional appropriate criteria to refine the passive or default enrollment algorithm. Therefore, we decline to add the suggested criteria to the final regulation text. We appreciate the commenter alerting us to the omission in the proposed criteria for default assignment in proposed § 438.54(d)(7)(ii); the language “accessibility of provider offices for people with disabilities (when appropriate)” should have been included in both proposed paragraphs. That omission will be corrected in the final text at § 438.54(d)(8)(ii).

Comment: A few commenters recommended extending the confirmation notices proposed for voluntary programs that use passive enrollment in § 438.54(c)(8) to mandatory programs that utilize passive enrollment. Commenters believed that enrollees in mandatory programs would benefit from receiving a notice confirming which managed care plan they had been enrolled in. Commenters believed this was true even if the enrollee made an active plan selection.

Response: We understand the commenters’ recommendation and believe the provision as proposed may not have clearly conveyed our intent. In a voluntary program that uses passive enrollment, enrollees must first decide whether to remain in the managed care delivery system or be moved to the FFS delivery system. This is the decision that the notice in § 438.54(c)(8) is intended to confirm (that is, that the enrollee has failed to elect FFS coverage). We are finalizing paragraph (c)(8) with additional text to make the purpose of the notice and the deadline for issuing it clearer. As the enrollee in a mandatory managed care program is only choosing among managed care plans and does not have the option to elect FFS coverage, we believe that it is

not necessary to require this notice in a mandatory managed care program subject to § 438.54(d).

After consideration of the public comments, we are finalizing § 438.54 with revisions as follows:

- Paragraph (b), we are finalizing revised introductory text to clarify that an enrollment system is required for both voluntary and mandatory managed care programs;
- Paragraph (c)(1), we are finalizing text to permit a state to provide an enrollment choice period or to use a passive enrollment process without mandating a period of FFS coverage, for reasons discussed in the comments above;
- Paragraph (c)(2), we are finalizing the regulation text without reference to the proposed 14-day choice period with FFS coverage (as discussed above) and with minor editorial changes to preserve the flow and meaning of the text;
- Paragraphs (c)(3), we are finalizing additional requirements for the notice from the state to potential enrollees to provide more complete information;
- Paragraphs (c)(5)(i), we are adding “; and” to indicate that the requirements in both paragraphs must be applied;
- Paragraph (c)(8), we are finalizing revised text to more clearly explain the content of the final notice required for voluntary programs that use a passive enrollment process and to clarify the deadline for that notice;
- Paragraph (d)(2), we are finalizing the regulation text without reference to the proposed 14-day choice period with FFS coverage (as explained above) and with new text to clarify the enrollment process options available in mandatory programs, including passive enrollment;
- Paragraph (d)(3), we are finalizing additional requirements for the notice from the state to potential enrollees to provide more complete information;
- Paragraph (d)(5), we are finalizing the regulation text without reference to the proposed 14-day choice period (as explained above) and with “; and” between paragraphs (i) and (ii) to indicate that the requirements in both paragraphs must be applied;
- Paragraph (d)(6), we are finalizing text that clarifies requirements for enrollee assignment using a passive enrollment process in a mandatory program;
- Paragraph (d)(7) (redesignated from (d)(6)), we are revising “. . . the main source . . .” to “. . . a main source . . .” to clarify that multiple existing relationships should be maintained in both passive and default enrollment processes if possible and making non-substantive revisions to the text to

acknowledge use of a passive and a default enrollment process;

- Paragraph (d)(8) (redesignated from (d)(7)), we are finalizing a conforming change to recognize the redesignation of (d)(7) and in paragraph (ii), to include a reference to accessibility for disabled enrollees.

b. Disenrollment Standards and Limitations (§ 438.56)

In the proposed rule, we proposed to retain the majority of the regulation text currently in § 438.56, with four substantive exceptions:

- We proposed, as discussed in more detail in section I.B.5.e. of this final rule, to add references to “PCCM entity” as applicable;

- We proposed to revise the text in paragraph (c)(2)(i) concerning the start of the statutorily mandated 90-day period during which an enrollee may disenroll without cause;

- We proposed to explicitly provide that a state may accept, at its option, either oral or written requests for disenrollment; and

- We proposed in (d)(2)(iv) to specify an additional cause for disenrollment. We also proposed grammatical and clarifying corrections to the regulation text.

In our proposal, paragraphs (a) through (c)(1) were unchanged from the current rule except for the addition of PCCM entity. In paragraph (c)(2)(i), we proposed to modify our approach to an enrollee’s 90-day without cause disenrollment period. Section 1932(a)(4)(A) of the Act specifies that a state plan must permit disenrollment without cause from a managed care entity during the first 90 days of enrollment under mandatory managed care programs. As part of the 2002 final rule, we exercised authority under section 1902(a)(4) of the Act to extend this standard to state plans with voluntary managed care programs and to PIHPs and PAHPs (whether voluntary or mandatory). As finalized in 2002, we interpreted the clause “90 days following the date of the beneficiary’s initial enrollment” to mean enrollment with a particular MCO, PIHP, PAHP, or PCCM and to allow an enrollee to disenroll from a MCO, PIHP, PAHP, or PCCM every 90 days until he or she had exhausted all contracted MCO, PIHP, PAHP, or PCCM options for which he or she is eligible. As noted in the preamble to the proposed rule, we believe that this provision has been applied in an inconsistent manner, and that such an approach is disruptive to the goals of establishing enrollee-provider relationships that support a coordinated delivery system and contribute to

medical and administrative inefficiencies. Therefore, we proposed in paragraph (c)(2)(i) to revise the regulation to limit the 90-day without cause disenrollment period to the first 90 days of an enrollee’s initial enrollment into any MCO, PIHP, PAHP, or PCCM offered through the state plan; therefore, an enrollee would have only one 90-day without cause disenrollment opportunity per enrollment period. We explained that the revised approach is consistent with our interpretation of the intent of section 1932(a)(4)(A)(ii) of the Act, represents current practice in some states, and supports efficiency under the Medicaid program. We proposed no changes to paragraphs (c)(2)(ii) through (iv).

We proposed to add the phrase “as required by the state” to § 438.56(d)(1) to clarify that this section of the regulation was intended to give states the flexibility to accept disenrollment requests either orally, or in written form, or both ways if the state so desires. We expressed our intent to interpret “written request” for purposes of this regulation to include online transactions or requests conducted with an electronic signature. A state could also accept requests orally, but require written confirmation of the oral request. Under our proposal, the state’s standard for the form of disenrollment requests would have to be clearly communicated to enrollees to take advantage of this flexibility.

In paragraph (d)(2)(iv), we proposed to add a new cause for disenrollment: the exit of a residential, institutional, or employment supports provider from an enrollee’s MCO, PIHP, or PAHP network. We noted that provider network changes can have a significant impact on those enrolled in MLTSS programs, since such providers are typically integral to residential and work services and supports. Therefore, if the state does not permit participants enrolled in MLTSS to switch managed care plans (or disenroll to FFS), at any time, we proposed that states must permit enrollees to disenroll and switch to another managed care plan or FFS when the termination of a provider from their MLTSS network would result in a disruption in their residence or employment. We proposed to codify this additional cause for disenrollment as § 438.56(d)(2)(iv) and to redesignate the existing text at that paragraph to (d)(2)(v). In paragraph (d)(3), we proposed to add text to clarify that disenrollment requests that the MCO, PIHP, PAHP, PCCM, or PCCM entity does not approve would have to be referred to the state for review. This would not change the meaning but we

believed it would improve the readability of the sentence. The existing text was otherwise retained in paragraph (d)(5), except to add PCCM entities to its scope as discussed elsewhere. We also proposed two minor grammatical corrections to paragraph (d) of this section. In current paragraph (d)(1)(ii), the term “PIHP” is in its singular form, but must be changed to plural to conform to other terms in the paragraph. We also proposed to use the possessive form for MCO, PIHP, and PAHP where applicable.

In paragraph (e)(1), we proposed changes for clarification. Currently in paragraph (e)(1) of this section, the timeframe for a state to process a disenrollment request is intended to apply to enrollee requests for disenrollment. The timeframe applies regardless of whether the enrollee submits the request—directly to the state or to the MCO, PIHP, PAHP, PCCM, or PCCM entity (if permitted by its contract with the state.) However, § 438.56(d)(1)(ii) permits states to allow MCOs, PIHPs, PAHPs, and PCCMs to process disenrollment requests. Additionally, in these instances, the managed care plan can approve the request, but it cannot actually disapprove the request. Instead, per § 438.56(d)(3), it must forward the request to the state. In these instances, the timeframe for the state to process a disenrollment request referred by the plan is the same as if the enrollee had submitted it directly to the state. To clarify this intent, in paragraph (e)(1), we proposed to insert the term “requests” after the term “enrollee” and replaced the term “files” with “refers.” No changes were proposed in paragraphs (f) and (g).

We received the following comments in response to our proposal to revise § 438.56.

Comment: Many commenters supported the proposed provision to limit disenrollment during the initial 90 days of managed care plan enrollment in § 438.56(c)(2)(i). Commenters believed limiting this disenrollment option to one 90 day period during the initial enrollment period would promote continuity and facilitate plans’ coordination efforts. We also received many supportive comments for the additional cause disenrollment reason for enrollees using LTSS in § 438.56(d)(2)(iv). Commenters believed that it is appropriate to include this reason given the nature of the services that enrollees receive from these types of providers.

Response: We thank the commenters for their support of our proposals in § 438.56 to limit enrollees to only one

90 day disenrollment opportunity and the new for cause reason for enrollees using LTSS.

Comment: A few commenters requested that CMS not use the word “disenrollment” when referencing a change among managed care plans in proposed § 438.56. Commenters believed “disenrollment” more appropriately described the process of losing eligibility for managed care or Medicaid completely, rather than merely changing from one managed care plan to another. One commenter suggesting that the right to change managed care plans at least every 12 months be called “open enrollment.”

Response: We understand the commenters’ suggestions but decline to adopt a different word in § 438.56. The term “disenroll” is consistent, and we believe clear, in relation to the uses of “enrollee” and “enroll” as used throughout part 438. We understand the commenter’s suggested use of “open enrollment” given the common use of that term in the Marketplace and private group market; however, we decline to adopt that term in part 438. States are free to adopt that terminology if they choose to but we do not believe it is appropriate to mandate its use.

Comment: One commenter stated that § 438.56(b) should be removed because managed care plans should not have the ability to request disenrollment of an enrollee under any circumstances. Another commenter believed that before a state approves a managed care plan’s request for disenrollment of an enrollee, the managed care plan should have to demonstrate why it is unable to provide the needed services and how many times they performed outreach to the enrollee to resolve the issue.

Response: We do not agree with the first commenter. This provision was included in the final rule in 2002 and it provides a reasonable mechanism for managed care plans to have available to them in unusual circumstances when it is unable to properly serve an enrollee. We agree with the second commenter to the extent that states should have an appropriate review process for disenrollment requests from a managed care plan. Section 438.56(b)(3) requires the contract to specify the method by which the managed care plan, PCCM, or PCCM entity assures the state that it does not request disenrollment for prohibited reasons, which are listed in paragraph (b)(2) (that is, change in enrollee’s health status, an enrollee’s utilization of services, or an enrollee’s uncooperative behavior resulting from special needs). Such requests should be a rare occurrence that are duly scrutinized by the state to avoid

disruptions in care. The commenter’s suggestion that the managed care plan must demonstrate why it cannot provide needed services and document the failed attempts at a resolution of the issue may not be applicable in every circumstance where a managed care plan would request disenrollment of an enrollee. Therefore, we decline to require such justifications on the part of the managed care plans.

Comment: Some commenters recommended that CMS include additional prohibited reasons for a managed care plan to request disenrollment. Those suggestions included enrollee’s race, color, national origin, disability, age, sex, gender identity, sexual orientation, mental health condition, disability, need for language services, and need for long term care services. Commenters believed proposed § 438.56(b)(2) needed additional specificity to prevent inappropriate requests for disenrollment. One commenter also requested that CMS clarify that enrollment in long-term care is not disenrollment from acute care due to health status.

Response: We understand the commenters’ concerns but believe that all of the suggestions are already addressed in part 438. Race, color, national origin, disability, age, and sex, are addressed in proposed § 438.3(f)(1), which applies to all provisions of every managed care contract; further, § 438.206(c)(2) (discussed in section I.B.6.a), requires managed care plans to provide access to services in a culturally competent manner to all enrollees, regardless of limited English proficiency, sexual orientation, gender identity, and gender. It is not necessary to duplicate these restrictions on plan conduct in § 438.56(b)(2). Behavioral health conditions and disability status are already clearly addressed in several of the prohibited reasons listed in proposed § 438.56(b)(2), including adverse change in the enrollee’s health status, or because of the enrollee’s utilization of medical services, diminished mental capacity.” We are unclear what clarification is being requested in the comment that “enrollment in Long Term Care is not disenrollment from acute care due to health status” since an “adverse change in health condition” is already list in proposed § 438.56(b)(2) as a reason when a managed care plan cannot request disenrollment.

Comment: We received suggestions for a new section that would list conditions when a state must disenroll an enrollee from their assigned managed care plan. These suggestions included

the following: An enrollee’s Medicaid eligibility is terminated; the state did not assign the enrollee to the managed care plan requested or assigned due to incorrect information provided by the state or due to prohibited marketing practices; request for disenrollment is due to plan merger; change of place of residence to outside the plan’s service area; anytime an enrollee requests disenrollment outside of a restricted disenrollment period; for a reason in § 438.56(d)(2); and when the enrollee is ineligible for managed care enrollment as defined in § 438.54.

Response: We believe states currently disenroll enrollees when Medicaid eligibility is terminated and as specified in the provisions of proposed § 438.56(d)(2). We believe that states have mechanisms to appropriately address cases when there is evidence of a compliance violation or processing error; such mechanisms should provide for disenrollment when warranted. The suggestion that all disenrollment requests made outside of a restricted disenrollment period is addressed in proposed § 438.56(c)(2)(i) with the provision of a 90 disenrollment period and in § 438.56(c)(2)(ii) with the provision of an annual disenrollment opportunity. During those times, enrollees do not need a for cause reason to change plans. We do not believe additional “no cause” disenrollment opportunities should be mandated; however, states have the flexibility to provide additional opportunities if they desire. A change in residence outside the managed care plan’s service area is already addressed in § 438.56(d)(2)(i). We do not agree that plan merger should necessitate automatic disenrollment; we believe the provision of disenrollment rights as the result of a merger should be decided based on the specific circumstances of the merger. For example, if the merger does not reduce the provider network or benefits available to the enrollee, forced disenrollment may cause unnecessary disruption and confusion. We support flexibility to allow states to determine the most appropriate procedures for addressing mergers as well as their ability to offer enrollees the option of changing plans if they believe that is the best approach. We are not adopting additional regulation text in § 438.56(c) or (d) in response to these comments.

Comment: We received one suggestion that disenrollment reasons should be made public and submitted to CMS so it can be determined if certain managed care plans are not meeting performance standards. Another commenter believed that states should make disenrollment reasons known to

the managed care plans for their use in improving their performance.

Response: We understand the importance of analyzing disenrollment data for insight about managed care plan performance, real and perceived. We encourage states to share that information with their managed care plans as it can be a valuable source of opportunities for performance improvement. We believe that part 438 includes sufficient requirements for states and managed care plans for making information available to the public and for reporting to CMS. We do not believe revisions are needed to § 438.56 in response to these comments.

Comment: One commenter believed that proposed regulation at § 438.56 would bar the beneficiary from changing MCOs without showing good cause during the 90-day disenrollment period in proposed § 438.56(c)(2)(i).

Response: We appreciate the opportunity to clarify that § 438.56(c)(2)(i) does not limit the enrollee's right to disenroll provided in section 1932(a)(4)(A) of the Act, which provides for disenrollment without cause from a managed care entity during the first 90 days of enrollment under a mandatory managed care program. In the 2002 final rule and again in this final rule, we extend this disenrollment right to all types of managed care plans, not only MCOs and PCCMs.

Comment: We received one comment requesting clarification if a state can offer a "no cause" period longer than 90 days.

Response: We appreciate the opportunity to clarify that states do have flexibility to extend the period beyond 90 days, but they cannot provide less than 90 days.

Comment: We received many comments on our clarification of "initial enrollment" in proposed § 438.56(c)(2)(i). Many commenters were supportive of limiting enrollees to only one 90 day period; these commenters believed this supported better care coordination and transition planning. Conversely, many other commenters were opposed to the limitation and believed that enrollees may need more than the first 90 days to determine if there are access or network issues that necessitate a plan change.

Response: We appreciate all of the comments on this provision. After consideration of the revision to § 438.54 to remove the proposed 14 day choice period, we believe it is prudent not to finalize the proposed revision in § 438.56(c)(2)(i) limiting enrollees to only one 90-day without cause disenrollment opportunity for each initial managed care plan enrollment.

While we agree with some commenters that multiple no cause disenrollment opportunities can be disruptive to transition and coordination efforts, we believe not finalizing the limitation of one 90-day period is appropriate given the removal of the mandatory FFS choice period for managed care plan selection. We want to clarify that the 90-day disenrollment opportunity is driven by an enrollee's initial enrollment into each managed care plan, not by the enrollment period itself. Additionally, for readability and clarity, we are adding text to clarify that the 90-day disenrollment period begins after an initial enrollment into a specific managed care plan or the date the State sends the notice about enrollment into that specific plan. Section 438.56(c)(2)(i) will be finalized to state that during the 90 days following the date of the beneficiary's initial enrollment into the specific MCO, PIHP, PAHP, PCCM, or PCCM entity, or during the 90 days following the date the State sends the beneficiary notice of that enrollment, whichever is later.

Comment: We received several comments asking that CMS require alignment between an enrollee's eligibility redetermination and their annual right to change managed care plans. We also received a few comments asking that CMS clarify that ". . . 12 months thereafter." in proposed § 438.56(c)(2)(ii) begins on the first day of enrollment in the managed care plan, rather than from the end of the 90 day period.

Response: Aligning an enrollee's eligibility redetermination and their right to change managed care plans is a common method that states utilize; however, given the variation in states' programs and how they implement the change of managed care plan process (under to § 438.56(c)(2)(ii) and their redetermination process, it may not always be feasible. As such, we decline to revise § 438.56 and will continue to leave the timing of these processes to a state's discretion. This regulation does not impose a requirement that the two events occur at the same time.

We appreciate the opportunity to clarify "12 months thereafter." A state can use either the first day of enrollment in the managed care plan or the end of the 90 day period to begin the 12 month period so long as the enrollee is provided at least one opportunity to change their managed care plan without cause within 12 months from the selected date. We understand the commenters' issue that the result of using the end of the 90-day period is that the enrollee is in the managed care plan for a minimum of 15 months.

However, during that time, the enrollee will have had at least 2 opportunities to disenroll without cause: the first opportunity being the initial 90 days and the second being within the 12 months beginning on the 91st day.

Comment: We received one comment requesting that CMS confirm that states can offer disenrollment more than once every 12 months.

Response: We appreciate the opportunity to clarify that § 438.56(c)(2)(ii) requires a without cause disenrollment opportunity at least once every 12 months. This provides flexibility for states to offer more than one disenrollment opportunity during a 12 month period.

Comment: One commenter recommended that proposed § 438.56(d)(1) require that oral disenrollment requests be followed up in writing. Another commenter recommended that states be required to allow oral requests.

Response: We believe specifying the method for enrollees to request disenrollment is best left to the states' discretion, given the wide variation in program design and the frequency of disenrollment opportunities permitted.

Comment: One commenter requested that CMS require enrollees to exhaust their grievance and appeal rights prior to the state approving their disenrollment request. The commenter believed that would provide the managed care plan the opportunity to resolve the issue and prevent the disruption associated with disenrollment.

Response: We believe states are in the best position to determine the best process for disenrollment based on their program design and covered populations. We acknowledge that the grievance system processes may eliminate an enrollee's desire to disenroll by resolving the issue that led to the disenrollment request, which we agree is beneficial for continuity and quality of care. However, we believe that states should have the flexibility to decide whether the grievance process is beneficial for enrollees requesting disenrollment. In terms of the commenter's suggestion that enrollee's be required to exhaust the appeals process before a for cause disenrollment would be processed, we decline to modify the text since the situations addressed in the for-cause reasons for disenrollment in § 438.56(d)(2) may not be remedied through the appeals process as those situations would not constitute an adverse benefit determination, as defined in § 438.400.

Comment: Some commenters requested that CMS develop an

expedited disenrollment process. These commenters' suggestions included expedited disenrollment for American Indian or Alaska Native enrollees, enrollees that are in foster care or adoption assistance, enrollees that have a complex condition, enrollees in a section 1915(c) or 1915(i) waiver program, or enrollees that have experienced a breakdown in the patient-physician relationship.

Response: We do not agree that a separate process is needed to address these situations. States have the ability to effectuate disenrollment requests as quickly as they deem necessary; § 438.56(e)(i), as proposed and as finalized, states that regardless of the procedures followed, the effective date of an approved disenrollment must be no later than the first day of the second month following the month in which the enrollee requests disenrollment or the MCO, PIHP, PAHP, PCCM or PCCM entity refers the request to the State. This allows states complete flexibility to effectuate disenrollments in shorter timeframes based on the enrollee's circumstances. Additionally, other enrollee protections exist in part 438 to ensure that enrollees receive the services they need. For example, § 438.206(b)(4) allows coverage of out of network providers if the necessary services are not available within the network. We decline to revise § 438.56 to include an expedited process.

Comment: Many commenters suggested additional for cause disenrollment reasons in proposed § 438.56(d)(2). Suggestions included if an enrollee's primary care provider, regularly utilized provider, home health, home care aid, medical home, integrated health system, or ACO, nursing home, or in home helper leaves the network; a family member is in a different managed care plan; a PACE organization becomes available; and poor quality case management.

Response: We appreciate the wide variety of suggestions on this provision. However, we believe § 438.56(d)(2)(i) through (v) is sufficient as a minimum list of for cause disenrollment reasons. States are free to offer, and we encourage states to consider, additional for cause reasons as they deem appropriate for their programs and enrollees.

Comment: One commenter recommended that states be required to perform adequate network monitoring in an attempt to reduce disenrollments. One commenter believed that managed care plans should do more transition planning and not just disenroll enrollees.

Response: We agree that state monitoring of network adequacy may help reduce some disenrollment requests and believe that appropriate monitoring mechanisms are included in § 438.66 and § 438.207, discussed elsewhere in this final rule. We also agree that robust transition planning can also help reduce disenrollment requests. We encourage states and managed care plans to consider this when developing their transitions plans as required in proposed in § 438.62(b).

Comment: We received one comment requesting that CMS define "employment, residential, and institutional supports provider" as used in § 438.56(d)(2)(iv).

Response: Employment, residential, and institutional supports is a broad category of services defined by each state in the design of its program. Further, we review the services proposed as part of a state's statutory authority request that authorizes such services. Appropriate detail on the scope of covered services should be included in each managed care plan contract. Given the variation that may exist among states' use of these terms, we decline to add definitions to the final regulation.

Comment: We received many comments on the proposed disenrollment reason for enrollees receiving LTSS in § 438.56(d)(2)(iv). Many of them were supportive but some commenters had concerns. A few commenters believed that managed care plans should be allowed the opportunity to negotiate single case agreements with the departing provider prior to approval of the disenrollment request. Other commenters were concerned that the automatic approval of these requests may be detrimental to the enrollee if the provider is being terminated for quality of care issues. One commenter suggested that CMS adopt two criteria for states approving these disenrollment requests: The MCO, PIHP, or PAHP cannot reach a mutually agreeable agreement with the provider to maintain continuity of coverage on an out-of-network basis; and a change in residential, institutional or employment supports provider would constitute a significant hardship to the enrollee. One commenter requested clarification on if the disenrollment process allows enrollees to return to FFS or only to change managed care plans.

Response: We thank the commenters for their supportive comments. We also appreciate the comments that raise the concern of disruption to the enrollee's ability to retain their residence, employment, or institutional provider. In the preamble at 80 FR 31136, we

provided: "Therefore, if the state does not permit participants enrolled in MLTSS to switch managed care plans (or disenroll to FFS), at any time, states must permit enrollees to disenroll and switch to another managed care plan or FFS when the termination of a provider from their MLTSS network would result in a disruption in their residence or employment." However, proposed § 438.56(d)(2)(iv) did not accurately reflect that a disruption in the enrollee's place of residence or employment was critical to approving the for-cause disenrollment in this context. To correct this omission, we will finalize § 438.56(d)(2)(iv) with text to reflect that the enrollee must experience a disruption in their residence or employment to utilize this disenrollment reason. As stated in the 2013 MLTSS guidance, there must be a heightened level of intervention by the state in instances where a participant's residence and services are linked, and therefore where the loss of the provider also means that the participant might lose employment and/or have to move out of his or her current residence to maintain services.

We believe that permitting the managed care plan to attempt to negotiate with a provider to either not terminate their contract or to continue seeing certain enrollees on an out-of-network/limited participation basis should be part of the managed care plan's provider termination process, rather than the enrollee's disenrollment process. If a state elects to accommodate the managed care plan's attempt to permit the provider to continue seeing individual enrollees on an out-of-network basis in their disenrollment process, we remind states and managed care plans of the timeframe for disenrollment determinations in § 438.56(e) and expect states and managed care plans to adhere to them in a manner that does not disadvantage the enrollee. Any efforts by the managed care plan to use a single case agreement with a provider to maintain an enrollee's ability to access the provider must be concluded within the timeframes for disenrollment determinations in § 438.56(e). Otherwise, the disenrollment request must be processed.

Comment: We received a few comments recommending that a new requirement be added in proposed § 438.56(e) to require states to send notices to enrollees confirming their disenrollment within 5 days of processing the request. We also received a comment on proposed § 438.56(e)(1) requesting that ". . . or the MCO, PIHP, PAHP, PCCM or PCCM entity refers the

request to the State” be deleted. The commenter believed the timeframe for approving a disenrollment request should always be from the date the enrollee requests it. We received one comment stating that the effective date deadline in paragraph (e)(1) (“ . . . be no later than the first day of the second month following the month in which the enrollee requests disenrollment or the MCO, PIHP, PAHP, PCCM or PCCM entity refers the request to the State”) was too long and recommending that the effective date for the disenrollment be sooner.

Response: Given the variation in disenrollment processes among states, we decline to require a confirmation notice in § 438.56(e). When enrolled in a new managed care plan, the enrollee receives an identification card and other information from the new managed care plan, which clearly conveys to the enrollee that their disenrollment from the previous managed care plan has occurred. Receiving a notice of disenrollment could be confusing for the enrollee; therefore, we decline to mandate it. However, states are free to send notices if they believe it would be a benefit to their enrollees, particularly given the increased flexibility provided in this rule for the use of electronic communications. We also decline to delete “. . . or the MCO, PIHP, PAHP, PCCM or PCCM entity refers the request to the State” because many states do not permit their managed care plans to be involved in the disenrollment process. We are confident that the states that do permit managed care plan participation, have processes, including time frames, that provide the state with adequate processing time to meet the requirement in § 438.56(e)(1). We take this opportunity to clarify that § 438.56(e)(1) sets the outside limit for the effective date of the disenrollment, which permits states to effectuate the disenrollment at any time prior to the first day of the second month.

Comment: One commenter recommended that disenrollment information be provided at the time of the application for Medicaid eligibility and enrollment.

Response: Section 438.54 (c)(3) and (d)(3), as proposed and finalized, require the provision of disenrollment information at the time of enrollment. Additionally, § 438.10(e)(2)(i) includes the requirement that notice to potential enrollees must include the disenrollment information described in § 438.56. It is outside the scope of this rule to make requirements for the information provided at the time of application for Medicaid eligibility in general.

Comment: We received one comment suggesting that CMS add a requirement that the notice required in § 438.56(f) must include information on enrollee’s disenrollment rights provided in § 438.56(c)(2).

Response: We agree that § 438.56(f) could be clearer. Therefore, we have finalized § 438.56(f) to require that the notice include an explanation of all of the enrollee’s disenrollment rights as specified in this section.

Comment: We received one comment requesting that proposed § 438.56 (g) permit automatic reenrollment after longer than 2 months of ineligibility.

Response: Section 1903(m)(2)(H) of the Act specifies a re-enrollment window of 2 months and implicitly authorizes a shorter time period but not a longer one.

After consideration of the public comments, we are adopting § 438.56 as proposed with four substantive revisions. First, in paragraph(c)(2)(i), we are revising “. . . enrollment into a . . .” to “. . . enrollment into the . . .” to clarify that more than one 90 day disenrollment period is permitted and adding “during the 90 days following” before “the date the State sends . . .” for added clarity. Second, in paragraph (d)(2)(iv), we are finalizing with text that was described in the preamble but erroneously omitted from the proposed regulation text that addressed MLTSS enrollees experiencing a disruption to residence or employment. Third, in paragraph (f)(1), we are finalizing an additional requirement to include information on all disenrollment opportunities in the required notice. Fourth, although not proposed, we are also removing “health” in paragraph (d)(2)(v) in the final rule to consistently reflect a less acute care approach and be more inclusive of enrollees receiving LTSS. This change is consistent with proposals (and final regulation text) throughout the rule to acknowledge the managed care programs increasingly include LTSS and that requirements for managed care plans generally apply to LTSS as well as health care services provided by the plan. Finally, we are making technical corrections throughout § 438.56 to add commas as applicable when referencing groups of managed care plan types.

c. Beneficiary Support System (§§ 438.2, 438.71, 438.810, 438.816)

Although the existing regulation at § 438.10 acknowledges the importance of information and disclosure in helping the beneficiary choose a managed care plan, we recognized in the proposed rule that some beneficiaries may need additional assistance when evaluating

their choices. This additional assistance includes having access to personalized assistance—whether by phone, internet, or in person—to help beneficiaries understand the materials provided, answer questions about options available, and facilitate enrollment with a particular managed care plan or provider.

We proposed a new § 438.71, entitled Beneficiary Support System, to require this additional assistance to potential enrollees and enrollees.

Proposed paragraph (a) established the requirement that a state develop and implement a beneficiary support system to provide support before and after managed care enrollment. Paragraph (b) proposed four minimum functions for a beneficiary support system: Paragraph (b)(1)(i) would make choice counseling available to all beneficiaries; paragraph (b)(1)(ii) would require training of plans and network providers on the type and availability of community based resources and supports; paragraph (b)(1)(iii) would require assistance to all beneficiaries in understanding managed care; and paragraph (b)(1)(iv) would add assistance for enrollees who receive or desire to receive LTSS. In paragraph (b)(2), we proposed that the system be available to the beneficiaries in multiple ways including phone, internet, in-person, and via auxiliary aids and services when requested.

We proposed at § 438.71(c)(1) that states provide choice counseling services for any potential enrollee (that is, prior to first enrollment in managed care) or to managed care enrollees when they have the opportunity or requirement to change enrollment under § 438.56(b) and (c). States have the flexibility to decide who can provide choice counseling; however, in paragraph (c)(2), we proposed that any individual or entity providing choice counseling services would be an enrollment broker under our regulations, and therefore, must meet the independence and conflict of interest standards of § 438.810 to provide those services. We noted that some entities may receive federal grant funding distinct from Medicaid funding that may require those entities, such as FQHCs or Ryan White providers, to conduct activities similar to those that would fall under the definition of choice counseling; if those entities do not have a memorandum of agreement or contract with the state to provide choice counseling on the state’s behalf, such entities would not be required to adhere to the conflict of interest standards in § 438.810 under our proposal at § 438.71(c)(2). While not discussed, we note here that such

separate obligation to provide services similar to choice counseling services would not satisfy the state's obligation under § 438.71(a). We noted that this was not an exhaustive list of federal grantees and was provided for illustrative purposes. We also requested comment on whether entities that provide non-Medicaid federally-financed protections to beneficiaries that includes representation at hearings should be allowed to also contract with the state to provide choice counseling as long as appropriate firewalls are in place; we proposed in paragraph (e)(3)(i) a firewall requirement for such entities to represent enrollees receiving LTSS from the managed care entity.

Under proposed paragraph (d), the beneficiary support system would provide training to MCO, PIHP, and PAHP staff and network providers on community based resources and supports that can be linked with covered benefits. As noted in the following responses to public comments, we are not finalizing proposed paragraph (d); therefore, the paragraphs following proposed paragraph (d) have been redesignated accordingly.

In proposed paragraph (e) (finalized as paragraph (d)), we proposed four elements for a beneficiary support system specific to beneficiaries who use, or desire to use, LTSS: (1) An access point for complaints and concerns about enrollment, access to covered services, and other related matters; (2) education on enrollees' grievance and appeal rights, the state fair hearing process, enrollee rights and responsibilities, and additional resources; (3) assistance (without representation), upon request, in navigating the grievance and appeal process and appealing adverse benefit determinations made by a plan to a state fair hearing; and (4) review and oversight of LTSS program data to assist the state Medicaid Agency on identification and resolution of systemic issues. Proposed paragraph (e)(1) (finalized as (d)(1)) applies to enrollees of MCOs, PIHPs, PAHPs, PCCMS, and PCCM entities while (e)(2) through (e)(4) (finalized as (d)(2) through (d)(4)) apply only to MCOs, PIHPs, and PAHPs since they reference the grievance and appeal process which PCCMs are not required to have.

We acknowledged that states may include many of these services already within their Medicaid program and indicated our intent that our proposed regulation does not require that states develop a new system of delivering all the functions proposed in § 438.71(e) (finalized as § 438.71(d)) for MLTSS. Under our proposal, states would be

permitted to draw upon and expand, if necessary, those existing resources to meet the standards proposed in this section.

We noted in the preamble of the proposed rule that the proposed scope of services for LTSS beneficiary supports may include what has been traditionally considered "ombudsman" services; however, rules concerning Medicaid-reimbursable expenditures remain in place, so we cautioned that not all ombudsman activities traditionally found in a Long-Term Care Ombudsman office may be eligible for Medicaid payment under this proposal. We issued an informational bulletin on June 18, 2013, entitled "Medicaid Administrative Funding Available for Long-Term Care Ombudsman Expenditures," that provided guidance on this issue. The informational bulletin is available at <http://www.medicaid.gov/Federal-Policy-Guidance/downloads/CIB-06-18-2013.pdf>.

We also proposed to move the definition of choice counseling to § 438.2, which was previously defined in § 438.810, and to revise the definition to the provision of information and services designed to assist beneficiaries in making enrollment decisions, including answering questions and identifying factors to consider when choosing among managed care plans and primary care providers. We proposed to clarify in the revised definition that choice counseling does not include making recommendations for or against enrollment into a specific MCO, PIHP, or PAHP. Further, we proposed in § 438.810 to include PCCM entities in the regulatory text when other managed care plans were mentioned, and we proposed to add electronic methods of communication as a means through which enrollment activities could be conducted in the definition of "enrollment activities" in § 438.810(a).

Finally, we proposed a new section § 438.816 that would impose conditions that must be met for the state to claim FFP for the LTSS-specific beneficiary support system activities proposed in § 438.71(e) (and finalized as paragraph (d)). We modeled this standard, in part, on current rules for claiming FFP for administrative services and, in part, on the current rules for enrollment broker services. We proposed, consistent with our current policy, that beneficiary support services for MLTSS enrollees be eligible for administrative match subject to certain standards. Specifically, in paragraph (a), we proposed that costs must be supported by an allocation methodology that appears in the state's Public Assistance Cost Allocation Plan;

in paragraph (b) that the costs do not duplicate payment for activities that are already being offered or should be provided by other entities or paid by other programs; in paragraph (c) that the person or entity providing the service must meet independence and conflict of interest provisions applicable to enrollment brokers in § 438.810(b); and in paragraph (d) that the initial contract or agreement for services in this section be reviewed and approved by CMS.

We received the following comments in response to our proposals at §§ 438.2, 438.71, 438.810, and 438.816.

Comment: Many commenters supported the provisions at § 438.71 and provided several examples for how a beneficiary support system would play an integral role in a state's Medicaid managed care program, including supports for complex populations and individuals receiving LTSS.

Response: We thank commenters for their support and agree that a beneficiary support system will play an integral role in a state's Medicaid managed care program, including supports for complex populations and individuals receiving LTSS. We maintain that the resources provided by the beneficiary support system will benefit all covered populations in navigating the managed care delivery system.

Comment: Several commenters had concerns regarding the provisions at § 438.71 generally. For example, a few commenters believed that states with mature managed care programs did not need to provide this type of support for potential enrollees and enrollees. Other commenters specified that states have developed their own systems and that § 438.71 would undermine current state systems or add unnecessary and administratively burdensome requirements. One commenter stated that some beneficiaries may not be interested in the resources and information provided by the beneficiary support system. One commenter recommended that CMS only outline key principles of beneficiary engagement and not require the development of a beneficiary support system.

Response: We maintain that states must make available an independent resource to aid potential enrollees in selecting a managed care plan and to assist enrollees in navigating the managed care delivery system. We understand that some states may have established arrangements to provide some or all of the resources specified in the beneficiary support system and remind commenters that states need not develop a new system if the current

system meets the standards specified at § 438.71. The elements of the beneficiary support system specified in § 438.71 are the benchmark for the provision of independent information and supports for Medicaid enrollees that must be applied across all Medicaid managed care programs. States are permitted to draw upon and expand their current beneficiary support systems as necessary and applicable in order to meet this new standard. We also recognize that not all potential enrollees or enrollees will need or want to engage with the beneficiary support system, but this is not a compelling reason to eliminate the system altogether or fail to make those services available to enrollees and potential enrollees who do want them.

Comment: Several commenters had concerns with § 438.71(a) regarding the availability of resources for states to operate beneficiary support systems. One commenter recommended that CMS clarify if beneficiary support and enrollment broker services are eligible for the enhanced match of 75 percent under section 1903(a)(2) of the Act. Several commenters stated that the beneficiary support system would create a significant administrative and financial burden for states. One commenter was concerned that beneficiaries might be charged for the system, and another commenter suggested that managed care plans might be assessed fees for states to develop and operate these systems. Other commenters recommended that certain requirements be scaled back to make the system more affordable and less onerous on states. One commenter stated that the beneficiary support system should make greater use of existing resources, such as State Health Insurance Assistance Programs (SHIPs) to reduce costs. Other commenters had concerns about CMS' capacity to oversee and ensure that beneficiary support systems are adequately funded and meet the standards specified in the regulation.

Response: We understand commenters' concerns regarding the potential financial burden of maintaining the beneficiary support system and remind commenters that Medicaid administrative funding, as outlined at § 438.810 and § 438.816, is available to states. We clarify that beneficiary support and enrollment broker services are not eligible for the enhanced match of 75 percent under section 1903(a)(2) of the Act but are eligible at the administrative match rate. The commenter's concern regarding beneficiary financial liability for accessing the beneficiary support

system is unfounded and prohibited as beneficiary financial liability is limited to services covered under the state plan or to premiums as permitted under 42 CFR part 447. We agree with commenters and encourage states to use existing resources and systems as feasible, including various community organizations and resources that otherwise meet the standards in this final rule. With respect to CMS capacity and oversight, we will provide appropriate oversight consistent with other aspects of the Medicaid managed care program.

Comment: Several commenters recommended that CMS strengthen overall state monitoring, evaluation, and oversight of the beneficiary support system. A few commenters recommended that CMS revise the requirement at proposed § 438.71(e)(4) (finalized as paragraph (d)(4)) for the beneficiary support system's review and oversight of LTSS program data to all program data, including specific grievance, complaint, and appeal data. Other commenters recommended that CMS require states to analyze and publicly report on the performance of their beneficiary support systems. A few commenters recommended that CMS require beneficiary survey data and feedback as part of the beneficiary support system's functions. Commenters also recommended that CMS require the LTSS advisory committee to be involved in the review of program data and all aspects of the beneficiary support system. One commenter recommended that CMS provide technical assistance in the identification and review of systemic issues identified through the beneficiary support system. Finally, one commenter recommended that CMS develop accountability measures to ensure that each state develops and maintains a competent and effective beneficiary support system.

Response: We appreciate commenters' thorough recommendations. Many of the commenters' recommendations related to state monitoring and oversight are addressed in § 438.66. We agree with commenters that the activities of the beneficiary support system should be included in state monitoring and believe that the reference at § 438.66(b)(4) to customer services is sufficient to include the beneficiary support system maintained under § 438.71; to make this clearer, we are finalizing additional regulatory text to explicitly include the beneficiary support system in that category (see section I.B.6.c.). We also agree with commenters that states should include information on and an assessment of the state's beneficiary support system in the managed care

program assessment report required at § 438.66(e). We believe it is important to not only report on the activities of the beneficiary support system, but to also assess the performance of the beneficiary support system to drive continual improvements. Therefore, as discussed in section I.B.6.c. we are finalizing regulatory text to include the beneficiary support system as a required element of this report at § 438.66(e)(2)(ix) to ensure that it is addressed. Many of the commenters' other recommendations, including data on grievances and appeals and beneficiary survey data and feedback, are also included at § 438.66. We have also required that states provide the managed care program assessment report to the LTSS stakeholder group at § 438.66(e)(3)(iii), and we require that states post the report publicly on their Web site at § 438.66(e)(3)(i). Finally, we agree with commenters that we should provide technical assistance in the identification and review of systemic issues identified through the beneficiary support system and believe that this will be done as a regular part of our review and oversight of the program. Therefore, we do not believe it is necessary to include any additional regulatory requirements at § 438.71 regarding state monitoring, evaluation, or oversight of the beneficiary support system, or about CMS technical assistance.

Comment: Several commenters recommended that CMS require that managed care plans have input into the design and implementation of the state beneficiary support system.

Response: Managed care plans may be effective partners for states when designing and implementing the beneficiary support system. However, due to the functions of the beneficiary support system, it must remain independent from the managed care plans. We encourage states to consider the best methods for engaging and incorporating feedback from managed care plans and a variety of other stakeholders as states develop and implement their beneficiary support systems.

Comment: Several commenters recommended that CMS add caregivers to § 438.71(b)(2) since, for enrollees with complex health needs, it is often the caregiver that is selecting the managed care plan for enrollment. One commenter stated that the 2013 MLTSS guidance included references to caregivers in the context of choice counseling and recommended the same language be incorporated into the regulatory text.

Response: Section § 438.71(b)(2) provides that the beneficiary support system “must perform outreach to beneficiaries and/or authorized representatives.” The term “authorized representatives” has more limited applicability than “caregiver,” which could include individuals who are not in a decision making role on behalf of the beneficiary. While we do not intend to minimize the significant role of caregivers in supporting individuals with special health care needs, expanding the scope of § 438.71 beyond authorized representatives could result in unintended consequences for the beneficiary. Therefore, we decline to adopt commenters’ recommendations to revise the regulatory text, but we encourage states to consider the critical importance of caregivers in supporting enrollees as they develop education, outreach, and support strategies.

Comment: Several commenters recommended that CMS clarify the outreach requirement at § 438.71(b)(2), which requires that the beneficiary support system must perform outreach to beneficiaries and/or authorized representatives and be accessible in multiple ways including phone, Internet, in-person, and via auxiliary aids and services when requested. Commenters supported the provision but recommended that CMS provide additional specificity regarding the scope of the outreach requirement. Other commenters recommended that CMS add stronger language about cultural and linguistic competence and outreach for those with limited English proficiency and/or cognitive disabilities. Finally, one commenter recommended additional protections regarding beneficiary privacy when outreach is conducted using the telephone or Internet.

Response: We understand commenters’ concerns regarding the general outreach requirement at § 438.71(b)(2) but decline to add specificity in the regulatory text, as we do not believe it is necessary to prescribe such requirements for states or their beneficiary support systems. We expect that beneficiary support systems will utilize a variety of tools and mechanisms to reach enrollees and believe that such methods will vary. We expect that states will work with beneficiary support systems to provide outreach as part of the process in assisting beneficiaries with managed care plan selection and as a way to educate enrollees on the managed care delivery system more generally. We also expect states to use beneficiary support systems as a tool to ensure that enrollees fully understand their enrollment and

disenrollment options, especially during the enrollment and disenrollment timeframes specified in §§ 438.54 and 438.56. We agree with commenters that states should consider cultural and linguistic competence and outreach for those with limited English proficiency and/or cognitive disabilities as appropriate. The regulatory text includes auxiliary aids and services when requested. We decline to include additional specific requirements in the regulatory text but encourage states to consider these elements when designing and implementing their beneficiary support systems. Finally, states are required to comply with § 438.224 regarding confidentiality and to safeguard protected beneficiary information in the conduct of any outreach activities.

Comment: Several commenters supported the choice counseling provision at § 438.71(c) but recommended that CMS provide greater specificity in the final regulation, while several other commenters recommended that CMS provide greater flexibility. Several commenters recommended that CMS explicitly require choice counselors to disclose all options to the beneficiary, including services not funded through Medicaid and services for those dually eligible for Medicare and Medicaid. Several commenters recommended that CMS include the following four principles for choice counseling in the regulation: Comprehensive, Competent, Conflict-Free, and Continuous/Timely. One commenter stated that the information provided by the beneficiary support system should encompass medical, LTSS, and a wide range of other services, such that it would constitute a “one stop shop” for Medicaid enrollees.

Response: As defined in § 438.2, choice counseling is related to managed care plan enrollment; therefore, we decline to accept commenters’ recommendations in this area. States can choose to expand the scope and types of resources available under the beneficiary support system as appropriate.

Comment: A few commenters recommended that CMS require choice counseling at § 438.71(c) to include managed care plan performance data to assist the beneficiary in making an enrollment choice.

Response: We agree with commenters that transparency of quality data is important for both potential enrollees and current enrollees of managed care plans. At § 438.334, states are required to develop and publish a Medicaid managed care quality rating system (MMC QRS) for managed care plans in

the state. Additionally, at current § 438.364(b)(2), states are required to make available the EQR technical reports upon request. In particular, the quality ratings in particular will be a helpful tool for potential enrollees and enrollees. We encourage states to include such information in the materials provided to choice counselors, but we decline to add this specific requirement to the duties of the beneficiary support system when such quality data will be readily available on the state’s Web site.

Comment: One commenter recommended that the beneficiary support system perform the same roles as an ombudsman program. One commenter recommended that CMS clarify the oversight role of the beneficiary support system to ensure that there is no duplication of effort with other oversight functions. Other commenters stated concerns regarding oversight and the potential for conflict of interest when a legal entity is providing guidance to beneficiaries related to grievances, complaints, and hearings, and is also responsible for reviewing the program data referenced in proposed § 438.71(e)(4) (finalized as paragraph (d)(4)).

Response: We intentionally chose to differentiate the beneficiary support system at § 438.71 from long-term care ombudsman programs. Consistent with the preamble of the proposed rule at 80 FR 31137, we also note that not all traditional ombudsman activities may be eligible for Medicaid funding. Further, states are responsible for oversight of their respective Medicaid programs and use a variety of entities and tools to assist in that effort. The beneficiary support system will be one of a number of such tools but ultimately the state has oversight responsibility. The review of program data that is included at proposed § 438.71(e)(4) (finalized as paragraph (d)(4)) is designed to provide states with information to be used for oversight and monitoring of their MLTSS programs; however, we clarify that the beneficiary support system will not be providing direct oversight of any such MLTSS program.

Comment: One commenter recommended that CMS expand the responsibility of the beneficiary support system to include facilitating Medicaid enrollment. One commenter recommended that CMS require an established relationship between the beneficiary support system and the care coordination programs within each managed care plan, particularly during beneficiary transitions between managed care plans.

Response: We clarify for the commenter that the beneficiary support system includes facilitating enrollment for managed care plans, which is consistent with our definition of choice counseling under § 438.2 and our general approach throughout § 438.71. We note the definition of choice counseling under § 438.2 is defined as the provision of information and services designed to assist beneficiaries in making enrollment decisions; it includes answering questions and identifying factors to consider when choosing among managed care plans and primary care providers. Choice counseling does not include making recommendations for or against enrollment into a specific MCO, PIHP, or PAHP. The beneficiary support system is intended to provide personalized assistance and assist beneficiaries in making enrollment decisions with regard to managed care plans. This additional assistance includes facilitating enrollment by helping beneficiaries understand materials and answering questions about available options. We decline to mandate that the beneficiary support system be part of a state's transition of care policy in § 438.62 because the coordination of services during the transition period occurs between the state and the managed care plan or between managed care plans. Those entities will have the most relevant information and processes in place to communicate with one another to ensure that services are continued in accordance with the state's transition of care policy and the enrollee's needs.

Comment: One commenter recommended that CMS revise the language at § 438.71(c) to only require that choice counseling be made available to beneficiaries, not provided, since some beneficiaries will not be interested in such services.

Response: We agree that not all beneficiaries will want to access choice counseling or beneficiary support system services in general, but we do not agree that modifying the language at § 438.71(c) is necessary. We expect choice counseling to be available to all potential enrollees and enrollees who disenroll from a managed care plan, even if some enrollees ultimately do not seek such assistance. The beneficiary support system should make an effort to reach and support all beneficiaries in such situations.

Comment: One commenter recommended that CMS add timeliness standards for the beneficiary support system and recommended that CMS include a requirement for beneficiary

support system services to be available outside of regular business hours.

Response: We agree with the commenter that timeliness in providing beneficiary support system services is important; however, we disagree that such prescriptive standards should be included in the regulation. We believe that states should consider such standards when developing and implementing their beneficiary support systems. States are in the best position to understand the unique characteristics of their programs and populations and should consider timeliness and availability standards as appropriate.

Comment: Several commenters recommended that CMS clarify whether the beneficiary support system functions (for example, choice counseling and an access point for complaints) can be provided by different entities, or if CMS is requiring that all functions be performed by the same entity. Some commenters stated that additional beneficiary protections could result from the state choosing different entities for each function. One commenter recommended that states be provided with the flexibility to delegate certain aspects of the beneficiary support system to particular entities and not have one single beneficiary support system entity. Several commenters recommended that CMS allow states to build the beneficiary support system from existing programs and multiple entities that perform similar functions, such as the functions of Area Agencies on Aging, Marketplace Navigators, SHIPs, FQHCs, long-term care ombudsmen programs, and others. One commenter stated that CMS should explicitly separate choice counseling from the other beneficiary support functions.

Response: We clarify for commenters that nothing in the regulation at § 438.71 prohibits states from using different entities for different functions of the beneficiary support system, so long as the requirements of independence and freedom from conflicts of interest are met as incorporated into § 438.71(c)(2). We believe that many states will choose multiple entities when developing and implementing their beneficiary support system and agree that there could be additional beneficiary protections realized if states choose this approach; however, we believe that states are in the best position to determine which beneficiary support system arrangements are most beneficial to their respective programs and populations and the unique structures of their health care and social service delivery systems.

We remind commenters that states need not develop a new system if current structures meet all of the standards specified at § 438.71. We maintain that the elements of the beneficiary support system specified represent the benchmark for the provision of independent information and supports for Medicaid enrollees that must be applied across all Medicaid managed care programs. States are permitted to draw upon and expand their current beneficiary support systems as necessary and applicable. We also encourage states to consider these programs and resources and to consult with a variety of stakeholders as they develop and implement their beneficiary support systems. However, the beneficiary support system should be built in a manner to ensure that the state can maintain appropriate oversight of the system and ensure ease of access for beneficiaries when accessing the system.

We do not agree that choice counseling should be distinct from the beneficiary support system because choice counseling is an important form of beneficiary support. The state may select a distinct entity to provide choice counseling, subject to requirements in § 438.71(c)(2), from other entities that provide other elements of the beneficiary support system.

Comment: Many commenters provided comments regarding the requirements at § 438.71(c)(2) related to the independence and freedom from conflict of interest standards. Many commenters supported these proposed provisions and recommended that CMS preserve strong conflict of interest standards in the final rule, including prohibiting entities with a financial interest, such as a provider, in a managed care plan from also serving as either a choice counselor or a beneficiary support system entity. However, other commenters disagreed and stated that having a financial interest in a managed care plan should not disqualify entities from also providing choice counseling or other functions under the beneficiary support system. Several commenters that currently provide services similar to choice counseling supported through non-Medicaid federal grant funding stated it would be difficult to meet the Medicaid conflict of interest standards to provide Medicaid choice counseling under this rule.

Response: We reiterate our position from the proposed rule at 80 FR 31137 that any individual or entity providing choice counseling services on behalf of the state (which would be necessary to fulfill the requirements of this rule) is

considered an enrollment broker under our regulations, and therefore, must meet the independence and conflict of interest standards at § 438.810 to provide such services. We understand that the term “enrollment broker” may have a different meaning in other programs, and we clarify that the requirements for independence and conflict of interest for enrollment brokers under Medicaid are specified in section 1903(b)(4) of the Act. This means the entity cannot have a financial relationship with any managed care plan which operates in the state where the entity is providing choice counseling, which would also include the entity’s participation with the managed care plan as a network provider. We also clarify that entities receiving non-Medicaid federal grant funding are not within the scope of this rule and therefore may continue to perform such activities as long as such entities are not performing these activities under a memorandum of agreement or contract with the state to provide choice counseling on the state’s behalf. We believe that having a financial relationship or interest with a managed care plan can present the appearance of bias, even with safeguards in place. Therefore, we decline to make revisions to the regulation in this area. We note that our regulation at § 438.71(c)(3) does not provide otherwise and reflects a policy (described in more detail below) that is specific to states entering into agreements with entities that provide representation to Medicaid enrollees at hearings under non-Medicaid funding.

Comment: Several commenters recommended that community-based organizations, Indian health care providers, and other representatives within the Indian Health System be exempt from the requirements at § 438.71(c)(2) to be considered an enrollment broker if providing choice counseling services. Several commenters also noted that Marketplace Navigators are not required to meet such standards.

Response: We reiterate our position that any individual or entity providing choice counseling services is considered an enrollment broker under our regulations that implement section 1903(b)(4) of the Act, and therefore, must meet the independence and conflict of interest standards at § 438.810 to provide such services. This means the entity cannot have a financial relationship with any managed care plan which operates in the state where the entity is providing choice counseling. This includes participating with the managed care plan as a

network provider. We also clarify that entities, including Indian Health providers and the Indian Health System, receiving non-Medicaid federal grant funding (distinct from Medicaid funding) may continue to perform such activities as long as such entities are not performing these activities under a memorandum of agreement or contract with the state to provide Medicaid choice counseling on the state’s behalf. While we understand that Marketplace Navigators have different conflict of interest standards, it is not our intention to adopt the Marketplace Navigator program’s conflict of interest standards for the beneficiary support system; the statutory basis and the specific standards for these programs are different.

Comment: Several commenters stated that some governmental entities, typically counties, also serve as the managed care plan and provide choice counseling services. Some commenters recommended that CMS prohibit governmental entities from serving as both the managed care plan and the beneficiary support system, including choice counseling. Several commenters recommended that the beneficiary support system be fully independent of any state and/or local government, regardless of whether the state or county serves as the managed care plan. Other commenters recommended that CMS allow governmental entities to serve in both capacities as the managed care plan and the beneficiary support system, including choice counseling.

Response: If a governmental entity is operating as the managed care plan, the conflict of interest requirements at § 438.71(c)(2) and § 438.810(b)(1) and (2) apply if the state seeks to use that entity to provide the choice counseling services required under this rule. Governmental entities that operate as the managed care plan would not be permitted to provide choice counseling to fulfill § 438.71(c), as this is incompatible with the conflict of interest and independence standards.

Comment: One commenter recommended that CMS clarify whether managed care plans can provide beneficiary support system activities, excluding choice counseling.

Response: The beneficiary support system is designed to operate outside of the managed care plan and is not intended to replace the current resources that exist within managed care plans for beneficiaries to get information and assistance, including customer service. In fact, we expect the beneficiary support system to educate beneficiaries about managed care plan processes and resources and redirect

them to the managed care plan when applicable. We also clarify, as the commenter noted, that it is impossible under statute and regulation for managed care plans to provide choice counseling, as this is incompatible with the conflict of interest and independence standards. We also believe that it is impossible for managed care plans to provide the LTSS-specific activities at proposed § 438.71(e) (finalized as paragraph (d)). The beneficiary support system functions at proposed § 438.71(e) (finalized as paragraph (d)) are intended to specifically assist beneficiaries with complex health needs who currently utilize or desire to receive LTSS. The beneficiary support system should serve as a general access point for complaints and concerns as described at proposed § 438.71(e)(1) (finalized as paragraph (d)(1)), so that beneficiary support systems can educate enrollees and refer their concerns to the appropriate entities. This function is not intended to replace or act in lieu of the grievance and appeal process detailed at subpart F of 42 CFR part 438. Beneficiary support systems are intended to provide additional education and assistance in navigating the grievance and appeal process, including information on how to file a grievance or appeal with the managed care plan. Beneficiary support systems can also refer enrollees to sources of legal representation as appropriate. Therefore, we clarify for the commenter that it is not appropriate for any managed care plan to provide any of the beneficiary support system activities as specified at § 438.71.

Comment: Many commenters recommended revisions at §§ 438.71(d) and 438.71(b)(1)(ii) regarding the requirement for the beneficiary support system to provide training to MCOs, PIHPs, PAHPs, PCCMs, PCCM entities, and network providers on community-based resources and supports that can be linked with covered benefits. Several commenters supported the proposed provision but did not believe that the requirements went far enough; several commenters recommended that specific training for beneficiaries also be required. A few commenters also recommended that CMS require training for specific staff positions at managed care plans, such as care coordinators and those responsible for conducting person-centered planning. One commenter recommended that CMS require training for all new managed care plan staff and recommended annual training requirements. One commenter recommended that CMS require managed care plans to use the

SHIP training standards. Other commenters recommended that CMS require managed care plans to partner with or fund specific community-based organizations, such as Area Agencies on Aging.

Several commenters also recommended that CMS require training to be linked to the goals in the person-centered plan and require training on the independent living and recovery philosophies.

However, several other commenters also stated that the requirements of the beneficiary support system to train network providers went too far and recommended that the provision be removed, as beneficiary support system individuals and entities are not qualified to train network providers. Several commenters also stated that some managed care plans are opposed to the training requirements and recommended that training for managed care plans remain optional. A few commenters stated that the requirement to train managed care plans was overly burdensome.

Response: After review of the comments and careful consideration, we believe that it is not appropriate to require the beneficiary support system to provide training to MCOs, PIHPs, PAHPs, PCCMs, PCCM entities, and network providers. Just as it is the responsibility of managed care plans to train their own staff, most managed care plans also have established training programs for network providers. We encourage managed care plans to include training related to the community-based support systems used by individuals with complex and special health care needs, including individuals using or needing LTSS. We also encourage managed care plans to work with their network providers regarding the best methods of accessing and coordinating the resources that are available to support beneficiaries in achieving better health outcomes. We also clarify that states have the flexibility to add specific training elements to their beneficiary support systems as appropriate in addition to the minimum standards in this regulation. We believe that states are in the best position to determine whether specific training elements are needed given their unique delivery systems to health care and social services and the needs of their covered populations. We are therefore not finalizing the regulatory text proposed at § 438.71(b)(1)(ii) and § 438.71(d); in this final rule, we redesignate the paragraphs following those proposed provisions accordingly.

Comment: Several commenters stated that CMS should require the specific beneficiary support elements at proposed § 438.71(e) (and finalized at § 438.71(d)) to be available for all beneficiaries and not just those receiving LTSS. A few commenters recommended that the entire content of proposed (e) (finalized as paragraph (d)) should be moved to (b), while other commenters recommended that only those elements related to complaints, grievances, and appeals should be available to all beneficiaries.

Response: The additional elements specified at proposed § 438.71(e) (and finalized at § 438.71(d)) are intended to provide specific protections and safeguards for enrollees who use or desire to use LTSS. Enrollees using LTSS generally have more complex health needs than traditional managed care enrollees, and we believe LTSS enrollees would benefit most from these additional beneficiary support elements. We also recognize that states are increasingly looking to managed care delivery systems to support these complex populations, and we believe these additional elements are particularly beneficial in assisting enrollees who may be transitioning from a traditional LTSS program to an MLTSS program. The protections proposed at § 438.71(e) (finalized as paragraph (d)) were intentionally focused on enrollees using LTSS, and we do not believe it is necessary to require these additional elements for all beneficiaries. However, we note that states have the flexibility to establish these additional elements for all populations in their respective programs as they deem appropriate.

Comment: Several commenters stated concerns regarding possible beneficiary confusion surrounding the grievance and appeal process and the role of the beneficiary support system at proposed § 438.71(e) (finalized as paragraph (d)). Commenters recommended that CMS clarify how the access point for complaints and concerns at proposed § 438.71(e)(1) (finalized as paragraph (d)(1)) would function and what relationship it has to the grievance and appeal process detailed at subpart F of this part. One commenter stated the importance of educating LTSS beneficiaries to the process of filing complaints, grievances, and appeals. Several commenters recommended that CMS require beneficiary support systems to establish networks and systems to ensure that representation at state fair hearings is available to LTSS beneficiaries.

Response: The beneficiary support system is designed to operate outside of

the managed care plan and is not intended to replace the current resources that exist within managed care plans for beneficiaries to access information and assistance, including customer service. In fact, we expect the beneficiary support system to educate beneficiaries about managed care plan processes and resources and redirect them to the managed care plan when applicable. The beneficiary support system functions at proposed § 438.71(e) (finalized as paragraph (d)) are intended to specifically assist beneficiaries with complex health needs who currently utilize or desire to receive LTSS. This function is not intended to replace or act in lieu of the grievance and appeal process detailed at subpart F of 42 CFR part 438. We also clarify that beneficiary support systems are intended to provide additional education and assistance in navigating the grievance and appeal process, including information on how to file a grievance or appeal with the managed care plan; beneficiary support systems can refer enrollees to sources of legal representation as appropriate.

Comment: Several commenters disagreed with the provision at proposed § 438.71(e)(3) (finalized as paragraph (d)(3)) that prohibits the beneficiary support system from also representing the beneficiary during the grievance, appeal, and state fair hearing processes. Commenters stated that beneficiary support systems should be permitted to provide representation.

Several commenters believed that entities that receive non-Medicaid funding to represent beneficiaries at hearings should also be permitted to provide choice counseling within the beneficiary support system with adequate firewalls in place as proposed at § 438.71(e)(3)(i). Other commenters believed that such firewalls should not be permitted and recommended that such entities not be permitted to serve in both capacities for it is possible, even with firewalls in place, for an advocacy group that represents beneficiaries in the appeals and State fair hearing processes to have strong formed opinions about managed care plans that could cloud their impartiality in the provision of choice counseling services and result in inadvertent steering toward or away from a particular managed care plan.

Response: The beneficiary support system is eligible for federal financial support as part of the Medicaid program as specified in §§ 438.810 and 438.816 and legal representation is not among the activities eligible for FFP. Direct case advocacy for Medicaid beneficiaries under the Long Term Care Ombudsman Program is eligible for

Medicaid administrative funding as discussed at 80 FR 31137.

We proposed at § 438.71(e)(3)(i) a provision to permit a state to engage, for the purposes of providing choice counseling as required under this final rule at § 438.71(a), an entity that receives non-Medicaid funding to represent beneficiaries at hearings only if the state requires firewalls to ensure that the requirements for the provision of choice counseling are met and only in the context of LTSS-specific activities. We are finalizing a similar provision at paragraph (c)(3) to permit such engagement in connection with firewalls for the provision of choice counseling generally.

In response to comments received on this proposal, we believe that an entity that provides legal representation at hearings should generally not be permitted to also provide choice counseling on the state's behalf, unless the appropriate firewalls have been put in place to ensure that the entity can meet the requirements for choice counseling—namely, to provide the required information and assistance in an unbiased manner. We do not believe it is necessary to prohibit states from utilizing such entities for the provision of choice counseling under these conditions, and we will leave such decisions to the state's discretion. We are finalizing the firewall provision for entities that provide legal representation to provide choice counseling at paragraph (c)(3) to provide that this flexibility is directly related to choice counseling and not limited to LTSS-specific activities. Note that the provision of choice counseling makes the entity an enrollment broker and the memorandum of understanding or contract is subject to CMS review and approval per § 438.810(b)(3); the independence and freedom of conflict of interest protections also apply. Therefore, we will finalize § 438.71 with the substance of proposed paragraph (e)(3)(i) and finalized at paragraph (c)(3).

Comment: Many commenters supported the provisions at § 438.810 regarding federal expenditures for enrollment broker services. One commenter recommended that CMS remove choice counseling from the definition of an enrollment broker at § 438.810(a). One commenter recommended that CMS revise the term “enrollment broker” and use consumer friendly terminology to refer to persons who perform choice counseling or enrollment services. One commenter recommended that CMS clarify that enrollment activities and enrollment services include activities and services “before and after enrollment” into a

managed care plan because the beneficiary support system is available to individuals before and after enrollment into a managed care plan.

Response: We do not agree with commenters that we should separate choice counseling from the definition of enrollment broker. Consistent with our requirements at § 438.71 and the existing rule at current § 438.810, we clarify that any individual or entity providing choice counseling services on behalf of the state is considered an enrollment broker under our regulations, and therefore, must meet the independence and conflict of interest standards of § 438.810 to provide those services. As noted in the proposed rule (80 FR 31137), we understand that some entities may receive federal grant funding (distinct from Medicaid funding) that may require those entities, such as FQHCs, Ryan White providers, or grantees (and sub-grantees) of the Title V Maternal and Child Health Block Grant, to conduct activities similar to those that would fall under the definition of choice counseling. We note here that such separate obligation to provide services similar to choice counseling services would not satisfy the state's obligation under § 438.71(a). We also note that this is not an exhaustive list of federal grantees and is provided for illustrative purposes. If those entities do not have a memorandum of agreement or contract with the state to provide choice counseling on the state's behalf, such entities would not be required to adhere to the conflict of interest and independence standards in § 438.810. We also note that some entities, such as FQHC look-alikes, as a condition of their federal designation, may be required to conduct activities similar to those that would fall under the definition of choice counseling. If those entities do not have a memorandum of agreement or contract with the state to provide choice counseling on the state's behalf, such entities would also not be required to adhere to the conflict of interest and independence standards in § 438.810. The rule finalized here at §§ 438.71 and 438.810 applies when the state engages—under a contract, memorandum of understanding, or other written agreement—an entity to provide these services in order to fulfill the state's obligations under § 438.71(a) or claims FFP for the payment of those services under § 438.810 or section 1903(b)(4) of the Act.

We decline to revise the term “enrollment broker” as the statute uses this term in section 1903(b)(4) of the Act. We also clarify for the commenter that enrollment activities and

enrollment services would include all activities and services consistent with the definitions at § 438.810(a), including activities and services both before and after enrollment as applicable. The beneficiary support system offers resources and supports beyond the resources provided by an enrollment broker subject to § 438.810. Therefore, it would not be appropriate to extend the definition of “enrollment services” or “enrollment activities” to include all functions of the beneficiary support system at § 438.71.

Comment: Many commenters supported the provisions at § 438.810(b)(1) and (2) regarding the conditions that enrollment brokers must meet. One commenter recommended that instead of the prescriptive independence and freedom from conflict of interest requirements at § 438.810(b)(1) and (2), CMS allow state flexibility to determine any inherent bias during the state selection process. One commenter also recommended that CMS revise the freedom from conflict of interest requirements to include only the financial interests of direct or indirect ownership of the managed care plan.

Response: We are bound by the statutory provision on enrollment brokers at section 1903(b)(4) of the Act. Sections 1903(b)(4)(A) and (B) of the Act specifically prohibit the availability of FFP for enrollment brokers who are not independent and free from conflict of interest. Therefore, we decline to adopt commenters' recommendations to either allow state flexibility to determine any inherent bias during the state selection process or to revise the freedom from conflict of interest requirements to include only the financial interests of direct or indirect ownership of the managed care plan. We believe that the language in section 1903(b)(4) of the Act, as reflected in § 438.810, is very specific about limitations as to who can serve as an enrollment broker. A broker is either independent of “any” managed care plan and of “any health care providers” that provide services in the state, or it is not. Similarly, a broker either does or does not have an owner, employee, consultant or other contract with a person who (1) has a direct or indirect interest in a managed care plan or provider, or (2) has been excluded, debarred, or subject to civil money penalties.

Comment: One commenter recommended that CMS include requirements at § 438.810 to require the use of evaluation tools and assessments to ensure that enrollment brokers are not engaging in self-referral or referrals

to organizations with whom they have a contracted interest.

Response: We do not agree with the commenter that such a specific recommendation should be included in the regulatory text at § 438.810. We believe the current regulatory text is very specific and reflective of the statutory language at section 1903(b)(4) of the Act. While we encourage the use of evaluation tools and assessments to ensure that enrollment brokers are not engaging in self-referral or referral to organizations with whom they have an interest, as the existence of such arrangements would violate the conflict of interest provisions, states are in the best position to determine the exact tools and methods at their disposal to monitor the compliance of enrollment brokers.

Comment: Many commenters supported § 438.816 to permit FFP for the services outlined at proposed § 438.71(e) (finalized as paragraph (d)). One commenter opposed the proposed provision and recommended state flexibility regarding the requirements at proposed § 438.71(e) (finalized as paragraph (d)). One commenter recommended that CMS clarify whether the FFP match rate would be at the administrative match rate or the service match rate. One commenter recommended that CMS strike “independent consumer support services” in the section title and replace with “the beneficiary support system,” to be consistent with proposed § 438.71(e).

Response: We thank commenters for their support at § 438.816. We decline to remove this provision, as proposed § 438.71(e) (finalized as paragraph (d)) is not an optional requirement for states; therefore, it is necessary to include the applicable FFP for appropriate state expenditures that meet the conditions listed at (a) through (d) of § 438.816. We clarify for commenters that the FFP match rate would be at the administrative match rate and not the service match rate. We agree with the commenter that striking “independent consumer support services” in the section title and replacing with “the beneficiary support system,” to be consistent with proposed § 438.71 is appropriate and are modifying the regulatory text to adopt this recommendation.

Comment: One commenter recommended that CMS clarify the requirement at § 438.816(a) regarding the state’s approved Public Assistance Cost Allocation Plan in § 433.34 of this chapter.

Response: We clarify that a state plan under Title XIX of the Act must provide

that the single or appropriate state agency will have an approved cost allocation plan on file with CMS in accordance with the requirements contained in subpart E of 45 CFR part 95. Consistent with the requirements at § 95.505, a cost allocation plan means a narrative description of the procedures that the state agency will use in identifying, measuring, and allocating all state agency costs incurred in support of all programs administered or supervised by the state agency.

After consideration of the public comments, we are not finalizing the regulatory text proposed at § 438.71(b)(1)(ii) and (d). We are finalizing the remainder of the proposed rule at § 438.71 with modifications. First, we are redesignating proposed paragraph (e) as § 438.71(d). We are finalizing the firewall provision for entities that provide legal representation to provide choice counseling at paragraph (c)(3) to provide that this flexibility is directly related to choice counseling and not limited to LTSS-specific activities. We are also modifying the regulatory text at § 438.816 to strike “independent consumer support services” in the section title and replace with “the beneficiary support system,” to be consistent with proposed § 438.71. We are finalizing the definition of “choice counseling” at § 438.2 as proposed. We are finalizing §§ 438.810 and 438.816 largely as proposed, with grammatical corrections to the punctuation in § 438.810(b)(1)(iii) and a revision of the heading at § 438.816.

d. Coverage and Authorization of Services and Continuation of Benefits While the MCO, PIHP, or PAHP Appeal and the State Fair Hearing are Pending (§§ 438.210 and 438.420)

We grouped our discussion of proposals for §§ 438.210 and 438.420 because they address related benefit issues about the receipt and provision of covered services. Section 438.210 establishes standards for authorization periods set by managed care plans and § 438.420 addresses the duration of continued benefits pending appeal resolution. Although the current regulation at § 438.210 addresses MCOs, PIHPs, and PAHPs, the current regulation at § 438.420 addresses only MCOs and PIHPs. We proposed to add PAHPs to the subpart F appeal and grievance regulations as discussed in the Appeals and Grievance section of the proposed rule (I.B.1.b.).

Under existing regulations, continuation of benefits during an appeal is tied to coverage and authorization decisions made by the

MCO, PIHP, or PAHP. As more managed care programs include enrollees with ongoing and chronic care needs, including LTSS, we believe it is important that authorization periods for such services reflect the ongoing need for these services to avoid disruptions in care.

While we recognized that MCOs, PIHPs, and PAHPs have flexibility in applying utilization management controls for covered services, exercising that flexibility could result in the inappropriate curtailment of necessary services, particularly for those requiring on-going and chronic care services, including LTSS. We acknowledged that our current standards reflect an acute care model of health care delivery and do not speak to the appropriate medical management of individuals with ongoing or chronic conditions, or the authorization of home and community based services that maximize opportunities for individuals to have access to the benefits of community living and the opportunity to receive services in the most integrated setting. Therefore, we proposed to modernize the language in § 438.210 governing the coverage and authorization of services and establish standards for states to ensure through the managed care contract that MCOs, PIHPs, and PAHPs employ utilization management strategies that adequately support individuals with ongoing or chronic conditions or who require LTSS.

As background, the foundation of coverage and authorization of services is that services in Medicaid must be sufficient in amount, duration, or scope to reasonably be expected to achieve the purpose for which the services are furnished, and services must not be arbitrarily denied or reduced because of the diagnosis or condition of the enrollee. Our proposal was to permit an MCO, PIHP, or PAHP to place appropriate limits on a service on the basis of criteria applied under the state plan, such as medical necessity or for the purpose of utilization control, provided that the services furnished can reasonably achieve their purpose. This is the same standard applied to a state’s coverage decisions under the state plan. See § 440.230. We proposed to reflect this by revising pertinent text in § 438.210(a)(3)(1) to delete “be expected to” as it is used relative to services reasonably achieving their results and align with the FFS standard in § 440.230.

We proposed no changes to § 438.210(a)(1) and (2).

We proposed that existing paragraph (a)(3)(iii) be redesignated as (a)(4) and existing paragraphs (a)(3)(iii)(A) and (B)

be redesignated without change as paragraphs (a)(4)(i) and (ii), with new paragraphs added at (a)(4)(ii)(A), (B) and (C). In paragraph (a)(4)(ii)(A), we proposed text to incorporate the proposed revisions in paragraph (a)(3)(i) deleting the phrase “to be expected to” as it is used relative to services reasonably achieving their purpose in stating a limit on how utilization controls may be used. We also proposed to add two new conditions on when and how an MCO, PIHP, or PAHP may impose utilization controls. First, we proposed in paragraph (a)(4)(ii)(B) that the state must ensure, through its contracts, that service authorization standards are appropriate for and do not disadvantage those individuals that have ongoing chronic conditions or need LTSS. The proposal would require that clinical services that support individuals with ongoing or chronic conditions, as well as LTSS would be authorized in a manner that reflects the beneficiary’s continual need for such services and supports. As this would be a contractual standard for managed care programs that cover both medical and LTSS, we stated our expectation that states monitor MCO, PIHP, and PAHP compliance with setting reasonable authorization periods, and also proposed a requirement for monitoring utilization management in our proposed revisions to § 438.66(b)(8). Second, we proposed that utilization controls may not interfere with the enrollee’s freedom to choose a method of family planning. Specifically, we proposed that utilization controls are permissible so long as family planning services are provided in a manner that protects the enrollee’s freedom to choose the method of family planning to be used consistent with § 441.20. We proposed this language under to our authority under section 1902(a)(4) of the Act; our proposal was intended to ensure that all beneficiaries, whether receiving family planning services through FFS or managed care, have the same freedom to choose the method of family planning to be used. This proposal would not alter the state’s ability under FFS or a managed care plan’s ability to apply medical necessity criteria for an individual’s request for family planning services but prohibited utilization controls that would interfere with an enrollee’s freedom to choose the method of family planning. We requested comment on this proposal.

We proposed that existing paragraph (a)(4) be redesignated as (a)(5) and paragraph (a)(5)(i) remained unchanged. In paragraph (a)(5)(ii), we proposed to revise the criteria for defining medically

necessary services by adding that such criteria must meet the requirements for providing the early and periodic screening and diagnosis and treatment (EPSDT) benefit beneficiaries under age 21. We believed this addition was necessary to ensure that managed care plans that provide the EPSDT benefit use definitions of medical necessity that comply with federal EPSDT laws. In paragraph (a)(5)(iii)(A), we proposed to revise the criteria for defining medically necessary services by replacing “health impairments” with “an enrollee’s disease, condition, or disorder that results in health impairment and/or disability” because the change more accurately reflected our intent than the existing text. In paragraph (a)(5)(iii)(A) through (C), we proposed grammatical revisions to accommodate a proposed new paragraph (a)(5)(iii)(D) that would add an LTSS focus by requiring that medically necessary services address the opportunity for an enrollee to have access to the benefits of community living.

In paragraph (b), we proposed to add specificity related to LTSS services. No changes were proposed for (b)(1) and (2)(i); however, in (b)(2)(ii) we proposed to add “for medical services” to address requests for non-LTSS, and in paragraph (b)(2)(iii), we proposed to add a standard that MCOs, PIHPs, and PAHPs authorize LTSS based on an enrollee’s current needs assessment and consistent with the person-centered service plan. In paragraph (b)(3), we proposed to change the text from “treating the enrollee’s condition or disease” to “addressing medical, behavioral health, or long term services and supports needs.”

We proposed the changes in paragraph (c) to add “PAHP” to the standards of this paragraph and to revise “notice of adverse action” to “notice of adverse benefit determination.” In paragraph (c), we also proposed to correct the heading to reflect the change from “action” to “adverse benefit determination.” As discussed in section I.B.1.b. of this final rule, we proposed to add PAHPs to subpart F and replace “action” with “adverse benefit determination” throughout 42 CFR part 438.

We also proposed to remove the provision that referenced notices to providers of adverse benefit determinations need not be in writing as an exception to § 438.404. Provider notices are not currently addressed in § 438.404, thus this reference is erroneous.

The only change proposed to paragraph (d)(1) was to delete “health”

to use the more comprehensive term “condition”.

We proposed in § 438.210(d)(2)(i) and (ii) to change the timeframe for MCOs, PIHPs, and PAHPs to make expedited authorization determinations within 72 hours, rather than the current standard of 3 working days, after receipt of the request for the service to align expedited authorization determination timeframes with the expedited managed care plan level of appeal in proposed § 438.408(b)(3). We discuss in section I.B.1.b. of this final rule how these proposed timelines align with the MA and private market standards for expedited appeals. We did not propose any revisions to § 438.210(e).

In section § 438.420, we proposed conforming revisions, consistent with other proposals throughout subpart F: specifically, to change “action” to “adverse benefit determination,” to add PAHPs to standards currently applicable only to MCOs and PIHPs, and to specify all time limits expressed in days as calendar days. To address the limit on enrollee’s access to benefits pending resolution of an appeal, we also proposed to eliminate the link between the duration of continued benefits pending appeal and the original service authorization period. Thus, we proposed to delete existing § 438.420(c)(4) that permits MCOs and PIHPs to discontinue coverage of services pending appeal when the time period or service limits of a previously authorized service has been met. The removal of this paragraph would mean that an enrollee must continue to receive benefits without interruption, if the enrollee elects to continue benefits, through the conclusion of the appeal and state fair hearing process if the enrollee appeals an MCO’s, PIHP’s, or PAHP’s adverse benefit determination. This change would apply to all authorized services covered by the MCO, PIHP, or PAHP. We indicated that this proposal represented a critical enrollee protection given the nature and frequency of many ongoing services, particularly for enrollees receiving LTSS.

In addition, in § 438.420(d), we proposed that the MCO’s, PIHP’s, or PAHP’s ability to recoup the cost of such continued benefits from the beneficiary under a final adverse decision be addressed in the contract and that such practices be consistent across both FFS and managed care delivery systems within the state. Under both managed care and FFS, the right to continuation of benefits is not exercised without potential financial risk to the beneficiary for payment for services provided if the final decision is adverse

to the beneficiary. Rather, the decision to hold the beneficiary financially liable for such services is left to the state under § 431.230(b) and that decision would be applied equally to FFS and managed care programs. For example, if the state does not exercise the authority for recoupment under § 431.230(b) for FFS, the same practice must be followed by the state's contracted MCOs, PIHPs, and PAHPs. We requested comments on the proposed revisions to §§ 438.210 and 438.420.

We received the following comments in response to our proposal to revise § 438.210.

Comment: Many commenters supported the proposed revisions to § 438.210. Commenters believed that proposed § 438.210 added needed specificity and clarity. Commenters were particularly supportive of the addition to LTSS throughout.

Response: We thank the commenters for their support.

Comment: One commenter recommended that CMS address the prohibition on discrimination under section 1557 of the Affordable Care Act in § 438.210. The commenter believed that most services that are not covered or authorized for transgender persons are already covered for cisgender persons.

Response: As required in § 438.3(f)(1), all managed care contracts must comply with all applicable federal and state laws and regulations including Title VI of the Civil Rights Act of 1964; Title IX of the Education Amendments of 1972 (regarding education programs and activities); the Age Discrimination Act of 1975; the Rehabilitation Act of 1973; the Americans with Disabilities Act of 1990 as amended; and section 1557 of the Patient Protection and Affordable Care Act. We do not believe revisions are necessary in the final rule to further address the prohibition on discrimination.

Comment: One commenter recommended that "health" be inserted in front of "condition" in proposed § 438.210(a)(5)(ii) and another commenter provided the same recommendation for proposed § 438.210(a)(5)(iii)(A). The commenters believed the removal of the word "health" made "condition" overly broad.

Response: We understand the commenters' concern but decline to add "health" to "condition" in those provisions. We specifically proposed this change to acknowledge the increasing inclusion of the LTSS population in managed care and the non-medical nature of many of their needs and services.

Comment: A few commenters requested that court ordered services be considered as medically necessary.

Response: We decline to add compliance with court orders as an exception in § 438.210 as this section applies to the managed care plan's coverage and authorization of services in the normal course of business. The managed care plan's compliance with court orders is a matter to be addressed through the contract or through consultation with legal counsel.

Comment: One commenter recommended that proposed § 438.210(a)(2)(i) be amended to require that states that offer self-direction in their FFS LTSS programs are expected to continue them under MLTSS.

Response: There are enrollee protections in § 438.210(a) regarding the amount, duration, and scope of services. Additionally, as part of the stakeholder engagement process in § 438.70, states should consider the impact of altering the types of services available to enrollees under a MLTSS program. However, states have the flexibility to design a MLTSS program and it may differ from the program that was operated under FFS. Including self-direction in a MLTSS program remains a state decision.

Comment: One commenter suggested that there should no limits permitted on amount, duration, and scope as proposed in § 438.210(a)(1).

Response: Proposed § 438.210(a)(2) provides that services identified in paragraph (a)(1) of this section be furnished in an amount, duration, and scope that is no less than the amount, duration, and scope for the same services furnished to beneficiaries under FFS Medicaid. We believe this is an appropriate limitation, but are clarifying that any limits must be consistent with the approved state plan and § 440.230 and decline to completely remove the managed care plans' ability to define the amount, duration, and scope of covered services.

Comment: A few commenters recommended that CMS set national utilization management standards and/or authorization criteria for managed care plans in proposed § 438.210(a) and (b). The commenters believed this would add consistency among states and eliminate the use of standards and criteria based on a managed care plan's other line of business, such as the private market.

Response: We do not believe it appropriate for us to set the utilization management standards and/or authorization criteria for managed care plans. The provisions in § 438.210(a) and (b) do provide a sufficient level of

detail and will provide adequate consistency across states. We believe states and managed care plans have the expertise and experience to develop the specific standards and criteria that best meet the needs of their program.

Comment: We received several comments recommending that managed care plans be required to regularly review, update, and publish their utilization management criteria. Commenters believed this would ensure that the most current industry information is used to make decisions and that, making this information public would be beneficial to providers and those assisting beneficiaries.

Response: We agree that utilization management policies and procedures should be regularly reviewed and updated. However, we believe this is already occurring and that no specific requirement for this is needed in § 438.210. We are confident that managed care plans appreciate the importance of keeping the information used in their utilization management activities as current as possible and take appropriate steps to maintain it. The extent to which utilization management policies and procedures are routinely published is a decision best made by the managed care plan or addressed by the state in the contract.

Comment: A few commenters recommended that the proposed provisions relative to utilization management be removed as managed care plans have the experience and expertise needed to develop and implement utilization management processes without additional federal requirements.

Response: We believe that the proposed provisions set an appropriate level of detail while still preserving the managed care plans' ability to utilize its expertise to operate and manage its business. States choose to contract with managed care plans to improve and expand their programs as well as enable the program to provide additional services, benefits, and provider networks to their beneficiaries. We believe that § 438.210, with the proposed changes and as finalized here, provides consistency and clarity on program expectations without being an impediment to effective and efficient managed care plan operations.

Comment: We received a few comments recommending that CMS add a reference to parity standards in proposed § 438.210 since it establishes a relationship between authorizations and utilization management used for medical benefits and those used for behavioral health and substance use disorder.

Response: We do not agree that a reference to parity standards are necessary in § 438.210. The implementing regulations for mental health parity are addressed in the March 30, 2016 final rule (81 FR 18390) and will be codified in a new subpart K in part 438 when effective. Subpart K will address authorizations and utilization management relative to compliance with MHPAEA.

Comment: We received several comments on proposed § 438.210(a)(4) that recommended that CMS specify that managed care plans may not use utilization control criteria that require an enrollee to show improvement to continue receiving services; require managed care plans to prioritize safe and effective treatments, and deliver care in a manner that is the least intrusive and restrictive, consistent with the level of care that is clinically appropriate for enrollees; and require managed care plans to consider individual factors, including tolerance for side effects, differences in treatment types, and the patient's ability to adhere to the recommended treatment regimen during the utilization review process.

Response: We do not agree that we should specify utilization control criteria § 438.210 to the level of detail requested. We believe managed care plans try to apply service authorizations appropriately based on enrollee needs; further, when the enrollee believes there have been inappropriate changes made to the level of services, the enrollee has the benefit of the grievance and appeal system. We encourage managed care plans to consider including prioritizing safe and effective treatments, delivering care in a manner that is medically appropriate while the least intrusive and restrictive, and individual factors (including tolerance for side effects, differences in treatment types, and the patient's ability to adhere to the recommended treatment regimen) in the development and implementation of their authorization policies and procedures.

Comment: We received one comment that recommended changing the word "reflects" to "meets" in § 438.210(a)(4)(ii)(B) which currently states that the services supporting individuals with ongoing or chronic conditions or who require LTSS are authorized in a manner that reflects the enrollee's ongoing need for such services and supports.

Response: We appreciate the commenter's suggestion but do not believe "meets" clarifies or strengthens the provision. We are retaining "reflects" in the final rule.

Comment: We received one comment requesting that "as permitted in the covered services list" be added to proposed § 438.210(a)(4)(ii)(B).

Response: We do not believe that a revision is necessary. We did not intend to imply in proposed § 438.210(a)(4)(ii)(B) that a managed care plan was expected to provide services outside the scope of services specified by the state in the managed care plan's contract. This is true of all provisions in part 438, unless superseded by state or federal law.

Comment: Some commenters recommended that proposed § 438.210(a)(4)(ii)(C) be revised to further clarify that the managed care plan cannot impose limitations on family planning services.

Response: The intention of § 438.210(a)(4)(ii)(C) was to ensure that the provision of family planning services was consistent between FFS and managed care delivery systems and the incorporation of § 441.20 in this paragraph would accomplish that goal. The plain language of § 441.20 means that for medically necessary and utilization-appropriate services, the state cannot preclude individuals from having a choice of the method of family planning services. The state or managed care plan cannot dictate that a particular method be used first or impose a prior authorization requirement that involves anything other than the determination that the method is medically necessary and utilization-appropriate. Other types of prior authorization or utilization management policies would effectively deprive the beneficiary or enrollee of free choice of equally appropriate treatments.

Comment: Some commenters that recommended modification to proposed § 438.210(a)(5)(i) to clarify that medical necessity definitions should be no more restrictive than the FFS definition in terms of either quantitative or non-quantitative treatment limits.

Response: We agree with commenters. The regulation already requires that medical necessity definitions be no more restrictive than state law, the state plan, and other state policies and procedures for the Medicaid program; this necessarily includes the extent to which medical necessity definitions contain limits on coverage. Further, the longstanding requirement for MCOs, PIHPs, and PAHPs to cover services under the contract in an amount, duration and scope that is no less than the amount, duration and scope for the services under the state plan would apply as well to such limits. Therefore, we will add "quantitative and non-

quantitative treatment limits" to the final text in § 438.210(a)(5)(i).

Comment: We received many comments in support of our proposed addition of § 438.210(a)(5)(ii) addressing EPSDT requirements for enrollees under 21 years of age. We also received comments recommending that "chronic" be removed as it is not included in the definition in section 1905(r)(5) of the Act and "defects" be removed as it is considered by some to be a poor choice of words. One commenter suggested that CMS clarify that EPSDT requires coverage for services even though they may otherwise not be covered, while another commenter suggested that CMS clarify that when services not covered by the managed care plan's contract need to be covered, the state is responsible for coverage of the services. Some commenters recommended that CMS remove the reference to EPSDT proposed in § 438.210(a)(5)(ii) as part of the definition of medical necessity to safeguard against unintended consequences and that the reference could be interpreted to apply the requirements of EPSDT to enrollees over 21 years of age, as well as be interpreted to mean that medical necessity criteria could not be applied to EPSDT.

Response: In considering the diversity of the comments received on this provision, we realized that the proposed reference to EPSDT in § 438.210(a)(5)(ii) was not clear. Implying that medical necessity criteria could not be applied to EPSDT services or that EPSDT requirements should be applied to adult enrollees was not our intent. To correct this, we are moving the reference to EPSDT from § 438.210(a)(5)(ii) and are adding text to § 438.210(a)(2) which addresses coverage for children more broadly as part of the requirement that managed care plan coverage be no less than the amount, duration, and scope of coverage under the state plan for covered services; we are finalizing new text that states enrollees under the age of 21, as set forth in subpart B of part 441 of this chapter at the end of the paragraph. We believe these revisions will facilitate consistent understanding of this provision. Questions regarding the managed care plan's responsibility for coverage of services not covered by the contract, should be directed to the state for clarification as that is outside the scope of this rule. We are redesignating the paragraphs at § 438.210(a)(5)(i)-(ii) to reflect this change as well.

Comment: We received one comment recommending that compliance with state periodicity schedules for screenings and assessments should be

identified as part of “the extent to which the managed care entity covers services,” proposed in § 438.210(a)(5)(iii)(A).

Response: States and managed care plans are welcome to include references to compliance with state periodicity schedules within their definition of medically necessary services as they deem appropriate and necessary. We decline to add a reference to the final policy of proposed

§ 438.210(a)(5)(iii)(A), which we are redesignating as § 438.210(a)(5)(ii)(A).

Comment: We received several comments on proposed § 438.210(a)(5)(iii)(D) related to the opportunity for an enrollee receiving long term services and supports to have access to the benefits of community living. Commenters believed this provision could be strengthened by references to person centered goals and living in the setting of their choice. Other commenters believed there was ambiguity in the word “opportunity.”

Response: We agree that this provision could be strengthened and will be making some revisions; however, we will be retaining “opportunity” as LTSS also includes institutional care and we believe “opportunity” appropriately signals the need to provide access to home and community based services (HCBS) without requiring it for those who need institutional care. We are finalizing § 438.210(a)(5)(ii)(D) to state that the opportunity for an enrollee receiving LTSS to have access to the benefits of community living, achieve person-centered goals, and live and work in the setting of their choice. We believe this final text adequately captures the goals of LTSS as they should be used to make medical necessity determinations.

Comment: One commenter suggested CMS require the inclusion of community providers in the development of the managed care plan’s definition of “medically necessary services” and another commenter recommended that CMS require managed care plans to include a quality of life principle in their definition.

Response: We agree with both commenters that the input of community providers or other stakeholders in the managed care plan’s development of medical necessity criteria could be of value, as well as the addition of a quality of life component; however this level of specificity is not warranted in this regulation. We decline to add that to the regulation text we are finalizing at § 438.210(a)(5).

Comment: We received many comments on proposed § 438.210(b). One commenter believed that

authorization requirements should not be a burden on providers; another believed the prescriber of treatment should determine the purpose of the service, rather than the managed care plan’s staff; another believed authorization staff at the managed care plan should be available 24/7; another believed that authorization staff should be available to discuss decisions by phone; another believed managed care plans should have to use the same authorization criteria as the state; and another commenter believed that managed care plans should be prohibited from using criteria used in private market insurance and group health plans.

Response: We appreciate the commenters’ concerns that an appropriate balance among many factors (physician independence in exercising medical judgment, enrollee access to services, administrative responsibilities of the plan, etc.) must be struck when authorizing services, but decline to include the recommended changes in the final rule at § 438.210(b). We encourage managed care plans to consider the burden on and input from providers and the prescribers when developing their authorization processes. States and managed care plans should consider the feasibility of extended hours for authorization staff, as well as the sharing of authorization criteria. Managed care plans utilize many sources of information when developing their authorization policies and we believe that the criteria and processes currently used to make authorization decisions for the Medicaid population are appropriately evaluated and determined appropriate prior to use.

Comment: A few commenters recommended the inclusion of a new § 438.210(b)(3) addressing “reauthorizations.” The commenters suggested regulation text related to the timing of authorization requests and requirements on providers for submitting requests for authorization.

Response: It is unclear what situations the commenters are referencing when they address “reauthorizations” as the term is not used in part 438. We believe the commenters may be referencing a request for authorization of the same services that have previously been authorized for an enrollee. However, a request for additional services beyond the termination date of an authorization is not a reauthorization of a benefit, it is a new request for authorization of services. For a more complete explanation of continuation of benefits, we direct the commenters to the discussion of § 438.420 below.

Comment: We received one comment recommending that CMS issue a clear and detailed process for notice to providers and all members of the care team for authorization decisions in § 438.210(c). Another commenter requested that CMS provide clarity on the appropriate methods for notification of authorization decisions to providers.

Response: We decline to specify this level of detail in § 438.210(c). We believe that managed care plans already have notification methods included in their policies and utilize them daily. We encourage providers to collaborate with the managed care plans to determine the most efficient and effective communication methods. Upon review of the proposed text at § 438.210(c), however, we noticed that punctuation is missing and that a technical correction is necessary; we are finalizing the last sentence as, “For MCOs, PIHPs, and PAHPs, the enrollee’s notice must meet the requirements of § 438.404.”

Comment: Some commenters suggested changes to the notification timeframes for standard and expedited authorizations as proposed in § 438.210(d)(1) and (2). Some commenters supported the change from 3 working days to 72 hours for expedited authorizations, while others believed the proposed deadline would be difficult, if not impossible, to meet. A few commenters suggested alternative time frames such as 1 day for standard authorizations and 1 hour for expedited authorizations; another commenter suggested 3 business days for standard authorizations and 24 hours for expedited authorizations. One commenter suggested 24 hours from receipt of all necessary information for expedited requests. One commenter recommended that a cross reference to § 438.3(s)(6) be added since that also addresses an authorization time frame for covered outpatient drugs.

Response: We appreciate the comments on our proposed timeframes in § 438.210(d)(1) and (2). While we understand that transitioning from 3 business days to 72 hours may be difficult, we believe that it not only is in the best interest of the enrollees, but that many managed care plans will recognize efficiencies if they also provide MA and/or private market coverage. The 72 hour timeframe for expedited authorizations is the prevailing standard in those markets for expedited determinations and appeals and we do not see a compelling reason to treat Medicaid managed care plans differently. In addition, we decline to modify the timeframe for standard authorizations. We agree with the commenter that adding a reference to

the timeframes for responding to authorization requests reflected in § 438.3(s)(6) would make § 438.210(d) more complete. Accordingly, we will add a new paragraph (d)(3) with a reference to the timeframe for responding to prior authorization requests for covered outpatient drugs in section 1927(d)(5)(A) of the Act.

Comment: One commenter requested that CMS clarify that enrollees need not request that an authorization decision be handled as expedited.

Response: We agree that an enrollee is not responsible for requesting expedited handling of an authorization request, but maintain that § 438.210(d)(2)(i) is sufficiently clear as it references the ability of the provider to indicate the need for an expedited authorization or the MCO, PIHP, or PAHP to make such determinations. We expect that the need for an expedited determination would be reflected in the records used to make an authorization determination.

We received the following comments in response to our proposal to revise § 438.420.

Comment: We received many comments in support of the deletion of paragraph (c)(4) in proposed § 438.420. The commenters believed that requiring services to be continued during an appeal and/or state fair hearing was a critical enrollee protection particularly for enrollees receiving services for chronic conditions or LTSS.

Response: We thank the commenters for their support for the proposed deletion of paragraph (c)(4).

Comment: One commenter requested that CMS include the contents for the notice of adverse benefit determination in § 438.420(a)(i).

Response: The content requirements for a notice of adverse benefit determination is contained in § 438.404(b)(6), as proposed and finalized. We believe that is the appropriate location for that information and decline to repeat it in § 438.420.

Comment: A few commenters recommended that a managed care plan's ability to recoup the cost of services be eliminated if the managed care plan did not provide the notice of adverse benefit determination in the appropriate non-English language for enrollees that are limited English proficient or in the appropriate format to meet the needs of an enrollee with a disability.

Response: We understand the commenter's concern that notices for enrollees be understandable but believe we have adequately addressed this in § 438.10(d)(3) based on comments and revisions to that section. Proposed § 438.10(d)(3) is revised to add denial

and termination notices to the list of documents that must be made available in prevalent non-English languages, as well as in alternative formats. We believe there is an additional protection in § 438.10(d)(3) since we added critical to obtaining services in this final rule; (see section I.B.6.d.) we believe that any notice to an enrollee concerning a denial, termination, reduction, or suspension of services is critical. We remind managed care plans that any necessary translation or alternative formats must be completed in a manner that does not impede the enrollee's ability, or reduce the enrollee's time, to request continuation of benefits in order to comply with § 438.10.

Comment: A few commenters requested clarification on the guidance provided in the preamble for part 438 when finalized in 2002 (67 FR 41058) that addressed the difference between continuing benefits of a previously authorized service and a new request for the same service. Some commenters believed the proposed § 438.420 was implying that CMS was taking a different position on the question of whether the expiration of a previously authorized course of treatment constitutes a "termination" of that course of treatment.

Response: We appreciate the opportunity to clarify that it was not our intention to imply a new meaning to "termination" in proposed § 438.420. Consistent with the 2002 preamble, the request for days or services (whether the same or different) in addition to the original authorization should be treated by the MCO, PIHP, or PAHP as a new request for service authorization; denials or limitations, if issued, must be provided in accordance with § 438.404. If additional days or services were not authorized, ending treatment as provided in the original authorization would not constitute a termination triggering the right to continued benefits. For purposes of the continuation of benefits under this regulation, however, the removal of paragraph (c)(4) means that an enrollee must continue to receive benefits without interruption, if elected by the enrollee, through the conclusion of the SFH process if the enrollee appeals an MCO's, PIHP's, or PAHP's adverse benefit determination.

Comment: One commenter recommended that a provision be added to require states to develop an effective and consistent process for notifying the managed care plan when one of their enrollees has requested a state fair hearing. The commenter believes that without this, managed care plans may inadvertently allow authorizations to

lapse simply because they were unaware that the enrollee had filed for a state fair hearing.

Response: We agree with the commenter's concern and encourage all states to review their policies and procedures for notifying their managed care plans of a request for a state fair hearing and ensure that they are appropriately implemented in a manner that does not cause a disruption in the enrollee's care. However, we do not believe that revisions to our proposal are necessary.

Comment: A few commenters recommended that CMS add "course of treatment or" to § 438.420(b)(3) before "services."

Response: We believe that a course of treatment is made up of individual services; therefore, adding it to § 438.420(b)(3) before "services" does not change or enhance the meaning. We decline to make this suggested revision. However, for consistency, we will revise § 438.420(b)(2) to use "previously authorized services" in place of "previously authorized course of treatment."

Comment: Some commenters recommended that proposed § 438.420(b)(4), which provides that one of the conditions for continuation of benefits is that the original authorization period has not expired, be deleted. These commenters did not believe that enrollees should have to request continuation of benefits prior to the end of the original authorization period, particularly given that enrollees sometimes miss that deadline simply because the managed care plan did not provide the notice as far in advance as required. Some commenters also believed that the removal of existing paragraph (c)(4) related to the duration of continuation of benefits makes proposed paragraph (b)(4) unnecessary.

Response: We believe that revisions to § 438.420 are warranted to make our intent clearer. As the revisions impact paragraphs (a) and (b) of this section, we will address the interactions among these requirements and modifications in detail. First, the defined term "timely filing" (paragraph (a)) is used in (b)(1) as part of one of the conditions to be met for the managed care plan to continue the benefits; paragraph (b)(1) provides that the enrollee or the provider must "file the appeal timely." The plain language in (b)(1) regarding the reference to "timely," would impose a deadline on the enrollee's filing of the request for an appeal; however, the deadline described in § 438.420(a) is inconsistent with the deadline for requesting an appeal established in § 438.402(c)(2)(ii) (60 calendar days

from the date on the adverse benefit determination notice).

We did not intend for § 438.420(a) or (b) to truncate the period of time for the enrollee to request an appeal of the adverse benefit determination under § 438.402(c)(2)(ii). To correct this error, we have modified § 438.420(a) to replace “timely” with “timely files” and specify that “timely files” means “files for continuation of benefits on or before. . . .” This revision will clarify that all requirements related to the availability and the duration of continuation of benefits are contained in § 438.420.

We are also finalizing a revision to the deadline in this definition. As proposed, the deadline was the later of: (1) 10 calendar days of the MCO, PIHP or PAHP mailing the notice of adverse benefit determination or (2) the intended effective date of the plan’s adverse benefit determination. In the final rule, we will replace the term “mailing” with “sending” to recognize that electronic communication methods, subject to § 438.10, may be used. Taken together, the revisions to § 438.420(a) mean that if the managed care plan did not meet its obligation to send the notice of the adverse benefit determination 10 calendar days before the termination or reduction of previously authorized services, the enrollee has longer than the original authorization period to timely file a request for continuation of benefits. To illustrate, the enrollee’s original authorization period expires on the 30th day of the month and the managed care plan mails the notice of the adverse benefit determination on the 29th day of the month. The enrollee would have until the 9th day of the following month, which exceeds the period of the original authorization period, to timely file a request for continuation of benefits. Lastly, to recognize the use of electronic communication methods, the word “mailing” has been replaced with “sending.”

In paragraph (b)(1), we will add text to the regulation to clarify that the enrollee must file the request for appeal timely by adding a cross-reference to § 438.402(c)(ii) to incorporate the timeframe for the enrollee’s or provider’s request for an appeal. We are also finalizing slightly different text in § 438.420(b)(1) regarding who files the appeal to be consistent with our finalization of § 438.404 (see section I.B.1.b). The continuation of benefits is intrinsically linked to the appeals process so we believe that any continuation of benefits pending appeal of a termination, suspension or reduction of previously authorized

benefits must be conditioned on a timely request for an appeal. We acknowledge that an enrollee may request an appeal after the enrollee requests continuation of benefits due to the variation in timeframes; actual continuation of benefits is conditioned; however, on the filing of the appeal consistent with the timing requirements in § 438.402. We encourage managed care plans to specify in their notice of the adverse benefit determination that both the appeal and request for continuation of benefits may be filed concurrently. Paragraphs (b)(2) and (b)(3) are being finalized substantively the same as proposed, with the replacement of the term “course of treatment” with “services” in (b)(2); these paragraphs require that the appeal involve termination, suspension, or reduction of a previously authorized services ordered by an authorized provider.

Paragraph (b)(4) proposed that, as another condition for an enrollee to receive continuation of benefits, the original period covered by the original authorization has not expired. We believe it is important to have this requirement as the enrollee must have been entitled under the previous authorization to receive the benefit to receive continuation of benefits. However, we will finalize this paragraph with an modification to delete the word “original” preceding “period” as that word is not necessary to convey the intent of the provision. Whether the first or a latter authorization is in effect is itself immaterial so long as an authorization for the services that is subject to the adverse benefit determination has not expired or lapsed at the time of the enrollee’s timely filing of a request for continuation of benefits.

Lastly, we modify paragraph (b)(5) to incorporate the “timely files” standard in paragraph (a) and replaced the word “extension” with “continuation” for consistent use of terms. We are finalizing paragraph (b)(5) with these modifications to make clear that the enrollee must request continuation of benefits in a timely manner.

Comment: A few commenters suggested that enrollees should not have to request continuation of benefits because services should automatically be continued with the filing of an appeal or State fair hearing about the termination, suspension or reduction of a previously authorized service. We also received a few comments suggesting that providers should be added to proposed § 438.420(b)(5) and, thereby, permitted to request continuation of benefits on the enrollee’s behalf.

Response: We do not agree that continuation of benefits should be automatic or that the provider should automatically be able to request continuation on the enrollees’ behalf. Because an enrollee may be held liable for payment for those continued services, as specified in § 438.420(d), we believe it is critical that the enrollee—or an authorized representative of the enrollee who is not a provider—initiate the request.

Comment: We received several comments requesting that CMS clarify that managed care plans should not be required to continue benefits beyond state established quantitative limits.

Response: We decline to revise the rule to address this situation. Managed care plans need to address this question to their state and the processes for handling such cases should be stipulated in the managed care plan’s contract.

Comment: Many commenters supported the removal of existing § 438.420(c)(4). A few commenters were opposed to the deletion because they believed it could allow the costs of the continued benefits to grow quickly and for an undetermined amount of time, which would not be in the enrollee’s nor the managed care plan’s best interest.

Response: We appreciate the supportive comments and understand those in opposition to our proposed removal of existing § 438.420(c)(4). However, we believe that allowing enrollees to receive on-going services during an appeal or state fair hearing about the early termination or reduction of those services is an important protection for enrollees. Additionally, because the process includes the active participation of the enrollee (that is, the enrollee can elect the extent and duration of the services that they wish to continue receiving), the enrollee has some ability to control the amount of liability they are willing to assume. As such, we believe it is appropriate to finalize the amendment to § 438.420 without the text that currently appears in paragraph (c)(4).

Comment: We received many comments on proposed § 438.420(d). Several commenters were opposed to enrollees being held liable for the cost of the services if the final decision was adverse to the enrollee. A few commenters suggested that proposed § 438.420(d) include exemptions for enrollees unable to pay or if the enrollee received EPSDT services. One commenter suggested that enrollees only be held liable for those services continued during a state fair hearing.

Response: We understand the commenters' opinions on this provision; however, this provision has been included in part 438 since it was finalized in 2002, as well as in part 431 since 1979. It is outside the scope of this rule to mandate exemptions for certain populations or limit its applicability to just services provided during the state fair hearing.

Comment: We received several comments suggesting that states provide, or require the managed care plan to provide, manageable repayment plans. We received a few comments recommending that states be required to ensure that managed care plans do not take any punitive or negative actions against enrollees from whom they are attempting to recoup payment. One commenter believed states should monitor managed care plans to ensure that excessive or abusive recoupment practices are not utilized.

Response: While we agree with commenters' concerns generally, we decline to include language in the regulation because we believe that the standards for the process of recoupment should remain with the states. We agree with commenters that manageable repayment plans are a reasonable way to implement this provision and encourage states and managed care plans to consider it. We also agree that states should have monitoring mechanisms in place to ensure that their managed care plans are not taking punitive or negative actions against enrollees nor engaging in excessive or abusive recoupment practices. Monitoring complaints received through the state's beneficiary support system, as well as grievance reports from the managed care plans would be one such mechanism.

Comment: One commenter recommended that CMS set standards for recoupment activity by managed care plans as permitted in proposed § 438.420(d).

Response: The states have the option to determine whether to permit recoupment in their managed care programs if they also take recoupments under FFS; therefore, we believe developing the necessary policies and procedures should also remain with the states and decline to adopt regulation text as recommended by the commenter.

Comment: We received some comments on the language "Such practices must be consistently applied within the State under managed care and FFS delivery systems" in proposed § 438.420(d). Some commenters believed this sentence should be deleted while others requested clarification on the definition and scope of "practices" and "consistently."

Response: We agree that language could be clearer. In the final rule, we are combining "consistent with state's usual policy on recoveries under § 431.230(b)" and "as specified in the MCO's, PIHP's, or PAHP's contract" and moving these phrases earlier in the first sentence to make the provision easier to understand. The last two sentences proposed in paragraph (d) are not being finalized since the first sentence now captures the substance of those sentences.

Comment: A few commenters requested that CMS clarify that managed care plans permitted to pursue recoupment must only pursue recovery from the enrollee, not the provider. Some commenters believed it was inappropriate to retract funds from the provider simply because it was easier.

Response: As explained in the previous comment, § 438.420(d) is being finalized to read that managed care plans may, if permitted in their contract with the state, pursue recovery "consistent . . . with § 431.230(b)", and § 431.230(b) clearly states ". . . the agency may institute recovery procedures against the applicant or beneficiary to recoup the cost of any services furnished the beneficiary, to the extent they were furnished solely by reason of this section." We believe these provisions are sufficiently clear and decline to revise § 438.420(d).

Comment: We received a few comments stating that the costs of pursuing recoupment and the amount likely to actually be recouped should be taken into consideration during the rate setting process.

Response: This is a reasonable adjustment for actuaries to consider during the rate setting process. As § 438.5(f) establishes general standards for adjustment, we decline to explicitly reference the treatment of recoupments in the rate setting process.

Comment: One commenter recommend that CMS create a new section in part 431 to require that the state fair hearing be reviewed de novo to ensure the fairness of that process. The commenter believed that under *Goldberg v. Kelly*, 397 U.S. 254 (1970), a constitutionally impartial hearing will not occur until the individual reached the state fair hearing level of appeal. To ensure this fairness, the state fair hearing needs to occur de novo.

Response: We decline to add a new section specifying the level of review for the state fair hearing as that is addressed in § 431.233. That section permits a beneficiary to request a *de novo* review but does not require that standard of review as a default. This is consistent

with the holding of *Goldberg v. Kelly*, 397 U.S. 254 (1970).

After consideration of the public comments, we are finalizing § 438.210 substantially as proposed with a few modifications. In paragraph (a)(2), we are including a cross-reference to the coverage standards in part 440 for beneficiaries under age 21. In § 438.210(a)(5)(i), we are finalizing as proposed except for the addition of quantitative and non-quantitative treatment limits. In § 438.210(a)(5)(ii), we are deleting the proposed text and redesignating paragraph (iii) as (ii); in § 438.210(a)(5)(ii)(D), we are modifying to include the opportunity for enrollees receiving LTSS to achieve person-centered goals and live and work in the setting of their choice. In § 438.210(b)(3), we are revising to use individual instead of health care professional since the definition of health care professional is not being finalized. In paragraph (c), we are finalizing the text with technical corrections. In § 438.210(d)(3), we are finalizing text for the timing standard applicable to authorizations of covered outpatient drug authorizations as described in section 1927(d)(5)(A) of the Act.

After consideration of public comments, we are finalizing § 438.420 substantially as proposed with several modifications. In § 438.420(a), we are correcting "Definitions" to "Definition," using "timely files," and clarifying the definition; in § 438.420(a)(i), we are replacing the term "mailing" with "sending" to recognize the use of electronic communication methods. In § 438.420(b)(1), we are also finalizing slightly different text regarding who files the appeal, consistent with our finalization of § 438.404, to prohibit a provider from filing the request for continuation of benefits. In § 438.420(b)(2), we are replacing "course of treatment" with "services." In § 438.420(b)(4), we are not finalizing "original" before "period" for clarity. In § 438.420(b)(5), we are finalizing minor text revisions for clarity. We are also finalizing grammatical changes in (b)(1) through (4) to clarify that the all of the conditions must be met. In § 438.420(c)(1), we are adding a reference to state fair hearing for consistency with rest of section. In § 438.420(d), we are finalizing more succinct wording for clarity and not finalizing specific policies about the content of the managed care plan contract.

e. Continued Services to Beneficiaries and Coordination and Continuity of Care (§§ 438.62, 438.208)

To ensure consistent continuity of care and coordination of services for beneficiaries, we proposed revisions to §§ 438.62 and 438.208.

The existing regulatory framework for coordination of care focuses on three elements: (1) All enrollees must have an ongoing source of primary care; (2) a person or entity will coordinate the care provided by the MCO, PIHP, or PAHP; and (3) additional assessments and treatment plans are in place for individuals identified by the state as having special health care needs. In 2002, when the current regulations were finalized, the use of managed care for delivery of LTSS or providing medical services to more complex populations was not prevalent and, therefore, not substantially reflected in the regulations.

The proposed changes sought to align the Medicaid managed care framework with other public and private programs and improve coordination and continuity of care. To that end, we proposed to: set standards for transition plans when a beneficiary moves into a new MCO, PIHP, or PAHP; expand beyond the emphasis on primary care when considering care coordination; strengthen the role of the assigned care coordinator; ensure more accurate and timely data gathering and sharing; and include enrollees with LTSS needs in the identification, assessment and service planning processes. The proposals were to modify sections §§ 438.62 and 438.208.

(1) Transition Between Medicaid Delivery Systems (§ 438.62)

Our only explicit transition of care standards included in current Medicaid managed care regulations (codified at § 438.52) focus on when a beneficiary is mandated into a single MCO, PIHP or PAHP in a rural area. As stated in our preamble, we believed there should be transition of care standards for all Medicaid beneficiaries transitioning from one delivery system to another within Medicaid (even MCO to MCO), and not just rural area enrollees.

We proposed no changes to paragraph (a) other than to add PCCM entity as discussed elsewhere in this rule. We proposed to add a standard to § 438.62(b) which would require that states have a transition of care policy in place for individuals moving to managed care from FFS, or from one MCO, PIHP, PAHP, PCCM, or PCCM entity to another when an enrollee without continued services would

experience serious detriment to their health or put them at risk of hospitalization or institutionalization. Under this proposal, states would define the transition policy, as long as it met the standards proposed in paragraph (b)(1), and would have the flexibility to identify the enrollees for which the MCOs, PIHPs, PAHPs, PCCMs, or PCCM entities would need to provide transition activities. Paragraph (b)(1) proposed that state transition policies include: Permitting the enrollee to continue to receive the services they are currently receiving from their current provider for a specified period of time in paragraph (b)(1)(i); referring the enrollee to an appropriate participating provider in paragraph (b)(1)(ii); assuring that the state or MCO, PIHP, or PAHP comply with requests for historical utilization data in paragraph (b)(1)(iii); and assuring that the enrollee's new provider is able to obtain appropriate medical records in paragraph (b)(1)(iv). References to "services" mean services covered under the contract, which would include prescription drugs if the managed care plan is obligated to provide such services under the contract. We also proposed, at paragraph (b)(1)(v), that additional procedures for the transition plan may be specified by the Secretary as necessary to ensure continued access to services for an enrollee to prevent serious detriment to the enrollee's health or to reduce the risk of hospitalization or institutionalization.

In paragraph (b)(2), we proposed that states include a requirement for a transition of care policy meeting the standards in the regulation (and the state transition policy) in their MCO, PIHP, and PAHP contracts. We proposed to interpret the regulation text in a way to provide flexibility for states to decide whether to apply the state developed policy consistently to their MCOs, PIHPs, and PAHPs, or whether to permit the managed care plans to have different policies, as long as the state's minimum standards are met. We believed this approach would achieve an appropriate balance between assuring ongoing care for individuals who have significant needs while permitting states flexibility to determine how best to implement these transitions. At a minimum, the proposed regulation would also require the transition policies to be included in the state's comprehensive quality strategy, be publicly available, and included in information provided to potential enrollees.

We received the following comments in response to our proposal to revise § 438.62.

Comment: We received many comments in support of our proposed expansion of § 438.62. Commenters believed the additional detail in this section is needed and will ensure that enrollees will have better access to continued services during time of transition.

Response: We thank the commenters for their support of the additional detail. While we will be making some revisions in the final rule, we have retained the proposed structure and much of the proposed text of § 438.62.

Comment: We received a few comments that recommended CMS remove much of the proposed text to be less prescriptive in the final rule. These commenters believed that the states were in the best position to design their transition of care policies and procedures.

Response: We believe some level of specificity in this section is necessary to establish minimal requirements across all states to protect beneficiaries as they transition across health care options. We believe the requirements strike a balance between assuring minimal protections for enrollees and consistency and state flexibility.

Comment: We received many comments for additional situations that would trigger the use of the transition of care policy proposed in § 438.62(b). In addition to the proposed situations of enrollees transitioning from FFS to managed care and between managed care plans, commenters suggested adding transitions from managed care to FFS, from (or to) the Marketplace or private insurance; from (or to) Medicare; when an enrollee's provider leaves the network; upon release from incarceration, and when significant changes are made to the delivery system. Commenters believed that enrollees would benefit from transition planning when any of these occurred.

Response: We agree that many of these suggestions present good transition situations for states and managed care plans to consider including in their policies; however, we decline to include them in the final rule in part due to limits on the scope of this rule and concerns about the practicality of the suggested requirements. For most of these suggestions, the requirement for transition planning would be one sided. Part 438 cannot impose requirements on the Marketplace QHPs, private insurance, or Medicare. These other, non-Medicaid entities would be under no obligation to cooperate or provide information to the Medicaid program or managed care plans within Medicaid. We encourage states and plans to attempt transition planning in the

suggested situations but do not believe it would be appropriate to mandate it in § 438.62(b).

When significant delivery system changes are being made, we believe that states and managed care plans are already performing transition planning. Since states are required to notify and sometimes obtain approval from CMS for significant delivery system changes, we receive information on their transition planning efforts and have the opportunity to review and provide feedback. Providers leaving a network may warrant providing transition services for enrollees; however, these situations frequently do not. Therefore, we leave the decision of determining when a network change warrants transition services to the state.

Comment: One commenter suggested that states and managed care plans obtain stakeholder input when developing their transition policies to ensure that they are comprehensive and represent all populations and their needs.

Response: We agree that stakeholders may provide valuable input into the development of states' and managed care plans' transition policies and encourage states and managed care plans to utilize stakeholder input as appropriate. We decline, however, to require the inclusion of stakeholder input in the final rule.

Comment: We received some comments on proposed § 438.62(b) requiring transition of care policies to ensure continued access to services, specifically suggestions for additions to the language "when an enrollee, in the absence of continued services, would suffer serious detriment to their health or be at risk of hospitalization or institutionalization." Some commenters recommended adding the following triggers for requiring transition of care: when an enrollee is completing a course of treatment; has a scheduled procedure within 60 days of the transition; is receiving care for a terminal illness; is receiving pregnancy or post-partum care; or the state determines that other circumstances warrant continued access. A few commenters recommended deleting the language altogether as they believed it was too limiting because transition planning could prevent gaps in treatment or ensure that an enrollee has appropriate access to time-sensitive services in other situations.

Response: We appreciate the comments on this provision but conclude that most of the suggested additions are adequately captured in the proposed standard for when the regulation requires continued access to

services. Additionally, the standard in § 438.62(b), as proposed and as finalized, is a minimum; states and Medicaid managed care plans have latitude to add to their policies as they deem appropriate. As to specifying no criteria at all in § 438.62(b), we do not believe that is prudent. While we agree that there may be additional enrollees that may benefit from transition planning, we believe it is best to set minimum standards and permit states and managed care plans to expand from that minimum. This approach gives states and plans flexibility to customize their policies to meet the needs of their program and covered populations. Therefore, we will be finalizing this provision as proposed.

Comment: A few commenters recommend that CMS specify in proposed § 438.62(b)(1)(i) that "providers" includes providers such as pharmacies, transportation, and ancillary services.

Response: The use of the term "providers" in § 438.62(b)(1)(i), as proposed and finalized, is intended to be as broad as possible and allow the inclusion of any necessary provider types. As such, we decline to add specific provider types to this provision.

Comment: We received many comments on "period of time" as used in proposed § 438.62(b)(1)(i) relating to continued access to services from current providers. Some commenters believed CMS should define the length of the period for continued services while others recommended specific lengths of time ranging from 30 days to one year. A few commenters recommended requiring the length of the period for enrollees in a nursing or assisted living facility be indefinite. Some commenters recommended including the duration of the enrollee's course of treatment or scheduled procedure including any necessary follow-up appointments, or—in the case of a pregnant or post-partum enrollee—until 60 days post-partum, or—in the case of an enrollee with a terminal illness—for the duration of the illness, or—in the case that the state identifies other circumstances that warrant continued access—for a period of time identified by the state, if that provider is not in the MCO, PIHP or PAHP network. A few commenters recommended that transition plans for enrollees receiving LTSS should continue until the enrollee's service plan is due for re-evaluation or the enrollee's condition changes. Some commenters believed that defining the length of the period of time should not be left to state discretion. One commenter suggested that plans be

required to notify enrollees before the end of the transition period to confirm understanding.

Response: We urge states and managed care plans to ensure that the period of time for continued access (to a provider who is no longer in-network) is appropriate for the circumstances of the applicable enrollee when developing transition plans under this regulation. However, given the variation in the amount of time needed to safely transition an enrollee under different circumstances, specifying a time frame in § 438.62(b)(1)(i) would not be the best approach. We agree that a reminder notification to the enrollee may be helpful in some circumstances and encourage states and plans to consider this option.

Comment: A few commenters recommended that § 438.62(b)(1)(i) be revised to include access to all services and providers the enrollee had access to previously while a few commenters recommended that access to services and providers should be limited to only those that, without transition accommodations, would actually cause serious detriment to the enrollee's health or place the enrollee at risk of hospitalization or institutionalization.

Response: We understand the commenters' concerns and clarify that paragraph (b)(1)(i) should be read as a complete sentence so that "current provider" is associated with the access to services. It was not our intent to imply that providing an enrollee time to make a transition was the same as allowing the enrollee unfettered access to their previous network of providers. To the comment on limiting transition services to only those enrollees that, without transition accommodations, would actually suffer serious detriment to their health or place the enrollee at risk of hospitalization or institutionalization, we note that the regulation text sets that as the minimum standard in paragraph (b) generally by identifying the enrollees for whom the transition of care policy must apply. The regulation sets a minimum requirement and states and plans have the flexibility to include additional enrollees and/or qualifying criteria.

Comment: We received a few comments on the sharing of data in proposed § 438.62(b)(1)(iii) and the difficulties inherent in this provision. Commenters believe issues around confidentiality, particularly given regulations at 42 CFR part 2, *Confidentiality of Alcohol and Drug Abuse Patient Records*, make compliance with this provision difficult. Several commenters recommended that CMS confer with the Office of the

National Coordinator for Health IT (ONC) on ensuring consistency with their work on interoperability standards. Another commenter recommended CMS encourage the adoption of standards such as requiring the use of standardized transport, message and content formats for required reporting, and aligning expectations for these standards as specified in the ONC Interoperability Standards Advisory.

Response: We acknowledge the challenges around data sharing and note that the proposal, and the final rule at § 438.62(b)(1)(iii), require that the sharing of information be in compliance with Federal and State law. We support the work of ONC and endorse the use of ONC's Roadmap and the 2015 Interoperability Standards Advisory in achieving compliant data sharing while meeting the goals of these provisions. We do not believe that this final rule is the appropriate forum for changes to other regulatory frameworks for protecting patient data and privacy.

Comment: A few commenters suggested that CMS remove proposed § 438.62(b)(1)(v) that reads "Any other necessary procedures as specified by the Secretary to ensure continued access to services to prevent serious detriment to the enrollee's health or reduce the risk of hospitalization or institutionalization." The commenters believed any criteria should be specified in the rule and, if additional provisions are added later, they should be added through a process that permits public comment.

Response: We understand the commenters' concerns but find it prudent to finalize the proposed text to provide the ability to reflect industry or practice changes and best practices that may warrant specific inclusion at a later time; we believe that the standard reflected in the regulation (necessary to "ensure continued access to service to prevent serious detriment to the enrollee's health or reduce the risk of hospitalization or institutionalization") effectively limits the scope of any additional procedures identified by the Secretary at a later date. Only by applying this standard and making the affirmative determination that additional procedures are necessary for this purpose may the Secretary (through CMS) adopt additional procedures for the transition of care policies. Further, the regulation does not prohibit us from using rulemaking or soliciting public comment in identifying such additional procedures.

After consideration of the public comments, we are finalizing § 483.62 as proposed with two modifications. In paragraph (a), we are adding a comma

between "PCCM" and "or." In paragraph (b)(3), we are finalizing the regulation text without the word "comprehensive" modifying the term "quality strategy" to be more consistent with how this final rule generally refers to the quality strategy required under § 438.340.

(2) Applicability of Care Coordination (§ 438.208(a))

The current regulation at § 438.208(a) requires the State to ensure through its contracts, that each MCO, PIHP, and PAHP meet specific coordination and continuity of care standards outlined in paragraphs (b) and (c), with two exceptions. We proposed technical changes to the exceptions for MCOs, PIHPs, and PAHPs serving dually eligible individuals. We proposed no changes to paragraph (a)(1). We proposed to delete paragraph (a)(2)(i) as it is redundant to language proposed in paragraph (b)(1); however, doing this necessitates incorporating the existing provisions in paragraph (a)(2)(ii) into (a)(2). We proposed minor technical corrections in § 438.208(a)(3)(i) to replace the outdated reference to "Medicare+Choice plan" with "MA organization." Additionally, in § 438.208(a)(3)(ii), we proposed that the decision to grant an exception to a MCO serving dually eligible individuals would be based on the needs of the population served rather than on what services are covered under the contract.

We received the following comments in response to our proposal to revise § 438.208(a).

Comment: We received one comment on proposed § 438.208(a)(2) regarding the exception permitted for PIHPs and PAHPs from the treatment plan requirements proposed in § 438.208(c)(3). The commenter believed that this provision should be narrowed to only allow exceptions in appropriate and limited circumstances.

Response: The proposed text in § 438.208(a)(2) limits the exceptions a state may grant for identifying, assessing, and producing a treatment plan for an individual with special health needs. We believe the language, based on the scope of the entity's services, and on the way the State has organized the delivery of managed care services, provides sufficient parameters for state decision making while still affording latitude to account for the characteristics of the variety in state programs.

Comment: We received a few comments requesting clarification of proposed § 438.208(a)(3)(ii) regarding the exception for MCOs that serve dually eligible enrollees. The

commenters believed this provision as proposed was overly broad and unclear. Another commenter questioned whether this provision would allow a state to permit an MCO covering LTSS to assign a primary care provider to the enrollee while acute medical care was covered by Medicare as the primary payer.

Response: We proposed the change in § 438.208(a)(3)(ii) because the provisions in § 438.208(c) are by their nature, driven by the needs of the population. The need for an assessment and treatment/service plan should be determined by the needs of the enrollees, not by how covered services are defined in a contract. In regard to the question whether the state would permit an MCO covering LTSS to assign a primary care provider to the dually eligible enrollee when acute medical care was covered by Medicare, the exception proposed in § 438.208(a)(3)(ii) only addresses exceptions relative to the provisions proposed in § 438.208(c) (which are applicable to enrollees who require LTSS or have special health care needs). The commenter should consult with their state for clarification regarding primary care provider assignment in that circumstance.

After consideration of the public comments, we are finalizing § 438.208(a) as proposed, with a modification to include a cross-reference to the definition of "Medicare Advantage Organization" in § 422.2.

(3) Care Coordination Activities (§ 438.208(b))

As noted in the preamble to the proposed rule, the Agency for Healthcare Research and Quality (AHRQ) defines care coordination as "deliberately organizing patient care activities and sharing information among all of the participants concerned with a patient's care to achieve safer and more effective care. This means that the patient's needs and preferences are known ahead of time and communicated at the right time to the right people, and that this information is used to provide safe, appropriate, and effective care to the patient."⁹ Although we believe most MCOs, PIHPs, and PAHPs are already doing these activities, we proposed to update our regulations to align with the governing policies of the MA program and the Marketplaces. We also proposed several modifications to § 438.208(b) and (b)(1): (1) To revise the language in paragraph (b)(1) from services "furnished to" enrollees, to services "accessed by"

⁹ AHRQ Web site: <http://www.ahrq.gov/professionals/prevention-chronic-care/improve/coordination/index.html>.

enrollees, to more adequately describe the entire range of services covered by the regulations; (2) to remove references to “primary” to ensure each enrollee receives access to an ongoing source of care appropriate to their needs, regardless of whether the service provider is considered a primary care provider; and (3) to remove the words “health care” to explicitly recognize that MCOs, PIHPs, and PAHPs may coordinate not only health care services but a full range of community based support services to provide services in the most integrated setting to enrollees.

We proposed to expand the standards in paragraph (b)(2) so that care coordination activities by MCOs, PIHPs, and PAHPs involve coordination between care settings in paragraph (b)(2)(i) and coordination with services provided outside of the MCO, PIHP or PAHP, including with another MCO, PIHP, or PAHP in paragraph (b)(2)(ii) and FFS Medicaid in paragraph (b)(2)(iii).

We also noted in the preamble that we believe that managed care plans must ensure that appropriate information is available to, shared with, and maintained by all providers and the MCO, PIHP, or PAHP that is coordinating the care. Therefore, we proposed, under our authority at section 1902(a)(4) of the Act, to add standards in new paragraphs (b)(3) and (b)(5) that each MCO, PIHP and PAHP make their best effort to complete an initial health risk assessment within 90 days of the effective date of enrollment for all new enrollees and that all providers maintain and share an enrollee health record according to MCO, PIHP, or PAHP standards. We also proposed to remove the phrase “with special health care needs” from existing paragraph (b)(3) (proposed to be redesignated at (b)(4)) and change the word “its” to “any” in that same paragraph to broaden the standard for sharing assessment results to avoid duplication of services. The standard of an initial health assessment is explicit in the MA regulations in § 422.112(b)(4)(i), so we believed these changes established consistent standards for MCOs participating in Medicare and Medicaid, thereby easing administrative burden. Finally, in the redesignated paragraph (b)(4) regarding the sharing of the results of an enrollee’s need assessment with another MCO, PIHP, or PAHP that serves the enrollee, we proposed to add the state as a recipient of that information if the state (through FFS) provides coverage of some services to an enrollee, such as behavioral health or pharmacy coverage. In addition, we proposed that existing paragraph (b)(4)

be moved without change to paragraph (b)(6).

We received the following comments in response to our proposal to revise § 438.208(b).

Comment: We received many comments expressing strong support for the proposed revisions in this section. Commenters believed our proposed revisions better reflect the reality of the current managed care environment by acknowledging LTSS and removing the previous focus on medical needs and services. Commenters were particularly supportive of the expanded detail proposed for coordination requirements in § 438.208(b)(2) and health risk assessments in § 438.208(b)(3).

Response: We thank the commenters for their support and agree that the revisions to § 438.208(b), as proposed and finalized, will provide stronger protections and improve the care experience for managed care enrollees across the spectrum of services that may be covered under the contract.

Comment: We received a few comments recommending that CMS remove its proposed revisions to § 438.208 and leave coordination and continuity to the states’ discretion. Another commenter stated that the proposed provisions should be less prescriptive to permit greater state flexibility.

Response: Given the changes in Medicaid managed care programs since 42 CFR part 438 was finalized in 2002 and the more complex populations being enrolled, additional specificity in this section is appropriate. We attempted to strike the appropriate balance and believe § 438.208(b), as proposed and finalized here, still leaves ample flexibility to the states.

Comment: We received a few comments on proposed § 438.208(b). Commenters recommended that state and managed care plan coordination policies be made publicly available along with instructions for how enrollees may request coordination services. A few other commenters recommended that states and managed care plans ensure that their subcontractors are also aware of their coordination policies and how to access coordination services for an enrollee. A few commenters suggested that the states should act as a repository for data needed for coordination activities since they have both FFS data and encounter data.

Response: We appreciate the commenters’ recommendation and states are welcome to make their coordination policies publicly available if they so choose. We agree that states and managed care plans should educate

their enrollees and all subcontractors on the process and the contact information for accessing care coordination. This is especially important for providers since they may recognize the need for coordination more quickly than the enrollee. Maintaining a central repository of data is an innovative idea but is likely not feasible in most states without a significant investment of time and resources. We encourage states and plans to collaborate on the feasibility and usefulness of such a database or other tools to facilitate data needs related to care coordination.

Comment: We received comments supporting proposed § 438.208(b)(1) that would require each enrollee receiving care coordination to have a designated person or entity responsible for their care coordination. A few commenters suggested that enrollees be notified of the name and contact information for their designated person or entity.

Response: We agree that enrollees who are assigned a care coordinator should know how to contact the coordinator for questions or issues about their coordination plan. Managed care plans must implement procedures to ensure that this information is provided to enrollees in a timely manner; therefore, we will revise § 438.208(b)(1) to reflect this requirement.

Comment: We received many comments on proposed § 438.208(b)(2). One commenter recommended that if care coordination is not provided or not provided in a person-centered way, the enrollee should be able to request an appeal.

Response: If an enrollee has a concern about the delivery of coordination of care, they should contact their managed care plan and file a grievance. Doing so will not only bring resolution for that enrollee but provide valuable information to the managed care plan alerting it to possible systemic issues. Issues about the quality of care coordination would not be eligible to be appealed as quality issues do not meet the definition of adverse benefit determination. Coordination of care is not itself a separate covered service but a means of how services are assessed and furnished to enrollees.

Comment: We received many comments in response to our request for comment on including an additional standard relating to community or social support services in paragraph § 438.208(b)(2). The commenter suggested that this provision could include linking enrollees to services through organizations such as Protection and Advocacy organizations, Legal Aid, Aging and Disability Resources Centers, Centers for

Independent Living, Area Agencies on Aging, or United Way 311 lines. We received overwhelming support for the proposal to add the additional standard.

Response: We thank the commenters for their support of this proposal. We will finalize an additional provision at § 438.208(b)(2)(iv) that includes services the enrollee receives from community and social support providers.

Comment: Some commenters recommended that behavioral health, substance use disorder, pharmacy, durable medical equipment, and all ancillary services be specifically identified in proposed § 438.208(b)(2). Commenters believed these types of services are frequently overlooked by managed care plans in their care coordination efforts.

Response: We decline to modify the regulation text as recommended here. As proposed and finalized in this rule, § 438.208(b)(2)(i) through (iv) addresses services received by the enrollee in all settings of care and from, another MCO, PIHP, PAHP, or FFS Medicaid, or community and social support providers. These categories are sufficiently broad to capture all of the specific services suggested by commenters.

Comment: We received some comments recommending that § 438.208(b)(2) include specific situations when care coordination may be beneficial. Commenters' recommendations included transitions from managed care to FFS, from or to the Marketplace or private insurance; from or to Medicare; when an enrollee's provider leaves the network; upon release from incarceration, and when significant changes are made to the delivery system. Commenters stated that they believe managed care plans often miss these types of opportunities to provide care coordination.

Response: We appreciate the commenters' recommendations and encourage managed care plans to consider them in the development and implementation of their care coordination policies. However, we decline to revise the regulation text to explicitly refer to these situations.

Comment: One commenter recommended that § 438.208(b)(2) include an exemption for managed care plans that attempt care coordination but cannot complete it due to a needed health or medical record that is not available or provided by the holding entity.

Response: We understand the commenter's concern but believe the inability to obtain a record is a common occurrence and managed care plans should train staff on appropriate steps to

take to address it. We decline to revise § 438.208(b)(2) to provide such an exemption.

Comment: We received many comments on the initial health risk assessment of enrollee needs proposed in § 438.208(b)(3). The most common comment was that use of "assessment" in this paragraph seemed inconsistent with the way the term was used in § 438.208(c)(2). Commenters suggested that requirement in § 438.208(b)(3) be called a "health risk screening" to avoid confusion. The commenters believed that term more accurately reflected CMS' intention. A few commenters appeared to interpret this provision as requiring a visit with a primary care provider. We also received a few comments that states should act as a repository for all of the data collected and forward the data to the appropriate managed care plan(s) upon enrollment. Commenters believed having the state be responsible for sharing the data among plans would make the process much easier and consistent given that all contracted managed care plans already have data sharing agreements and interfaces established with the state.

Response: We thank the commenters for their suggestions and agree that proposed § 438.208(b)(3) was unclear given our use of "assessment" in § 438.208(c)(2). We agree that "screening" better describes our intended meaning and have made this change in the final rule. We take this opportunity to clarify that our intent in § 438.208(b)(3) was for the managed care plan to administer a survey type instrument to gather health needs related information from each enrollee, not to have enrollees receive a PCP visit within the initial 90 days.

We appreciate the suggestion that the state act as a repository for all of the data collected and assume responsibility for facilitating sharing of the data but decline to include that in the final rule. States are not prohibited from taking that approach but we do not believe it should be a requirement. We are finalizing § 438.208(b)(3) to reflect "screening," as well as rearranging some of the text for better grammatical flow.

Comment: A few commenters recommended that CMS design the tool to be used in § 438.208(b)(3) to facilitate consistency. One commenter requested clarification as to whether this task could be contracted to an outside entity. One commenter recommended that CMS establish measureable goals to assess the completion rate within the required time frame. One commenter recommended that the assessment proposed in § 438.208(b)(3) be required to be completed through a home visit.

Response: We understand the commenter's concern about consistency but decline to produce the tool to be used in § 438.208(b)(3). We believe states should have flexibility for this given the differences in program design, covered populations, and benefits. In response to the question of subcontracting this function to another entity, we clarify that there is no prohibition on delegating this task but remind managed care plans that any subcontracting agreement must meet the requirements of § 438.230, including adequate provisions for protected and timely data sharing. While we agree that establishing completion goals and measuring against them is an effective monitoring tool, we decline to set such standards. The states are better positioned to develop and implement such criteria. Home visits are an option available to managed care plans, or their designee, but we leave this approach as an option for states and decline to include it as a requirement.

Comment: Many commenters sought clarification on our use of "best effort" in proposed § 438.208(b)(3) for completion of the health risk screening. Some commenters believed it was too vague and that managed care plans should be required to complete the assessment. A few commenters recommended that CMS define "best effort" by specifying the number and type of attempts that must be made by the plan. One commenter suggested removing "including subsequent attempts." A few commenters suggested that enrollees be required to cooperate in completing these assessments while other commenters believed that states need to provide more accurate contact information for enrollees.

Response: We understand the commenters' concerns about the flexibility in the proposed "best effort" standard and the challenges inherent in contacting enrollees. However, it is the challenges in contacting enrollees and obtaining their cooperation to complete the screening that makes the flexibility of a "best effort" standard necessary. We believe that managed care plans and states understand the value of the information obtained during these early screenings and will make appropriate efforts to complete them. We do not believe mandating specific number and/or type of attempts would make the requirement more productive, given the wide range of issues that managed care plans encounter when trying to complete the screening. We also acknowledge that maintaining accurate contact information has its challenges, but are hopeful that the flexibility provided elsewhere in this final rule for

the use of electronic communication and to subcontract the health risk screening will reduce these issues. We understand that completing an initial health risk screening is not without its challenges and, therefore, believe that the flexibility permitted in the provision strikes an appropriate balance.

Comment: We received some comments on the 90 day time frame for completion of the health risk screening proposed in § 438.208(b)(3). Commenters offered suggestions ranging from 30 days to 120 days while some recommended an exemption for times when there are large influxes of enrollees in a short period of time. Some commenters recommended that enrollees be prioritized based on known risks with those screenings done sooner. Others recommended that screenings only be completed on known high-risk enrollees while others suggested that screenings not be required for enrollees that would be getting an assessment under the provisions proposed in § 438.208(b).

Response: While we understand commenters' statements that having the information from the screening sooner will benefit the enrollee and managed care plan, we believe the requirement must include a reasonable time frame for completing the screenings. As discussed in the response to other comments, there are challenges to completing these screenings. Given these challenges, we believe that it may not be feasible for a managed care plan to complete the process in 30 days. Similarly, we believe that extending the time frame could erode the benefits completing the screening and acting on the information. We believe 90 days is an appropriate timeframe and strikes a balance between these competing concerns. We understand that when there is a large influx of enrollees at once or in a short period of time, even 90 days may not be sufficient. We believe that "best effort" provides flexibility for unusual circumstances and encourage managed care plans to continue outreach to new enrollees to attempt completion even if the 90 day period has ended.

For the commenters that suggested prioritizing enrollees and excluding those being assessed under § 438.208(c), we are unclear on what information the managed care plan would use to determine that a new enrollee is high risk or would be eligible for the assessment in § 438.208(c). Managed care plans may be able to identify some of these types of enrollees (perhaps through eligibility codes), but it does not appear that the information necessary to accurately determine high

risk enrollees or those in need of LTSS or with special health care needs would be consistently or reliably available at the time of enrollment. We do not believe it is appropriate to completely exclude enrollees from the health risk screening simply based on their eligibility for an assessment in § 438.208(c). While we are not expressly prohibiting prioritization for the health risk screening, we urge plans to be careful in its application and to ensure that resources are appropriately utilized to attempt screening completion for all enrollees within the specified timeframe.

Comment: A few commenters requested that CMS clarify that a plan's inability to reach an enrollee to complete the health risk screening or the enrollee's refusal to participate in the health risk screening cannot be used as grounds for disenrollment or reduced benefits. Another commenter recommended that managed care plans use community resources when they are having difficulty contacting an enrollee as these resources often have other information or in person resources available. The commenter believes this is particularly useful for homeless enrollees or those with behavioral health or substance use disorders.

Response: We understand the commenters' concern and take this opportunity to remind states and managed care plans that the inability to reach an enrollee to complete the screening or if the enrollee will not participate in the screening cannot be used as grounds for disenrollment, reduced benefits, or any other negative or punitive action by the state or managed care plan. Disenrollments requested by the managed care plan are regulated at § 438.56, finalized elsewhere in this rule. We agree with the commenter's suggestion to use community resources, when appropriate, to assist with hard to reach enrollees. We encourage plans to consider whether utilizing community resources would be helpful as drawing on such resources would support the "best effort" standard set forth § 438.208(b)(3).

Comment: We received a few comments recommending that all screening tools used to comply with proposed § 438.208(b)(3) contain elements addressing social determinants of health. The commenters believed these elements can provide valuable information that would provide the managed care plan with a more comprehensive and accurate profile of the enrollee's needs.

Response: We encourage managed care plans to include elements

addressing social determinants of health in their health risk screening tool as they deem appropriate but decline to specify that such elements must be included as part of the health risk screening to satisfy federal requirements.

Comment: We received some comments on proposed § 438.208(b)(5) regarding the sharing of health records. One commenter asked CMS to clarify the meaning of "health record." Several commenters requested that CMS specifically identify which providers and how much of the health record was intended in this proposed provision. One commenter recommended that providers be required to share health records with the state and managed care plan. Lastly, a few commenters expressed concern that compliance with this provision is hampered by stringent confidentiality laws and the number of providers that do not utilize electronic health records.

Response: We proposed the term "health record" as opposed to "medical record" to recognize the inclusion of services not traditionally considered medical in nature, such as LTSS. Although we are not defining the term, in general, a health record is any information that relates to the past, present, or future physical health, mental health or condition of an individual or the past, present, or future provision of services to an individual. As to specifically defining which providers and the quantity of information to share, we believe managed care plans have extensive experience in this area and are capable of using their judgment and clinical expertise to determine how much and with whom they share all or part of the health record. While we understand the challenges of obtaining health records, placing requirements directly on service providers is outside the scope of this rule. For providers in FFS or managed care networks, access to health records should be addressed in the provider's agreement. Lastly, we understand that the use of electronic health records is not consistent across the health care industry. Managed care plans will have to use whatever methods they find necessary to successfully and securely exchange information with providers. We also acknowledge the complex laws and regulations on privacy and data sharing and the impact they have on compliance with requirements to share enrollee information. We expect states and managed care plans to comply with all applicable laws and regulations.

After consideration of the public comments we are finalizing paragraph (b) of § 438.208 with modifications. In

§ 438.208(b)(1), we are finalizing new text to require that enrollees be provided the contact information for their care coordinator; in § 438.208(b)(2)(iv), we are adding text to require coordination with community and social support providers; and in § 438.208(b)(3), we are changing “assessment” to “screening” and revising the sentence for better grammatical flow. We will also finalize punctuation and grammatical changes to the various subparagraphs in paragraph (b) to preserve readability and clarity.

(4) Long-Term Services and Supports (§ 438.208(c))

As we stated in the preamble to the proposed rule, the current Medicaid managed care regulations were written at a time when a managed care delivery system was not frequently utilized for LTSS. With states using managed care to deliver covered services to populations with more complex needs, care coordination that is appropriate for individuals using LTSS becomes an important component of managed care.

We proposed changes in paragraph (c)(1) of § 438.208 to add enrollees who need LTSS to the populations for which the state must have mechanisms to identify these enrollees to the MCO, PIHP, or PAHP. We proposed a change to paragraph (c)(1)(i) to reflect that the mechanisms required in paragraph (c)(1) must be included in the state’s comprehensive quality strategy as defined in proposed § 438.340. We also proposed that states may use their staff, their enrollment brokers, and the MCOs, PIHPs, and PAHPs as part of these identification mechanisms. There were no changes proposed to paragraph (c)(1)(ii). Other changes we proposed to paragraph (c) included:

- Amending paragraph (c)(2) so that assessments for both individuals in need of LTSS as well as those with special health care needs are comprehensive and are conducted by appropriate providers or LTSS service coordinators having qualifications specified by the state or the MCO, PIHP, or PAHP. We believe this to be a critical standard to avoid insufficient service or treatment plans or a disruption in services to enrollees.

- Amending paragraph (c)(3) to clarify that treatment plans would also be considered service plans and that they are developed for individuals needing LTSS in addition to individuals with special health care needs.

- Amending paragraph (c)(3)(i) to propose that treatment or service plans are developed by an individual meeting the managed care plan or state’s service coordination provider standards in

consultation with other providers caring for the enrollee. This change was intended to permit a MCO, PIHP, or PAHP to use internal staff for service coordination, even though those staff would not be considered providers and, thus, not permitted to perform assessments under current regulation.

- Adding new standards under paragraphs (c)(3)(ii) to require that treatment or service plans developed for those in need of LTSS conform with the person centered planning standards found in § 441.301(c)(1) and (2). This proposal is consistent with the HCBS final rule released in 2014 (CMS–2249 and CMS–2296).

- Redesignating current paragraphs (c)(3)(ii) and (iii) without change as paragraphs (c)(3)(iii) and (iv). Proposed a new standard under paragraph (c)(3)(v) that service and treatment plans be reviewed and revised upon reassessment of the enrollee’s functional needs, at least every 12 months, when the enrollee’s circumstances or needs change significantly, or at the request of the enrollee.

No changes were proposed for paragraph (c)(4).

We received the following comments in response to our proposal to revise § 438.208(c).

Comment: We received several comments supporting proposed § 438.208(c)(1) requiring states to identify enrollees who need LTSS or have special health care needs. Many commenters suggested that CMS should use greater specificity in the definition of person with special health care needs, including adding a provision to specify that special health care needs includes children, children with SED, and adults with SMI or SUD. One commenter stated that, in identifying those with special health care needs, some enrollees may not have higher costs, but merely need more care coordination.

Response: We thank the commenters for their support of the provision requiring states to identify enrollees who need LTSS or special health care needs. We believe there is merit in leaving the definition of special health care needs in proposed § 438.208(c)(1) to the discretion of the states and decline to modify the regulation to specify the scope of special health care needs. There is no universal definition of special health care needs, and attempting to define it in the regulation could result in the inadvertent exclusion of some populations that a state may consider as having special health care needs. We believe that leaving special health care needs undefined allows states to tailor their

systems to reflect the particular needs of their populations and increase the likelihood of covering the largest number of people who need the additional protections that the provisions in this section offer.

Comment: One commenter expressed concern about the identification of enrollees with special health care needs after enrollment, and stated that the regulation should specify the actor responsible for identifying these enrollees.

Response: We agree with the commenter that the identification of enrollees with special health care needs should not just occur at the point of enrollment. Although the state’s identification would occur at the time of enrollment, § 438.208(c)(1)(ii) allows for the state to subcontract the identification of individuals with special health care needs to the managed care plans. The regulation at § 438.208(c)(1) does not specify that the identification of enrollees with special health care needs should only occur at the time of enrollment and we expects that states and managed care plans will have ongoing mechanisms to identify these individuals as their needs change throughout their period of eligibility. We decline to modify § 438.208(c)(1).

Comment: One commenter recommended that CMS remove “comprehensively assess each Medicaid enrollee . . . as needing LTSS . . .” in § 438.208(c)(2) and limit the requirement to assessing just the need for LTSS. The commenter believed states should be permitted to define the type and frequency of care coordination for their MLTSS enrollees since care coordination standards vary among states. However, a number of other commenters stated that there should be greater specificity from CMS. Several commenters recommended that CMS should develop a uniform assessment tool, along with guidelines and processes to be used across all states. These commenters clarified that a uniform tool would facilitate the collection of high quality data, as well as improve service delivery. Several other commenters stated that CMS should require that such standardized assessment tools be developed with input from community-based LTSS providers.

Response: We believe that the requirement in the regulation to comprehensively assess enrollees who need LTSS is an essential protection, and should not be revised or narrowed. We recognize that care coordination protocols vary because of the diversity in the design, benefits, and populations covered in Medicaid and LTSS

programs. However, we believe that a comprehensive assessment is appropriate and that the enrollee, providers and managed care plan benefit when an individual's total care needs are known and coordinated. We decline to remove or revise "comprehensively" in § 438.208(c)(2).

We supports states' efforts in the development of standardized assessment instruments and processes; however, we decline to require a uniform assessment tool or establish criteria for such a tool in this regulation.

Comment: Several commenters provided specific recommendations for the content of the assessments in proposed § 438.208(c)(2). Several commenters believed that the assessment should include both medical and non-medical/functional needs as well as the need for housing, while another commenter stated that the assessment should include the need for occupational therapy. Several commenters recommended that the assessment should address the needs of children aging out of the pediatric medical system into the adult system to assist families in managing their child's ongoing health needs. Another commenter stated that the assessment should be comprehensive enough to capture both physical and behavioral health needs, as well as the needs of those with cognitive disabilities. A commenter suggested that the assessment only apply to enrollees in need of LTSS.

Response: We appreciate the suggestions on the content of the assessment but decline to specify such content in the final rule. We believe the word "comprehensively" in proposed § 438.208(c)(2) is sufficient to describe our expectations for states and managed care plans regarding the content of such assessments. We do not agree with commenters who requested that the requirement (which exists in current § 438.208(c)(2) for special health care needs enrollees) only apply to enrollees in need of LTSS. The purpose of the assessment is to determine the appropriate course of treatment or regular care monitoring for enrollees with special health care needs, as defined by the state, and for enrollees in need of LTSS. A comprehensive assessment could include criteria such as physical health, behavioral health, and non-medical needs, the needs of those transitioning between provider specialties (for example, pediatric to adult medicine), and ancillary services. While these may be relevant criteria for consideration, the scope of the assessment should reflect the state's definition of enrollees with special

health care needs and the nature of the enrolled population that require LTSS.

Comment: Some commenters suggested that the assessment should address caregiver needs along with their capacity to do so and their need for training prior to delivering care. Several commenters noted that this would be consistent with language at § 441.720(a)(4) that provides "if unpaid caregivers are required to implement any elements of the person-centered service plan, a caregiver assessment (must be conducted)".

Response: We agree that ascertaining caregiver capacity before including their services in a treatment or service plan is important to ensure that the enrollee's needs can be met; however we believe that requiring a caregiver assessment is outside the scope of this regulation and inconsistent with the principle of allowing states utilizing managed care to develop their own assessment standards.

Comment: We received a number of comments on proposed § 438.208(c)(2) regarding the use of appropriate health care professionals or individuals meeting LTSS service coordination requirements set by the state or the managed care plan to conduct the assessment. Some commenters supported the provision as written; however, a number of commenters stated that having the MCO, PIHP or PAHP or their employees conduct the assessment represented a conflict of interest, and recommended that proposed § 438.208(c)(2) be revised to reflect that the assessment should be independent of the managed care plan and not conducted by managed care plan staff. A commenter noted that assessments often are used by managed care plans as a tool to limit services or establish enrollee budgets. Further, several commenters noted that the assessment should be fully 'conflict-free', and that the person conducting the assessment be neither a managed care plan employee nor a provider of services. Finally, one commenter referenced language in CMS 2013 MLTSS Guidance that prohibited managed care plan involvement in functional assessments used for eligibility determinations, and asked CMS to clarify how that was different from the assessment in proposed § 438.208(c)(2).

Response: We do not agree that MCOs, PIHPs, and PAHPs should be prohibited from conducting assessments on their own enrollees. In fact, such assessments are a critical component of care management systems that managed care plans rely on to monitor the health needs and outcomes of their enrollees.

States have the flexibility to contract with an independent assessment entity but such arrangements are not required under this regulation. Additionally, while we agree that assessments are often used by managed care plans to establish the medical necessity for services, the same is true of home and community based providers in FFS, where assessments often determine the need for services as well as the budget.

We appreciate the opportunity to clarify how the assessment referenced in the 2013 MLTSS Guidance is different than the assessment proposed in § 428.208(c)(2). The 2013 MLTSS Guidance prohibited managed care plan involvement in functional assessments conducted prior to enrollment for the purpose of determining initial eligibility for services. The assessments in § 428.208(c)(2) are conducted by managed care plans after enrollment and are assessments of their own enrollees. We do not perceive the same conflict of interest in having MCOs, PIHPs and PAHPs assess individuals already enrolled in their plans to determine the appropriate care to be provided by the plan.

Comment: Several commenters stated that CMS should require that those who conduct assessments have specific training and extensive experience with LTSS, and that they include specific professionals, such as registered nurses, social workers, behavioral health counselors, community health workers, and other similarly credentialed professionals. One commenter suggested that CMS modify the language in § 428.208(c)(2) to clarify that a state can use an enrollment broker for both the identification and assessment functions.

Response: We do not believe additional specificity regarding the credentials of persons that can conduct assessments is warranted since it is the responsibility of the state to develop the standards. However, we restate that § 438.208(c)(2) requires that the assessment process use appropriate provider or individuals meeting LTSS service coordination requirements. We are also correcting the regulation text at § 438.208(c)(2) to use "provider" in place of the proposed use of "health care professional" for reasons discussed in section I.B.9.a. of this final rule.

Comment: One commenter expressed concern for the cost of conducting assessments and stated that rates should consider the cost of training assessors to properly administer an assessment tool.

Response: We agree that the cost of conducting assessments and training assessors is a legitimate administrative cost for the non-benefit component of

the capitation rate for plans with these responsibilities.

Comment: Several commenters recommended that systems be in place to protect those who are assessed incorrectly and are in danger of losing services. A few commenters stated that CMS should create adequate appeal mechanisms that apply to the assessment process.

Response: We believe that adequate safeguards already exist at 42 CFR part 438, subpart F for appeals where the assessment results in a reduction or denial of services, or a grievance when the enrollee believes that the assessment does not adequately reflect functional need. Therefore, we believe that no change in § 428.208 is necessary.

Comment: The regulation at § 438.208(c)(3) requires MCOs, PIHPs and PAHPs to develop treatment or service plans, if the state requires it, for enrollees who require LTSS or those with special health care needs who are determined through the assessment to need a course of treatment or regular care monitoring. A number of commenters stated that this requirement should be mandatory, not optional. Other commenters believed that it should be mandatory for all MCOs, PIHPs and PAHPs, not based on whether the state requires it only for those who require LTSS. Another commenter stated that limiting the scope to only those identified by the state potentially excludes those with complex care needs.

Response: We agree with commenters that treatment or service plans are critical for those needing LTSS and may be appropriate for individuals with special health care needs. Requiring treatment or service plans for individuals needing LTSS is also consistent with the preamble discussion at 80 FR 31143. Therefore, we are finalizing § 438.208(c)(3) to reflect that treatment or service plans are required for enrollees using LTSS but at the state's discretion for individuals with special health care needs. We are also adding text to clarify that treatment/service plans for enrollees using LTSS must meet paragraphs (b)(i) through (v), while treatment/service plans for enrollees with special health care needs must meet paragraphs (b)(iii) through (v).

Comment: Several commenters stated that the use of the terms 'treatment' and 'service' plans in proposed § 438.208(c)(3) was confusing. One stated that the term 'service plan' or 'care plan' should be used exclusively instead. Another stated that the word 'treatment' applied to the overall health

of the individual and the term 'care plan' made more sense.

Response: In using both terms in proposed § 438.208(c)(3), we intended to incorporate the terminology most widely used for individuals needing LTSS or those with special health care needs. In reality, there may be other terms in use as well, particularly in programs that focus on specific populations. To list them all in the regulation would be not be feasible or appropriate. Further, while some treatment/service plans are clearly related to 'treatment', for example for those with complex or rare medical conditions, in other cases or for some populations the word 'care' or 'treatment' is objectionable, as it implies a medical model that may not be applicable for those needing long term support to live independently. For that reason, we believe it is appropriate to use both terms, and decline to revise § 438.208(c)(3) as recommended by the commenter.

Comment: We received a number of comments stating that the MCO, PIHP or PAHP should not develop the treatment or service plan proposed in § 438.208(c)(3)(i), as that would present a conflict of interest. Several commenters recommended adding the word 'independent' to the text describing the individual developing the treatment or service plan. We also received a comment stating that § 438.208(c)(3)(i) should not provide that the treatment/service plan be developed by the enrollee's provider as that does not comply with § 441.301(c)(1)(vi).

Response: The language in § 438.208(c)(3)(i) is intended to address a wide variety of situations for individuals with needs ranging from medical conditions that require additional monitoring to those with extensive support needs, such as LTSS. We believe that managed care plans appreciate the importance of complete and thorough treatment/service plans and states have sufficient experience to ensure that appropriate levels of oversight and review are in place to evaluate compliance with the requirements in § 438.208(c)(3)(i). Therefore, we decline to require that the treatment or service plan be developed independently of the MCO, PIHP or PAHP.

We agree with the last comment that, as drafted, the reference to the enrollee's provider in proposed § 438.208(c)(3)(i) was inconsistent with the regulation governing home and community based services generally in § 441.301. To correct this, we are finalizing paragraph (c)(3)(i) without the text "the enrollee's

provider;" we rely on the reference to § 441.301(c)(1) in § 438.208(c)(3)(ii) to address a provider's level of involvement. As a conforming change, we are finalizing (c)(3)(i) without "other" in the phrase "in consultation with any. . . ."

Comment: Some commenters stated that the individual and his or her caregiver should be able to choose who develops the treatment or service plan, including the individual him/herself.

Response: Section § 438.208(c)(3) provides that the MCO, PIHP, or PAHP produce a treatment or service plan. Paragraph (c)(3)(ii) provides that the process for developing the treatment or service plan is conducted in a person-centered manner consistent with § 441.301(c)(1) and (2), which requires that the person-centered planning process will be led by the individual where possible. We do not believe that modification to the regulatory text is necessary.

Comment: One commenter recommended that the person conducting the treatment or service plan should be licensed and credentialed; another recommended that the person should have expertise in the enrollee's special condition, and several stated that it is critical that someone who is involved in caring for the individual is also involved in the development of the treatment or service plan. One commenter suggested that the person creating the treatment or service plan should have training in the person-centered planning process. Another commenter asked if existing MCO, PIHP or PAHP staff would be grandfathered in and asked CMS to clarify who was responsible to pay the costs to train them in person-centered planning and if it was a Medicaid reimbursable cost.

Response: Regarding the credentials of those developing the treatment or service plans, § 438.208(c)(3)(ii) provides that it be developed by a person trained in person-centered planning using a person-centered process as defined in § 441.301(c)(1) and (2). We believe it is unnecessary to provide greater specificity in § 438.208(c)(3)(ii) about the credentials or training of the person developing the treatment or service plan. Training staff on the person-centered planning process is a legitimate administrative cost for the non-benefit component of the capitation rate for plans with these responsibilities.

Comment: We received a few comments regarding person centered planning requirements. One commenter thought the requirement would limit the ability of managed care plans to conduct utilization management. Another

commenter thought service providers should do the person-centered planning, and not the managed care plans. Finally a commenter thought the regulation should specify a requirement for person-centered care.

Response: We believe that person-centered planning is the foundation of effective long term services and supports. Because LTSS support an individual to engage in their daily life activities, the enrollee should be the leader in identifying key goals and desired outcomes of the service plan. This does not mean that an enrollee automatically is, or should be, approved for every requested service and support; rather, that the enrollee's goals are the basis for the types of services and supports approved. The managed care plans must apply the criteria set forth by the state for approval or denial of services as noted in § 438.208(c)(3)(iv). Service planning functions rest with the enrollee and the managed care plan, or other entity the state designates as is outlined in § 438.208 and must be implemented consistent with in § 441.301(c)(1–2).

Comment: The regulation at § 438.208(c)(3)(ii) requires that treatment or service plans are developed using the process and plan as defined in § 441.301(c)(1) and (2) for LTSS treatment or service plans. Several commenters supported this proposed provision, but others believed that greater clarity was needed to reinforce that the process to be used by a managed care plan must be consistent with § 441.301(c)(1) and (2). Another commenter stated that the reference was unnecessary and suggested that it be deleted.

Response: We believe it is important that states use the process and plan in § 441.301(c)(1) and (2) for LTSS because the service and treatment plans developed under § 438.208 should also be consistent with standards for a person-centered process. The provisions in § 441.301(c)(1) and (2) include important details about the process and plan that help to ensure thorough and consistent results. We do not believe it is necessary to add additional detail in § 438.208(c)(3)(ii).

Comment: We received a number of comments regarding the content of the treatment or service plan and the various processes and protocols related to it. One commenter suggested that treatment or service plans should be developed from the health risk assessments that are required under § 438.208(b)(3) of this regulation. Another commenter stated that the treatment or service plan should include documentation of referrals to other

providers, and evidence that such referrals were effective. One commenter suggested that the requirements of the 2013 MLTSS guidance should be incorporated in this regulation. Several commenters mentioned the importance of addressing transitions in the treatment or service plan, including for those transitioning from pediatric to adult health care, and those with behavioral health needs. A few commenters stated that the treatment or service plan should describe how LTSS is coordinated with other community services and physical and behavioral health services. One commenter suggested that the enrollee should approve the treatment or service plan. Finally, a commenter suggested that protocols for care coordination be made publicly available and specified in the MCO, PIHP or PAHP contract.

Response: We do not agree that the treatment/service plan required by § 438.208(c)(3) should be developed from the health risk assessment proposed in § 438.208(b)(3). As explained elsewhere in these responses, the health risk assessment is not expected to collect or be based on the same level of detail as the assessment in § 438.208(c)(2), and therefore, would be inappropriate as the sole source of information for the development of a treatment/service plan. We believe that the standards in § 441.301(c)(1) and (2) are sufficient to address referrals, transitions, and coordination with other services and are consistent with the 2013 MLTSS guidance. In regard to the comment about the enrollee approving the treatment or service plan, § 441.301(c)(2)(ix), which is incorporated by reference in § 438.208(c), specifies that the individual provides written informed consent to the treatment or services plan. We believe that no revisions are needed in § 438.208(b)(3).

Comment: One commenter recommended that states and MCOs, PIHPs and PAHPs be required, in the planning process, to address the needs of family caregivers. In particular, they stated that family caregivers should not be included in the treatment or service plan if they have not agreed to provide services; that a family caregiver assessment should be conducted consistent with the section 1915(i) language and that the family caregiver should be directed to supports to help reduce caregiver burden.

Response: We agree that family caregivers are usually a critical component of LTSS, and that, if they are part of the service plan, the caregiver must be capable of, and willing to, provide the services just as any provider

of services. We agree the needs and abilities of the informal network of caregivers supporting individuals are an important component of the treatment or service plan and encourage states to give these issues appropriate consideration. However, we believe this is outside the scope of part 438 and that no revisions are needed to § 438.208(c).

Comment: We received many supportive comments for proposed § 438.208(c)(3)(v) which requires that treatment or service plans be reviewed and revised upon reassessment of functional need, at least every 12 months, or when the enrollee's circumstances or needs change significantly, or at the request of the enrollee per § 441.301(c)(3). We received one comment suggesting this provision only require treatment/service plans to be updated instead every 3 years, since that was less burdensome to providers and plans and more appropriate for enrollees.

Response: We believe that the standards in proposed § 438.208(c)(3)(v) are necessary to ensure that the needs of enrollees with special health care needs or needing LTSS are addressed in a timely manner, and are modified when the enrollee's needs change. We disagree with the 3-year time frame because that period is too long to it would not keep the plan useful and meaningful. We decline to make changes to § 438.208(c)(3)(v).

Comment: One commenter stated that all providers under contract with the managed care plan should be required to follow the treatment or service plan.

Response: It is the responsibility of the MCO, PIHP or PAHP to ensure that its contracted providers are providing care to enrollees in a manner consistent with the enrollee's treatment or service plan, as well as with all applicable standards and protocols of the managed care plan. We believe managed care plans understand this responsibility and do not believe modification to § 438.208(c)(3) is necessary.

Comment: Several commenters supported proposed § 438.208(c)(4) regarding direct access to specialists. One commenter recommended requiring managed care plans to use standing referrals, and stated that a strong care planning system should result in standing referrals for those who need them.

Response: We thank the commenters for their support and will retain the language in § 438.208(c)(4) as proposed with one minor revision. Standing referrals are one approach to ensure direct access to specialists but we decline to specify the exact process for how a managed care plan should meet

its obligations under § 438.208(c)(4). We are finalizing the regulation text at § 438.208(c)(4) to use “network provider” in place of the proposed use of “health care professional” for reasons discussed in section I.B.9.a. of this final rule.

After consideration of the public comments, in § 438.208(c)(2) and (c)(3)(i), we are finalizing a change to “provider” in place of the proposed use of “health care professional” for reasons discussed in section I.B.9.a. of this final rule; in § 438.208(c)(3), we are finalizing the provision to clarify the populations for which treatment/service plans are required and added “;” and “and” as appropriate between (3)(i) through (v); in § 438.208(c)(3)(i), we are removing “enrollee’s provider;” and “other;” and in § 438.208(c)(4), we revised “health care professional” to “network provider” for accuracy of intent.

f. Advancing Health Information Exchange

As explained in the preamble to the proposed rule, health information technology (health IT) and the electronic exchange of health information are important tools for achieving the care coordination objectives proposed in § 438.62, § 438.208, and other parts of this final rule. The Department supports the principle that all individuals, their families, their healthcare and social service providers, and payers should have consistent and timely access to health information in a standardized format that can be securely exchanged among the patient, providers, and others involved in the individual’s care (HHS August 2013 Statement, “Principles and Strategies for Accelerating Health Information Exchange.”) Further, the Department is committed to accelerating health information exchange (HIE) through the use of health IT across the broader care continuum and across payers. Health IT that facilitates the secure, efficient and effective sharing and use of health-related information when and where it is needed is an important contributor to improving health outcomes, improving health care quality and lowering health care costs. Health IT can help health care providers recommend treatments that are better tailored to an individual’s preferences, genetics, and concurrent treatments. In addition, it can help individuals make better treatment decisions and health-impacting decisions outside of the care delivery system.

On October 6, 2015, the Office of the National Coordinator for Health Information Technology (ONC) published the final “Connecting Health

and Care for the Nation: A Shared Nationwide Interoperability Roadmap” (available at <https://www.healthit.gov/sites/default/files/nationwide-interoperability-roadmap-version-1.0.pdf>). This final roadmap focuses on how interoperable health IT can enable better health and wellness for all Americans, regardless of where they live, learn, work and play.

In addition, ONC released the final version of the “2016 Interoperability Standards Advisory” (available at <https://www.healthit.gov/standards-advisory/2016>). This final 2016 Interoperability Standards Advisory is focused on clinical health IT interoperability and is published at <https://www.healthit.gov/sites/default/files/2016-interoperability-standards-advisory-final-508.pdf>. Updates to the final 2016 advisory’s substance and structure reflect input obtained from the public at large throughout 2015 and the HIT Standards Committee. This final document contains a list of the best available standards and implementation specifications to enable priority HIE functions. Providers, payers, and vendors are encouraged to take these “best available standards” into account as they implement interoperable HIE across the continuum of care, including care settings such as behavioral health, long-term and post-acute care, and community service providers (for example, home and community-based service providers).

In the proposed rule, we encouraged states, MCOs, PIHPs, PAHPs, PCCMs, PCCM entities, and other stakeholders to utilize HIE and certified health IT to effectively and efficiently help providers improve internal care delivery practices, support management of care across the continuum, enable the reporting of electronically specified clinical quality measures (eCQMs), and improve efficiencies and reduce unnecessary costs. We welcomed comment on how we might reinforce standards through future rulemaking or guidance to states and plans as standards become more mature and adoption of certified health IT increases.

We received the following comments in response to this discussion.

Comment: Many commenters supported the preamble discussion in the proposed rule at 80 FR 31141 regarding health information exchange. A few commenters recommended that CMS broaden the HITECH Act to include additional provider types to facilitate greater health information exchange. A few commenters also recommended that CMS modify the electronic health record (EHR) Incentive Programs.

Response: We do not have the statutory authority to broaden the HITECH Act to include additional incentives for provider types nor do we have the statutory authority to modify the EHR Incentive Programs.

Comment: Many commenters recommended that CMS include HIE adoption standards and requirements within states’ managed care contracts. One commenter recommended that CMS require states’ managed care contracts to leverage ONC certification. Several commenters recommended that CMS permit a 90/10 federal match for HIE activities within states’ managed care contracts. Several commenters recommended that CMS allow expenditures for EHRs and HIE activities within states’ managed care contracts. One commenter recommended that CMS require states to develop plans within their managed care contracts to address connectivity to the broader health information system, especially for LTSS providers.

Response: Consistent with our discussion in the proposed rule at 80 FR 31124 and regarding § 438.6(c)(1)(ii), states have the flexibility to require managed care plan participation in broad-ranging delivery system reform or performance improvement initiatives, such as broad-based provider health information exchange projects. Broad-based provider HIE projects were provided only as an example; we do not believe it is appropriate for us to require or mandate this option, as states may have various options or paths to increase EHR and HIE adoption outside of their managed care contracts. If a state incorporated such a project in the managed care contract, the regular federal match applied to actuarially sound capitation payments would apply. Finally, any delivery system or provider payment initiative pursued under the managed care contract would be subject to a federal review and approval process as specified in § 438.6(c)(2).

Comment: Several commenters recommended that CMS consider sub-regulatory guidance after the final rule is published to address health information exchange. A few commenters recommended that CMS release guidance to encourage a uniform national standard for all HIE activities, including uniform standards for all state and public health agencies. A few commenters recommended that CMS convene a stakeholder group to inform states and future HIE development activities. A few commenters recommended that CMS and ONC partner to provide state resources, tools, and guidance to assist providers in

better understanding the technical requirements for certified EHR technology (CEHRT). One commenter recommended that CMS release guidance that is consistent with ONC's Interoperability Roadmap and the draft Interoperability Standards Advisory. Finally, one commenter recommended that CMS release guidance on the use of clinical decision support (CDS) and appropriate use criteria (AUC) to assist states and providers achieve health IT goals and improve quality.

Response: We appreciate commenters' concerns and recommendations regarding additional CMS guidance related to HIE. As discussed in the preamble of the proposed rule at 80 FR 31141, we believe that health information technology and the electronic exchange of health information are important tools for achieving improved population health. We agree with commenters that CMS, the Department, and ONC should continue to convene stakeholders, partner together, and support and release guidance consistent with the Interoperability Roadmap and ONC's annual Interoperability Standards Advisories.

As this section of the preamble provided a discussion of ONC's Interoperability Roadmap and Interoperability Standards Advisory and did not result in regulation, there is no regulatory section to finalize in this rule.

g. Managed Long-Term Services and Supports (§§ 438.2, 438.3, 438.70, 438.71, 438.214, 438.330, 438.816)

Managed long term services and supports (MLTSS) refers to an arrangement between state Medicaid programs and MCOs, PIHPs or PAHPs through which the MCO, PIHP, or PAHP receives a capitated payment for providing long-term services and supports (LTSS). MLTSS programs have grown significantly over the past decade and are expected to increase even more in the coming years. Recognizing this significant shift in delivery system design, we developed ten key principles inherent in a strong MLTSS program. These principles were released on May 21, 2013, in guidance¹⁰ for states using a section 1915(b) waiver or section 1115(a) demonstration to implement a MLTSS program. We proposed in this rule to revise the Medicaid managed care regulations to ensure that all MLTSS programs, regardless of underlying authority, operate in

accordance with these elements. Our proposal for amendments throughout part 438 incorporated and reflected these elements; proposals and regulations specific to MLTSS were discussed in the proposed rule in section I.B.5. Some of the changes we proposed—while prompted by MLTSS considerations—applied broadly to all beneficiaries, and so have been applied to all managed care programs.

(1) Defining Long-Term Services and Supports

We proposed to add a definition of Long-term services and supports (LTSS) to § 438.2 for purposes of applying the rules in part 438 of this chapter; however, the definition will not be applicable to any other part of title 42 of the CFR. Our proposal defined LTSS as “services and supports provided to beneficiaries of all ages who have functional limitations and/or chronic illnesses that have the primary purpose of supporting the ability of the beneficiary to live or work in the setting of their choice, which may include the individual's home, a provider-owned or controlled residential setting, a nursing facility, or other institutional setting.” We intended for community based services within the scope of this definition to be largely non-medical in nature and focused on functionally supporting people living in the community. Examples of what we would consider community based LTSS include Home- and Community-Based Services (HCBS) delivered through a section 1915(c) waiver, section 1915(i), or section 1915(k) state plan amendments, as well as personal care services otherwise authorized under the state plan. We note that individuals with chronic illness that may receive LTSS include individuals with mental health conditions and substance use disorders.

We noted that we considered defining LTSS in a way that references specific services in title 42 such as HCBS and Nursing Facility services (defined in part 440), but determined that would be too limiting and not allow for future innovation in what services are considered LTSS. We requested comment on the proposed definition and whether it is appropriate in scope.

We received the following comments in response to our proposal to add a definition of long-term services and supports to § 438.2.

Comment: Several commenters believed the definition for LTSS as proposed in § 438.2 was satisfactory. However, the majority of commenters wrote that one or more of the definitional elements should be

modified. One writer stated that there should be no definition given at all. A number of commenters suggested that the definition as proposed is too broad and would thus obligate states to broaden their LTSS coverage. A couple of commenters said that the definition should be based on a nursing facility level of care, while another suggested limiting the definition to requirements under section 1902(a) of the Act.

Response: We clarify that the definition in this section is not intended to describe minimum service requirements for LTSS in states; rather, it defines the scope of supports and settings that would be covered by the regulatory requirements for managed LTSS programs. Managed care enrollees who have a functional limitation or chronic illness and receive any service that falls within the LTSS definition will be expected to have available a beneficiary support system and the other protections defined in this regulation for people using managed LTSS. The actual LTSS available to a beneficiary continues to be defined by the state in applications to CMS and the contracts with managed care plans. Because most states have LTSS programs that have less stringent and/or different criteria than nursing facility level of care and include a more expansive scope than section 1902(a) services, we believe such modifications to the definition to limit it based on those parameters would be too restrictive.

Comment: Many commenters suggested additions or alternatives to the definition of the beneficiary who may be considered to be eligible for LTSS. Most suggested additions to the text “has a functional limitation and/or chronic illness” as proposed in § 438.2. Several commenters recommended the addition of “and family or informal caregivers”, several suggested “or cognitive impairments” be added, a few suggested adding “people with disabilities”, one commenter suggested “physical and behavioral disabilities”, and a few commenters suggested that people with “social determinant challenges” be added. Additionally, one commenter suggested that “chronic illness” be changed to “chronic condition” to more accurately reflect disabilities such as brain injuries that have multiple components.

Response: We thank commenters for so many thoughtful suggestions for the definition of LTSS. We note that the definition of LTSS does not establish eligibility criteria for enrollees to receive LTSS; those eligibility criteria are established in the state plan and related state documents, including the

¹⁰ <http://www.medicaid.gov/medicaid-chip-program-information/by-topics/delivery-systems/downloads/1115-and-1915b-mltss-guidance.pdf>.

contracts with the managed care plan that furnishes or covers LTSS. The reference in the definition of LTSS is to establish the scope of the benefits and services that are LTSS.

Further, in the *International Classification of Functioning, Disability and Health* (2001), the World Health Organization defines functional limitation as any health problem that prevents a person from completing a range of tasks, whether simple or complex, see <http://www.cdc.gov/ncbddd/disabilityandhealth/types.html>. Functional impairment encompasses any type of disability—physical, cognitive, intellectual or behavioral—as is intended in the LTSS definition. We agree that family and caregivers are often inextricably linked to the beneficiaries, but services and supports provided for caregivers are, from the perspective of the Medicaid agency or managed care entity, on behalf of the individual with the functional limitation or chronic illness. Social determinant challenges, while likely to exacerbate the effects of functional limitations or chronic illness, are common amongst Medicaid beneficiaries, not just those using LTSS. As to the comment to change “chronic illnesses” to chronic conditions,” we believe that, in combination with functional impairments, chronic illnesses is more common terminology that may be more descriptive of the health care considerations inherent in a LTSS model. After much careful consideration, we have decided to retain the reference to people receiving MLTSS in the definition of LTSS as beneficiaries of all ages who have functional limitations and/or chronic illnesses.

Comment: Several commenters recommended that CMS change the definition to include how LTSS should be planned and delivered. Specifically, a few commented that CMS should add person-centered planning in the definition, and a few others suggested that the definition should specify the preference by individuals for home and community-based services. One commenter stated that CMS prohibit states from limiting congregate settings in the definition. Additionally several commenters requested that the definition specify that individuals must participate in the community to the fullest extent possible. One commenter wanted CMS to add “as appropriate” to institutional placement.

Response: Person-centered planning is addressed in § 438.208(c)(3)(ii) of the proposed and final rule; this final rule requires the MCO, PIHP, or PAHP to follow the person-centered planning

process found in home and community-based regulations at § 441.301(c)(1) and (2). The home and community-based services (HCBS) page on [Medicaid.gov](http://www.Medicaid.gov) provides detailed information on what this person-centered requirement entails, see <http://www.Medicaid.gov/Medicaid-CHIP-Program-Information/By-Topics/Long-Term-Services-and-Supports/Home-and-Community-Based-Services/Home-and-Community-Based-Services.html>.

Section 438.3(o), as proposed and finalized, also requires the HCBS regulation at § 441.301(c)(4) to be followed for all HCBS settings where the services could be in a sections 1915(c), 1915(i), or 1915(k) of the Act program. The HCBS settings requirements describe how HCBS settings must offer community integration opportunities. Additionally, § 438.3(f)(1), as proposed and finalized, requires all contracts to comply with the ADA, which describes the rights of people with disabilities including institutionalization issues. Because of these provisions, and because the LTSS definition is only intended to describe the scope to which the proposed rule managed LTSS regulations apply (rather than to create the substantive requirements that will apply to the provision of LTSS), we have decided not to adopt these requested changes to the definition.

Comment: Many commenters recommended that CMS include specific services in the LTSS definition. The suggested services recommended by one or two commenters were orthotics, prosthetics, durable medical equipment, services that may prevent disability, medical supports such as medical adult day services and private duty nursing, community activities and supportive housing. Many commenters also suggested that there not be specific services included in the definition because it could serve to limit the scope of what would be considered LTSS. A few commenters suggested that CMS define the duration that services must be needed to qualify as LTSS.

Response: We agree with the commenters who thought adding individual services in the definition could serve to limit the scope of what is covered by the LTSS provisions. We have therefore decided not to amend the LTSS definition to include any specific services. Additionally, because the duration of need to be LTSS is a state decision to be addressed in submissions to CMS and contracts with managed care plans, we decline to include such specificity in the LTSS definition in the final rule.

Comment: The majority of commenters stated that the portion of

the LTSS definition that reads “have the primary purpose of supporting the ability of the beneficiary to live or work in the setting of their choice, which may include the individual’s home, a provider-owned or controlled residential setting, a nursing facility or other institutional setting” is confusing and/or misleading because it implies that the listed settings are the only ones where an individual may work. Many commenters suggested that the settings listed include an individual’s workplace to clarify that a person may work somewhere other than a private home, residential or institutional setting. Another commenter recommended that “shared living” should be added as another setting.

Response: We agree with the commenters who recommended that the settings listed should be expanded to include worksites so there are not unintended misinterpretations on where individuals may be supported to work. However, we believe that shared living arrangements would fall into the category of either a provider owned and controlled setting or an individual’s home in which the individual has some form of tenancy agreement, so we do not agree that shared living as a setting for LTSS needs to be added to the definition. Therefore, we are modifying this section of the LTSS definition to include a worksite in the list of settings where an individual may be supported.

After consideration of the public comments and for reasons outlined above, we are modifying the LTSS definition to state that long term services and supports (LTSS) means services and supports provided to beneficiaries of all ages who have functional limitations and/or chronic illnesses that have the primary purpose of supporting the ability of the beneficiary to live or work in the setting of their choice, which may include the individual’s home, a worksite, a provider-owned or controlled residential setting, a nursing facility, or other institutional setting.

(2) Codifying MLTSS Guidance

The principles in CMS’ May 2013 guidance were developed after extensive review of numerous published findings, interviews with states as to lessons learned in the start-up and implementation of MLTSS programs, and recommendations from our HHS partners and other external stakeholders. The 10 elements identified in our 2013 guidance and used as the basis for our proposed regulation are:

- (1) Adequate Planning.
- (2) Stakeholder Engagement.

(3) Enhanced Provision of Home and Community Based Services.

(4) Alignment of Payment Structures and Goals.

(5) Support for Beneficiaries.

(6) Person-centered Processes.

(7) Comprehensive, Integrated Service Package.

(8) Qualified Providers.

(9) Participant Protections.

(10) Quality.

In the preamble to the proposed rule, we described how we have incorporated these elements into the proposed rule. As noted previously, the elements were incorporated in proposed changes throughout this part, and we reference those sections of this final rule where the associated proposals are further discussed. In this section, we summarize the LTSS specific proposals and finalized regulations in the context of the ten elements of our guidance and explain how, together, they strengthen MLTSS programs. We requested comment on the incorporation of these elements in the proposed rule.

Element 1: Adequate Planning: We believe the most effective MLTSS systems are the result of a thoughtful and deliberative planning process with a clear vision for the program. Thoughtful planning in the development of MLTSS programs helps to ensure a smooth transition for persons with LTSS needs as they transition from FFS to managed care delivery systems. We proposed to incorporate this element in the existing regulatory structure as follows:

- Amending § 438.66 to propose that there is appropriate state monitoring and accountability of the program that includes readiness reviews. While this standard applies broadly to all managed care programs and is discussed in section I.B.6.c. of the proposed rule, LTSS, as a covered service under the contract, would be included in this review to the same extent as all other covered services.

- Amending § 438.10 to propose additional standards for enrollee and potential enrollee materials, including information on transition of care, who to contact for support and other standards for provider directories. The specific proposed changes to § 438.10 are discussed in the Information standards section of the proposed rule in section I.B.6.d. While LTSS is not specifically referenced, states (under § 438.10(e)) and managed care plans (under § 438.10(g) and (h)) would provide information on all covered benefits and provider directory information under our proposal.

Element 2: Stakeholder Engagement: Successful MLTSS programs have

developed a structure for engaging stakeholders regularly in the ongoing monitoring and oversight of the MLTSS program. Educated stakeholders, including beneficiaries, providers, and advocacy groups, inform decisions as to what works and what does not in the managed care system, allowing the state to design systems that are responsive to the needs of stakeholders and to address any implementation issues discovered early in the process. While Medicaid already has a standard for a Medical Care Advisory Committee (MCAC) outlined in § 431.12 and while in some states this forum has proved to be a useful venue for actionable feedback regarding a state's managed care program, we acknowledged that the MCAC in other states may not provide the opportunity to receive meaningful input from MLTSS stakeholders. Our proposed provisions for gathering stakeholder input are discussed in more detail in section I.B.5.h. of this final rule.

Element 3: Provision of Home and Community Based Services: All MLTSS programs must be implemented consistent with the Americans with Disabilities Act (ADA) and the Supreme Court's *Olmstead v. L.C.*, 527 U.S. 581 (1999), decision. Accordingly, we proposed to be codified at § 438.3(o), that all contracts with MCOs, PIHPs, and PAHPs comply with all applicable federal and state laws including the ADA under our current regulations. That proposal and the associated final rule provision is discussed in section I.B.2. of this final rule.

Element 4: Alignment of Payment Structures and Goals: Payment to MCOs, PIHPs, and PAHPs should support the goals of MLTSS programs to improve the health of populations, support the beneficiary's experience of care, support community integration of enrollees, and reduce costs. We incorporated this element into our proposed rule under § 438.66 by proposing that states include MLTSS program elements in the annual program summary report. This proposal and how it is finalized is discussed in section I.B.6.c. of this final rule.

Element 5: Support for Beneficiaries: Support and education, including enrollment and disenrollment assistance and advocacy support services, are critical for all beneficiaries in a MLTSS program. As discussed in more detail in section I.B.5.c of this final rule, we proposed to incorporate this element in § 438.71, which would have states provide a beneficiary support system, including choice counseling services. While applicable to all managed care programs, the proposed changes to

§ 438.71 would provide assistance to those with complex needs, such as those receiving LTSS, who would benefit most from these activities. As proposed in § 438.71, states would incorporate four beneficiary support functions for all individuals using, or expressing a desire to use, LTSS within a managed care program:

- Provide an access point for complaints and concerns pertaining to the MCO, PIHP, PAHP, PCCM, or PCCM entity on the enrollment process, access to services, and other related matters (§ 438.71(e)(1)) (finalized as paragraph (d)(1));
- Educate beneficiaries on the grievance and appeal process, the state fair hearing process, enrollee rights and responsibilities, as well as resources outside of the MCO, PIHP or PAHP (§ 438.71(e)(2)) (finalized as paragraph (d)(2));
- Assist in navigating the grievance and appeal process for MCOs, PIHPs and PAHPs or state fair hearing excluding providing representation (§ 438.71(e)(3)) (finalized as paragraph (d)(3)); and
- Review and oversight of LTSS program data to assist the state Medicaid Agency on identification, remediation, and resolution of systemic issues (§ 438.71(e)(4)) (finalized as paragraph (d)(4)).

We also incorporated this element by proposing and finalizing a new for cause reason for disenrollment for enrollees receiving LTSS in § 438.56(d)(2)(iv), which is discussed in section I.B.5.b. of this final rule. The proposal was based on recognition that provider network changes can have a significant impact on those enrolled in MLTSS programs, since some providers are integral to residential and employment services and supports. Therefore, if the state does not permit participants enrolled in MLTSS to switch managed care plans (or disenroll to FFS), at any time, states should permit MLTSS enrollees to disenroll and switch to another MCO, PIHP, PAHP, or FFS when the termination of a provider from their MLTSS network would result in a disruption in the enrollee's use of that provider. Under this proposal, an enrollee would be permitted to change their MCO, PIHP, or PAHP if their residential, institutional, or employment supports provider terminates their participation with the enrollee's current MCO, PIHP, or PAHP.

Finally, as discussed at I.B.5.c., we proposed and finalized a new § 438.816 that would describe the conditions that must be met for the state to claim FFP for the LTSS-specific beneficiary support system activities proposed in

§ 438.71(e) (and finalized as paragraph (d)). We modeled this standard, in part, on current rules for administrative services claiming and, in part, on the current rules for enrollment broker services. We proposed, consistent with our current policy, that beneficiary support services for MLTSS enrollees be eligible for administrative match subject to certain standards. Specifically, in paragraph (a), we proposed that costs must be supported by an allocation methodology that appears in the state's Public Assistance Cost Allocation Plan; in paragraph (b) that the costs do not duplicate payment for activities that are already being offered or should be provided by other entities or paid by other programs; in paragraph (c) that the person or entity providing the service must meet independence and conflict of interest provisions applicable to enrollment brokers in § 438.810(b); and in paragraph (d) that the initial contract or agreement for services in this section be reviewed and approved by CMS.

We noted in the preamble of the proposed rule that the proposed scope of services for LTSS beneficiary supports may include what has been traditionally considered "ombudsman" services; however, rules concerning Medicaid-reimbursable expenditures remain in place, so we cautioned that not all ombudsman activities traditionally found in a Long-Term Care Ombudsman office may be eligible for Medicaid payment under this proposal. We issued an informational bulletin on June 18, 2013, entitled "Medicaid Administrative Funding Available for Long-Term Care Ombudsman Expenditures," that provided guidance on this issue. The informational bulletin is available at <http://www.medicaid.gov/Federal-Policy-Guidance/downloads/CIB-06-18-2013.pdf>.

Element 6: Person Centered Process: Ensuring that beneficiaries' medical and non-medical needs are met and that they have the quality of life and level of independence they desire within a MLTSS program starts with person-centered processes including comprehensive needs assessments and service planning policies. We proposed to incorporate this element through proposed changes to § 438.208(c) requiring identification, assessment, and treatment/service planning for individuals receiving LTSS who are enrolled in a MCO, PIHP or PAHP. This proposal, which is discussed and finalized in section I.B.5.e. of this final rule, would have an overall effect of shifting from a strictly medical, acute care focus to one that addresses all covered services.

Element 7: Comprehensive, Integrated Service Package: In instances in which a state managed care program divides services between contracts or delivery systems, it is important that there is robust coordination and referral by the managed care plan to ensure that the beneficiary's service plan, which may include LTSS, is comprehensive and person-centered. We proposed to incorporate this element by proposing to expand § 438.208(b)(2), so that MCOs, PIHPs, and PAHPs coordinate an enrollee's care between settings of care, with services received from another MCO, PIHP, or PAHP, and with services received from FFS. This proposal is discussed more fully and finalized in section I.B.5.e. of this final rule.

Element 8: Qualified Providers: As with traditional managed care programs, MCOs, PIHPs, and PAHPs in a MLTSS program must have an adequate network of qualified providers to meet the needs of their enrollees. While current credentialing and network adequacy systems have been developed based on an acute and primary care service delivery model, managed care networks also meet the needs of MLTSS beneficiaries, including adequate capacity and expertise to provide access to services that support community integration, such as employment supports, and the provision of training and technical assistance to providers. We proposed the following changes to incorporate this element:

- Amending § 438.68(b)(2) to propose that states establish time and distance standards specifically for MLTSS programs. This proposal addressed time and distance standards for LTSS provider types in which the enrollee must travel to the provider and the use of standards other than time and distance for LTSS provider types that travel to the enrollee to deliver the service. We believe it is important to recognize that standards must reflect the high utilization of services outside of the traditional medical office setting by enrollees using LTSS. Other changes to § 438.68 are discussed in section I.B.6.a. of this final rule.

- Amending § 438.206(c)(3) to propose that MCOs, PIHP, and PAHPs ensure that network providers have capabilities to ensure physical access, accommodations, and accessible equipment for enrollees with physical and mental disabilities. Given the high number of enrollees with a disability receiving some LTSS, we believed this to be an important factor when evaluating qualified providers in a MLTSS program. Other changes to § 438.206 are discussed in section I.B.6.a. of this final rule.

- Amending § 438.207(b)(1) to propose that MCOs, PIHPs, or PAHPs submit documentation to the state to demonstrate that it complies with offering the full range of preventive, primary care, specialty care, and LTSS services adequate for the anticipated number of enrollees. Under this proposal, the state would review the submitted documentation and certify its adequacy in paragraph (d) of this section. These changes are discussed in section I.B.6.a. of this final rule.

- Amending § 438.214(b)(1) to propose that each state establish a credentialing and re-credentialing policy that addresses all the providers, including LTSS providers, covered in their managed care program regardless of the type of service provided by such providers. We proposed this to emphasize the importance of a credentialing and re-credentialing policy for all provider types for the services covered under the contracts. We also proposed that each MCO, PIHP, and PAHP must follow the state policy but did not propose to prohibit additional policies at the state or managed care plan level. These proposals, comments, and responses to the proposal, and the provisions of the final rule on this are discussed below in this section.

Elements 9 and 10: Participant Protections and Quality: Participant health and welfare is an important tenet in a program providing LTSS. We incorporated these two elements by proposing to add a contract standard in § 438.330(b)(6) that MCOs, PIHPs, and PAHPs participate in state efforts to prevent, detect, and remediate all critical incidents. We intended this standard to be interpreted to apply to incidents that adversely impact enrollee health and welfare and the achievement of quality outcomes described in the person centered plan. Under this proposal, states would specify the MCO, PIHP, or PAHP's roles and responsibilities related to these activities in the MCOs, PIHPs, and PAHP's contract.

We noted in the proposed rule our belief that a quality system for MLTSS is fundamentally the same as a quality system for a state's entire managed care program, but should include MLTSS-specific quality elements. We specifically proposed § 438.330(b)(5) to address specific MLTSS quality considerations. Under proposed paragraph (b)(5), the MCO, PIHP, or PAHP would have mechanisms to assess the quality and appropriateness of care provided to LTSS enrollees including between settings of care and as compared to the enrollee's service plan.

In addition, under § 438.330(c)(1)(iii), we proposed that the state includes the results of any rebalancing efforts by the MCO, PIHP, or PAHP for individuals using LTSS in its annual program review. These provisions related to § 438.330 are discussed in more detail in section I.B.6.b. of this final rule.

These ten elements were the basis for many of our proposals related to LTSS provided through a managed care delivery system. We solicited comment on the extent to which our proposals—those discussed specifically above and the other LTSS-specific provisions in this final rule—successfully incorporate the elements.

We received comments in response to our proposals; comments specific to proposals and finalized provisions discussed in more detail in other sections can be located in the section noted after each citation: §§ 438.2 (definitions at I.B.5.g), 438.3 (standard contract provisions at I.B.2), 438.10 (information requirements at I.B.6.d), 438.66 (state monitoring standards at I.B.6.c), 438.68 (network adequacy standards at I.B.6.a), 438.70 (stakeholder engagement for MLTSS at I.B.5.h), 438.71 (beneficiary support system at I.B.5.c), 438.206 (availability of services at I.B.6.a), 438.207 (assurances of adequate capacity and services at I.B.6.a), and 438.816 (beneficiary support system at I.B.5.c). We discuss our proposals, comments, and responses, and finalized provisions related to § 438.214 here.

We received the following comments in response to our proposal in § 438.214.

Comment: We received several comments recommending that CMS require states to permit, and ideally require, managed care plans to delegate credentialing of clinicians to FQHCs who undergo the Federal Torts Claims Act credentialing process. Commenters generally stated that such delegation is not inconsistent with the requirement to establish a “uniform credentialing and recredentialing policy” under paragraph § 438.214(b)(1).

Response: Decisions on the permissibility and extent of delegated credentialing rest with the states. We do not believe it is appropriate or necessary for that to be specified in § 438.214, because we maintain that states are in the best position to understand and articulate standards for their states. States are in the best position to address the nuance of the scopes of practice, disciplinary board, and availability of information for other credentialing criteria.

Comment: A few commenters requested that § 438.214(c) include a

reference to section 1557 of the Affordable Care Act.

Response: We appreciate the opportunity to clarify that, as provided in § 438.3(f)(1), all Medicaid managed care plan contracts must comply with all applicable federal and state laws and regulations including Title VI of the Civil Rights Act of 1964; Title IX of the Education Amendments of 1972 (regarding education programs and activities); the Age Discrimination Act of 1975; the Rehabilitation Act of 1973; the Americans with Disabilities Act of 1990 as amended; and section 1557 of the Patient Protection and Affordable Care Act. Under these identified statutes and their implementing regulations, managed care plans are prohibited from discriminating against providers (for example, rejecting a provider’s participation in a plan’s network) on the basis of the provider’s race, color, national origin, disability, age, or sex. The department’s 1557 guidance and the final 1557 regulation provide more information on what constitutes sex discrimination. See www.hhs.gov/ocr. Other laws, such as state laws, that prohibit discrimination may also be applicable to manage care plans.

Comment: We received some comments on the language “uniform credentialing and recredentialing policy” in proposed § 438.214(b). The commenters believed that this provision, if applied to all providers, is unnecessarily burdensome and fails to acknowledge the unique nature of different types of providers, particularly when considering LTSS services or services provided by non-licensed providers. One commenter believed that unlicensed provider types must be credentialed and that setting training requirements might be a method of addressing this issue, while ensuring that LTSS consumers are served by qualified providers. One commenter recommended that CMS require that governance, leadership, and financial viability be included in LTSS credentialing policies. Another commenter recommended that states should have discretion in determining the categories of LTSS providers that should be credentialed when alternative methods of assuring quality care and beneficiary protection may be sufficient.

Response: We appreciate the opportunity to clarify our intent in proposed § 438.214(b). Our use of “uniform” was not intended to convey that credentialing policies and procedures had to be identical for all provider specialties and types. That would be unrealistic and inappropriate. Our intent was to convey that credentialing and recredentialing

policies need to be consistently developed and applied to ensure accurate and equitable outcomes, to prevent discriminatory practices, and enable managed care plans to build and maintain networks that meet the needs of their enrollees. We acknowledge and agree that credentialing policies must be tailored by provider type or specialty to appropriately reflect criteria such as education, training, experience, and/or licensure or certification.

Given the challenges of determining common criteria among certain types of LTSS providers, selecting appropriate criteria becomes even more important. As one commenter suggested, training may be a method to help address this for some LTSS providers. Lastly, we interpret the comment requesting that the state have discretion to determine which types of LTSS providers to credential to mean that states want to be able to have no credentialing or evaluation process at all for certain LTSS providers when alternative methods of assuring quality care and beneficiary protection may be sufficient. If that interpretation is correct, then we restate that LTSS providers, regardless of the type of service provided, must undergo the credentialing and recredentialing process. We note that the criteria for credentialing may differ based on the type of LTSS provider.

In a self-directed model, there may be individual credentialing based on beneficiary-defined parameters, along with certain state-wide criteria such as passing a criminal background and fraud check, and/or being of age to perform the work. When an individual specifies self-directed provider enrollment criteria, the state must have or delegate to the managed care entities a process by which the provider credentials are verified, and that safety monitoring and appropriate payment oversight occurs. This usually occurs through a financial management services entity qualified to perform payroll and other actions on behalf of the self-directing individual. We do not agree that assurances of quality of care or other beneficiary protections would be sufficient unless used in a well-structured self-direction program as a post review process where beneficiary risk and mitigation has been worked through at initiation of services in a person-centered planning process.

Comment: We received one comment suggesting that states have a centralized credentialing approach throughout the state, particularly for anesthesiologists, radiologists, pathologists, emergency room physicians, per diem, and locum tenens providers, and facilities.

Response: The decision to operate a centralized credentialing approach is a state decision and currently permitted at § 438.214(a); we do not believe that additional text in the regulation at § 438.214 is necessary to permit this.

Comment: One commenter recommended that CMS require that licensing be instituted in all states. The commenter believed that certain states do not require that all LTSS providers—such as home care agencies providing personal care services—be licensed, and thus prevents appropriate credentialing.

Response: Section 438.214 only sets forth the minimum federal requirements for provider selection. We believe the decision to require or mandate licensure requirements for specific LTSS providers should be at the state's discretion. Therefore, we decline to add additional text in the regulation.

Comment: A few commenters recommended that any credentialing requirements that apply to network providers of managed care plans be equally applied to FFS programs to promote consistent beneficiary rights across the Medicaid program.

Response: Mandating credentialing requirements in the context of FFS programs is outside the scope of this rule.

Comment: We received a few comments recommending that CMS establish a time frame for managed care plans to act on credentialing applications and require that, once a provider is credentialed, the managed care plan should consider them as a participating provider and pay any claims for services back to the date of the provider's credentialing application to the managed care plan. Another commenter recommended that CMS require managed care plans to publicly report (on the state Web site) the average length of time each managed care plan takes to process credentialing applications, starting from the date that a complete application package is received.

Response: We believe that setting specific timeframes for credentialing processes, disclosure of processing times, and any payment requirements are decisions best made by each state, which may choose to leave such decisions regarding network composition and the business relationship between plans and providers to the MCOs, PIHPs and PAHPs. We decline to revise § 438.214 as recommend by these comments.

Comment: One commenter suggested that managed care plans get input on the development of their LTSS credentialing policies from LTSS providers.

Response: We agree that getting input from LTSS providers could be a valuable source of information and encourage states and managed care plans to consider it. However, we decline to make this a requirement in this final rule.

Comment: We received a few comments that recommend that managed care plans must ensure that their credentialing process is developed in a way that does not “medicalize” LTSS or unintentionally impede HCBS providers from participating in the system of care.

Response: We agree that managed care plans need to develop their credentialing policies and procedures consider the unique features and nature of LTSS, which is different than the feature applicable acute care. This is consistent with our intent throughout this rule and we encourage states and plans to review existing policies and procedures to ensure that they reflect this perspective. We believe that the regulation text is sufficient that different standards are appropriate for different types of providers and do not plan to finalize additional text on this point.

Comment: We received one comment suggesting that CMS add pediatric nurse practitioners and other licensed providers and facilities that meet the standard for accreditation to the list of providers in proposed § 438.214(b).

Response: The list in § 438.214(b)(1) is a minimum and states are free to add provider types as they deem appropriate. We decline to revise § 438.214 as recommended in this comment.

Although not proposed, we are making two technical corrections in § 438.214. In paragraphs (a), (b)(2), and (c), we are adding “network” before “provider” for accuracy given that these paragraphs address topics applicable only to network providers, that is, contracts, credentialing, and provider selection. In paragraph (b)(2), we are deleting “who have signed contracts with the MCO, PIHP, or PAHP” to remove the redundancy that phrase adds given the definition of “network provider” in § 438.2.

After consideration of public comments, we are finalizing § 438.214 as proposed without modification.

h. Stakeholder and Member Engagement in LTSS (§ 438.70 and § 438.110)

Since stakeholder and member engagement plays a critical role in the success of a MLTSS program, we proposed that states and managed care plans must have appropriate minimum mechanisms in place to accomplish this in a new § 438.70 regarding the state's

creation and maintenance of a stakeholder group so that opinions of beneficiaries, providers, and other stakeholders are solicited and addressed during the design, implementation, and oversight of the MLTSS program. We proposed that states set the composition of the stakeholder group and the frequency of meetings to ensure meaningful stakeholder engagement. Our proposal specifically uses a “sufficiency” standard rather than setting quantitative parameters for the composition of the group or the frequency of meetings to permit states a significant degree of flexibility. We requested comments on the overall approach for these changes, as well as on the composition of the stakeholder group, stakeholder group responsibilities, and approach to meeting frequency for both states and managed care plans.

In concert with the new § 438.70, we also proposed a new § 438.110. While the stakeholder group proposed in § 438.70 is maintained by the state, we believe that each MCO, PIHP, and PAHP should also establish a regular process to solicit direct input on the enrollees' experiences. Therefore, in § 438.110(a), we proposed that for any MCO, PIHP, or PAHP contract that includes LTSS, the MCO, PIHP, or PAHP must establish and maintain a member advisory committee. Paragraph (b) proposed that the member advisory committee include a reasonably representative sample of the covered LTSS populations. We included PAHPs in this standard, because we understand there are some PAHPs in operation that cover LTSS. We have combined our discussion of the requirements in §§ 438.70 and 438.110 throughout this section; therefore we use the terms stakeholders and members interchangeably when referring to the general requirements for a state to establish and maintain a state stakeholder group in § 438.70 and for the MCO, PIHP, or PAHP to establish and maintain a member advisory committee in § 438.110.

We received the following comments in response to our proposal to add a new §§ 438.70 and 438.110.

Comment: One commenter recommended there should be no state level stakeholder engagement and that all stakeholder engagement should be through managed care plans, although many other commenters wrote in support of stakeholder engagement at the state level. Many commenters suggested that CMS define “stakeholder”, the term “meaningful input”, the number of stakeholders that should be represented, the frequency at which the stakeholders meet with the

state and/or the roles of stakeholders who are engaged at the state level regarding the managed care program.

Response: We are appreciative of the many comments supporting stakeholder involvement. We also appreciate the suggestions to define several terms used in this section and the recommendations to set more specific requirements, but we decline to do so. We believe that the critical stakeholders would be those who are directly affected by the managed care program, and so would vary from state to state.

Beneficiaries and providers are already specified in this section, and additional stakeholders may include beneficiary family members or representatives, caregivers, advocates, regional and tribal representation, specific ethnic populations or representatives of other groups deemed by the state to be sufficient to allow for meaningful engagement. We would anticipate that the frequency of meetings would vary based on the age and stability of the program. A program being developed and/or modified significantly may need monthly or more frequent meetings, while a program that has been running for a number of years may be well-served through quarterly or semi-annual meetings. The number of stakeholders is also rightly a variable for several reasons, such as the size and scope of the MLTSS program. Questions that would trigger different types of stakeholder input could include whether the program is very large and run statewide, or more local, and what types of LTSS are offered, and what types of individuals are served by the plans—elders, people with disabilities, and/or people with certain types of disabilities. Meaningful stakeholder input would be defined by whether the major constituency groups in a given state affected by the LTSS program have the ongoing forum to express program issues and concerns. We believe it would be impossible for us to create definitions and more specific standards that would be appropriate for all MLTSS programs in every state and decline to do so in this regulation.

Comment: Many commenters recommended that CMS identify which particular providers, constituents, or stakeholders must be included in the state stakeholder group or member advisory committee. Specifically, at least one commenter each thought CMS should require consumer advocacy groups/disability support agencies, home-based providers, rehabilitation professionals (Physical, Occupational or Speech therapists), state *Olmstead* committee representation, Area Agencies on Aging, hospice providers,

healthcare professionals (pharmacist, nurse, physician), Pacific Islanders, Native Americans, people with disabilities, people with severe mental health issues, staff from the Beneficiary Support System (*see* § 438.71), family members, at least one of each provider type, and managed care plan representatives. One commenter thought that one statewide committee representing everyone would be too large, another thought managed care entity representatives should be limited, and yet another that there should be a minimum required number of beneficiaries.

Response: We agree that any of these suggested participants may be appropriate candidates for the state stakeholder group or member advisory committee, but believe the actual composition of the group that includes those most affected by a given state program is best determined by the state. We agree that family members or other individuals that represent enrollees are always a critical stakeholder component. Therefore, we are adding representatives of beneficiaries or enrollees to the list of individuals who should be part of the state stakeholder group and to the managed care plan member advisory committee in §§ 438.70 and 438.110, as finalized here. We caution that there is also a need to include beneficiaries on these committees who can represent themselves as they may have somewhat different priorities than family members in regard to LTSS. This is why we are leaving beneficiaries and individuals that represent enrollees as two different categories of participants. We believe that both states and managed care plans are in the position to best determine how many of each type of stakeholder will best represent those most affected by the managed LTSS programs, and that both states and managed care plans need to have flexibility to determine the mix and number of stakeholders and members in the respective groups.

Comment: A few commenters thought CMS should require public comment on any proposed managed care program or program amendment, while a few commenters requested ongoing general stakeholder input outside of a committee structure. One commenter recommended that stakeholders should have approval authority over state programmatic decisions, where several commenters thought the states should respond on a Web site to all public comments.

Response: Although we encourage states to maintain strong communications with stakeholders even beyond the requirements of this

regulation, we believe the stakeholder engagement process required here along with the managed care plan member advisory committees (at § 438.110), Beneficiary Support System (§ 438.71), Quality Measurement and Reporting (42 CFR part 438 subpart E), Grievance and Appeal systems (42 CFR part 438 subpart F) and the reporting requirements for each of these requirements is sufficient to ensure that stakeholder concerns are identified and addressed. Most new managed LTSS programs already must go through a public comment period either through the section 1115(a) demonstration process, or by virtue of having a concurrent section 1915(c) home and community based services submission. Where states have the responsibility for the operation of Medicaid programs within federal guidelines, it would not be appropriate or within our jurisdiction to mandate that stakeholders have the authority to override those decisions.

Comment: A commenter recommended that CMS provide training to the stakeholder group. A few commenters suggested that stakeholders should be given advance notification of any new information prior to the committee meetings, and a few suggested that the stakeholders should review and advise on quality measures and results. One commenter thought the stakeholder process should be in place prior to contract finalization with the managed care plans, and another thought there should be a federal stakeholder process. One commenter asked that members be mandated to attend, and several others thought the regulation should require states to provide supports for individuals to participate such as transportation or personal care assistance. Finally, several commenters thought there should be a stakeholder engagement evaluation conducted by states to measure effectiveness or a type of financial incentive arrangement for managed care plans that excel at stakeholder engagement.

Response: We agree that the stakeholder community should be informed about the program the state is proposing to provide meaningful input. However, we believe this is implicit in § 438.70 that stakeholder views must be solicited. We are not aware of any stakeholder process in a state where individuals were asked to give opinions without first being given a description of the program to be discussed. We also agree that it is desirable to have information shared ahead of a meeting, but understand that sometimes the state itself does not have advance notice. We believe a requirement for advance notice

on items may result in a state being unable to share time sensitive items that have little turnaround time, so we decline to amend the regulation in this manner.

We concur that individuals must be offered accommodations to participate in stakeholder engagement activities. This could include telephonic meetings, use of computer messaging, interpreter services, or other means identified by participants that may be necessary to participate. The ADA requires reasonable accommodations for persons with disabilities, so we do not believe the need for accommodations should be specified here as well. In regard to stakeholder engagement performance reviews or payment incentives, we are not aware of evidence-based standards upon which such an evaluation or payment could be based. We are, therefore, not adding an evaluation component to stakeholder engagement at this time.

Comment: Many commenters supported § 438.110(a) requiring managed care plans to establish and maintain a member advisory committee when LTSS are covered under a risk contract. Several commenters recommended that CMS provide additional specificity regarding this requirement. Commenters recommended that CMS add requirements for member advisory committee operations, responsibilities, transparency requirements, public notice requirements, and committee meeting frequency standards. Specifically, commenters recommended that CMS add specificity for member advisory committee participation in program policy development, program administration, program oversight, quality activities, appeals and grievances reporting, data from member and provider satisfaction surveys, and periodic program updates. A few commenters recommended that member advisory committees be required to meet at least quarterly. One commenter also recommended that CMS remove the requirement triggering § 438.110 that LTSS be covered under a risk contract through an MCO, PIHP, or PAHP, as PCCM entities are evolving to cover LTSS and should not be exempt from the member advisory committee requirement. One commenter did not support § 438.110(a) and recommended that CMS remove the requirement in entirety, as states and managed care plans should be given flexibility to determine the most effective process for member input.

Response: We thank commenters for their support and thorough recommendations for § 438.110(a).

While we understand commenters' concerns regarding the lack of specificity in the requirement for managed care plans to establish and maintain a member advisory committee, we believe that states and managed care plans should work with their stakeholder communities to establish the most effective and efficient process for member engagement. We therefore decline to add commenters' detailed requirements to the regulatory text, as we believe that such requirements are overly prescriptive and would not allow the appropriate level of flexibility to design the stakeholder engagement process for LTSS programs. We note that states can establish such detailed requirements in their contracts with managed care plans.

We also decline to remove the requirement that LTSS be covered under a risk contract through an MCO, PIHP, or PAHP as a condition for the requirements in § 438.110 to apply, as we do not believe that PCCM entities are directly providing LTSS and are instead focused solely on care coordination activities and arranging for the provision of services outside of the PCCM entity. While we do not believe that it would be appropriate for such PCCM entities to be required to establish and maintain a member advisory committee, we encourage states to consider how their PCCM entities operate in determining whether to impose a stakeholder engagement or member advisory committee requirement in the state contract. Finally, we decline to remove § 438.110(a) in entirety, as we disagree with the commenter that states and managed care plans should be given discretion on whether to establish and maintain a member advisory committee. We believe that the establishment and maintenance of a member advisory committee is a critical beneficiary protection to ensure that enrollees' feedback is heard and included as appropriate when those enrollees are receiving LTSS services.

Comment: Several commenters recommended that CMS add specificity at § 438.110(b) regarding committee composition. Commenters recommended that CMS add requirements for managed care plans to include consumers, enrollees, family members, service providers, and advocates. Several commenters recommended that CMS define "LTSS populations" and "reasonably representative." Other commenters recommended that CMS include specific thresholds for committee composition, such as 50 percent of committee members must be consumers

and enrollees. One commenter recommended that CMS add the phrase "or other individuals representing those enrollees" after "LTSS populations."

Response: Consistent with our approach at § 438.110(a), we believe that states and managed care plans should work with their stakeholder communities to establish the most effective and efficient process for member engagement and therefore we decline to implement commenters' detailed recommendations, as we believe that such requirements are overly prescriptive and would not allow the appropriate level of flexibility for LTSS programs. However, we agree with the commenter that the phrase "or other individuals representing those enrollees" after "LTSS populations" should be added to the regulatory text, as we believe it would be beneficial to include individuals who represent LTSS enrollees. We are modifying the regulatory text to adopt this recommendation.

Comment: A few commenters recommended that CMS establish broader requirements for a statewide managed care advisory committee or board. One commenter also recommended that CMS include requirements for states to establish consumer advisory committees. One commenter recommended that CMS include requirements for states to establish pediatric advisory committees, especially for children with special health care needs.

Response: While we understand commenters' concerns regarding stakeholder feedback and appropriate representation, we believe these recommendations are duplicative of the requirement at § 431.12 of this chapter, requiring states to establish and maintain a Medical Care Advisory Committee. This committee is required to include representatives who are familiar with the medical needs of low-income population groups and with the resources available and required for their care. The committee is also required to include members of consumer groups, including Medicaid beneficiaries and consumer organizations. We therefore decline to accept commenters' recommendations to establish broader requirements for more managed care advisory committees; we are finalizing only the two specific committees that were proposed.

Comment: A few commenters recommended that CMS establish requirements to support enrollees who participate on member advisory committees. Specifically, commenters recommended that CMS require

managed care plans to support and facilitate enrollee participation, including transportation, interpreter services, personal care, compensation, and other enrollee supports that will encourage participation.

Response: While we encourage states and managed care plans to establish mechanisms, where appropriate and feasible, to support enrollees who participate on member advisory committees, we decline to adopt commenters' specific recommendations to require that managed care plans provide transportation, interpreter services, personal care, compensation, and other enrollee supports that encourage participation. We believe that states and managed care plans should work with their stakeholder communities to establish the most effective and efficient process for member engagement, including the best methods for encouraging and supporting enrollee participation on member advisory committees.

After consideration of the public comments, we are finalizing §§ 438.70 and 438.110 as proposed with a revision to include other individuals that represent beneficiaries or enrollees to the list of individuals included in the committees required by the two regulations.

6. Modernize Regulatory Standards

a. Availability of Services, Assurances of Adequate Capacity and Services, and Network Adequacy Standards (§§ 438.206, 438.207, 438.68, 440.262)

As indicated in I.B.6.a of the proposed rule, assessment of the network adequacy of contracted MCOs, PIHPs, and PAHPs is a primary component of our determination of a state's readiness to implement and sustain managed care programs. We proposed a new regulation section and revisions to existing regulations to establish minimum standards in this area. The proposed changes had the goal of maintaining state flexibility while modernizing the current regulatory framework to reflect the maturity and prevalence of Medicaid managed care delivery systems, promoting processes for ensuring access to care, and aligning, where feasible, with other private and public health care coverage programs. To that end, we proposed to set standards to ensure ongoing state assessment and certification of MCO, PIHP, and PAHP networks, set threshold standards for the establishment of network adequacy measures for a specified set of providers, establish criteria for developing network adequacy standards for MLTSS

programs, and ensure the transparency of network adequacy standards. These proposed changes would create a new § 438.68 specific to the development of network adequacy standards for medical services and LTSS and modify §§ 438.206 and 438.207.

(1) Requirements for the Network Adequacy Standards set by the State for a Specified Set of Providers (§ 438.68)

Our current regulatory framework provides states with significant flexibility to determine whether an MCO, PIHP, or PAHP adequately makes services accessible and available to enrollees under the managed care contract. Because our existing regulations were developed at a time when managed care for the delivery of LTSS was extremely limited and involved only a handful of programs limited in geographic scope, we proposed to amend the existing regulations to establish standards for states to follow in the development of Medicaid managed care network adequacy standards that address medical services, behavioral health services, and LTSS. In accordance with our underlying goal to align Medicaid managed care standards with other public programs where appropriate, we analyzed the network adequacy standards applicable under the Marketplace and the MA program to inform our proposed rule. In section I.B.6.a of the proposed rule, we provided a short summary of the standards utilized by these programs.

Similar to the rules finalized for Marketplaces and QHPs, the existing network adequacy standards for Medicaid managed care do not include detailed and specific time and distance standards or provider to enrollee ratios but deferred to each state to develop specific standards; the current regulations rely heavily on attestations and certifications from states, with supporting documentation, about the adequacy of the network. Consistent with the primary role of states in Medicaid, our proposal kept to this general approach. Therefore, we proposed to add a new § 438.68 that would stipulate that the state must establish, at a minimum, network adequacy standards for specified provider types.

Proposed paragraph (a) specified that a state that contracts with an MCO, PIHP, or PAHP must develop network adequacy standards that satisfy the minimum parameters in § 438.68. This proposed provision is the counterpart to our proposal at § 438.206 that the state ensures that enrollees of MCOs, PIHPs, and PAHPs have access to all services covered under the state plan in a

manner that is consistent with the state-set standards for access and availability. These proposals would apply to contracts that cover medical services, behavioral health services, and LTSS; the standards for LTSS proposed in paragraphs (b)(2) and (c)(2) are described in the MLTSS-specific discussion at the end of this section.

Proposed paragraph (b)(1) would stipulate that states must establish time and distance standards for the following network provider types: Primary care (adult and pediatric); OB/GYN; behavioral health; specialist (adult and pediatric); hospital; pharmacy; pediatric dental; and additional provider types when it promotes the objectives of the Medicaid program for the provider type to be subject to such time and distance standards. We intended that this proposal be applicable only to the services covered under the MCO, PIHP, or PAHP contract(s). We proposed that states, at a minimum, establish time and distance standards as such standards are currently common in the private market and many state Medicaid managed care programs; further, we believe time and distance standards present a more accurate measure of the enrollee's ability to have timely access to covered services than provider-to-enrollee ratios. We requested comment on whether we should propose a different national type of measure for states to further define, such as provider-to-enrollee ratios, or whether we should permit states the flexibility to select and define the type of measure for the network's adequacy of the specified provider types. Additionally, we requested comment on whether we should define the actual measures to be used by states such that we would set the time and distance or provider-to-enrollee ratio standard per provider type, per county, or other appropriate geographic basis.

Given the large number of pediatric Medicaid enrollees, we noted that it is important for states and plans to specifically include pediatric primary, specialty, and dental providers in their network adequacy standards. Network adequacy is often assessed without regard to practice age limitations, which can mask critical shortages and increase the need for out-of-network authorizations and coordination. We requested comment on whether standards for behavioral health providers should distinguish between adult and pediatric providers. We considered adding family planning providers to the list of providers that would be subject to time and distance standards but declined to do so because section 1902(a)(23) of the Act guarantees freedom of choice of family planning

providers and providers of family planning services would include physicians and OB/GYNs. We requested comment on this approach.

Appreciating that provider networks can vary between geographic areas of a state and states have different geographic areas covered under managed care contracts, as proposed in paragraph (b)(3), states would have to establish time and distance standards for specified provider types that reflect the geographic scope of the Medicaid managed care program. Our proposal would permit states to vary those standards in different geographic areas to account for the number of providers practicing in a particular area. Our proposal would not limit states to only the mandatory time and distance standards but also would have states consider additional elements when developing network adequacy standards.

Proposed paragraph (c)(1) specifies the minimum factors a state must consider in developing network adequacy standards; most of the elements proposed here are currently part of § 438.206(b)(1) as considerations for MCOs, PIHPs, and PAHPs in developing their managed care networks. These are: Anticipated Medicaid enrollment; expected utilization of services; taking into account the characteristics and health needs of the covered population; number and types of health care professionals needed to provide covered services; number of network providers that are not accepting new Medicaid patients; and the geographic location and accessibility of the providers and enrollees.

Disparities in access to care related to demographic factors such as race, ethnicity, language, or disability status are, in part, a function of the availability of the accessible providers who are willing to provide care and are competent in meeting the needs of populations in medically underserved communities. Additionally, new enrollees in Medicaid managed care, including those who are dually eligible for Medicare and Medicaid, may present with multiple chronic conditions and need the services of multiple specialists. Absent an adjustment for new populations enrolled in a state's Medicaid managed care program, existing plan networks may be inadequate to meet new enrollees' needs.

Accordingly, we proposed changes to the required factors that we proposed to move from current § 438.206(b)(1). We proposed to make existing § 438.206(b)(1)(ii) into separate factors

that the state must consider: Expected utilization and the characteristics and health needs of the covered population; these are codified as § 438.68(c)(1)(ii) and (iii) and use substantially the same language as in the current regulation. Similarly, we proposed two separate factors, to be codified at § 438.68(c)(1)(vi) and (viii), in place of the current § 438.206(b)(1)(v), which are geographic location and accessibility. Although we proposed to use the same language regarding geographic considerations, we proposed in § 438.68(c)(1)(viii) that each state must also consider the ability of providers to ensure physical access, accommodations, and accessible equipment available for Medicaid enrollees with physical or mental disabilities, with proposed additional standards that the accommodations be reasonable and that the ability of providers to ensure culturally competent communication be considered as well. Also, we proposed to add a new element, at proposed paragraph (c)(1)(vii), so that states must also consider the ability of network providers to communicate with limited English proficient (LEP) enrollees in their preferred language when the state is developing time and distance access standards.

In effect, our proposal was that the states develop standards by which to review the provider networks used in Medicaid managed care, which should ensure that these elements are also taken into consideration by MCOs, PIHPs, and PAHPs that maintain and monitor the provider networks. We intended that compliance with our proposal would be best met if states looked to standards established by the insurance regulator (for example, Department of Insurance, or similar agency within the state) for private market insurance, and the standards set under the MA program, as well as historical patterns of Medicaid utilization—including utilization specific to sub-populations that may be more relevant to the Medicaid program than in private or Medicare markets—to inform the standards the state establishes for Medicaid managed care programs under § 438.68. While we did not propose to dictate the particular time and distance standards or set a quantitative minimum to be adopted by a state, we noted our intent to assess the reasonableness of the particular standard adopted by a state under our proposed § 438.68 within the context of other existing standards should the need for such evaluation of the state's performance arise.

We recognized that situations may arise where a MCO, PIHP, or PAHP may need an exception to the state established provider network standards. A number of states currently permit exceptions, and have a process for seeking exceptions, under the state standards imposed on a managed care entity under existing §§ 438.206 and 438.207. Therefore, proposed § 438.68(d) provides that, to the extent a state permits an exception to any of the provider network standards, the standard by which an exception would be evaluated must be specified in the contract and must be based, at a minimum, on the number of health care professionals in that specialty practicing in the service area. Under our proposal, the state would monitor enrollee access to providers in managed care networks that operate under an exception and report its findings to us as part of its annual managed care program monitoring report provided under proposed § 438.66. We invited comment on our proposal related to exceptions a state may grant to its network adequacy standards established by the state for Medicaid MCOs, PIHPs, or PAHPs.

Finally, in proposed paragraph (e), to promote transparency and public input for these managed care network adequacy standards, we proposed that states would have to publish the network adequacy standards developed in accordance with § 438.68 on the Medicaid managed care Web site under § 438.10. In addition, states would have to make these standards available at no cost, upon request, to individuals with disabilities through alternate formats and using auxiliary aids and services.

We received the following comments in response to our proposal to add a new § 438.68 that would stipulate that the state must establish, at a minimum, network adequacy standards for specified provider types.

Comment: Many commenters supported proposed § 438.68(b)(1) that would require states to develop network adequacy standards for a distinct set of provider types and categories, including (i) adult and pediatric primary care; (ii) OB/GYN; (iii) behavioral health; (iv) adult and pediatric specialist; (v) hospital; (vi) pharmacy; (vii) pediatric dental; and (viii) additional provider types when it promotes the objectives of the Medicaid program, as determined by CMS. Many commenters specifically recommended additional provider types and categories for CMS to include at § 438.68(b)(1). In total, commenters recommended more than 30 additional provider types and categories. One commenter recommended that CMS remove the language at

§ 438.68(b)(1)(viii) pertaining to “additional provider types when it promotes the objectives of the Medicaid program, as determined by CMS” because the language is too broad. Finally, in response to our request for comment to add family planning providers to the list of providers that would be subject to time and distance standards, several commenters recommended that CMS finalize the regulation with family planning providers included in the network adequacy standards.

Response: We thank commenters for their support of proposed § 438.68(b)(1). We decline to list additional provider types and categories as commenters recommended. We believe that the proposed list strikes the appropriate balance of ensuring access to care and state flexibility. States have the authority to add additional provider types to their network adequacy standards to reflect the intricacies of their Medicaid programs. We also decline to remove the proposed language at § 438.68(b)(1)(viii). We believe this flexibility is important to address future national provider workforce shortages and future network adequacy standards. If we apply this flexibility and the regulation standard to identify additional provider types for which a state should establish time and distance standards, we intend to solicit public input. Consistent with both our rationale as described in the proposed rule (80 FR 31145) and as described above, we decline to add family planning providers to the list of providers that would be subject to time and distance standards in § 438.68; however, in light of these public comments and additional comments received in § 438.206, we have provided additional discussion on the availability of family planning services at I.B.6.a.3.

Comment: Several commenters recommended that CMS add the full range of pediatric providers to the provider-specific network adequacy standards at § 438.68(b)(1). Specifically, commenters recommended that CMS add pediatric specialty pharmacies, pediatric specialty hospitals, pediatric medical subspecialists, pediatric surgical specialists, and pediatric dental specialists. One commenter recommended that CMS add age categories to the specific list of provider types. One commenter also recommended that CMS define “pediatric dental” at § 438.68(b)(1)(vii).

Response: We understand the concerns underlying the recommendation to develop the full range of pediatric network adequacy standards; however, we decline to add

these specialty providers to the list. While we understand the need to ensure access to care for pediatric populations, we believe it would be difficult for states to set an appropriate standard for these specialty providers. States can use the “specialist” category to define pediatric specialists and subspecialists for which the state believes it is appropriate to set specific network adequacy standards. We also decline to add age categories to the specific list of provider types. We believe this would be difficult for states to operationalize and present additional barriers for states in setting appropriate and meaningful network adequacy standards. We also decline to define “pediatric dental” at § 438.68(b)(1)(vii). We do not believe it is necessary to define this provider type category at the federal level, as we believe that states understand which dental providers provide services to their pediatric populations.

Comment: Several commenters recommended that CMS add requirements at § 438.68(b)(1) for states to specifically set network adequacy standards for provider types and specialists for which the state has a known workforce shortage.

Response: We appreciate the recommendation to add requirements for states to specifically set network adequacy standards for provider types and specialists for which the state has a known workforce shortage; however, we decline to add such requirements. We believe it is inappropriate to add federal requirements on such a state-specific issue. States will be in the best position to make this decision and add network adequacy standards as appropriate. Our regulation on this point—the obligation of the state to establish time and distance standards—establishes the minimum that a state must do; states are able, and encouraged, to set additional standards consistent with the needs of their programs.

Comment: Several commenters recommended that CMS add requirements at § 438.68(b)(1) for states to set network adequacy standards for essential community providers (ECPs). One commenter also recommended that CMS add requirements for states to set network adequacy standards for all providers that provide essential health benefits (EHBs).

Response: The Affordable Care Act created an ECP requirement for QHPs to ensure that those specific private plans were providing adequate access to care for low-income and medically underserved individuals and populations, who were likely to be enrolled in QHPs upon gaining access to

coverage and in light of the federal financial assistance for those plans. The Medicaid program has a long history with ECPs, and we believe that most Medicaid managed care plans contract with ECPs on a regular basis. In addition, Medicaid has different statutory authorities that treat some ECPs differently than the private market, which drives variations in provider network supply and demand. Therefore, we find the requirement to add specific access standards for ECPs in the Medicaid program to be duplicative and unnecessary. We also decline to add all providers that provide EHBs. We believe this requirement is unnecessary, as the current list of provider types includes providers that would render such services.

Comment: Several commenters recommended that CMS include both “adult and pediatric” behavioral health at § 438.68(b)(1)(iii) to account for varying standards in care, provider training, access to care issues, and population dynamics. One commenter recommended that CMS not include both “adult and pediatric” behavioral health, as it would be challenging for states to set meaningful standards.

Response: We agree with commenters that it is important to include both adult and pediatric behavioral health in a state’s network adequacy standards. This is consistent with the requirement of separate pediatric providers associated with physical health. We are modifying the regulatory text at § 438.68(b)(1)(iii) to adopt this recommendation.

Comment: Many commenters recommended that CMS clarify that the “behavioral health” provider type/category at § 438.68(b)(1)(iii) includes both mental health (MH) and substance use disorder (SUD) providers.

Response: We agree with commenters that our language at § 438.68(b)(1)(iii) could be strengthened to specify that “behavioral health” includes both MH and SUD provider types. We are modifying the regulatory text to adopt this recommendation and clarify that behavioral health includes both MH and SUD in § 438.68(b)(1)(iii).

Comment: Many commenters recommended that CMS define the “specialist” category at § 438.68(b)(1)(iv). Several commenters recommended specific specialists for CMS to add. A few commenters recommended that CMS delete this language in its entirety, as the category would be too broad and unmanageable for states to set appropriate and meaningful network adequacy standards. One commenter recommended that CMS clarify that

states only set network adequacy standards for high-volume specialists. A few commenters recommended that CMS clarify that states can define the “specialist” category and set network adequacy standards that are appropriate at the state level.

Response: We agree with commenters that states should define this category and set network adequacy standards that are appropriate at the state level. We believe that allowing states to define the “specialist” category better reflects the needs of their respective programs, and we believe it would be inappropriate for CMS to define this standard at the federal level. We also believe that states are in the best position to engage a variety of stakeholders when defining the “specialist” category and setting appropriate network adequacy standards for such defined “specialist” providers. We specifically encourage states to be transparent in this process.

Comment: A few commenters recommended that CMS remove “pharmacy” at § 438.68(b)(1)(vi) as a provider type. Commenters stated that managed care plans and states should have the flexibility to work with their pharmacy benefit managers (PBMs) to define pharmacy networks.

Response: We thank commenters for their recommendation but decline to remove “pharmacy” at § 438.68(b)(1)(vi). We understand the need for managed care plans and states to have flexibility, but we believe that access to pharmacies is a critical aspect of care for many beneficiaries. Some beneficiaries have limited access to transportation, and we believe it is important to have network adequacy standards to ensure appropriate access to care in this area.

Comment: Many commenters supported proposed § 438.68(b)(1), requiring states to develop time and distance standards for specific provider types. While many commenters supported time and distance standards, many other commenters did not believe that proposed § 438.68(b)(1) went far enough. Many commenters recommended that CMS include other network adequacy standards in addition to time and distance. Commenters recommended that CMS add provider to enrollee ratios, appointment and office wait times, beneficiary complaint tracking, and other network adequacy standards. Several commenters recommended that CMS not include a proposal for states to develop time and distance standards and instead allow states to adopt alternative network adequacy standards that are more appropriate for the scope of their

program and populations covered. A few commenters also recommended that states be allowed to adopt “reasonable access” standards similar to those in the state and federal marketplaces.

Response: We thank commenters for their support of proposed § 438.68(b)(1). We decline to add additional network adequacy standards in addition to time and distance. We believe that the regulation strikes the appropriate balance among the goals of avoiding overly prescriptive federal requirements, ensuring standards that ensure access to care, and permitting state flexibility. States will have the authority to add additional network adequacy standards if they choose. Many states have additional network adequacy standards, such as provider to enrollee ratios, and timely access standards such as appointment and office wait times. This proposed provision will still allow states to establish those network adequacy standards in their managed care contracts. It is for these same reasons that we decline to remove time and distance standards as a requirement in § 438.68(b)(1) or allow states to only adopt a “reasonable access” standard similar to the state and federal Marketplaces. While we understand the need for states to have adequate flexibility, we also believe that the flexibility must be subject to some national requirements; requiring that states establish and use time and distance standards is a minimal way for us to ensure access to care for Medicaid managed care beneficiaries.

Comment: Many commenters recommended that CMS set quantitative time and distance standards in § 438.68(b)(1). Several commenters also recommended that CMS set quantitative standards for provider to enrollee ratios, appointment and office wait times, and other quantitative standards. Several commenters recommended that CMS adopt MA’s quantitative standards or set quantitative standards that are as stringent as MA. One commenter stated concern regarding the possibility of redundancies and duplications between Medicare and Medicaid network adequacy standards, if the managed care plan is serving dually eligible enrollees.

Response: We appreciate the recommendations regarding proposed § 438.68(b)(1); however, we decline to adopt quantitative standards for time and distance, provider to enrollee ratios, appointment and office wait times, or other quantitative standards. We believe that states should be allowed to set appropriate and meaningful quantitative standards for their respective programs. We also believe that states are in the

best position to set specific quantitative standards that reflect the scope of their programs, the populations served, and the unique demographics and characteristics of each state. As many commenters stated, it is crucial for CMS to strike an appropriate balance between prescriptive federal standards and state flexibility. We also decline to adopt MA’s network adequacy standards or quantitative standards that are as stringent as MA. Consistent with our role in the Medicaid managed care context compared to our role in the MA context, we do not believe it is appropriate to prescribe MA’s network adequacy standards on state programs. Additionally, given the differences in the Medicaid and MA populations, it is unclear if such standards would be appropriate. Finally, it is unclear to us how the network adequacy standards finalized in this rule would be redundant or duplicative of Medicare standards. If a managed care plan operates in both Medicare and Medicaid markets and is serving dually eligible enrollees, Medicare’s network adequacy standards would apply.

Comment: A few commenters recommended that CMS add requirements at § 438.68(b)(1) for states to specifically track the percentage of care provided out-of-network and set specific quantitative limits. A few commenters also recommended that CMS add additional requirements for states to set specific benchmarks for HEDIS measures as a proxy measure for network adequacy.

Response: We thank commenters for the recommendation to add these requirements at § 438.68(b)(1); however, we decline to do so. While we believe that such standards could be beneficial, it would be inappropriate to set a national requirement in these areas. States will have the flexibility to innovate in these areas and add network adequacy requirements as appropriate for their respective programs. We believe it is best to not be overly prescriptive regarding specific quantitative network adequacy standards and give states the flexibility to build upon the required time and distance standards as they deem appropriate and meaningful for their programs and populations.

Comment: Many commenters recommended that CMS clarify that states can vary their time and distance standards by provider type. Several commenters also recommended that CMS clarify that states can implement additional network adequacy standards in addition to the time and distance standards required at § 438.68(b)(1).

Response: We clarify that states are not required to set the same network adequacy standards across all provider types and can vary such standards based on appropriate state benchmarks. We also clarify that states will have the authority to add additional network adequacy standards if they choose in addition to the required time and distance standards.

Comment: A few commenters recommended that CMS allow for alternative network adequacy standards when beneficiaries are enrolled in integrated care models.

Response: The network adequacy requirements at § 438.68(b)(1) require that states establish, at a minimum, time and distance standards for MCOs, PIHPs, and PAHPs. States operating integrated care models that do not fall into one of those arrangements would not be bound by this section or 42 CFR part 438 generally.

Comment: Several commenters recommended that CMS clarify that states should set specific quantitative time and distance standards for both adult and pediatric populations to meet the requirements at § 438.68(b)(1).

Response: States must develop quantitative time and distance standards for both adult and pediatric provider types under § 438.68(b)(1)(i), (iii), and (iv). States must also develop quantitative time and distance standards for pediatric dental providers under § 438.68(b)(1)(vii).

Comment: Several commenters recommended that CMS include requirements at § 438.68(b)(1) to include secret shopper standards and benchmarks. A few commenters also recommended that CMS require specific patient satisfaction standards.

Response: We thank commenters for the recommendation to add these requirements to § 438.68(b)(1); however, we decline to do so. While secret shopper and patient satisfaction standards may be beneficial, we are unclear if such standards and requirements are an appropriate and meaningful national standard monitoring for network adequacy across all states and populations. We believe that such standards should be considered at the state level and would encourage states to continue exploring innovative and meaningful standards that ensure access to care for Medicaid beneficiaries.

Comment: One commenter recommended that CMS include public notice and public comment requirements at § 438.68(b)(1). The commenter recommended that CMS ensure that states are transparent when setting their specific network adequacy

standards, including quantitative time and distance standards.

Response: We believe that transparency is critical to Medicaid beneficiaries and proposed in § 438.68(e) that states publish their network adequacy standards on a public Web site. We also encourage states to include appropriate and meaningful stakeholder engagement and feedback when setting their network adequacy standards. States should be using their already established public notice and public comment mechanisms and processes when promulgating future rules and requirements to comply with these standards.

Comment: A few commenters recommended that CMS adopt TRICARE network adequacy standards, particularly at § 438.68(b)(1)(vi), for pharmacy providers.

Response: We appreciate the recommendation to adopt TRICARE network adequacy standards at § 438.68(b)(1)(vi); however we decline to adopt this recommendation. We believe it is unclear if such standards would be appropriate for the Medicaid managed care program, given the differences between the TRICARE and Medicaid populations. We reiterate that states will have the authority and flexibility to set the specific quantitative time and distance standards for the list of provider types at § 438.68(b)(1)(i) through (vii).

Comment: Many commenters supported § 438.68(b)(3) that would require states to establish network adequacy standards for all geographic areas covered by the managed care program or contract. Several commenters also supported permitting states to have varying network adequacy standards for the same provider type based on geographic areas. A few commenters recommended that CMS clarify this language and define specific criteria for standards that vary based on geographic area. A few commenters did not support permitting states to vary their network adequacy standards based on geographic areas, as this flexibility would allow states to set different standards in rural areas and might disadvantage beneficiaries living in rural communities. Finally, several commenters recommended that CMS clarify that states have the flexibility to set varying network adequacy standards across rural and urban population centers.

Response: We thank commenters for the support and recommendations regarding § 438.68(b)(3). We clarify that states do have the flexibility to set varying network adequacy standards across rural and urban population

centers, because this is the same as allowing states to have varying network adequacy standards for the same provider type based on geographic areas. States are not required to set the same network adequacy standards across all provider types for the entire state and can vary such standards based on appropriate state benchmarks. We decline to define specific criteria for network adequacy standards that vary based on geographic area, as we believe this would be inappropriate for CMS to define at a federal level. States are in the best position to define these criteria, as they have a unique understanding of their state's communities and geography. We also disagree with commenters that believe this flexibility will disadvantage beneficiaries living in rural communities. We believe it is appropriate for states to retain this flexibility, as states can set appropriate network adequacy standards that account for a rural community's population demographics and service needs.

Comment: Many commenters supported § 438.68(c)(1), requiring that states consider a minimum list of elements when developing their network adequacy standards. Many commenters specifically supported § 438.68(c)(1)(vii) and (viii), requiring that states consider LEP enrollees, physical access, reasonable accommodations, cultural competency, and accessibility for enrollees with physical or mental disabilities. Several commenters requested that CMS include specific standards and thresholds for states to include, such as ensuring that network adequacy standards consider the top 15 languages of enrollees in a particular area, or ensuring that network adequacy standards consider any language that is spoken or written by at least 5 percent of enrollees (or at least 500 enrollees). A few commenters recommended that CMS remove the LEP and access language at § 438.68(c)(1)(vii) and (viii), concerned that such requirements would be harmful and burdensome to smaller providers.

Response: We thank commenters for the support and recommendations regarding § 438.68(c)(1)(vii) and (viii). We believe that states should consider LEP enrollees, physical access, reasonable accommodations, cultural competency, and accessibility for enrollees with physical or mental disabilities when developing their network adequacy standards. We also encourage states to work with a variety of stakeholders to ensure that such standards are adequate to ensure access to care for Medicaid's vulnerable populations. We do decline to set

specific standards and thresholds in this area, as we believe it is most appropriate for states to assess their populations and set thresholds and standards accordingly. We also decline to remove such elements from what states must consider when developing access and adequacy standards, as we believe it is important to set a national framework that guides states in the development of common network adequacy standards.

Comment: Many commenters supported § 438.68(c)(1)(iii) and (vi) requiring states to consider the characteristics and health care needs of specific populations and the means of transportation ordinarily used by enrollees when setting their network adequacy standards. However, many commenters did not believe that CMS went far enough in prescribing these elements. Commenters recommended that CMS include specific criteria for enrollees that use public transportation. Other commenters recommended that CMS include specific criteria for enrollees with complex or chronic health conditions, such as children and special populations with special health care needs.

Response: We thank commenters for the support and recommendations regarding § 438.68(c)(1)(iii) and (vi). We believe it is important for states to consider these criteria when setting their network adequacy standards. We also restate our belief that it is important for states to work with their stakeholder community. We decline to set additional specific standards and thresholds that states must consider, as we believe it is inappropriate to prescribe a national benchmark when states are in the best position to understand the unique needs of their populations and can best set criteria and standards that are most meaningful to their respective programs. We instead have adopted a general national framework that we believe will guide states in the development of network adequacy standards that strengthen access to care for all Medicaid populations.

Comment: Several commenters recommended that CMS include specific criteria at § 438.68(c)(1) regarding provider panels, provider capacity, and the capacity of providers to provide both emergency and non-emergency care to enrollees.

Response: We thank commenters for the recommendations at § 438.68(c)(1) to ensure that CMS has included criteria for network adequacy that is inclusive of provider panels, provider capacity, and the capacity of providers to provide both emergency and non-emergency care to enrollees. For provider panels

and general provider capacity, we believe these elements are captured at § 438.68(c)(1)(i), (ii), (iv), and (v). We have included elements specific to the anticipated Medicaid enrollment, expected utilization of services, the numbers and types of network providers, and the number of network providers not accepting new Medicaid patients. We believe these elements are inclusive of the commenters' recommendations and require states to consider and analyze provider panels and general provider capacity. For the capacity of network providers to provide both emergency and non-emergency care to enrollees, we believe this recommendation is included at § 438.68(c)(1)(iv) specifically. States must not only consider the numbers and types of network providers, but they must also consider their training, experience, and specialization. We believe this element will ensure that provider networks are capable of providing both emergency and non-emergency care.

Comment: Many commenters recommended that CMS strengthen the language at § 438.68(c)(1) and change the word "consider" to "factor" or "utilize." Commenters stated that they were concerned that the current language would not require states to demonstrate and support that they considered all of the elements when developing their network adequacy standards.

Response: We believe that the current language is clear that states must consider, at a minimum, the elements listed in the regulation text when developing their network adequacy standards. We encourage states to be thorough in their approach when developing network adequacy standards. We also encourage states to work with a variety of stakeholders as they develop their network adequacy standards to ensure that such standards are representative of the program and populations at large.

Comment: Several commenters recommended that CMS add elements at § 438.68(c)(1) to include triage lines or screening systems, as well as the use of telemedicine, e-visits, and/or other evolving and innovative technological solutions. Commenters stated that such elements could impact the needs of enrollees in particular areas.

Response: We agree with commenters that such services and technological solutions could impact the needs of enrollees in a particular area and could change the manner and extent to which other network providers are needed and utilized. We encourage states to consider how current and future

technological solutions could impact their network adequacy standards. Therefore, we agree with adding these criteria to the list of elements that states should consider when developing network adequacy standards. We are modifying the regulatory text to adopt this recommendation at § 438.68(c)(1)(ix).

Comment: Many commenters supported proposed § 438.68(d)(1), allowing states to provide an exception to any of the provider-specific network standards. A few commenters recommended that CMS be more prescriptive in this area and structure a detailed process for states to follow. A few commenters recommended that CMS make clear that states have full flexibility in designing and implementing exceptions criteria. Other commenters recommended that CMS not allow any exceptions under paragraph (d)(1) and remove the language in its entirety. Several commenters recommended that CMS strengthen the language to make clear that states are only permitted to grant exceptions in rare circumstances, such as when a managed care plan cannot possibly meet the network adequacy standard, or the standard is in regard to a rare medical condition. One commenter also recommended that CMS not allow exceptions to provider-specific network standards and instead enforce that states must allow such services on a FFS basis.

Response: We thank commenters for their support and recommendations for proposed § 438.68(d)(1). We believe that it is important for states to retain flexibility in this area, as states are in the best position to understand the unique provider characteristics and demographics in their respective programs. We also agree with commenters that exceptions should not be permitted lightly, and that states should only grant exceptions in rare circumstances. This is why we proposed § 438.68(d)(2), which requires states to monitor access to care for any provider types that are permitted an exception, and that states must include their findings in the managed care program assessment report required at § 438.66. We decline commenters' recommendations to never allow states to permit an exception, as we believe this is unrealistic. We cannot predict future provider workforce shortages and should not penalize states and managed care plans by removing their flexibility to seek and permit reasonable and appropriate provider-specific network exceptions. Finally, we also decline the recommendation to require that states must allow for services to be provided

through FFS rather than allow for any provider-specific exceptions. It is unclear to us that these concepts are related. Managed care plans are already required to offer services out-of-network, if they cannot provide covered services within the network.

Comment: One commenter recommended that CMS add exemption criteria at § 438.68(d)(1) for any managed care plan that has achieved and met accreditation standards for network adequacy.

Response: We thank commenters for the recommendation at § 438.68(d)(1); however, we decline to add exemption criteria for any managed care plan that has achieved and met accreditation standards for network adequacy. We believe that this would be a broad exemption to § 438.68 in whole, and we believe that is not consistent with our general approach in requiring network adequacy standards and ensuring access to care. Since it is impossible for us to account for all of the exact standards and thresholds that might lead a managed care plan to gain accreditation for network adequacy, we find it appropriate for states to require accredited managed care plans to also meet the network adequacy standards at § 438.68.

Comment: One commenter recommended that CMS add specific exceptions criteria at § 438.68(d)(1) for MLTSS programs and providers.

Response: We believe that the current language and criteria at § 438.68(d)(1) is inclusive and sufficient for both non-MLTSS and MLTSS programs. We believe that the process that a state would follow to permit an exception would be the same for all programs and contracts.

Comment: A few commenters recommended that CMS specifically approve all exceptions at § 438.68(d)(1) before allowing states to permit the provider-specific network exception. A few commenters also recommended that CMS require strict documentation from the state to support the exception.

Response: We understand that commenters are concerned with access to care, and CMS is committed to improving access to care through several mechanisms and processes, including network adequacy standards. This is why we proposed § 438.68(d)(2), which requires states to monitor access to care for any provider types that are permitted an exception, and that states must include their findings in the managed care program assessment report required at § 438.66. We believe that this is the appropriate mechanism and process for CMS to review and monitor both state-specific and provider-specific

exceptions. Therefore, we decline to modify the regulation text as recommended by the commenters here.

Comment: Many commenters supported proposed § 438.68(e) requiring states to publish their network adequacy standards on the state public Web site. Several commenters also recommended that CMS publish these standards on a federal platform, such as Healthcare.gov or Medicaid.gov.

Response: We thank commenters for their support and recommendations at § 438.68(e). We do not believe that it is necessary for CMS to also post a state's network adequacy standards on Healthcare.gov or Medicaid.gov, as states are required to post their network adequacy standards on their own state public Web site. We believe this is more effective in facilitating discussions with the stakeholder community in that state.

Comment: A few commenters recommended that CMS specifically approve a state's network adequacy standards at § 438.68(e) and that CMS should publish a review of the state's network adequacy standards on the CMS public Web site for public comment.

Response: Consistent with our general approach throughout § 438.68, we do not believe it is necessary for CMS to actively approve a state's network adequacy standards and publish our review on the CMS Web site. Throughout § 438.68, we have provided an overarching federal framework for network adequacy standards that we hope will guide states toward the development of common network adequacy standards that improve access to care for all Medicaid beneficiaries. However, it is not our intention to prescribe exact quantitative standards or set a national floor for such standards, as we believe this approach to be overly prescriptive and does not allow for appropriate and meaningful state flexibility in their respective programs. We therefore decline to adopt the commenters' recommendations, as we do not believe it is possible for CMS to actively approve a state's network adequacy standards without prescriptive metrics. Instead, we encourage states to include appropriate and meaningful stakeholder engagement and feedback when setting their network adequacy standards, and we believe that requiring states to publish such standards on their state public Web site will enhance and improve transparency.

(2) Criteria for Developing Network Adequacy Standards for MLTSS Programs (§ 438.68(b)(2) and (c)(2))

In the proposed rule, we proposed minimum standards for how states adopt network adequacy standards to ensure the availability of critical services and supports for beneficiaries as more of them transition to MLTSS programs. We noted that, unlike medical and behavioral health services, there are no commonly used access standards for LTSS in the private market or in Medicare, as LTSS are primarily covered through Medicaid. Further, as states have begun to deliver LTSS through managed care, they have created standards for their individual programs, which vary widely. Likewise, the level of oversight by the state that is necessary to enforce network adequacy standards for LTSS provided through managed care contracts varies, ranging from a minimal level of effort to an in-depth review of service plan authorizations compared to actual claims experience.

We noted that LTSS can also be delivered in a person's home, a provider's office, in various community locations, such as places of employment or recreation, or in an institution. In § 438.68(b)(2), we proposed that states would set standards that encompass time and distance and other measures of access when delivering LTSS through their managed care plans, noting that the type of standard that the state would adopt under our proposal depends on whether the enrollee or the provider must travel to provide the services. While we did not specify a specific set of providers in our LTSS-specific proposal, we indicated that we expect the state to consider all LTSS delivered through managed care when developing the standards which may include, but are not limited to, institutional, community-based, residential, and employment supports providers, depending on the program. Proposed paragraph (c)(2) set forth the elements that states would have to consider when developing standards for LTSS in a managed care program. Under our proposal, when developing time and distance standards, states would consider the same elements as when setting medical services network standards and also consider strategies to ensure the health and welfare of enrollees using LTSS and to support community integration of individuals receiving LTSS. We noted that LTSS enrollees may have different needs than those enrollees only using acute, primary, and behavioral health services. For example, assessing network

adequacy for individuals receiving LTSS in their place of residence may be based on enrollee-to-provider ratios. Additionally, the ability of the enrollee to choose a provider is a key protection that must be considered when developing network standards for MLTSS so we proposed to include that here. We also noted that supporting health and welfare and choice of provider are important tenets already in place in the LTSS FFS system and MLTSS should maintain those protections. Finally, our proposal included a substantive standard which we would apply to determine if states must include other considerations under § 438.68(c)(2)(iv).

We received the following comments in response to our proposal to add new § 438.68(b)(2) and (c)(2).

Comment: One commenter thought states should have full discretion and there should not be any defined network adequacy standards for MLTSS; all other commenters recommended the adoption of some form of standards for LTSS. Many commenters stated that time and distance standards were appropriate for LTSS services where the individual must travel to a provider, although a few commenters added that beneficiary disability and transportation considerations need to factor in to the time and distance standards. Several commenters thought CMS should establish how much time and what distance the states must adopt as the standard, and several others commented that CMS should set a baseline requirement upon which states could develop their full network adequacy standards. One commenter thought CMS should convene a technical expert panel to establish national network adequacy standards for LTSS; a couple of commenters asked for a workgroup to study the issue; and one other proposed that residential providers would not need to have time and distance network adequacy standards.

Response: We thank commenters for their support for the use of time and distance standards for LTSS services where the member travels to the provider for services. Section 438.68(c)(2) specifies considerations that must be taken into account in establishing LTSS network adequacy standards including other considerations that are in the best interest of the enrollees who need LTSS. We believe this language is sufficiently broad to ensure consideration of the needs of the LTSS population. Although we had requested further comment in the area of network adequacy standards for LTSS, no respondent provided specific time or distance standards that

have been used or that have proven adequate to assure network adequacy. For these reasons, we continue to believe that, at this time, the best strategy is for states to develop their own time and distance standards for LTSS provider types to which a beneficiary travels, based on the state's unique service, beneficiary and geographic considerations.

Comment: Several commenters addressed network adequacy standards for LTSS providers that travel to the individual's home. A couple of commenters suggested that provider ratios were not a satisfactory measure, while others recommended using direct care provider ratios to LTSS beneficiary service plan hours. Additionally, a few commenters recommended adopting time and distance standards even when the provider travels to the member. A few commenters addressed network adequacy standards for LTSS where providers travel to the enrollee and there was no clear consensus for one type of measure over another.

Response: We believe that the few number of comments and lack of consensus regarding the measure of network adequacy for services when a provider travels to the enrollee confirm our position that states should establish standards based on their unique mix of services and characteristics and evaluate and amend these standards, as appropriate. A ratio of direct provider capacity to treatment or service plan hours may inform the development of network adequacy standards, but there are circumstances, such as self-directed services, where this analysis may not be possible. Therefore, we are finalizing our standards in paragraph (b)(2) as proposed in this final rule.

Comment: Some commenters suggested that there are multiple entities that should be involved in establishing network adequacy standards for LTSS. A few commenters believed that states, managed care plans, and counties should work together to develop standards; another commenter thought providers should participate in establishing standards; and a number of commenters thought beneficiaries should participate in establishing the network adequacy standards.

Response: We support the inclusion of stakeholders in the development of network adequacy standards at the state level but decline to specify the nature the development process in regulation beyond what is required by § 438.68(c) in this final rule. As each state is responsible for assuring that their managed care Medicaid beneficiaries have access to covered and necessary services at § 438.207, we believe the

state must be the entity responsible for establishing the network adequacy standards. Per § 438.68(e), the network adequacy standards will be available on the state's Web site.

Comment: Several commenters requested that beneficiary choice of LTSS provider be factored into network adequacy standards. A couple of commenters thought LTSS network adequacy standards should consider wait times, provider availability in a region, and the provider type. Several commenters pointed out that LTSS provider credentialing standards are important to consider; some commenters stated that incentives be provided to managed care plans who meet the state LTSS network adequacy standards; and one commenter suggested that beneficiaries should have access to out of network LTSS providers whenever timely access is denied. One commenter suggested that managed care plans should be required to provide recruitment and retention bonuses to LTSS providers. One commenter believed that there are not enough LTSS providers available in general to meet demand. A number of commenters recommended that states should be required to report to CMS on enrollee outcomes after LTSS network adequacy standards have been implemented. A few commenters suggested that periodic audits should be conducted by states and provided to the public on network adequacy.

Response: We appreciate the commenters' concerns and thank commenters for the many suggestions. We agree with the commenters that beneficiary choice of provider be factored into network adequacy standards. Enrollee choice of provider is a factor for consideration in § 438.68(c)(2)(ii). We believe that the language is sufficient to require states to consider enrollee choice, without being overly prescriptive on how it should be considered.

CMS also agrees with commenters that timely access and availability of services is critical for all enrollees and especially for enrollees needing LTSS. Section 438.207(d) requires managed care plans to document and provide assurance that they are meeting the state's requirements for the availability of services as set forth in § 438.206. States are required to review this documentation and submit an assurance to CMS that managed care plans are meeting the state's requirements for the availability of services. We decline to add requirements because states need flexibility to tailor their program to the populations served and the benefits provided.

We also decline to require additional reporting on the network adequacy requirements. Section 438.207(d) requires that documentation and analysis be submitted to CMS. Likewise, § 438.66(e)(2)(vi) requires states to report on the availability and accessibility of services in the annual report. We believe that these two requirements provide an appropriate balance between CMS oversight role, public transparency, and administrative burden on states.

Comment: Several commenters thought there should be separate network adequacy standards for pediatric LTSS providers, and several thought geographical considerations must be taken into account.

Response: We agree that if pediatric LTSS providers offer necessary services that an adult LTSS provider cannot appropriately provide, states should consider the most appropriate way to address these providers in the network adequacy standards. However, we decline to include any specific type of LTSS provider in the regulations. We believe that states are in the best position to determine the providers to include to best meet the needs of the LTSS program. We agree with the commenters that geographical considerations are an important consideration in developing network adequacy standards. As proposed and finalized here, § 438.68(c)(1)(vi) requires states to consider geographic factors and § 438.68(b)(3) permits states to vary standards for the same provider type based on geographical area. We believe that these sections address the commenters' concerns.

After consideration of the public comments, we are modifying the regulatory text at § 438.68(b)(1)(iii) to include both "adult and pediatric" behavioral health. We are also modifying the regulatory text at § 438.68(b)(1)(iii) to clarify that the "behavioral health" provider type/category includes both mental health (MH) and substance use disorder (SUD) providers. We are finalizing the regulation text at paragraphs (c)(1)(vi) through (viii) to use "network provider" in place of the proposed use of "health care professionals" for reasons discussed in section I.B.9.a. of this final rule. We are modifying the regulatory text at § 438.68(c)(1)(ix) to include triage lines or screening systems, as well as the use of telemedicine, e-visits, and/or other evolving and innovative technological solutions, as criteria that states should consider when setting their network adequacy standards and, to account for this additional text in the final rule, are modifying paragraph

(c)(2)(i) to refer to paragraphs (c)(1)(i) through (ix). We are finalizing all other paragraphs in § 438.68 as proposed.

(3) Availability of Services (§ 438.206 and § 440.262)

Currently, in § 438.206, states must ensure that all services covered under the state plan are available and accessible to enrollees of MCOs, PIHPs, and PAHPs. Throughout § 438.206, we proposed to use the terms "network provider" and "provider" as applicable to be consistent with the proposed new definitions of these terms (see section I.B.9. of this final rule) and to provide greater clarity to our regulations. We consider such changes largely technical in nature.

We also proposed to revise paragraph (a), which currently sets forth the basic rule for the availability of services, to add a new sentence such that states must ensure that MCO, PIHP, and PAHP provider networks for services covered under the MCO, PIHP, or PAHP contract meet the state's network adequacy standards established under proposed § 438.68. In addition, we also proposed to clarify that services are to be made available and accessible in a timely manner. The timeliness standard is currently in paragraph (b)(4), pertaining to access to out-of-network providers, and in paragraph (c)(1); we indicated that we believe it is appropriate to incorporate timeliness into the general rule for availability of services in paragraph (a).

In paragraph (b), we proposed substantive changes only to (b)(1) and (b)(5). We proposed to move the second sentence of (b)(1) and the provisions at existing paragraphs (b)(1)(i) through (b)(1)(v) to the new § 438.68(c) so that all regulatory standards related to the measurement of adequate MCO, PIHP, and PAHP provider networks are contained in one section. We proposed to add text to (b)(1) to clarify that the sufficiency and adequacy of the provider network and access to services is for all enrollees, including those with limited English proficiency and physical or mental disabilities. We proposed to amend paragraph (b)(5) to include PAHPs in the payment standard for covered services that are provided out-of-network. We stated that this represents a technical correction as the preamble for the 2002 final rule refers to PAHPs (67 FR 41038) and we believe PAHPs were inadvertently excluded from the final regulatory text.

We did not propose any substantive changes to existing paragraph (c)(1) but proposed changes to improve the readability and clarity of the regulation text. We also clarified our intent to

interpret and apply the provisions in paragraph (c)(1) as requiring states to set standards for timely access to all state plan services covered under the managed care contract. For purposes of setting timely access standards, state plan services may be reasonably classified as routine, urgent, or emergency care. We noted that for access standards to be effective, states will need to have mechanisms in place for ensuring that those standards are being met by the managed care plan networks. We considered requiring a mix of approaches, such as conducting enrollee surveys, reviewing encounter data, calculating and reporting of HEDIS measures related to access, implementing secret shopper efforts, and a systematic evaluation of consumer service calls. We requested comment on approaches to measuring enrollee's timely access to covered services and to evaluating whether managed care plan networks are compliant with such standards. We also requested comment on the value of requiring some or all of these mechanisms for ensuring that access standards are being met.

In paragraph (c)(2), we proposed to add to the standards to ensure that MCOs, PIHPs, and PAHPs participate in states' efforts to promote access in a culturally competent manner to all enrollees. This includes those with limited English proficiency, diverse cultural and ethnic background, disabilities, and regardless of an enrollee's gender, sexual orientation, or gender identity. We also proposed to add a corresponding standard in a new § 440.262 so that the state would similarly ensure cultural competence and non-discrimination in access to services under FFS. We believe that the obligation for the state plan to promote access and delivery of services without discrimination is necessary to assure that care and services are provided in a manner consistent with the best interest of beneficiaries under section 1902(a)(19) of the Act. We noted that the best interest of beneficiaries is appropriately met when access is provided in a non-discriminatory manner; adopting these additional methods of administration is also necessary for the proper operation of the state plan under section 1902(a)(4) of the Act.

We proposed to add a new paragraph (c)(3) to emphasize the importance of network providers having the capabilities to ensure physical access, accommodations, and accessible equipment for the furnishing of services to Medicaid enrollees with physical or mental disabilities. We noted that this proposal was mirrored in proposed

§ 438.68(c)(1)(vii) relating to considerations for developing network adequacy standards.

We received the following comments in response to our proposal to revise § 438.206 and add new § 440.262.

Comment: Many commenters supported § 438.206(a). A few commenters recommended additional regulatory text to clarify that specific state plan services must be made available by managed care plans.

Response: We thank commenters for their support of § 438.206(a). We disagree with commenters that we should add regulatory text to clarify that specific state plan services must be made available by managed care plans. We believe the current regulatory text is clear that all services covered under the state plan must be available and accessible to enrollees of managed care plans. States are free to design the methods of delivery of those services to eligible beneficiaries.

Comment: Many commenters supported § 438.206(b)(1). Several commenters recommended that CMS include specific references to §§ 438.2 and 438.3 regarding contract requirements. Several commenters also recommended that CMS include a specific reference to § 438.68(c) regarding network adequacy standards.

Response: We disagree with commenters that we should include specific references at § 438.206(b)(1) to include §§ 438.2, 438.3, and 438.68(c), as we find these references to be duplicative and unnecessary. All managed care contracts must comply with the standard contract requirements at § 438.3. We proposed in § 438.206(a) that all services covered under the managed care contract must meet the standards developed by the state in accordance with § 438.68. It is unclear why commenters have recommended that we include a reference to § 438.2, as this is in the definitions section of part 438; we therefore decline to add such a reference, as the definitions apply to all sections contained in this part.

Comment: Many commenters recommended revisions or clarifications at § 438.206(b)(2) regarding direct access to a women's health specialist. Many commenters recommended that CMS clarify that this requirement also applies to adolescent women who are under the age of 18 but still require the services of a women's health specialist. Many commenters recommended that CMS remove the language "routine and preventive" as they believe that managed care plans use this language to exclude direct access to specialty health care services for women. Many

commenters also recommended that CMS add language to clarify that specialty health care services for women are included in the direct access requirement. Several commenters recommended that CMS define "routine and preventive" health care services for women, and a few commenters recommended that CMS list all women's routine and preventive health care services that are included in the direct access requirement. Several commenters recommended that CMS add language to clarify that if either the managed care plan or provider has religious objections to specific health care services for women, such health care services must be allowed out of network and without cost to the enrollee. Finally, many commenters recommended that CMS add regulatory text to clarify that direct access for all family planning providers (both in and out of network), services, and supplies must be allowed for all enrollees, regardless of age, sex, or gender, if such enrollees can be considered to be sexually active, consistent with the requirements at sections 1902(a)(23) and 1905(a)(4)(C) of the Act.

Response: We appreciate commenters' recommendations at § 438.206(b)(2). A managed care plan is required to provide female enrollees with direct access to a women's health specialist within the network for routine and preventive health care services. This includes initial and follow-up visits for services unique to women such as prenatal care, mammograms, pap smears, and for services to treat genitourinary conditions such as vaginal and urinary tract infections and sexually transmitted diseases. Further, we use the term "female enrollees" to include minor females. We believe that if there is a medical need to see a women's health specialist, there should be no impediment based on the age of the enrolled female. However, we disagree with commenters that regulatory text revisions are necessary and instead believe that our clarification above is sufficient to remove any further ambiguity regarding the age of a female enrollee and the context of "routine and preventive" health care services for women.

We also disagree with commenters that we should add language regarding out of network access to care for services not provided by a managed care plan due to religious objections. Within part 438, we have included references for religious objections at § 438.10(e)(2)(v)(C), § 438.10(g)(2)(ii)(A) and (B), and § 438.100(b)(2)(iii). Consistent with the context of the regulatory text, § 438.206(b)(2) is related

to the availability of services within the managed care plan's delivery network. It is not appropriate to add regulatory text to address all circumstances that could warrant out of network care or services, including religious objections.

Comment: In addition to comments regarding the availability of family planning services, we also received comments in response to our request for comment in § 438.68 as to whether family planning should be included in the network adequacy provisions. The comments received on family planning indicate that, while network adequacy standards may not be needed due to enrollees' ability to access services out of network, some clarification on states' and managed care plans' responsibility for ensuring the availability of these services would be helpful.

Response: We agree with commenters that the statutory protections for family planning services should be reflected in part 438 regulations. We included, in the proposed rule and this final rule, the references for family planning services and supplies being available at §§ 438.10(g)(2)(vii) and 438.210(a)(4)(ii)(C) to be consistent with the statutory requirements in sections 1902(a)(23)(B) and 1905(a)(4)(C) of the Act. We are also finalizing additional text in section 438.10(g)(2)(vii) to specify that enrollees cannot be required to obtain a referral prior to choosing their family planning provider.

In § 438.206, we have added a new paragraph (b)(7) that requires states to include a contract provision in all MCO, PIHP, and PAHP contracts requiring the managed care plan to demonstrate that it has sufficient providers for family planning services in network to provide timely access. Despite the ability of enrollees to access family planning services out of network without a referral, we agree with commenters that it is important for managed care plans to be able to provide sufficient timely access to these services within the network as well. Use of network providers facilitates claims payment, helps enrollees locate providers more easily, and improves care coordination. While the ability to choose a family planning provider from outside a managed care plan's network is an important beneficiary option, we do not believe it negates the managed care plan's responsibility to ensure timely access within its network. For these reasons, we are finalizing new paragraph (b)(7).

Comment: Several commenters supported § 438.206(b)(3). One commenter recommended that CMS add the term "timely" to ensure that second opinions are obtained in a timely

manner. One commenter recommended that CMS add “internists” as specific health care professionals that could be consulted when a second opinion is needed.

Response: We agree with commenters that timely access to a second opinion is important to ensure timely access to care; however, we decline to add the term “timely” at § 438.206(b)(3), as timely access is considered at § 438.206(c)(1). We further decline to add “internists” as specific network providers that could be consulted when a second opinion is needed, as it is not consistent with the general approach of the regulatory text to allow a second opinion from any qualified network provider. We are finalizing the regulation text at § 438.206(b)(3) to use “network provider” in place of the proposed use of “health care professional” for reasons discussed in section I.B.9.a. of this final rule.

Comment: Many commenters recommended revisions or clarifications at § 438.206(b)(4) regarding out of network services and benefits for enrollees. Many commenters recommended that CMS specifically include language to clarify that if the provider network is unable to provide necessary specialty services or specialty care, managed care plans must cover such services out of network. A few commenters also recommended that CMS add specific language for out of network services for rare conditions and provider shortages. One commenter recommended that CMS allow direct access to HIV specialists. Many commenters recommended that CMS add the term “timely” and specifically reference the time and distance standards at § 438.68 and the assurances of adequate capacity and services at § 438.207(b) and (c). One commenter recommended that CMS add requirements to ensure that if managed care plans must arrange for out of network services, the managed care plan must cover the cost of the care and must provide transportation for the enrollee. One commenter recommended that CMS clarify that § 438.206(b)(4) does not require states to offer out of network benefits unless the managed care plan does not have contracted providers to meet the needs of enrolled populations, and the provision does not negate internal processes that must be followed by enrollees to obtain approval for out of network services.

Response: We appreciate the thoroughness of commenters’ recommendations at § 438.206(b)(4). While we understand commenters’ concerns regarding specialty services and care, rare conditions, provider

shortages, and direct access to HIV specialists, we decline to add these specific circumstances to the regulatory text, as we believe such text would be duplicative and unnecessary. The current text requires managed care plans to adequately and timely cover services out of network for enrollees if their current provider networks are unable to provide the necessary services covered under the contract. We believe this text is inclusive of specialty services and all other circumstances when the provider network is unable to provide the necessary services needed for enrollees. We also decline to add specific references to § 438.68 and § 438.207(b) and (c), as we believe it is duplicative and unnecessary. We have already included the appropriate reference to § 438.68 at § 438.206(a). We decline to add the term “timely,” as timely access is required at § 438.206(c)(1). We also decline to add requirements that managed care plans must cover the cost of transportation, as NEMT is generally a covered benefit provided to enrollees, either through the managed care plan, or through other arrangements provided by the state. We also clarify that consistent with § 438.206(b)(5), the cost to the enrollee for out of network services can be no greater than if the services were furnished within the network. Finally, we clarify for the commenter that out of network benefits are only required when the provider network is unable to provide the necessary services covered under the contract. We also note that the provisions at § 438.206(b)(4) do not negate internal state or managed care plan processes for enrollees to obtain approval for out of network services.

Comment: Several commenters recommended that CMS add requirements at § 438.206(b)(5) to set payment parameters for out of network providers. A few commenters recommended that CMS require managed care plans to pay FFS rates to out of network providers. One commenter recommended that CMS allow states to set a specific percentage of FFS that managed care plans must pay out of network providers. One commenter recommended that CMS allow states to incentivize single source contracts between managed care plans and out of network specialists.

Response: We decline to adopt commenters’ recommendations at § 438.206(b)(5), as we believe the issue of payment for out of network providers is between managed care plans and health care providers. Our regulation only requires that the cost to the enrollee is no greater than it would be if the services were furnished within the network. The regulations in this part do

not prohibit single source agreements, also known as single case agreements, between managed care plans and out of network providers and we acknowledge that such arrangements may be necessary for the managed care plan to meet its obligations under the contract.

Comment: Many commenters supported § 438.206(c)(1)(i) but recommended that CMS add more specificity regarding the exact quantitative standards for timely access to care that states and managed care plans must implement and comply with. Many commenters recommended that CMS add specific quantitative standards for provider surveys, enrollee surveys, audits of encounter data, secret shopper efforts, appointment wait times, and the time and distance standards specified in § 438.68. Several commenters recommended that states retain flexibility regarding access to care standards for their respective programs, as states need to consider state-specific complexities, such as the populations enrolled, scope of the program, state-specific private market standards, and geography. A few commenters recommended that CMS require states to ensure their rates are adequate to provide timely access to care. One commenter recommended that CMS require separate access to care standards for primary care and specialty providers. One commenter also recommended that CMS require states to confer with clinicians and other providers with clinical expertise on appropriate state standards.

Response: We thank commenters for the variety of comments and recommendations on § 438.206(c)(1)(i) to ensure timely access to care for enrollees; however, we decline to adopt specific quantitative standards for provider surveys, enrollee surveys, audits of encounter data, secret shopper efforts, appointment wait times, the time and distance standards specified in § 438.68, or other quantitative standards. We believe that states should be allowed to set appropriate and meaningful quantitative standards for their respective programs. We also believe that states are in the best position to set specific quantitative standards that reflect the scope of their programs, the populations served, and the unique demographics and characteristics of each state. As many commenters stated, it is crucial for CMS to strike an appropriate balance between federal requirements and state flexibility. We also decline to add specific requirements for states to ensure their rates are adequate to provide timely access to care, as this requirement is already specified at

§ 438.4(b)(3) related to actuarial soundness. We also decline to add requirements for separate access to care standards for primary care and specialty providers, as we believe this is appropriately specified in the network adequacy standards at § 438.68. Finally, while we encourage states and managed care plans to engage their stakeholder communities regarding specific and appropriate timely access to care standards, we decline to add requirements for states to specifically confer with clinicians and other providers with clinical expertise on appropriate state standards, as we believe that states confer with clinicians and other providers on a regular basis through the Medical Care Advisory Committee required at § 431.12 of this chapter.

Comment: A few commenters recommended that CMS clarify that the requirement at § 438.206(c)(1)(iii) making services available 24 hours a day, 7 days a week, when medically necessary, is related to emergency and inpatient services.

Response: We agree with commenters that emergency and inpatient services are examples of care that should be available 24 hours a day, 7 days a week. We note that states may specify additional medically necessary services under their contract with the managed care plan that should be available 24 hours a day, 7 days a week.

Comment: Many commenters supported § 438.206(c)(1)(iv) but recommended that CMS add more specificity regarding the exact mechanisms that managed care plans must establish to ensure timely access to care. Many commenters recommended that CMS require direct measurement of standards to test access to care. Many commenters recommended that CMS require mechanisms such as phone surveys with enrollees, secret shopper efforts, network provider audits, and CAHP surveys. A few commenters also recommended that CMS require such mechanisms to be performed by an independent third party to ensure accurate and unbiased results.

Response: We appreciate the variety of comments and recommendations at § 438.206(c)(1)(iv) to ensure appropriate mechanisms are in place; however, we decline to adopt such specific mechanisms for managed care plans to establish, such as phone surveys with enrollees, secret shopper efforts, network provider audits, and CAHP surveys. While we agree that the mechanisms suggested by commenters could be beneficial in measuring and ensuring timely access to care, we believe that as an initial measure states

and managed care plans should work together to establish and implement appropriate and meaningful mechanisms for their respective programs. We also agree with commenters that such mechanisms could be performed by an independent third party and would encourage states and managed care plans to consider such arrangements. This is consistent with the approach that we have taken in other recently issued regulations (80 FR 67576) that discuss methods that states must take to assure access to care in their FFS systems. In addition, we issued a request for information (RFI) that will further inform our policies for access across the Medicaid program (including FFS and managed care delivery systems). See <https://www.federalregister.gov/articles/2015/11/02/2015-27696/medicaid-program-request-for-information-rfi-data-metrics-and-alternative-processes-for-access-to>. Based on the responses to the RFI and other efforts underway at CMS, we may, in the future, advance a national core set of access to care measures and thresholds or goals for access in the Medicaid program. If a core set of access measures were to be established, the process would be coordinated with the existing process of updating the child and adult core set of quality measures.

Comment: A few commenters recommended that CMS require annual reports or an annual certification at § 438.206(c)(1)(v) to ensure that managed care plans are monitoring network providers regularly.

Response: While we appreciate the recommendation to include annual reports or an annual certification at § 438.206(c)(1)(v), we do not believe it is necessary. Managed care plans are required to submit network adequacy documentation to the state on at least an annual basis at § 438.207(c)(2). We believe that this requirement is sufficient to ensure that managed care plans are monitoring network providers regularly. Additionally, we note that § 438.66(e)(2)(vi) requires states to report on their assessment of the accessibility and availability of services.

Comment: Many commenters supported § 438.206(c)(2) regarding access and cultural considerations. A few commenters recommended that CMS add specific requirements and standards, as the proposed text is ambiguous and hard to enforce. A few commenters also recommended specific language to ensure that services related to language access are provided to all potential enrollees and enrollees who are LEP.

Response: We appreciate the support and recommendations regarding

§ 438.206(c)(2) but decline to adopt these specific recommendations. We believe the language is clear that each managed care plan must participate in the state's efforts to promote the delivery of services in a culturally competent manner to all enrollees. States will have the authority to set specific requirements for managed care plans as appropriate.

Comment: Several commenters recommended revisions to § 438.206(c)(3) regarding accessibility considerations. One commenter recommended adding the phrase "age appropriate" before physical access. Other commenters recommended adding "programmatic access," "policy modifications," and "effective communication." One commenter recommended revising "accommodations" to "reasonable accommodations" to be consistent with § 438.68(c)(1)(viii). A few other commenters recommended that CMS remove the language, as providers must comply with the ADA, which is more comprehensive. One commenter recommended that CMS reference both the ADA and section 504 of the Rehabilitation Act. A few commenters recommended that CMS add specific requirements and standards regarding accessibility. Another commenter recommended that CMS require managed care plans to survey enrollees regarding provider accessibility. One commenter recommended that managed care plans add accessibility information to their provider directories.

Response: We appreciate the support and recommendations regarding § 438.206(c)(3). We decline to adopt the phrase "age appropriate" as we believe this is unnecessary. The current text requires that each managed care plan must ensure that network providers provide physical access for all enrollees with physical or mental disabilities. We believe this includes enrollees of all ages. We also decline to adopt "programmatic access," "policy modifications," and "effective communication," as we believe the current regulatory text provides the appropriate level of accessibility for enrollees with physical or mental disabilities. We agree with the commenter to revise "accommodations" to "reasonable accommodations" to be consistent with the language at § 438.68(c)(1)(viii). We are modifying the regulatory text to adopt this recommendation. We disagree with commenters that we should delete the regulatory language, as we believe it is appropriate to emphasize the importance of network providers having the capabilities to ensure physical

access, reasonable accommodations, and accessible equipment for the furnishing of services to enrollees with physical or mental disabilities. We also decline to reference the ADA or section 504 of the Rehabilitation Act specifically, as we believe this is addressed in § 438.3(f), and providers are already required to comply with the ADA and section 504 of the Rehabilitation Act, as appropriate. In addition, we do not believe we should add specific requirements and standards regarding accessibility or require managed care plans to survey enrollees regarding provider accessibility. States will have the authority to set specific requirements for managed care plans as appropriate. Finally, we note that the requirements regarding accessibility and provider directories is at § 438.10(h)(1)(viii); therefore, we decline to add such requirements here.

Comment: A few commenters supported the addition of methods at § 440.262 to promote access and delivery of services in a culturally competent manner to all beneficiaries across both Medicaid managed care and FFS. One commenter recommended that CMS clarify the specific standards against which state methods to ensure culturally competent access to care will be reviewed and recommended that CMS work with states and other stakeholders to develop appropriate review criteria.

Response: We encourage states to work with their stakeholder community to develop methods and promote access and delivery of services in a culturally competent manner to all beneficiaries. We decline to add specific standards at § 440.262, as we agree with commenters that we should work further with states and other stakeholders to develop appropriate methods and standards and review criteria.

After consideration of the public comments, we are adding new regulatory text at § 438.206(b)(7) to require a managed care plan to demonstrate that its network has family planning providers sufficient to ensure timely access to family planning services. We are modifying the regulatory text at § 438.206(c)(3) to revise “accommodations” to “reasonable accommodations” to be consistent with the language at § 438.68(c)(1)(viii). We are finalizing the regulation text at § 438.206(b)(3) to use “network provider” in place of the proposed use of “health care professional” for reasons discussed in section I.B.9.a. of this final rule. We are finalizing all other provisions in §§ 438.206 and 440.262 as proposed.

(4) Assurances of Adequate Capacity and Services (§ 438.207)

Currently in § 438.207(a), states have to ensure, through the contracts and submission of assurances and documentation from managed care entities, that the managed care plans have the capacity to serve the expected enrollment in accordance with state-set standards for access to care. In addition, under current § 438.207(b), the specified documentation must demonstrate the adequacy of the range of covered services and the provider network. We proposed to keep the existing regulation text in paragraphs (a) and (b) substantially the same, but proposed a minor amendment to specify in paragraph (b)(1) that supporting documentation must also address LTSS. This change is consistent with our broader proposal to incorporate LTSS throughout part 438, where applicable.

Under current § 438.207, states, through their contracts, must stipulate that MCOs, PIHPs, and PAHPs submit documentation that their network is sufficient in number, mix, and geographic distribution to meet, in accordance with state-set standards, the needs of anticipated enrollees. We proposed to amend § 438.207(c) so that managed care plans have to submit documentation and the state has to certify the adequacy of the provider networks on at least an annual basis. We requested comment on the appropriate timeframe for submission and review of network certification materials.

We also proposed to redesignate the regulation text currently at § 438.207(c)(2) as (c)(3), which stipulates submission of documentation of adequate networks when there has been a significant change in the managed care plan’s operations that would affect capacity and services. We proposed that a significant change in the composition of a MCO, PIHP, or PAHP’s network itself would also trigger a submission of documentation to be codified in § 438.207(c)(3)(i). For example, we noted a significant change in the composition of the provider network would occur when the only participating hospital terminates the network provider agreement, or similarly, when a hospital that provides tertiary or trauma care exits a managed care plan network. We also proposed minor edits to introductory text in paragraph (c)(3) to improve the readability of the paragraph.

In paragraph (d) of § 438.207, addressing the obligation of the state to review documentation from the MCO, PIHP, or PAHP and submit an assurance to us that the managed care plan meets

the state’s standards for access to services, we proposed to add an explicit standard that the submission include documentation of the analysis supporting the certification of the network for each contracted MCO, PIHP, or PAHP. We indicated that this is appropriate because it would demonstrate to us how the state evaluates plan compliance with state standards and that the state’s assurance is supported by the data. In addition, we proposed to replace the word “certify” with “submit an assurance of compliance” to more clearly describe the responsibility of the state under paragraph (d). We did not propose any revision to § 438.207(e), which establishes our right to inspect the documentation provided under § 438.207. We requested comments on the overall approach to § 438.207.

We received the following comments in response to our proposal to revise § 438.207.

Comment: A few commenters recommended that CMS add a reference to § 438.68 at § 438.207(a) to be consistent with § 438.206(a) and other sections throughout part 438. One commenter also recommended that CMS add a reference to § 438.206(c)(1).

Response: We agree with commenters that § 438.207(a) could be clarified with additional references to the specific access to care standards at §§ 438.68 and 438.206(c)(1). We are modifying the regulatory text to adopt this recommendation.

Comment: Many commenters recommended specific revisions at § 438.207(b)(1) and (2) related to the documentation requirements to support that each managed care plan is offering an appropriate range of preventive, primary care, specialty services, and LTSS (if appropriate) and maintaining a network of providers that is sufficient in number, mix, and geographic distribution to meet the needs of the anticipated number of enrollees in the service area. Many commenters recommended that CMS set specific quantitative standards regarding the sufficient number of specific provider types and categories that each managed care plan must include in their documentation. Specifically, commenters recommended that CMS include specific data submission requirements when submitting the specified supporting documentation. A few other commenters recommended that CMS include specific documentation requirements for pediatric and specialty providers, including specialists that treat rare and highly specialized health conditions. A few commenters recommended that

CMS specify the types of analyses that managed care plans should be conducting and submitting to the states. One commenter recommended that CMS require that states compare managed care plan documentation submissions to the provider directories of each managed care plan to ensure compliance. A few commenters recommended that CMS specify LTSS requirements in more detail and be specific about the kinds of documentation states should be allowed to accept to ensure an adequate number and mix of LTSS providers. Several commenters also recommended that CMS include specific requirements for stakeholder engagement, especially for LTSS programs and providers.

Response: We thank commenters for the comments and recommendations at § 438.207(b)(1) and (2) but decline to adopt commenters' recommendations regarding specific quantitative thresholds or the specific and sufficient number of provider types and categories that each managed care plan must include in their documentation. Consistent with our approach at both § 438.68 regarding time and distance network adequacy standards and § 438.206(c)(1) regarding state established timely access to care standards, we are not setting specific quantitative standards or thresholds for Medicaid managed care programs. We believe that states should set appropriate and meaningful quantitative standards for their respective programs and that they are in the best position to set specific quantitative standards that reflect the scope of their programs, the populations served, and the unique demographics and characteristics of each state. As many commenters stated, it is crucial for CMS to strike an appropriate balance between federal requirements and state flexibility. We are finalizing the rule that we think does that.

We decline to add specific documentation requirements for pediatric and specialty providers, as we believe this is appropriately specified in the network adequacy standards at § 438.68. We also decline to set specific data submission requirements or set specific requirements regarding the types of analyses that managed care plans should be submitting to states. These recommendations are too prescriptive and would not provide states the flexibility to specify the types of analyses and the format of such analyses for their respective programs. We believe it is appropriate to require supporting documentation as an overarching federal framework but decline to set prescriptive requirements

on the kinds or format of such documentation. We also decline to require states to compare managed care plan documentation submissions to provider directories. While this might be a beneficial exercise, it may not be the most appropriate method for states to verify compliance. States should be allowed flexibility in the methods they utilize to verify the documentation and ensure that managed care plans are meeting all of the requirements at § 438.207(b)(1) and (2).

Finally, we thank commenters for the recommendations regarding more specificity related to LTSS programs and providers. Consistent with our approach at § 438.68, we decline to include specific requirements regarding the numbers and types of LTSS providers to ensure an adequate mix. We believe that states are in the best position to determine the exact requirements, depending on the scope of their LTSS programs and the populations served. We also note that at § 438.70, states must ensure the views of beneficiaries, providers, and other stakeholders are solicited and addressed during the design, implementation, and oversight of a state's managed LTSS program. This includes the supporting documentation requirements at § 438.207(b)(1) and (2). We encourage states and managed care plans to engage their stakeholder communities regarding specific and appropriate timely access to care standards and supporting documentation requirements.

Comment: Many commenters supported § 438.207(c)(2) regarding the annual requirement for managed care plans to submit the supporting documentation to states related to the network adequacy and timely access to care standards specified at § 438.207(b)(1) and (2). Many commenters also disagreed with the annual requirement, as they found such a requirement to be burdensome on both managed care plans and states and found the requirement to be duplicative of existing EQR requirements. Many commenters recommended that CMS revise the annual requirement to once every 3 years. Other commenters recommended that CMS remove the annual requirement in its entirety. A few commenters recommended that CMS revise the annual requirement to quarterly to ensure a greater level of compliance between states and managed care plans. Several commenters supported the annual requirement but recommended that the annual requirement include independent verification by a third party. Finally, several commenters also recommended that CMS include requirements for

states to conduct annual reviews of the data to ensure compliance.

Response: We thank commenters for the thoroughness of their recommendations regarding § 438.207(c)(2) and the annual requirement for managed care plans to submit supporting documentation to states regarding network adequacy and access to care. We understand commenters' concerns regarding burden and costs on both managed care plans and states. However, we believe that the annual requirement should remain in place to ensure the highest level of access to care for enrollees. Network adequacy and access to care have increasingly become important aspects of the health care market and industry. We believe it is reasonable to expect that managed care plans evaluate their provider networks and ensure access to care for all enrollees on at least an annual basis. Therefore, we decline to adopt commenters' recommendations to revise the requirement or remove it in its entirety. While we appreciate commenters' recommendations to ensure that all supporting documentation is verified by an independent third party and that states should conduct annual reviews of the data to ensure compliance, we believe that states should be allowed flexibility in the methods they use to verify the documentation and ensure that managed care plans are meeting all of the requirements at § 438.207(b)(1) and (2).

Comment: Many commenters supported § 438.207(c)(3)(i) and (ii) regarding documentation requirements at any time there has been a significant change in the managed care plan's operations that would affect the adequacy of capacity and services. Several commenters recommended that CMS define "significant change" to add further specificity. Several commenters recommended that CMS also clarify that such documentation should be required within 10 working days of a "significant change."

Response: We understand commenters' concerns regarding the definition of "significant change" and the recommendation to set timeframe parameters around the requirement of submitting documentation to coincide with the occurrence of a "significant change." However, as we proposed, we believe that states should define "significant change" for their respective programs. In § 438.207(c)(3), states must include, at a minimum, significant changes related to the managed care plan's services, benefits, geographic service area, composition of or payments to the provider network, and

any enrollment of new populations in the managed care plan. We also decline to adopt the specific recommendation to clarify that documentation should be required within 10 working days of a "significant change." We encourage managed care plans to submit and for states to require documentation as soon as feasible after a significant change has occurred to ensure that access to care is not compromised for enrollees. We also encourage states and managed care plans to consider the impact of such significant changes and ensure that documentation timeframes are commensurate with the level and impact of changes on enrollees.

Comment: Many commenters supported § 438.207(d) regarding the state's review and certification to CMS that managed care plans meet requirements for availability and accessibility of services. Several commenters recommended that CMS include a specific reference to § 438.68 related to the state's network adequacy standards. Many commenters also recommended that CMS add requirements for the documentation and certification of such documentation to be made public and posted on the state's Medicaid Web site.

Response: We agree with commenters that § 438.207(d) could be strengthened with an additional reference to the network adequacy standards at § 438.68 as well as a reference to § 438.206. We are modifying the regulatory text to adopt this recommendation. However, we decline to add requirements for the documentation and certification of such documentation to be made public and posted on the state's Medicaid Web site, as § 438.66(e)(3)(i) already addresses public disclosure of information related to networks and access. States must include information regarding the performance of both their network adequacy standards and the availability and accessibility of services at § 438.66(b)(11) in their managed care program assessment report. We believe this is the most appropriate place for this requirement.

After consideration of the public comments, we are modifying the regulatory text at § 438.207(a) to add references to §§ 438.68 and 438.206(c)(1) to be consistent with § 438.206(a) and other sections throughout part 438. We are also modifying the regulatory text at § 438.207(d) to include a specific reference to § 438.68 to be consistent with the reference to § 438.206. We are finalizing all other sections as proposed.

b. Quality of Care (Subparts D and E of Part 438)

Section 1932(c) of the Act establishes quality assurance standards for Medicaid managed care programs, specifically, a quality assessment and improvement strategy and an external independent review of contracting MCOs. Regulations at 42 CFR part 438, subparts D (Quality Assessment and Performance Improvement) and E (External Quality Review) implement this statutory provision; subpart D became effective on August 13, 2002 (67 FR 40989) and subpart E became effective on March 25, 2003 (68 FR 3586). Based on the authority under section 1902(a)(4) of the Act, we included capitated entities in addition to MCOs, within the scope of the regulatory requirements. The existing regulations describe quality standards for all states contracting with MCOs, PIHPs, and in some cases PAHPs, for the delivery of Medicaid services to beneficiaries. This final rule modifies these standards.

Approaches to assessing quality, access, and timeliness of care have evolved significantly over the past 10 years. At the federal level, CHIPRA, the American Recovery and Reinvestment Act (ARRA), the Affordable Care Act, the National Quality Strategy, and the CMS Quality Strategy all build on one another to decrease burdens, improve alignment, and encourage innovative approaches to quality measurement and improvement, among other activities. States also have expanded the use of managed care for the delivery of primary care, acute care, behavioral health services, and LTSS to Medicaid beneficiaries, and the proposed regulation reflected that development. Throughout the proposed rule, we proposed changes to maximize the opportunity to improve health outcomes over the lifetime of individuals. Specifically, we proposed to strengthen quality measurement and improvement efforts in managed care by focusing on the following three principles:

(1) *Transparency:* Public reporting of information on quality of care is a widely recognized tool for driving improvements in care across settings. A key component in designing health care quality transparency initiatives is the use of meaningful and reliable data that is comparable across managed care plans, providers, and programs. The regulatory changes proposed are intended to improve transparency with the goal of increasing both state and managed care plan accountability in the quality of care provided to Medicaid beneficiaries. Transparency will help

stakeholders (including beneficiaries) to engage in informed advocacy, compare the performance of providers and managed care plans, and make informed managed care plan choices.

(2) *Alignment with other systems of care:* Integrating the approaches to quality measurement and improvement across different programs will result in a more streamlined system for states, managed care plans, stakeholders, and beneficiaries. Many managed care plans offer options in more than one program type, and beneficiaries may transition between programs as their circumstances change. Coordination of quality measurement and improvement across different programs can result in economies of scale and increase the effectiveness of quality improvement efforts in each program. The proposed regulation therefore sought to achieve alignment with the quality measurement and improvement standards applied to Medicare Advantage organizations and QHPs in the Marketplace.

(3) *Consumer and Stakeholder Engagement:* Consumer and stakeholder engagement is particularly important when designing an approach to measuring quality for Medicaid managed care, including programs delivering LTSS. Providing consumers with information about their managed care plan is one tool for engaging them in health care decision-making; another is soliciting consumer participation in the development of state strategies for improving care and quality of life. The regulatory changes proposed sought to strengthen the role of consumers in health care decision-making through use of new tools to enhance active engagement.

We received the following comments in response to our proposed quality principles.

Comment: Many commenters expressed support for the principles of transparency, alignment with other systems of care, and consumer and stakeholder engagement underpinning the quality revisions. One commenter recommended that CMS add a fourth principle focused on improved consumer experience of care.

Response: We thank the commenters for their support. While the principles identified were used in the development of the proposed rule and therefore cannot be altered, we agree that improving consumer experience of care is important and is supported by adherence to the other three principles. In particular, we believe that the increased availability of quality information (under §§ 438.334 and 438.364), the availability of the quality strategy online (per § 438.340), and the

application of EQR to PAHPs and select PCCM entities (described in § 438.310(c)(2)), in addition to MCOs and PIHPs will support an improved consumer experience of care.

(1) Proposed Revisions of Subpart D

(a) Subpart D Title and Subheadings

As discussed in the proposed revisions to subpart E below, we proposed that sections related to the quality strategy currently found in subpart D be moved to subpart E. We proposed to make minor conforming changes to subpart D and to change the name from “Quality Assessment and Performance Improvement” to “MCO, PIHP, and PAHP Standards.” We believe this change more accurately describes the remaining sections of subpart D, which address MCO, PIHP, and PAHP activities, some of which are measured as part of the state quality strategy. Additionally, we proposed to remove the subheadings found in subpart D to be consistent with the remaining subparts in part 438. These subheadings would no longer be necessary because the section titles discuss what types of standards are found in subpart D.

We did not receive any comments in response to our proposal to revise subpart D title and subheadings, and therefore, are finalizing as proposed.

(b) Removal of §§ 438.200, 438.202, 438.218, and 438.226

As discussed in section I.B.6.b(1)(a) of the proposed rule, the proposed consolidation of all quality-related standards under subpart E would render § 438.200, which describes the quality-centric scope of subpart D, unnecessary. We thus proposed to remove § 438.200 in its entirety.

We proposed to remove § 438.202, due to the standards we proposed in the new part 431, subpart I.

We proposed to remove § 438.218, which incorporates enrollee information requirements in § 438.10 into the state’s quality strategy. Proposed changes to both enrollee information requirements at § 438.10 and the elements of a state’s comprehensive quality strategy at § 438.340 would render § 438.218 duplicative and unnecessary.

Similarly, we proposed to remove § 438.226, which incorporates the enrollment and disenrollment standards in § 438.56 into the state’s comprehensive quality strategy. Because we proposed deleting these elements from inclusion in a state’s comprehensive quality strategy (see § 438.340), it would render § 438.226 unnecessary.

We did not receive any comments in response to our proposal to remove §§ 438.200, 438.202, 438.218, and 438.226. While we are withdrawing our proposal for a new subpart I of part 431 requiring a new comprehensive quality strategy that would have applied across all delivery models (see discussions in section b.(2)(f) below), it is still appropriate to remove § 438.202 due to revisions to § 438.340 in the final rule. Therefore, we are finalizing these removals as proposed.

(2) Proposed Revisions of Subpart E

(a) Scope (§ 438.310)

This section explains the basis, scope, and applicability of subpart E, which provides details on the EQR process for MCOs and PIHPs. Generally, subpart E covers the selection of EQR reviewers, their qualifications, types of EQR-related activities, the availability of EQR results, and the circumstances in which EQR may use the results from a Medicare or private accreditation review. Because we proposed to move and revise the existing standards related to both the managed care quality strategy and the QAPI program from subpart D to subpart E, we proposed in paragraph (a) to include section 1932(c)(1) of the Act as part of the statutory basis for the quality strategy provisions. In addition, we proposed to include section 1902(a)(19) of the Act as part of the statutory basis, which maintains that each state provide such safeguards as may be necessary to assure that eligibility for care and services under the plan will be determined, and such care and services will be provided, in a manner consistent with simplicity of administration and the best interests of the recipients. We believe this authority would be applicable to both existing provisions of the regulation and some of our proposed changes.

Under the existing quality provisions, states contracting with MCOs and PIHPs must draft and implement a quality strategy and all MCOs and PIHPs must undergo an annual EQR. As states expand their use of managed care for other services or populations, it is increasingly important to develop a comprehensive approach to measuring and improving quality. Because some PAHPs might provide dental or behavioral health services, we proposed that states address such plans in the state’s comprehensive quality strategy, with performance results publicly available in the EQR technical reports. Therefore, we proposed to rely on the authority of section 1902(a)(4) of the Act to apply the quality standards of section 1932(c) of the Act to PAHPs and PIHPs.

Throughout subpart E, as well as in § 438.310, we proposed the addition of “PAHPs” as necessary to reflect this proposal. Some PAHPs function as brokers of non-emergency medical transportation (NEMT), so much of subparts D and E would not apply to these NEMT PAHPs. The provisions that apply to NEMT PAHPs were identified in the proposed changes to § 438.9.

We also proposed to delete the specific reference to health insuring organizations (HIOs), throughout subpart E because with the exception of those HIOs that are expressly exempt by statutory law, HIOs under the proposed rule would be treated in the same manner as an MCO. We proposed in § 438.310(b) to identify the scope of subpart E, including specifications for a process to ensure review and approval of managed care plans, quality ratings, the quality strategy, and EQRs. In paragraph (c)(1), we proposed that these specifications apply to MCOs (including non-exempt HIOs), PIHPs, and PAHPs. Finally, we proposed in § 438.310(c)(2) to address the elements related to quality assessment and improvement for states contracting with PCCM entities. Specifically, we proposed that states assess the performance of PCCM entities consistent with § 438.3(r); such assessment would include a review of at least the mechanisms to detect under- and over-utilization of services, performance measures, and program review (by reference to specific provisions proposed at § 438.330).

We received the following comments in response to our proposal to revise § 438.310.

Comment: We received several comments in support of the proposal to require states to assess the performance of PCCM entities consistent with § 438.3(r).

Response: We thank the commenters for their support and are retaining this requirement in the final rule. However, to improve clarity, we are revising the regulation text in § 438.310(c)(2) in the final regulation to include the description of the types of PCCM entities § 438.330(b)(2), (b)(3), (c), and (e), § 438.340, and § 438.350 apply to, and revising § 438.3(r) to cross-reference § 438.310(c)(2).

Comment: One commenter asked for guidance as to how to apply the quality requirements described in § 438.3(r) to a PCCM entity that only provides case management services. Additionally, the commenter asked if CMS will require an EQR of PCCM entities.

Response: Only PCCM entities that meet the conditions specified in proposed § 438.3(r) and finalized in § 438.310(c)(2) (that is, PCCM entities

whose contract provides for shared savings, incentive payments or other financial reward for improved quality outcomes) are subject to the requirements set forth in §§ 438.330(b)(2), (b)(3), (c) and (e), § 438.340 and § 438.350. This means that under the final rule, PCCM entities (described in § 438.310(c)(2)) will be required to undergo an annual EQR (see section I.B.6.b(h) below for additional discussion of EQR, including its application to some PCCM entities). If the contract does not contain such financial incentives, compliance with these provisions is not required under the regulations; however, the regulations do not preclude states from opting to apply similar requirements to other PCCMs or PCCM entities at their discretion.

Comment: Several commenters supported the proposal to apply the quality standards of section 1932(c) of the Act to PAHPs and PIHPs. Most of those commenters noted that as PAHPs have expanded to provide a broader array of services, they should be subject to the quality standards required of other managed care programs.

Response: We thank the commenters for their support and are finalizing the addition of PAHPs as proposed. We note that these quality provisions have applied to PIHPs since the original EQR final rule was issued in 2003, and will continue to apply to PIHPs under this final rule.

Comment: One commenter expressed concern with the application of the quality standards to dental PAHPs and urged CMS to consider exempting dental PAHPs from the proposed rule.

Response: We are not accepting the comment, as we do not believe dental PAHPs are sufficiently different from other limited benefit PAHPs to warrant exemptions in part or in whole from 42 CFR part 438 subpart E.

Comment: One commenter believed that NEMT PAHPs should be held to the same federal quality standards under subpart E as other PAHPs since they provide a critical service to beneficiaries as the gateway to access needed care.

Response: While we agree that the services provided by NEMT PAHPs are critical to beneficiaries, we believe that NEMT PAHPs are sufficiently different from PAHPs that provide medical services and LTSS to warrant an exemption from subpart E.

Comment: A few commenters requested that CMS cross-reference § 438.14 to ensure the quality assessment activities in part 438 subpart E address compliance with provisions relating to managed care contracts involving Indians, IHCPs and IMCEs.

Response: We agree that a state's oversight practices should address all populations within its Medicaid managed care program, including Indians; however we disagree that part 438 subpart E broadly applies to § 438.14. Section 438.14 addresses network and payment requirements for managed care plans that serve Indians and contract with Indian health care providers; compliance with these provisions generally is outside of the scope of 438 subpart E. The one exception is § 438.358(b)(1)(iv), which requires network adequacy validation as part of the EQR process. We therefore are adding a cross reference to § 438.14(b)(1) (relating to network adequacy for managed care plans serving Indians) in § 438.358(b)(1)(iv).

After consideration of the public comments, we are finalizing this section with modification to clarify the application of part 438 subpart E to select PCCM entities. Specifically, we are modifying § 438.3(r) to cross-reference § 438.310(c)(2), which we are modifying to describe the types of PCCM entities subject to subpart E (those whose contract with the state provide shared savings, incentive payments or other financial reward for improved quality outcomes) and to correctly state that § 438.330(b)(2), (b)(3), (c), (e), § 438.340, and § 438.350 apply to these PCCM entities. We are revising § 438.310(b)(5) to address PCCM entities, consistent with our revision to § 438.310(c)(2). We are making corresponding changes in §§ 438.320, 438.330, 438.340, and 438.350 to reflect their application to these PCCM entities. Note that other sections of the regulation cross-referenced in § 438.350 also apply to PCCM entities described in § 438.310(c)(2) under the revisions made in the final regulation. We are also making a technical modification to paragraph (c)(1) to remove the reference to HIOs; by default, HIOs which are not expressly exempt under statute will be subject to the standards that apply to an MCO, consistent with section 1903(m)(2)(A) of the Act.

(b) Definitions (§ 438.320)

This section of the current regulations defines terms related to the EQR process, including EQR, EQRO, financial relationship, quality, and validation. We did not propose to change the definitions for EQR, financial relationship, and validation, other than the addition of "PAHP" as necessary. Because the EQR process involves an analysis and evaluation of the quality, timeliness, and access to services that a managed care plan

furnishes, we proposed adding a definition for access, as it pertains to EQR, by referring to the timely provision of services in accordance with the network adequacy standards proposed in § 438.68 and availability of services standards in § 438.206.

We proposed revising the definition of "external quality review organization" (EQRO) to clarify that an entity must also hold an active contract with a state to perform EQR or EQR-related activities to be considered an EQRO. Therefore, an entity itself would not be considered an EQRO if it has not yet entered into an EQRO arrangement with a state even if it meets all qualifications for entering into such a contract.

We also proposed to modify the definition of "quality" as it pertains to EQR to reflect that professional knowledge must be evidence-based and supported by current science. Consistent with the revised definition, states and their plans will be expected to stay up-to-date on the latest scientific findings and translate those findings into effective practices, as many states and plans already attempt to do. We also proposed to modify the definition of quality by including performance measure trends and performance improvement outcomes (which, for individuals receiving MLTSS, could include considerations around quality of life).

We received the following comments in response to our proposal to revise § 438.320.

Comment: A few commenters recommended that CMS use terminology and requirements for Medicaid that are similar to those used for Medicare/MA. The commenters believed doing so would promote efficiency.

Response: While we agree with and support alignment between Medicaid and Medicare, including MA, and we took into account Medicare terminology to the extent possible, the definitions for the QAPI program and EQR in this rulemaking reflect unique requirements for Medicaid managed care. Therefore, the definitions presented here are specific to the Medicaid program.

Comment: Several commenters supported the proposed definition of access. Most commenters also recommended that the definition should cross-reference the care coordination provisions of § 438.208 because adequate care coordination and protections for moving between providers are important components of access to care, particularly for individuals who require LTSS.

Response: We disagree with the recommendation to cross-reference the care coordination provisions in § 438.208 in the definition of access, which we are finalizing as proposed, except for minor revisions for clarity. The rules to ensure care coordination and continuity of services for all managed care plan beneficiaries are explicit in § 438.208. We believe that a plan's standards for network adequacy (§ 438.68, which requires the state to develop and enforce network adequacy standards) and accessibility (§ 438.206, which requires that all covered services be available and accessible to beneficiaries in a timely manner), along with the requirement that the results of EQR (per § 438.364) include an assessment of the quality, timeliness, and access to health care services, are sufficient to ensure that a state will measure whether care is coordinated to achieve the best outcomes.

Comment: Several commenters expressed concern that the proposed definitions of "external quality review" and "quality" include the phrase "health care services" or "health outcomes," which are clinically focused and do not reflect LTSS. Several commenters recommended that the definitions should reflect a broad understanding of health and well-being, including function, quality of life, and ability to independently live and engage in community life. One commenter referenced CMS guidance from 2012 that applied EQR protocols to LTSS. Commenters recommended striking descriptive adjectives that reflect solely health and clinical outcomes, such as striking "health care" prior to "services", and to instead use the term "covered services" to reflect all services that an MCO, PIHP, PAHP or their contractors furnish to Medicaid beneficiaries. Commenters also recommended alternatively adding a definition of "health care services" that is broad and includes all services covered under the managed care contract, including LTSS, if covered. Some commenters recommended adding a definition of "outcome" to include "changes in patient health, functional status, quality of life, goal achievement, or ability to live and engage in community life that result from health care or supportive services."

Response: Other than to include PAHPs within the scope of an EQR, we did not propose revisions to the definition of "external quality review" in the proposed rule and are finalizing only the revisions proposed. We are accepting the recommendation to replace the reference to "desired health

outcomes" in the definition of quality with "desired outcomes" to be more inclusive of LTSS. We agree with the commenter that the EQR should examine the full range of services provided by a managed care plan, and that LTSS are included within the scope of services subject to EQR. We also are adding a definition of "health care services" in § 438.320 of the final rule to mean all Medicaid services provided by an MCO, PIHP, or PAHP under contract with the State Medicaid agency in any setting, including but not limited to medical care, behavioral health care, and LTSS. We note that this is consistent with our 2012 guidance on the application of EQR protocols to managed long-term services and supports (MLTSS) (available at <http://www.medicaid.gov/medicaid-chip-program-information/by-topics/delivery-systems/downloads/cmcs-eqr-protocols.pdf>). We also agree with the inclusion of a comprehensive definition of "outcomes" in § 438.320. Rather than adopting the definition proposed by commenters, we are adopting the definition included in the 2012 guidance cited above. Finally, we did propose to delete "health" before "services" in reference to "the provision of services" that are consistent with current professional evidenced-based knowledge in paragraph (2) of the definition of quality in proposed § 438.320, which we retain in the final rule. We also finalize the other proposed revisions to the definition of "quality" in § 438.320.

Comment: A few commenters expressed concern that the proposed definition of EQRO applies only to entities that have contracts with states as the EQRO. They stated that this might prevent other entities from becoming an EQRO and could have an unintended impact of limiting the market to existing EQROs, even if they do not have adequate competence in LTSS. One commenter noted that limiting the market to EQROs that have contracts with states could over time lead the EQRO market to become overpriced, with insufficient capacity, and without incentive for innovation and investment. Another commenter requested that CMS reconsider including competence in LTSS in the definition.

Response: In proposing to clarify the definition of "external quality review organization," we did not intend to limit the field of potential EQROs to those holding contracts with states today. We agree that such a limitation could have a negative impact. To ensure that the definition is not inadvertently interpreted to limit the pool of entities

with which states can contract in the future to entities with EQR contracts in effect today, we are not finalizing the proposed revision. However, we disagree with the suggestion that LTSS competence be specifically included in the definition of an entity that qualifies to be an EQRO. Section 438.354(b) addresses the competence requirements for an EQRO that include having the clinical and nonclinical skills necessary to carry out EQR or EQR-related activities; we believe that the description is broad enough to cover the range of services a managed care plan might cover, including LTSS, and therefore are not accepting the suggestion.

Comment: Another commenter suggested that an EQRO-like and/or QIO-like entity with requisite competence and independence should always be deemed acceptable as an EQRO applicant as a state is evaluating and determining an organization to serve as their EQRO.

Response: We agree that an EQRO-like and/or QIO-like entity with the requisite competence and independence would be an acceptable EQRO applicant. However, not every EQRO-like or QIO-like entity necessarily meets the requirements in § 438.354, and only such entities that do so, as determined by state review, may be awarded an EQR contract with a state. It is the responsibility of a state to review an entity's bid to determine if the entity meets the requirements in § 438.354.

Comment: With regard to the proposed definition of quality, one commenter recommended that CMS remove the term "positive trends" from the reference to performance measures and outcomes because there may not always be positive trends. Another commenter requested guidance on how states may ensure that the provision of services is consistent with "current professional evidence-based knowledge." The commenter questioned whether measures from a reputable standard-setting entity will be assumed to meet the requirement. The commenter also requested guidance on what would be required in instances in which the Medicaid agency and its EQRO use metrics developed by other entities.

Response: We reexamined our proposed definition for quality and while we believe that the consideration of trends is important (as the directions and size of trends may offer valuable information about performance), performance measurement trends alone do not increase the likelihood of desired outcomes for a plan's enrollees. The intent of performance improvement

projects (PIPs) is to improve the quality of care provided to enrollees; therefore, while the results of these projects do not necessarily increase the likelihood of improved outcomes, the use of PIPs does. Similarly, the term “clinically significant results” focuses on the potential outcomes, rather than the PIP. Therefore we are revising the third part of the quality definition to remove the reference to positive trends in performance measures but leave the reference to interventions for performance improvement, though without the “clinically significant results” modifier. We will provide further guidance in EQR protocols regarding how states can ensure that the provision of services is consistent with “current professional evidence-based knowledge” and how this may affect measure selection.

Comment: Several commenters expressed concern that the use of the word “review” in the definition of “validation” could be construed to preclude the creation of new data as part of the validation process, such as through a secret shopper or beneficiary survey to validate a plan’s network adequacy. They recommended adding a reference to “direct testing” to the definition after the word “review” and to include a definition of direct testing, as it pertains to EQR, to mean the proactive testing of managed care plans’ compliance with state standards and requirements, including the accuracy of information maintained and reported by managed care plans. Commenters suggested examples of direct testing to include: making direct calls to network providers to determine availability and accessibility; conducting systematic evaluations of consumer service calls; and comparing encounter data against a statistically valid sample of individual medical records. Alternatively, a commenter recommended requiring direct testing in the EQR protocols.

Response: We did not propose revisions to the definition of “validation” and are not making any revisions in this final rule. We disagree with the need to revise the current definition of validation, which is broad enough to encompass a variety of techniques, including direct testing. The specifics of each EQR-related activity, such as those suggested by commenters, are appropriate for the EQR protocols, not the definition of validation in the regulation. We also disagree with the need for a definition of direct testing. This section provides definitions for terms within 438 subpart E; the term direct testing is not used in this subpart.

Comment: One commenter requested that CMS include a definition of “performance improvement project.”

Response: We disagree with the need to define “performance improvement project” in § 438.320. The expectations for PIPs are set forth in § 438.330(d) of the final rule.

After consideration of the public comments, we are modifying the regulatory text at § 438.320 to: (1) incorporate a definition for health care services and outcomes which are based on the definitions for these terms included in our 2012 guidance on the application of EQR to MLTSS; (2) modify the definition for quality to remove the reference to positive trends in performance measures and to clinical significant results; and (3) revert to the current definition for EQRO to ensure that the definition does not inadvertently limit the market to entities with EQR contracts in effect today. As discussed in section I.B.6.b(2)(a) of this preamble, we are modifying the definitions for EQR and quality to reflect that PCCM entities (described in § 438.310(c)(2)) must undergo an annual EQR.

(c) Quality Assessment and Performance Improvement Program (§ 438.330, Formerly § 438.240)

We proposed to recodify the standards related to a QAPI program, previously described in § 438.240, at § 438.330. In § 438.330(a)(1) we proposed incorporating PAHPs for the reasons mentioned previously in this preamble. We proposed including the word “comprehensive” to signal that states should consider all populations and services covered by managed care when developing QAPI standards for their contracted managed care plans. In § 438.330(a)(2), we proposed to revise the existing regulatory language at § 438.240(a)(2) to permit us, in consultation with states and other stakeholders, to specify performance measures and topics for PIPs for inclusion alongside state-specified measures and topics in state contracts with their MCOs, PIHPs, and PAHPs. We proposed to add that we would also establish a methodology for quality ratings, which is discussed in more detail below in connection with proposed § 438.334. We proposed this would be accomplished after notice and public comment to ensure that states, beneficiaries, and other stakeholders had the opportunity to provide input during the measure selection process. We proposed, in § 438.330(a)(2)(ii), to adopt a mechanism to permit an exemption from the nationally identified PIP topics and metrics for

states that request one. We considered which criteria might be appropriate for the exemption process and invited comment on instances in which an exemption may be appropriate.

In paragraph (b), we proposed to recodify and reorganize the substance of existing § 438.240(b) consistent with our proposal to move all quality program provisions to subpart E. In paragraph (b)(1), we proposed moving the description of what PIPs are designed to achieve to paragraph (d) to describe all PIP-specific details in one place. In paragraph (b)(2), we proposed to modify the existing language from “submit performance measurement data” to “collect and submit performance measurement data.”

We proposed in paragraph (b)(5) that MCOs, PIHPs, and PAHPs have specialized mechanisms to assess the quality and appropriateness of care furnished to enrollees receiving LTSS. This would include an assessment of the care that individuals receive when transitioning to different service settings, such as residential to community (or vice versa) or residential to hospital (or vice versa). We encouraged states to consider including language in their MCO, PIHP, and PAHP contracts that incorporates the use of surveys to assess the experience of beneficiaries receiving LTSS as a key component of the plan’s LTSS assessment process. We solicited comment on the current use of such surveys and how they might best be used to improve the delivery of LTSS to beneficiaries and improve their experience of care. We also proposed that MCOs, PIHPs, and PAHPs compare the services that an individual receiving LTSS has obtained with those that were in the individual’s LTSS treatment plan. Lastly, we proposed in paragraph (b)(6) that MCOs, PIHP, and PAHPs participate in efforts by the state to prevent, detect, and remediate critical incidents, based on applicable standards on the state for home and community based waiver programs.

In paragraph (c)(1), we proposed to delete the reference to § 438.204(c), as we proposed removing this from the managed care elements for inclusion in a state’s comprehensive quality strategy, as described in the proposed § 438.340 (currently § 438.204); our other proposed revisions to paragraphs (c)(1) through (c)(3) were to conform it to the remainder of our proposal and to incorporate PAHPs.

We proposed the addition of paragraph (c)(4), to require that MCOs, PIHPs, and PAHPs that provide LTSS include, in addition to other performance measures under paragraphs

(c)(1) through (c)(3), LTSS-specific performance measures that examine, at a minimum, beneficiaries' quality of life and a plan's rebalancing and community integration outcomes. We expected these measures would support and align with a plan's QAPI program function, as proposed in paragraph (b)(5). States whose MLTSS programs include a self-direction option should consider including measures specific to self-direction under this paragraph.

To streamline quality improvement standards for plans exclusively serving dual eligible beneficiaries, we proposed the option in paragraph (d)(3) for states to substitute an MA plan's quality improvement project conducted under § 422.152(d) in the place of a Medicaid PIP. Finally, under proposed § 438.330(e), states would continue annually to review the impact and effectiveness of each MCO's, PIHP's, and PAHP's quality assessment and improvement program. We also proposed that the state incorporate the results of any LTSS balancing efforts (community integration) at the managed care plan level into this program review. We requested comment on our approach to § 438.330.

We received the following comments in response to our proposal to revise § 438.330.

Comment: Commenters supported retaining the standard from § 438.240, now outlined in § 438.330(a)(1), that each MCO, PIHP, and PAHP establish and implement an ongoing comprehensive QAPI program for the services it furnishes to its enrollees.

Response: We thank the commenters for taking the time to express their support and are retaining the standard outlined in § 438.330(a)(1) that each MCO, PIHP, and PAHP establish and implement an ongoing comprehensive QAPI program for the services it furnishes to its enrollees.

Comment: CMS received many comments related to the proposed revisions in § 438.330(a)(2). Many commenters supported the specification of a standardized set of performance measures and topics for PIPs for inclusion alongside state-specified measures and topics in state contracts with their MCOs, PIHPs, and PAHPs. Commenters noted that a common set of measures can enable comparison across states; better demonstrate trends; help establish national quality benchmarks; help CMS establish and monitor national priorities for health care improvement; and help spur innovation and sharing of best practices. Other commenters noted that standardizing the quality measures could help alleviate reporting burden

(administratively and financially) for multi-state plans and allow plans as well as national health care organizations to focus resources on reducing wide variations and health disparities across states.

Other commenters suggested that CMS recommend, but not require, specific performance measures and PIP topics. Some urged CMS to allow states to select a minimum number of measures from a required menu of measures issued by CMS in consultation with states and other stakeholders. The same menu approach was also suggested for PIPs. Other commenters recommended that CMS develop a set of minimum required measures from a larger menu of measures and allow for state-identified optional measures beyond the core. Other commenters expressed concern that states will require both their own and CMS' required measures and projects, which could result in burdening plans and providers. They therefore suggested that CMS require states to implement the CMS-specified measures and projects or allow the state to propose an alternate set of measures and projects, subject to CMS approval. Some recommended that CMS identify high priority topics for PIPs, and offer technical assistance to states and plans around the implementation of these given topics.

Response: We thank the commenters for their recommendations. We have flexibility under proposed § 438.330(a)(2) to adopt the range of policies suggested by commenters, including identification of a common set of national QAPI performance measures and/or PIP topics for inclusion in state contracts with MCOs, PIHPs, PAHPs, and in the case of performance measures, PCCM entities (described in § 438.310(c)(2)). Should we elect to identify national performance measures and/or PIP topics for QAPI, we will provide additional guidance to states. We are finalizing this paragraph as it pertains to the potential identification of a common set of national QAPI performance measures and/or PIP topics with minor modifications for clarity. We note that in the final rule, this paragraph addresses only the selection of a common set of national QAPI performance measures and/or PIP topics; public engagement related to the QRS is addressed in § 438.334 of the final rule.

Comment: Several commenters expressed concern about the proposal in § 438.330(a)(2) that CMS would specify performance measures, a methodology for calculating quality ratings, and topics with performance indicators for PIPs in state contracts with MCOs,

PIHPs, and PAHPs, and recommended that states retain their current flexibility. Commenters expressed concern about the financial, administrative, measure collection, and reporting burden that this requirement could create for states, managed care plans, and providers. Some commenters expressed that their state's quality improvement system is working well and do not support the addition of quality metrics that may not align with the needs of the state. Others claimed that performance measures and PIPs are most effective when they are tailored to the unique issues and challenges in a specific state. One commenter opposed the CMS-specified measures and PIPs until more guidance is provided on the exemption process.

Response: We appreciate the importance of state flexibility in meeting the needs of each state. However, we also recognize the potential value of specifying a common set of national QAPI performance measures and PIPs across states in the future, provided that there is a robust process for public input from states and other stakeholders in the identification of any such standards, as provided under proposed § 438.330(a)(2) and finalized in this rulemaking. Further, regardless of the identification of any national performance measures or PIPs, states retain flexibility to select performance measures and/or PIP topics in addition to those identified by CMS which meet the specific needs of the state (see § 438.330(c) of the final rule).

Comment: Commenters asked how often new performance improvement topics and measures will be identified as part of the specification of national QAPI measures and PIP topics, and how this process will influence the length of time that each PIP is implemented. Another commenter recommended that the implementation of the measures should be applied on a prospective basis to ensure all stakeholders have adequate lead time to fully understand the measure specifications, data collection methodology, and reporting strategy.

Response: In section V.C.20 of the preamble (relating to the collection of information for § 438.330), we estimate that CMS might identify national QAPI performance measures and/or PIP topics once every 3 years, but this is an estimate and no firm timeline exists. We agree that states will need adequate lead time prior to implementation. Should we pursue identification of national performance measures and/or PIP topics, we will use the public notice and comment process finalized in § 438.330(a)(2) to consult with states and other stakeholders. For any nationally identified PIP topics, the

performance measures will be identified through a multi-stakeholder process similar to what occurs with the Core Set of Children's Health Care Quality Measures for Medicaid and CHIP (Child Core Set) and Core Set of Adult Health Care Quality Measures for Medicaid (Adult Core Set), collectively referred to as the CMS Child and Adult Core Measure Sets for Medicaid and CHIP. Details related to the implementation timeline would accompany any guidance relating to identified national performance measures and/or PIP topics.

Comment: Another commenter sought clarification on whether the proposed rule relates to establishing national PIP topics only, or if the rule means that CMS might establish specific interventions to be implemented nationwide.

Response: For a nationally identified PIP topic area, we expect that specific interventions will be chosen by the state or managed care plan.

Comment: Commenters generally supported including a public notice and comment process in § 438.330(a)(2), which would entail consultation with states and other stakeholders.

Some commenters sought clarification related to the process. Commenters recommended that CMS describe in the regulation the process they will use for soliciting public comments, which should include an outreach and education component, a minimum comment period and minimum time periods for such comment periods, and requirements to include responses to public comments in subsequent drafts. Some commenters noted that the comment period should be a minimum of 60 days.

Several commenters noted specific stakeholders and stakeholder groups that should be engaged, including states; patients and their families; consumer, LTSS, family caregiver, and health equity groups; MCOs, PIHPs, and PAHPs, including integrated Medicare-Medicaid Plans (MMPs) and dual eligible special needs plans (D-SNPs); the Aging Network sponsored by the Older Americans Act; and groups run by people with disabilities across multiple disability categories. Several commenters also suggested establishing a quality task force with balanced and meaningful representation from various advocates, Medicaid beneficiaries, and their families to increase stakeholders' awareness and expertise for future revisions of and additions to the core measures set. This could be achieved through regular required consultations with the state MCACs and, as applicable, LTSS stakeholder advisory

groups. One commenter recommended that states be required to have a component of the public notice and comment process that is specific to children's health. Commenters also recommended that future notice and comment include discussions on setting improvement targets, in addition to focusing on selecting metrics.

Finally, commenters requested additional information related to the public notice and comment process for the MMC QRS.

Response: In § 438.330(a)(2), we proposed "a public notice and comment process" to ensure that states, beneficiaries, and other stakeholders had the opportunity to provide input should we choose to specify national QAPI performance measures and improvement projects. To ensure broad participation, if we exercise the authority under § 438.330(a)(2), we will publish a public notice in the **Federal Register**.

As discussed in section I.B.6.b(2)(e) of this preamble, we are finalizing the public engagement process for the MMC QRS in § 438.334, rather than in § 438.330(a)(2) as was proposed. Please see section I.B.6.b(2)(e) below for additional discussion of the MMC QRS public engagement process.

Comment: Several commenters recommended that § 438.330 be revised to require states to engage in a public comment process during their managed care contract development activities, noting that stakeholders must have the opportunity to evaluate and comment on the state's proposed quality improvement plan, as well as individual managed care plans' proposed activities to meet quality improvement requirements.

Response: We decline the suggestion to require states to engage in a public process regarding QAPI during the managed care contract development process under § 438.330. The required elements for a state's quality strategy, finalized at § 438.340(b), must address the state's plans for performance measurement and PIPs in QAPI; this document, per § 438.340(c), is subject to a public engagement process, and thus will afford the public an opportunity to comment on the state's quality improvement plans.

Comment: Several commenters recommended that the final rule provide more detail on the federal process for stakeholder engagement and public input specifically for identifying federal standards for the Medicaid and CHIP managed care quality rating system, so that stakeholder engagement is not "lost in the planning process." Other commenters recommended that the

process be rigorous, and the final rule should enumerate expected outcomes of the process. Several commenters also recommended that CMS model this process after the transparency and public engagement requirements for the section 1115(a) demonstration approval process.

Several commenters requested that CMS include a consensus-building working group to support the identification of federal standards for the MMC QRS. Commenters made various recommendations for participants in the work-group or in the stakeholder engagement process including plans, state officials, advocacy groups and coalition groups, consumer advocates or other stakeholders. Some commenters additionally recommended that CMS should include a transparent, public application process for identifying working group members. One commenter requested that CMS define "meaningful input," and clearly describe how many and which organizations will participate, how often they should meet, and what their roles should be.

One commenter recommended that the states should be the primary partners in the development of a MMC QRS (§ 438.334) because states are the only "equity stakeholder" and have critical experience that should inform the practicality and utility of such systems as they understand the fundamental differences between programs and populations. The commenter believed that this would be imperative if CMS does not provide clear guidance for states to develop and use their own system.

Response: We thank the commenters for their input. We are removing the reference to the MMC QRS methodology from § 438.330(a)(2) and adding language to § 438.334 to address the public notice and comment process for developing federal standards for the MMC QRS.

Comment: Several commenters supported allowing states to select additional measures beyond those in the CMS-specified set to report, as described in § 438.330(a)(2)(i) of the proposed rule. One commenter noted that this is particularly important for states that contract with MCOs offering FIDE SNPs and D-SNPs. Another commenter offered specific criteria states should use when selecting additional measures, specifically whether the measures: (1) Are endorsed by a multi-stakeholder, evidence-based quality organization; (2) reflect higher performance in helping to achieve patient-centered outcomes; (3) are based on evidence-based processes or

outcomes; and (4) are aligned across multiple care settings and providers. One commenter recommended that CMS specify in regulation how states must engage with stakeholders and incorporate public comment into plans and assessments as it relates to § 438.330(a)(2)(i) of the proposed rule.

Response: We thank the commenters for taking the time to express their support. Regardless of whether CMS identifies a common set of national QAPI performance measures and PIP topics pursuant to § 438.330(a)(2), states are required to identify performance measures and PIPs which their contracted MCOs, PIHPs, PAHPs, and in the case of performance measures, PCCM entities (described in § 438.310(c)(2)), must include in each plan's QAPI program. This requirement, and its inherent flexibility for states to identify performance measures and PIPs which go beyond those which may be specified by CMS, was expressed in proposed § 438.330(a)(2)(i). Under the final rule, we have codified this requirement in § 438.330(c) and (d) and therefore have removed § 438.330(a)(2)(i) as its presence would be redundant in light of the revisions to § 438.330(c) and (d) of the final rule. We encourage states to engage a broad range of stakeholders in the selection of additional measures and projects but do not believe it is appropriate to further regulate that process.

Comment: Commenters requested that CMS support measure alignment and harmonization, including alignment across Medicaid managed care and FFS, with other markets (for example, Medicare, MA, QHPs in the Marketplace), and among payers in a state, and rely on existing national endorsed measures, measure sets, and other federal measurement frameworks (for example, National Quality Strategy) and initiatives (for example, Meaningful Use) when identifying the common set of national QAPI performance measures. A commenter noted that CMS should provide sufficient flexibility to allow states to align measures with other payers, as appropriate. Other commenters noted that any measures should take into account the resulting implications on providers and ensure that they take into account unique provider types and populations.

Several commenters recommended that all national QAPI measures be endorsed by the National Quality Forum (NQF). Several commenters recommended using the Measure Applications Partnership convened by NQF as part of the measure selection and measure gap identification process; selecting quality metrics that are

developed by national standard-setters, such as the National Committee for Quality Assurance (NCQA), including HEDIS measures; and aligning with the 15 improvement areas identified in the Institute of Medicine's *Vital Signs: Core Metrics for Health and Health Care Progress* report. Other commenters recommended the greater integration and adoption of the CMS Child and Adult Core Measure Sets for Medicaid and CHIP and the lessons learned from the Pediatric Quality Measures Program. Commenters also encouraged the adoption of measures that are common to both providers and plans.

To help alleviate measure collection and reporting burden, another commenter recommended harmonizing physician-related measures with existing programs such as the Physician Quality Reporting System or the NCQA Patient Centered Medical Home standards and streamlining reporting and utilization standardized reporting tools and metrics. Another commenter encouraged CMS to support HIV measure reporting alignment, consistent with the HIV Care Continuum Initiative. They recommended using the HIV Medicine Association's compilation of existing quality measures as a guide.

Another commenter suggested CMS consider a comprehensive review of both Medicare and Medicaid measures applied to integrated programs serving dually eligible beneficiaries and of issues that are of unique importance to producing quality outcomes for these populations. Lastly, one commenter also recommended that CMS strive to align not only the measures used for evaluating quality in Medicare and Medicaid, but also their timelines for reporting the data underlying those measures.

Response: We appreciate the importance of measure harmonization and alignment and the need to minimize measurement burden as much as possible; these are considerations in all of our performance measurement activities. Should we elect to identify national performance measures under the authority of § 438.330(a)(2) of the final regulation, we will take these recommendations into consideration during the public notice and comment process.

Comment: Several commenters noted the need for measures that are sensitive to the differences in populations served. Commenters noted the need to consider risk adjustment and/or stratification of the national QAPI performance measures to account for patient acuity, frailty, and/or socio-demographics. Another commenter recommended that CMS seek comment on risk adjustment

factors and methodologies specific to the Medicaid population. One commenter noted that any set of measures should include comparable patient characteristics (that is, apples to apples comparison) and recommend that CMS construct pediatric age subcategories that at least separates individuals 18 years and under into a category apart from the adult population. One commenter sought a specific methodology for U.S. territories that would take into account factors that influence quality metrics.

Response: We thank the commenters for their recommendations and will take these considerations into account during the public notice and comment process should we elect to identify national performance measures per § 438.330(a)(2) of the final regulation. Note that standards for risk adjustment are provided in §§ 438.5(g) and 438.7(b)(5).

Comment: One commenter noted that the proposed rule did not specify that quality reporting, measurement, and oversight should be conducted specifically on a managed care plan's Medicaid line of business. The commenter requested that CMS clarify in the regulations that any quality monitoring be evaluated specifically on a plan's Medicaid network(s) and not on non-Medicaid networks or the networks used by some or all of their other products (such as those in Medicare Advantage, Marketplace, and the private market).

Response: Section 438.1(b) of the final rule identifies the scope of part 438, which applies to the provision of Medicaid services through MCOs, PIHPs, PAHPs, PCCMs and PCCM entities. Therefore, the quality provisions in part 438 subpart E apply to Medicaid services provided via managed care plans, as described therein. The PIPs and performance measures, in § 438.330(b)(1) and (b)(2) respectively, must be specific to a managed care plan's Medicaid beneficiaries (including dual eligibles, if served by that plan). While a managed care plan could use the same intervention across its lines of business to drive improvement, and the same measures across its lines of business to assess performance, those reported to the state and in turn included in the annual EQR must be specific to the Medicaid managed care population and must be consistent with the requirements under the Medicaid regulations.

Comment: Several commenters sought clarification on how the state-selected performance measures and PIP topics described in § 438.330(a)(2)(i) of the

proposed rule relate to the state-selected measures specific to the proposed comprehensive quality strategy requirements in proposed § 431.502(b)(2). Commenters sought clarification on whether the national measures selected under QAPI would apply in the Medicaid FFS context, given that the comprehensive quality strategy in the proposed new subpart I of part 431 would apply statewide across delivery systems.

Response: We thank the commenters for their questions. Preliminarily, we note that we are withdrawing our proposal for a comprehensive quality strategy as under part 431 subpart I of the proposed rule (see section I.B.6.b.(2)(f) below). Section 438.330 applies specifically to Medicaid managed care plans. Medicaid FFS is not required to participate in a QAPI program, although states may elect to integrate their quality improvement efforts across delivery systems.

Comment: Commenters requested that CMS consider various principles as well as important populations and topic areas as part of the design of the QAPI program, specifically when selecting the national QAPI performance measure and PIP topics. Specific principles that commenters recommended CMS consider when selecting performance measures include focusing on inclusive, high-value measures that are useful in national comparisons and also actionable for quality improvement, and limiting the number of required performance measures and PIPs. Commenters also recommended incorporation of principles specific to pediatric populations, including replacing less impactful measures with validated measures coming out of the PQMP and other relevant sources and ensuring a pipeline of much needed pediatric quality of care and outcomes (health and cost) measures.

Commenters recommended several populations that require consideration, for example, pediatric populations, including children with complex conditions; Native Americans and Alaska Natives; persons with degenerative conditions, such as Alzheimer's Disease or dementia; persons with HIV/AIDS; and persons with serious mental illness or substance use disorders.

Commenters offered a range of measurement topics for CMS to consider when selecting the national QAPI performance measures, including but not limited to: measures focused on access to care, and certain subpopulations' access to medically necessary treatment for specified conditions; measures that address

health care disparities; meaningful outcomes of clinical care; patient-and caregiver-reported measures of outcomes; care experience and functional status; over-and under-utilization; person-centeredness; consumer's individual preferences and goals; patient activation scores or other similar measurements; quality outcomes beyond medical ones, specifically quality of life; screening; prevention and disease management for dental caries in children (specifically the measure set developed by the Dental Quality Alliance); behavioral health care; medication adherence; preventable events, including ambulatory-sensitive admissions, readmissions, preventable ER visits and hospital complications; effective management of HIV, in addition to routine HIV screening and viral load suppression; screening for exposure to intimate partner violence among pregnant woman; health and coordination across the continuum (specifically NQF-endorsed measures); social determinants of health care (specifically IOM metrics); and care coordination for the chronically ill.

Commenters also offered PIP topics for CMS to consider, including but not limited to improving population health; reducing adverse drug events, particularly in high-risk populations and high-risk therapeutic classes; and utilization of childbirth education. Commenters noted that CMS should choose PIPs that are broadly applicable to all states, are clearly important issues for improvement, can be aligned with other payers, and can have an impact.

Response: We thank the commenters for their input and will take these considerations into account as a part of the public notice and comment process should we elect to identify national performance measures and/or PIP topics per § 438.330(a)(2) of the final regulation.

Comment: One commenter encouraged CMS to apply the same measures used to assess dental PAHPs to MCOs that include dental services. Other commenters supported not requiring dental PAHPs to report the national QAPI performance measures in recognition that there are unique dental quality measures and that "medical" quality measures are not workable for dental plans.

Response: We thank the commenters for their input. Should we utilize the authority under § 438.330(a)(2) of the final regulation, CMS will work with stakeholder groups through a public engagement process to ensure requirements issued for plans are appropriate. We do not intend to require specialized plans to report measures

outside their specialized area. In the case of an MCO which provides dental services, if we were to identify dental performance measures we would require the MCO to report on those dental measures, along with any identified medical measures. Our intent is to apply measures to managed care plans which are appropriate to the services provided by the plan.

Comment: Several commenters urged HHS to ensure that states develop quality measurement programs with the capacity to evaluate health disparities and take the necessary steps to eliminate them. One commenter recommended that CMS require states to ensure, through their contracts with managed care entities, that managed care entities collect and submit performance data related to clinical outcomes for specified subpopulations and annually report to the state on health outcomes for subpopulations and minorities. Another commenter recommended that CMS improve data collection and reporting by requiring states in contracts with plans to include data stratified by race, ethnicity, primary language, gender identity and sexual orientation for measuring success. They recommended that CMS reinforce the data collection requirements under section 4302 of the Affordable Care Act by offering a financial incentive for improved data collection, and require plans to use the NQF consensus measures to assess cultural competency and language services. Another commenter recommended adding sexual orientation and gender identity to the list of areas that the Affordable Care Act requires any federally conducted or supported health care or public health programs, activities or surveys to collect and report data on.

Response: We thank the commenters for their input. As documented in a November 2014 Report to Congress on Improving the Identification of Health Care Disparities in Medicaid and CHIP, HHS has made progress in addressing health care disparities in Medicaid and CHIP by updating data-collection systems and tools; stratifying performance measures by demographic characteristics; developing new measures specific to populations of interest; and promoting data sharing, collaboration, and analyses. To improve upon these efforts, the report recommends improving upon the quality of health care disparities data across delivery systems, and the completeness of health care disparities data collection in managed care. We are committed to these efforts in partnership with states and other

stakeholders; to this end, under this final rule states will have to require their plans to address health disparities in their Medicaid managed care quality strategies consistent with § 438.340(b)(6) of the final rule.

Comment: One commenter sought clarification related to the data collection and submission process for the national QAPI performance measures. They noted the importance of reporting data consistently and recommended that the expectations for the quality of data submitted should be strengthened. Another commenter noted that metric collection should complement current reporting pathways, and leverage existing information technology and clinical decision support systems.

Response: We thank the commenters for their input. CMS recognizes the importance of collecting data consistently and is working to ensure that quality data is collected.

Comment: Some commenters supported the process outlined in proposed § 438.330(a)(2)(ii) that would allow for states to request an exemption from nationally identified performance measures and PIP topics. Commenters noted the mechanism for exemption would allow states to tailor their quality assessment processes to their specific populations, and allow states to innovate and respond to their unique aspects of their program.

Response: We thank the commenters for taking the time to express their support. We are finalizing this provision as proposed with non-substantive revisions for clarity. It can be found in § 438.330(a)(2) of the final regulation.

Comment: Many commenters provided input on the examples of exemptions outlined in the preamble, and offered additional recommendations or clarification. Many commenters agreed that states should be exempt from reporting measures that are not applicable to the population enrolled in Medicaid managed care in their state or that relate to the quality of a service not covered by or relevant to the managed care contract.

Some commenters urged CMS to limit the reasons for which a state could seek an exemption. While commenters recognize that flexibility would let states meet their own needs, it could lead to less alignment between states and potentially minimize transparency and stakeholder engagement efforts. Commenters suggested that CMS provide strict guidance to states regarding the removal of state-specific measures that overlap or conflict with the standard set of measures issued by CMS. Some commenters recommended

enumerating a set of specific reasons that would justify a state obtaining an exception and some encouraged CMS to allow states to receive exemptions only if the measure is not applicable to the covered population or if the measure is only relevant to a service or services not covered in the MCO contract. Others recommended that states with an exemption should still be required to gather data and report on quality metrics. One commenter recommended that the exemption process include specific pediatric components. Commenters also suggested setting time limits on how long an exemption could last without review and some commenters recommended establishing a 2-year time limit for exemptions.

Several commenters agreed with exempting states if the number of enrollees is too small to calculate a measure. One commenter suggested that exemptions within states be allowed for plans that serve specialty populations (for example, recipients with HIV/AIDS, or dual eligibles) that may not have sufficient numbers of eligible members for the required PIP topic indicators. Another commenter recommended that CMS specify in regulation or sub-regulatory guidance how small a measure population must be to not be meaningful. The commenter recommended that a minimum of 30 enrollees is a sufficient size to be valuable and meaningful.

Some commenters recommended allowing a state to seek an exemption if the state already meets and exceeds a performance threshold. Other commenters disagreed with allowing a state to seek an exemption if it surpasses a performance threshold for multiple years. They stated that thresholds are not always accurate measures of quality for states, especially for subpopulations, and granting such an exemption could allow for deterioration in performance after the exemption is granted. Several commenters noted that performance in the 90th percentile for more than 3 years, as suggested in the preamble, would not be attainable for even the highest performing plans. They also noted that for many measures, such as certain vaccinations or the frequency of “never events,” a threshold of 90 percent would not be considered successful. Commenters stated that allowing for an exemption may undermine HHS’ broader efforts to identify and reduce health disparities across key demographic groups. If CMS permits exemptions based on sustained achievement, the thresholds must be appropriate for each measure and states should have to prove that no significant disparities exist for key demographic

groups prior to receiving a time-limited exemption.

Some commenters noted that CMS did not explicitly identify examples of exemptions that would apply to the federally-identified PIP topics in the preamble and request that a clear exemption process be established for PIPs as well. Other commenters recommend that states be permitted, on an ongoing basis, to put forward a justification for other cases where an exemption would be warranted.

Response: We thank the commenters for their recommendations. While we are committed to ensuring robust performance measures are implemented in all states, we cannot anticipate all of the circumstances which may justify an exemption for a national performance measure or PIP topic. Therefore, we believe it is important to retain flexibility in the regulations and are finalizing proposed § 438.330(a)(2)(ii) with non-substantive revisions for clarity. This provision is now codified as part of § 438.330(a)(2) in the final regulation.

Comment: One commenter sought clarification as to whether a state could request an exemption for some, but not all, of the plans in the state (that is, only exempting those plans in their state that perform consistently well). This commenter suggested that CMS develop a state-dedicated technical assistance process, through which states could show what they have in place for various measures, PIPs, and processes, and receive guidance on how closely they match what CMS proposes.

Response: We thank the commenters for their input. We plan to issue future guidance, after consultation with states and stakeholders, related to the exemption process for performance measures and PIPs pursuant to § 438.330(a)(2) of the final regulation.

Comment: A few commenters made suggestions intended to ensure MCOs deliver high-quality, high-value care to patients and achieve contract goals in a fiscally responsible manner. One commenter urged that managed care entities be required to: Establish mechanisms to incorporate feedback from enrollees and providers; monitor and evaluate high-volume and high-risk services and the care of acute and chronic conditions; evaluate the continuity and coordination of care that enrollees receive; have mechanisms to detect both underutilization and overutilization of services; use systematic data collection of performance and patient results, provide interpretation of these data to their practitioners, and make needed changes indicated by the data; and make

available information on quality and outcomes measures to facilitate beneficiary comparison and choice of health coverage options. Another commenter encouraged CMS to detail the variety of opportunities for states to utilize mobile healthcare tools to improve their care coordination efforts for Medicaid recipients with major mental health and addiction disorders.

Response: We thank the commenters for their recommendations. We note that some of the recommendations already are incorporated into the final rule. Sections 438.330(b)(1) and (2) require performance measurement and PIPs; § 438.330(b)(3) requires QAPI to detail mechanisms to detect underutilization and overutilization of services; and § 438.330(b)(4) requires mechanisms to assess the quality and appropriateness of care provided to enrollees with special health care needs. While we decline to incorporate the commenters' other suggestions into the final rule, we encourage commenters to work with CMS and states through future public engagement processes.

Comment: One commenter noted their support for requiring PCCM entities to establish and maintain mechanisms to detect over- and under-utilization of services under § 438.330(b)(3) because such mechanisms can be important in detecting misuse, identifying access barriers, and evaluating network adequacy. Another commenter asked for clarification regarding the application of proposed § 438.330(b)(3) to PCCM entities, specifically if the mechanisms to detect underutilization and overutilization of services refers to case management services or medical services, or if the focus will be determined at the state level.

Response: Section 438.330(b)(3) requires comprehensive QAPI programs to include mechanisms to detect underutilization and overutilization of services. The services referenced include medical services only, not case management services. This means that PCCM entities (described in § 438.310(c)(2)) that are subject to § 438.330(b)(3) and are responsible for managing the care of their beneficiaries must assess whether beneficiaries are receiving timely access to appropriate medical services.

Comment: One commenter suggested that quality review of overutilization of services under § 438.330(b)(3) should include the "Choosing Wisely" components.

Response: We do not believe that it is appropriate to identify specific requirements for the overutilization review process used by managed care

plans in the regulations and are not doing so in this rulemaking.

Comment: One commenter noted their support for § 438.330(b)(6) but expressed concern that there is no national standard for the definition of the term "critical incidents." They recommended that CMS adopt a definition from MA or NCQA, if available.

Response: We thank the commenter for their support. Per § 438.330(b)(5)(ii) in the final rule, MCOs, PIHPs, or PAHPs providing LTSS should at a minimum base their efforts to prevent, detect, and remediate critical incidents (consistent with assuring beneficiary health and welfare per §§ 441.302 and 441.730(a)) on the requirements on the state for home and community-based waiver programs per § 441.302(h).

Comment: One commenter sought clarification related to the phrase "reasonable time period" (in proposed § 438.330(d)(2)) for completion of a PIP.

Response: We thank the commenter for their question. Proposed § 438.330(d)(2) is finalized at § 438.330(d)(3), with revision. Per section § 438.330(d)(3) of the final rule, the state must require each MCO, PIHP, and PAHP to report the status and results of each project to the state as requested, but not less than once per year. CMS intends to release future guidance in its EQR protocols (see § 438.352) to support states in their efforts to implement and report on the effectiveness of PIPs.

Comment: Several commenters supported the option in proposed § 438.330(d)(3) for states to substitute an MA plan's quality improvement project conducted under § 422.152(d) in the place of a Medicaid PIP. Commenters noted that this alignment is beneficial for dual eligibles and the entities that offer FIDE SNPs and D-SNPs, and creates streamlined efficiencies for issuers and providers, which will contribute to consistent care.

Response: We thank the commenters for taking the time to express their support. We are finalizing proposed § 438.330(d)(3) with non-substantive revisions for clarity. This provision can be found at § 438.330(d)(4) of the final regulation.

Comment: Some commenters expressed concern that allowing MCOs, PIHPs, and PAHPs serving only dual eligibles to substitute MA organizational quality improvement projects will reduce the likelihood of LTSS related PIPs. One commenter opposed this provision, stating that MA does not typically cover LTSS, so this could lead to excluding LTSS from improvement projects. Commenters recommend that

plans substituting MA quality improvement projects should ensure that LTSS related PIPs are included based upon input from a member advisory committee.

Response: First, we note that the decision to substitute an MA QIP for a Medicaid PIP for a plan serving exclusively dual eligibles lies with the state, not with the managed care plan. Thus, it is the state, not the plan, that will determine if this option best will serve its dual eligible beneficiaries. Second, election to use an MA QIP for a plan serving only dual eligibles does not relieve states of their responsibility to require plans to conduct PIPs that involve both clinical and nonclinical areas, which could include LTSS, under § 438.330(d) as finalized in this rulemaking. Further, plans providing LTSS services will be required, per § 438.330(c)(1)(ii) of the final rule, to measure LTSS performance. We believe that these measures will drive plans to engage in efforts to improve the quality of care for LTSS services.

Comment: Several commenters sought clarification related to the option in proposed § 438.330(d)(3) (re-codified as § 438.330(d)(4) in this final rule). One commenter noted the need for timely and complete Medicare data and recommended that CMS make timely and complete data on Medicare utilization available to states to aid quality projects relating to dual-eligible populations. Making this data available to EQROs would provide an immediate, likely cost-effective benefit to both Medicaid and Medicare. Another commenter noted that some Medicaid D-SNPs may not exclusively serve dually-eligible individuals. They recommended that states with plans that are D-SNPs and also serving other Medicaid beneficiaries be able to use a MA quality improvement project in place of a Medicaid PIP. Another commenter recommended that CMS establish standards across states rather than allowing states to choose which PIPs are adhered to by MCOs exclusively serving the dual eligible population.

Response: We believe that all populations served by a plan should receive the benefit of PIPs. Therefore, we are not accepting the recommendation to apply the option now codified at § 438.330(d)(4) to plans that serve Medicaid beneficiaries who are not dually eligible for Medicare, even if they serve a significant number of dually-eligible beneficiaries. However, nothing in this rule prevents a plan that serves a significant number of dual eligibles from focusing on the same topic for both a QIP and PIP, nor

from using the same interventions for a QIP and PIP, provided that the PIP and associated interventions meet the requirements set forth in the regulation.

Comment: CMS received many comments related to the revisions in proposed § 438.330(b)(5), relating to the assessment of quality and appropriateness of care to enrollees in LTSS in the QAPI program. Many commenters supported the inclusion of LTSS in state QAPI programs and the identification of mechanisms to assess the quality and appropriateness of care furnished to enrollees using LTSS. One commenter opposed including LTSS in the state QAPI program for managed care noting that enrollees using LTSS have different care needs, thus necessitating different efforts to measure the adequacy, appropriateness, and success of LTSS programs.

Response: We thank the commenters for their support. We note that under the proposed rule the inclusion of LTSS in the QAPI program would expand the program review from a single focus on acute care services, making it more comprehensive and valuable. We believe that performance measurement activities for LTSS that are similar to those for other managed care systems are appropriate and important to ensuring that efforts to drive improvements in the quality and appropriateness of care in LTSS are comparable to those related to other care and services. Additionally, quality measurement and improvement tools for LTSS are now underway within and across multiple HHS agencies and components. As a result, we are finalizing proposed § 438.330(b)(5) (redesignated at § 438.330(b)(5)(i) in the final regulation) with minor non-substantive revisions for clarity.

Comment: One commenter supported requirements to ensure that mechanisms are in effect to have managed care plans compare service and supports that an individual is receiving relative to the individual's LTSS treatment or service plan and suggested requirements for reporting frequency and public reporting under proposed § 438.330(b)(5).

Response: We appreciate support in proposed § 438.330(b)(5) for the requirement that states ensure that plans assess the services an individual is receiving as compared to the services identified in the individual's LTSS treatment or service plan. We are retaining this provision at § 438.330(b)(5)(i) of the final rule. We are not adding any reporting requirements to § 438.330(b)(5); such requirements were addressed in proposed § 438.330(c), under which

each MCO, PIHP, PAHP, or PCCM entity (as described in § 438.310(c)(2)) is required annually to measure and report to the state annually its performance using standard measures.

Comment: A few commenters recommended that states be allowed to determine the process to assess the quality and access to care in LTSS. One commenter stated that this would allow states to align LTSS quality activities with other quality initiatives which are already in place in the state.

Response: We thank the commenters for their concern and recommendations. We believe that the proposed rule provides a broad framework for states to utilize in assessing the quality and appropriateness of care in LTSS, and that this framework allows states the flexibility to align their quality initiatives (where appropriate), strengthen quality efforts, and prevent duplication of effort.

Comment: Several commenters recommended that CMS require states to include measures specific to self-direction when an MLTSS program includes self-direction per proposed § 438.330(b)(5). A couple of commenters cited HHS guidance identifying potential concerns and opportunities related to self-direction as states expand Medicaid managed care.

Response: We thank the commenters for their input. While we encourage states where MLTSS programs include a self-direction option to consider including measures specific to self-directed service delivery, CMS currently gives states the flexibility to identify specific measures to monitor performance. As such, we decline to make such measures a requirement for QAPI.

Comment: Several commenters specifically stated that they supported the revisions in proposed § 438.330(c)(4) regarding additional quality and performance measurement activities required for LTSS.

Response: We thank the commenters for their support. We are finalizing proposed § 438.330(c)(4) with non-substantive revisions for clarity. This provision can be found in § 438.330(c)(1)(ii) of the final regulation.

Comment: CMS received many comments related to proposed § 438.330(c)(4). Many commenters suggested additional required performance measures, in addition to those outlined for assessing LTSS. Several commenters suggested that the required performance measures also include care coordination, the needs assessment process, and self-direction in states that implement this option. Several other commenters

recommended that required performance measurement activities for LTSS also include additional specific clinical areas such as: Quality of life, transfer of care, person-centered elements, and rebalancing and community integration activities. Several other commenters recommended that non-medical measures be added to the list of required measures including: Adequacy of the direct care workforce; consumer grievances and appeals; number of cases of neglect or abuse; number of cases involving a denial or reduction in services; and achievement of equality of opportunity, independent living, economic self-sufficiency and full participation as defined in the ADA.

Response: We appreciate the commenters concerns and input, and thank the commenters for the suggestions regarding required performance measurement activities and areas of measurement. We are finalizing § 438.330(c)(4) as § 438.330(c)(1)(ii) of the final regulation. While the state must identify performance measures relating to quality of life, rebalancing and community integration activities for individuals receiving LTSS, the state may elect to identify additional LTSS-focused areas of measurement for MCOs, PIHPs, or PAHPs providing LTSS services. CMS will also take these considerations into account as part of the public notice and comment process per § 438.330(a)(2) of the final regulation should we elect to identify national performance measures under this authority. Additionally, we note that the Department of Health and Human Services, including CMS, is working with the NQF to further performance measurement activities in the areas of home and community-based services, person and family-centered care, dual eligible beneficiaries, and other areas that impact Medicaid MLTSS enrollees.

Comment: Several commenters supported the requirements outlined in § 438.330(c)(4), which they noted would help advance better and more comprehensive metrics for LTSS, but believed that there is a need for further development of performance measures in the area of LTSS. A few commenters recommended that quality measurement activities be developed to evaluate the needs and utilization patterns in LTSS for persons with behavioral health needs as well as metrics appropriate for persons with physical, intellectual and other disabilities. Additionally, several commenters supported the use of interim measures until an adequate number of validated measures are available. One commenter noted that the

use of interim measures will help support the quality and availability of LTSS, pending formal validation of additional LTSS measures. These commenters also recommended that CMS build out or adopt measures that already are in development through a national consensus-based approach and ensure that any LTSS measure used for Medicaid is both feasible and replicable.

Several commenters recommended that LTSS performance measurement activities be developed and implemented in alignment with other CMS quality initiatives. One commenter recommended that efforts should align with MA, private market, and Medicaid requirements and quality measurements, and that organizations who care for dual eligibles be subjected to same quality measures as MA, such that comprehensive care is coordinated and administrative burden is lessened.

Several commenters requested a delay or flexibility in the implementation of performance measurement and assessment activities until appropriate quality metrics for LTSS are developed and endorsed. One commenter stated that national quality and performance measurement for LTSS is not as well-developed as it is for medical services and noted reservations about the robustness, validity, and reliability of LTSS measures at this time. A couple of commenters requested that the agency delay the implementation of this requirement until national accrediting bodies and other stakeholders are able to establish a meaningful set of quality measures for use. One commenter stated concerns that managed care plans will not be able to meet the QAPI program regulations because of the lack of robust and comprehensive LTSS quality measures and performance assessment tools.

Response: We thank the commenters for their feedback and concerns regarding the status of measure development in LTSS and for recommendations regarding the use of interim measures and areas for future measure development. To better understand the landscape in quality measurement for LTSS and HCBS, HHS and CMS have been working with contractors, state and other federal partners, and external stakeholders on several measurement initiatives:

- Risk- and reliability-adjustment models for three composite measures for HCBS after identifying potentially avoidable hospital admissions as an important quality measurement domain for individuals receiving HCBS.
- The NQF convened a multi-stakeholder group in 2014 to conduct a measure gap analysis and develop

recommendations for performance measurement to address person- and family-centered care. Specific recommendations focused on patient-centered communications; shared decision making; the concordance of care plans with individual preferences, values, and goals; and measures based on patient-reported outcomes. NQF's Measure Applications Partnership (MAP) also convened a time-limited task force in 2014, drawn from the membership of the MAP Coordinating Committee and four advisory workgroups, to identify a family of measures focused on person- and family-centered care. Families of measures are sets of related available measures and measure gaps that span programs, care settings, levels of analysis, and populations.

- NQF is currently working on a similar effort to address the gaps in HCBS measures through a multi-stakeholder process to consider the definition of home and community-based services (for the purposes of this project), develop a conceptual framework using domains for measurement, and make recommendations for HCBS measurement development.

- The Experience of Care (EoC) Survey elicits feedback on beneficiaries' experience with the services they receive in Medicaid community-based LTSS programs. In addition to the survey, the electronic Long-Term Services & Supports (eLTSS) Initiative is an Office of the National Coordinator for Health Information Technology (ONC)-CMS partnership focused on identifying and harmonizing electronic standards that can enable the creation, exchange and re-use of interoperable service plans for use by providers of both health care and home and community-based services, payers, and beneficiaries. Both of these initiatives are driven by the requirements of the CMS Testing Experience and Functional Tools (TEFT) Planning and Demonstration Grant Program funded by the Affordable Care Act.

- The Medicare-Medicaid Coordination Office is working across CMS to further efforts related to LTSS measure development and endorsement.

We agree with aligning with existing programs and measurements when possible for ease of measurement and burden reduction, and we will continue to look for opportunities for alignment and burden reduction.

We may issue additional information on LTSS performance measurement through subregulatory guidance.

Comment: Several commenters recommended that a beneficiary survey

be a required element in the QAPI to assess the quality and appropriateness of care furnished to enrollees using LTSS. Additionally, several commenters recommended that family caregivers (if applicable) should also be surveyed, especially when the plan of care depends on the involvement of a family caregiver. Suggestions for a specific beneficiary survey to use or domains to include in a beneficiary survey were provided by several commenters. One commenter recommended that, when implementing a beneficiary survey, states find ways to be inclusive in assessing care experience to ensure those with intellectual disabilities or other cognitive impairment, language, or cultural barriers are included, while ensuring that the results remain statistically reliable. Another commenter noted concern about the potential to use the results from a survey of beneficiary experience to impose payment penalties or sanctions on physicians.

Response: We thank the commenters for their recommendations and feedback on the current use of beneficiary surveys. Based on the current status of performance measurement for LTSS, we do not believe that it is the appropriate time to require a beneficiary survey; however, we would like to encourage states to explore with their stakeholders how to best utilize surveys (such as the HCBS Experience of Care Survey or the Nationwide Adult Medicaid CAHPS survey) to improve the delivery of LTSS to beneficiaries and to improve their experience of care. We anticipate that beneficiary surveys may be used as we move forward with the Medicaid and CHIP managed care quality rating system (MMC QRS) under § 438.334.

Comment: A couple of commenters requested a minor language modification related to the use of the term "treatment plan" citing that this term is often used in a medical context and does not fully capture the scope and person-centered nature of LTSS. Commenters suggested assessing the provision of LTSS services either in the beneficiary's person-centered service plan or in the individual care plan that may accompany the treatment plan.

Response: We thank the commenters for their recommendations. We recognize that the term treatment plan is a general medical term which in the context of LTSS should include information regarding the services that the beneficiary is receiving through LTSS and should be inclusive of their person-centered service plan or individual care plan as appropriate.

Comment: One commenter requested further clarification on what

“assessment of care between care settings” means as it relates to LTSS.

Response: In the preamble to the proposed rule, we defined this as an assessment of the care that individuals receive when transitioning to different service settings, such as residential to community (or vice versa) or residential to hospital (or vice versa), or hospital to nursing home (or vice versa). Among other CMS activities on this topic, we are testing new tools to collect and share information on the functional status of individuals through the TEFT Demonstration Grant Program. CMS is also engaged in the implementation of the IMPACT Act of 2014, which requires reporting of standardized assessment data in Medicare with regard to quality measures, resources use, and other measures—using common standards and definitions—to facilitate coordinated care and person-centered goals.

After consideration of the public comments, we are finalizing this section with modification. We are removing reference to the MMC QRS methodology from § 438.330 (a)(2) and will address the public notice and comment process for the MMC QRS methodology in § 438.334 of the final rule. We have struck proposed § 438.330(a)(2)(i) as this is now addressed in paragraphs (c) and (d) of this section. In light of this, we have combined proposed § 438.330(a)(2)(ii) with § 438.330(a)(2) in the final rule. We have made non-substantive revisions throughout § 438.330 to improve clarity. This includes adding paragraph (a)(3) to more clearly reflect which components of this section apply to PCCM entities described in § 438.310(c)(2) of the final rule. Finally, we are correcting a typographical error in paragraph (d)(1) so that it correctly references paragraph (a)(2) of this section.

(d) State Review and Approval of MCOs, PIHPs, and PAHPs (New § 438.332)

Under proposed § 438.332, as a condition of contracting with a state to provide Medicaid benefits, MCOs, PIHPs, and PAHPs must undergo a performance review. These options were proposed in § 438.332(a) and (b). In paragraph (a), we proposed that the state would review and approve based on standards that are at least as stringent as those used by the accreditation organizations that are recognized by CMS in MA or the Marketplace. We proposed that states would review and reissue approval of each MCO, PIHP, and PAHP at least once every 3 years. We also proposed that MCOs, PIHPs, and PAHPs maintain performance with state standards at the level necessary for

approval for as long as they participate in the state’s managed care program.

Under proposed paragraph (b), a state could rely on accreditation by one of the CMS-recognized private accrediting entities to deem one or more plans compliant with the review and approval standard proposed in paragraph (a). In paragraph (c), we proposed that states make the final approval status of each MCO, PIHP, and PAHP, publicly available on the state’s Medicaid Web site. For additional discussion of proposed § 438.332, see section I.B.6.b.1.d of the June 1, 2015 proposed rule.

We received the following comments on proposed § 438.332.

Comment: Numerous comments were submitted regarding options available to states for managed care plan review and approval. Some commenters supported adding a state review process, others opposed. Most commenters—even those supporting the concept—recommended changes to the proposed provision.

While several commenters supported allowing private accreditation received by Marketplace and Medicare plans to satisfy the Medicaid review process, many expressed concern that current private accreditation processes do not reflect the needs of vulnerable Medicaid beneficiaries—for example, children, pregnant women, individuals with special health care needs, or those receiving LTSS. A few commenters recommended that states only be permitted to accept accreditation specifically of the Medicaid managed care business line of an MCO, PIHP or PAHP. Other commenters supported state flexibility in determining the review and approval process, including use of existing state review processes. Several commenters requested that CMS clarify or identify the accrediting bodies recognized for MA and Marketplace plans that would also apply to Medicaid plans.

Several commenters expressed concern about the administrative burden and potential cost related to accreditation and/or a state review and approval process. Several commenters were concerned, in particular, that the proposed state review process would be duplicative of current EQR processes which are already required; some requested clarification on how state review and approval would differ from EQR and whether it would replace elements of EQR. Another commenter asked if stringent EQRs would satisfy the new state review and approval requirement for new plans. Others questioned the federal capacity to oversee a robust accreditation or review process for Medicaid plans. Some of

these commenters were concerned that a review process which lacked adequate resources at the state and federal level would undermine other measures aimed at improving quality and transparency for Medicaid beneficiaries.

Several commenters also were concerned that state review standards should include meaningful public stakeholder input. Several commenters noted, in particular, the importance of input from stakeholders knowledgeable about managed care long-term services and supports (MLTSS), behavioral health, child health care, and specialty plans. These commenters believed it critical that the final regulations specify measures to ensure robust stakeholder input. Several commenters also recommended full transparency of review standards, including private accreditation standards deemed by states through the review and approval process, and that these be available to the public at no cost or for a nominal fee.

Several commenters requested clarification on the timeline available for states to implement the review and approval process. One commenter recommended piloting the process first. A few commenters recommended a timeframe that allows for state procurement processes to be implemented, while several commenters requested the process be phased-in to accommodate costs and administrative burden. One commenter recommended the state review include a managed care plan readiness assessment. Another commenter recommended CMS adopt the approach for QHP accreditation (45 CFR 155.1045 and 156.275), which allows states to establish the timeline for plans to become accredited.

Response: We thank the commenters for the many thoughtful and specific recommendations regarding the potential impact of this requirement. After carefully considering the comments, we agree that the information to be obtained through the proposed state review and approval process is duplicative of other quality initiatives, such as existing EQR-related activities, validated data submitted through T-MSIS, and the proposed MMC QRS. We also share commenters’ concerns that private accreditation may not adequately reflect elements of quality of care that are key to vulnerable populations disproportionately represented in the Medicaid program. The resources required by states and CMS to implement this new requirement, including potentially requiring some states to develop their own accreditation standards and process, seem disproportionate to the

value that would be yielded. Therefore, to minimize administrative burden and enable states and CMS to focus more resources on the EQR and QRS processes, we have decided not to finalize the state review and approval provisions at proposed § 438.332(a) and (b). Note that this decision does not affect existing state authority to require accreditation of plans with which they contract. Indeed, CMS continues to view the accreditation process as a valuable tool for promoting the quality of care, and encourage states to use it as a tool.

We are retaining the requirement proposed at § 438.332(c), with revision, that states post the accreditation status of their Medicaid plans. This is consistent with the goals of maximizing the transparency of information on a plan's quality of care, and aligning with the availability of information for consumers in the Marketplace and Medicare. Because not all Medicaid plans may have received private accreditation, we are revising § 438.332 in the final rule to provide at paragraph (a) that states must confirm the accreditation status of the contracting MCOs, PIHPs, and PAHPs at least once per year. Under § 438.332(b) of the final rule, states must require their contracted managed care plans to authorize the release of the most recent accreditation review to the state. Finally, paragraph (c) requires that states post and update the accreditation status of their managed care plans on their Web sites at least annually.

While we are not finalizing a requirement to establish a new state review process, we agree that input from all stakeholders, including those representing individuals needing LTSS, is essential to states' quality improvement efforts. The stakeholder engagement process required under § 438.70 along with the managed care plan member advisory committees (at § 438.110), beneficiary support system (§ 438.71), quality measurement and reporting (part 438 subpart E), grievance and appeal system (part 438 subpart F) and the reporting requirements for each of these requirements, all contribute to a framework which ensures that stakeholder concerns are identified and addressed. In addition, regardless of operating authority (for example, section 1915(c) or section 1115(a) of the Act), states generally must go through a robust public notice and comment period to launch a new managed LTSS program. We are revising § 438.332 to require only that states confirm and publically post the accreditation status of each contracted MCO, PIHP and PAHP. This information must be

updated annually on the State's Web site.

Comment: Several commenters supported availability of state approval information on the state's Medicaid Web site. One commenter requested that CMS "explicitly include a requirement in regulatory language that information made available on the Web site must include whether approval is based on state review or private accreditation, level of accreditation, expiration of accreditation, and which approved private accreditation entity a plan is accredited by."

Response: As noted above, we are retaining the requirement to confirm and publicly post accreditation status. Under § 438.332(c) of the final rule, states must post the name of the accrediting entity as well as the accreditation program and level for each plan, or that the plan has not been accredited.

After consideration of the public comments, we are modifying the regulatory text at § 438.332 to: (1) Remove the requirement to implement a state review and approval process involving standards at least as stringent as the standards used by a private accreditation entity recognized by CMS; (2) revise the state review process to include review of accreditation status of each MCO, PIHP, and PAHP when entering into a contract with the state and on an annual basis thereafter; and (3) revise the type of information available on the State's Medicaid Web site to include the accreditation status of each contracted MCO, PIHP and PAHP and accrediting entity when applicable. We are also revising the title of this section to "State review of the accreditation status of MCOs, PIHPs, and PAHPs" to reflect the content of this section in the final rule.

(e) Medicaid Managed Care Quality Rating System (New § 438.334)

This new section proposed minimum standards that all states contracting with MCOs, PIHPs, and PAHPs would use in developing and implementing a MMC QRS in order to increase transparency regarding Medicaid managed care plan performance, increase consumer and stakeholder engagement, and enable beneficiaries to consider quality when choosing a managed care plan. For more discussion of the development of the MMC QRS proposal, see section I.B.6.b.1.e of the proposed rule at 80 FR 31098.

We proposed in § 438.334(a) that states establish a rating system that includes specific factors outlined in the proposed regulation. We also proposed that the MMC QRS would utilize the

same three summary indicators that are currently used to frame the Marketplace quality rating system (clinical quality management; member experience; and plan efficiency, affordability, and management). We proposed that the state's MMC QRS would measure and report on performance data collected from each MCO, PIHP, and PAHP on a standardized set of measures to be determined by CMS, through a public notice and comment process. Further, the measures would be categorized within the components proposed in paragraph (a)(2), and states would be able to adopt additional measures.

Under proposed paragraph (b) each state would apply a methodology, established by CMS under proposed § 438.330(a)(2), to the performance measures described in proposed paragraph § 438.334(a)(3) to determine the quality rating or ratings for each MCO, PIHP, and PAHP serving Medicaid beneficiaries in the state. We proposed in paragraph (c) that, subject to CMS approval, states may elect to use an alternative or preexisting MMC QRS in place of the MMC QRS developed per paragraphs (a) and (b). To avoid duplication of effort, in paragraph (d), we proposed providing states with the option to default to the MA Five-Star Rating system for those plans that serve only beneficiaries enrolled in both Medicare and Medicaid. Finally, in paragraph (e), we proposed that states prominently display the quality rating given by the state to each MCO, PIHP or PAHP online in a manner that complies with the language and format standards of § 438.10(d).

We received the following comments on proposed § 438.334.

Comment: Many commenters supported the creation of a MMC QRS, including several commenters that believed aligning the MMC QRS with the rating systems used for other coverage types will help individuals transitioning to and from other sources of coverage to better understand the quality of the plans to which they have access. A few commenters believed CMS should follow the Marketplace QRS rather than create another rating system that could cause confusion.

Response: We appreciate the commenters' support for the MMC QRS. We are finalizing this requirement with modification, as described below. We recognize there is benefit to alignment when appropriate and expect to align on the major summary indicators of the Marketplace QRS; however, since Medicaid and the Marketplace differ in the population groups covered and the services provided, the specific quality measures within each summary

indicator that comprise the MMC QRS may differ from those in the Marketplace QRS. For example, Medicaid covers a larger population of children and pregnant women than are enrolled in the Marketplace. As such, the MMC QRS summary indicator for clinical care will need to include a more robust set of measures to assess care for these populations than are included in the Marketplace QRS. Therefore, while we are not adopting in whole the Marketplace QRS, the final regulations at § 438.334(b) provide that the MMC QRS developed by CMS will align with the summary indicators used for of the Marketplace quality rating system.

Comment: Many commenters did not support using the MA Five-Star Rating system as an appropriate model for Medicaid managed care plans. Commenters believed that the MA Five-Star Rating system does not account for the differences in the Medicare and Medicaid populations in terms of socioeconomic risk factors, the higher occurrence of comorbidities in dual eligible beneficiaries, and the need for LTSS. A few also expressed concern that the MA Five-Star Rating system was designed primarily to serve adults age 65 and older and persons with disabilities; and therefore, would not adequately reflect Medicaid managed care plans' success in serving persons with special health care needs that are not in the Medicare population. Others requested that states opting to use the MA Five-Star Rating system require plans to report on LTSS measures as well. One commenter questioned if MCOs offering D-SNPs in combination with Medicaid services will be subject to both a MA Five-Star Rating and a second MMC QRS rating.

Response: After careful consideration of the comments and concerns received, we are not finalizing the proposed option for states to default to the MA Five-Star Rating system for those plans that serve dual eligible beneficiaries only. We will coordinate with other CMS components operating quality ratings systems in order to develop performance measures appropriate for enrollees needing LTSS, children, dual eligible beneficiaries, persons with special health care needs, and individuals with low socioeconomic status, as well as adjustments to the methodologies to account for these populations and measures.

Comment: Several commenters recommended that FFS programs and other emerging delivery systems be subject to the MMC QRS to ensure high-quality coverage for all Medicaid beneficiaries regardless of delivery system and to create comparable data

for use by state policymakers. One commenter noted a recent study in Missouri that compared the state's managed care and FFS programs.

Response: Performance measurement in the Medicaid FFS setting is in an earlier stage of development than exists for managed care. To obtain information on quality of care in FFS, CMS currently asks states to collect and report data on the CMS Child and Adult Core Measure Sets for Medicaid and CHIP for both FFS and managed care. However, we believe that application of methodologies developed for quality rating systems in managed care to FFS would be premature at this time.

Comment: One commenter asked that CMS consider LTSS performance measures as a separate summary indicator.

Response: We intend to utilize a robust public engagement process. In addition, § 348.334(b) of the final rule provides for a period of public notice and opportunity to comment during the development of the MMC QRS by CMS. We will consider such comments during that public engagement and notice and comment process.

Comment: Many commenters believed that CMS should allow states to adopt alternative MMC QRS to account for the variability of Medicaid programs, geographic variation, and medically diverse populations. Several commenters wanted minimum core parameters or key content areas included, while a few commenters believed CMS should establish a list/toolkit of existing and "well respected" standard performance measures, from which states would then be able to select measures that most closely align with their needs, and require that all states use roughly the same methodology for calculating rating scores to build consistency across programs.

Some commenters recommended that states be required to demonstrate a substantial state-specific purpose to utilize an alternative MMC QRS contingent upon CMS approval. One commenter believed that CMS should consider the following for justification: (1) Holding managed care plans more accountable for areas of quality outlined as priorities for improvement within a state's comprehensive quality strategy; or (2) giving greater weight to certain measures of greater importance to the quality of care for a particular population in that state. Some commenters also requested that the general public have an opportunity to view and provide comment on the states' justifications and requests.

A few commenters recommended that states be given broad latitude on the development, implementation, and timing of the MMC QRS to assure that it recognizes local needs and successes. They also recommended that CMS partner with states to outline the criteria for approval of alternative MMC QRS following promulgation of the final rule. One commenter noted that the alternative MMC QRS would give states the ability to leverage quality improvement by adopting developmental and innovative measures that are unlikely to appear in a national core measure set.

Response: We believe that the regulations requiring CMS approval of an alternative MMC QRS should retain sufficient flexibility to enable states to tailor an alternative system which meets the unique needs of the state, including the potential use of developmental measures, and are finalizing § 438.334(c) with revision. We will allow states to adopt an alternative MMC QRS upon approval by CMS, provided that the ratings generated by the alternative MMC QRS yield substantially comparable information regarding MCO, PIHP, and PAHP performance to that yielded by the CMS-developed MMC QRS. Changes to approved alternative MMC QRS will also require CMS approval.

Comment: A few commenters believe that in order to ensure a fair and accurate evaluation of quality, it is essential that performance measures are weighted consistently across the program. They asked that states not be given the option to modify the standard weights or definitions assigned to a measure to ensure a fair and accurate evaluation of quality because alternate systems could be less robust than federal standards, to the detriment of consumers. They believed that "fixed weights" would provide a transparent, unbiased view across State managed care programs. Several commenters also expressed concern that allowing alternate MMC QRS programs without federal prioritization and consolidation of quality measures will add administrative waste in the healthcare system.

Response: We interpret the commenters' terminology of "fixed weights" as a standard calculation methodology utilized for all states in order to allow consistent comparison of plans across states. We appreciate the commenters' concerns about the use of consistent weights or an alternative MMC QRS methodology. The methodology for the MMC QRS will be defined in consultation with experts and with a public engagement process

and a public comment period. However, we believe it is important to provide states with an option to tailor the MMC QRS, including measures and methodology, to the quality assessment needs of the state. We note that states cannot utilize an alternative MMC QRS under § 438.334(c) of the final rule without prior CMS approval and note that any alternative MMC QRS must yield information regarding MCO, PIHP, and PAHP performance which is substantially comparable to that yielded by the MMC QRS developed by CMS. Generally, this means that the measures and methodology a state chooses should result in a QRS that utilizes comparable information to that which will be included in the finalized CMS-developed QRS. We expect to issue final guidance on alternative QRS and comparability following the public notice and stakeholder engagement process.

Comment: A few commenters requested that CMS delay implementation of the MMC QRS until more guidance is given. Other commenters were in support of the proposed 3–5 year timeline for implementation.

Response: States will not be required to implement a MMC QRS until 3 years after CMS issues guidance specifying the measures and methodologies for the MMC QRS, which in turn first requires consultation with states and other stakeholders and a public notice in the **Federal Register** with opportunity to comment. We anticipate releasing guidance specifying the measures and methodologies for the MMC QRS in 2018, which would result in states implementing a MMC QRS in 2021 (within 3 years after issuance of the guidance). To formalize this timeframe, the regulations at § 438.334(a)(3) provides that states must implement such MMC QRS within 3 years of a final notice published in the **Federal Register**. This timeframe is designed to provide sufficient time for CMS to develop and for states to implement a robust MMC QRS.

Comment: One commenter believes there are limitations to utilizing a national model or national data in states where there may be few data points for percentile distributions. Additionally, the commenter noted that national data does not allow consumers to compare their state level options meaningfully.

Response: We are not proposing that states define their percentile distributions based on aggregated data across states. Rather each state's MMC QRS will use state level data that will provide comparisons across plans within a state.

Comment: One commenter requested that CMS consider the impact of the MMC QRS in areas where only one managed care plan is available. The commenter believed that in the instance where there is not choice of a managed care plan, a MMC QRS could deter Medicaid enrollment. Another commenter requested that CMS not require a MMC QRS in a state where only one managed care plan operates.

Response: We believe that a MMC QRS has benefits beyond managed care plan choice. Public reporting of quality ratings in regions with only one plan allows for informed consumers and stakeholders and thus, robust public awareness and discussion about managed care plan performance. It also can provide incentive for the managed care plan to improve the quality of care or for the state to consider securing a contract with a different managed care plan.

Comment: A few commenters asked CMS to gather data from states to evaluate the robustness of a MMC QRS within a reasonable time after implementation.

Response: We will periodically review the CMS-developed MMC QRS to determine the need for modification and to ensure continuing alignment with the Marketplace QRS. CMS will evaluate the robustness of each alternative MMC QRS prior to approving it for use to ensure that it yields information regarding MCO, PIHP and PAHP performance which is substantially comparable to the information yielded by the CMS developed MMC QRS. We will consider additional possibilities for evaluation during the MMC QRS post implementation period, however, it is premature to develop such a plan at this time.

Comment: A few commenters recommended that CMS seek input through robust stakeholder engagement using a consensus-building approach that involves the public, managed care plans, state officials, advocacy groups and other stakeholders, and that decisions about the measure selection and rating systems should be made in a transparent and open process with an opportunity for public comment. A few commenters requested that CMS use a public comment process similar to the requirements for section 1115(a) demonstration projects. Several commenters requested that the public comment process be explained in detail in the final rule.

Several also requested that CMS only approve an alternative system after states include evidence of consultation with stakeholders. Other stakeholders

asked that CMS develop a rollout strategy to ensure vetting of measures and alternative MMC QRS programs are comparable across states.

Response: We appreciate the need for an open public comment process. We will utilize a process similar to that used by CMS in the development of the Marketplace QRS, which included multiple stakeholder listening sessions. We also will publish the proposed methodology and quality measures framework in a **Federal Register** notice that will include opportunity for public comments. Information about the Marketplace QRS can be found at <https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/QualityInitiativesGenInfo/Health-Insurance-Marketplace-Quality-Initiatives.html>.

We will also require that states requesting to adopt an alternative MMC QRS, or to modify an approved alternative MMC QRS, provide an opportunity for public comment of at least 30-days and obtain the input of the state's Medicaid Medical Care Advisory Committee established under § 431.12. Under § 438.334(c) of the final rule, CMS expects that requests for alternative MMC QRS will document the public comment process utilized by the State including discussion of the issues raised by the Medical Care Advisory Committee and the public. The request must also document any policy revisions or modifications made in response to the comments and rationale for comments not accepted.

Comment: One commenter recommended CMS adopt the Marketplace standard for posting of QRS results and that CMS decline to post the results of the MMC QRS while they are being tested and validated.

Response: We will consider this request as we move forward with MMC QRS development and look forward to additional input regarding public display during the public engagement process.

Comment: A few commenters requested that CMS address the needs and vulnerabilities of Medicaid beneficiaries by identifying and acknowledging impacts of social determinants of health, such as lower health literacy, socioeconomic risk factors, and higher occurrence of comorbidities in the Medicaid population, on the quality ratings achieved by managed care plans. The commenters suggested we develop a risk stratification based on populations served, building on the work of the NQF and Measure Applications Partnership on core measure sets for adult and child

beneficiaries and risk adjustment for socio-demographic factors.

Response: We will consider such comments during the public engagement and notice and comment process that will be utilized for the development of the MMC QRS, which we anticipate will reflect risk stratification and other methodological adjustments for socioeconomic risk factors and other social determinants of health. We also note that CMS recently announced a new demonstration model, Accountable Health Communities, to develop approaches to the issues raised.

Comment: Several commenters offered suggestions for CMS to consider when choosing measures for the MMC QRS, including managed care plan performance related to access to care; managed care plan administration, claims processing and appeals processing; cultural competency and accommodation of people with disabilities at the provider and managed care plan level; and transportation. Commenters also suggested creating separate summary indicators, ratings, or separate reporting programs for certain subpopulations such as children, including children with complex medical needs, pregnant women, individuals needing behavioral health services and individuals needing LTSS. Several commenters recommended that a rating system should address all populations being served, as well as the care provided within the managed care plan.

Response: We will consider such input on quality reporting measures and requirements as part of the public engagement and public notice and comment process. The approach to measurement may differ depending on whether certain services that may apply to specific subpopulations are included in a MCO or if they are provided in a PIHP or PAHP (for example, one which provides only dental or behavioral health services). We anticipate releasing guidance in 2018 following the public engagement and notice and comment process.

We note that in states with PIHPs or PAHPs for behavioral health or other specialty services, the comprehensive managed care plans and the PIHPs and PAHPs are subject to both the MMC QRS and the requirements for the QAPI Program (§ 438.330). States, comprehensive plans and behavioral health PAHPs can draw from the behavioral quality measures in the Child and Adult Core Sets for Medicaid and CHIP for their QAPI program.

Comment: One commenter requested timely and comprehensive revision of managed care plan contracts to reflect

the financial burden associated with a MMC QRS.

Response: We interpret this comment as a request that the development of capitation rates take into account the administrative costs for managed care plans associated with the MMC QRS. As discussed in section V.C.22 of the preamble, we do not expect the MMC QRS to pose an additional burden for managed care plans; instead, we expect states will rely on information already provided by the managed care plans to develop the quality ratings (for example, performance measures required for QAPI per § 438.330(c)). Given this, we do not anticipate that the MMC QRS would necessitate a change in capitation rates.

Comment: One commenter requested that the data already being reported by managed care plans, including claims and administrative data, be leveraged where possible to reduce burden. A few commenters asked CMS to consider data collection; system capabilities; format; and content of MMC QRS reports; and to utilize education and outreach.

Response: We agree that available data should be utilized when possible to reduce burden. We will consider data collection, systems, reports, refinement, education, and evaluation as we develop the final guidance for the MMC QRS and would expect to take into consideration similar concerns in reviewing a state's request for approval of an alternative MMC QRS. We look forward to additional input through the future public engagement process.

Comment: A few commenters noted that only one dental measure is currently being considered for the Marketplace QRS and encouraged CMS not only to set a standard for quality rating for dental services that can be extended to MCOs and dental PAHPs in the future, but also to emphasize oral health preventive services covered by Medicaid's EPSDT benefit package for children. One commenter suggested that CMS allow states to continue implementation of dental-specific quality improvement programs until such time as appropriate accreditation, quality ratings systems and dental-specific survey tools are developed with dental industry stakeholders. The commenter stated that states do not generally extend accreditation or QRS standards to managed dental contracts or services contractors that administer these programs.

Response: We appreciate the commenters' concerns about quality measurement and improvement efforts related to dental services. Through the public engagement and MMC QRS development process, we will seek

input from HHS partners, stakeholders and other experts, on the specific measures that should be considered for dental services. The approach to measurement and improvement may differ depending on whether dental services are included in a comprehensive managed care plan or if they are provided in a dental-specific managed care plan (such as a dental PAHP). We anticipate releasing guidance in 2018 following the public engagement and notice and comment process.

We fully support the continuation of dental-specific quality improvement projects and have developed guidance for managed care dental PIPs. Section § 438.334 does not impact the PIPs required under § 438.330(d) and therefore has no bearing on the ability of a state or managed care plan to conduct a PIP relating to oral health.

Comment: A few commenters encouraged CMS to use and continuously test simple, straightforward language to display MMC QRS ratings for consumers. Commenters noted that Medicaid enrollees have varied levels of education and literacy and that it is important for language, definitions, and scoring of the MMC QRS to be easily understood.

Response: We appreciate the need to employ plain language and to ensure accessibility for LEP individuals both in the development of a MMC QRS as well as in displaying the data after collection. Section § 438.334(e) of the final rule requires states to prominently display the quality rating given to each managed care plan on the state Web site in a manner that complies with the standards in § 438.10(d), which requires taking into consideration the special needs of enrollees or potential enrollees with disabilities or limited English proficiency. We look forward to additional public engagement regarding beneficiary communication during the public notice and comment process required under § 438.334(b) of the final rule.

Comment: One commenter agreed that it is important that measures reflect current priorities and practices; however, they believed that updating measures every 2 to 3 years is too frequent, because system development and implementation of new or additional measures is resource intensive and does not allow adequate time to measure trends in managed care plan performance or results of improvement efforts. The commenter stated that continual changes to measures also limit the comprehensive development, implementation, and

effectiveness of interventions. Another commenter asked that CMS consider a 2 to 3 year measure development/change process to avoid retrospective changes in weighting star thresholds.

Response: We did not propose, and are not finalizing, a specified timeframe for updating performance measures, but will consider these comments as a part of the public engagement and notice and comment process we will use to develop final guidance.

Comment: One commenter asked CMS to ensure that all quality metrics have been tested and have performance expectations appropriate for managed care plans. Additionally the commenter asked that all quality metrics, incentives, or withholding of payments should reflect value-based purchasing concepts. The commenter recommended such methodologies be provided to the managed care plan prior to the effective period of the contract. Another commenter suggested that CMS replace the development of a MMC QRS with a measure of the degree of provider engagement in value-based purchasing. One commenter requested that CMS ensure that the MMC QRS not duplicate current quality incentive programs already in place at state or federal levels.

Response: We did not propose any value-based purchasing programs, quality incentives, or withholds of payments related to the MMC QRS.

Comment: One commenter requested that CMS align measures and reporting cycles with already existing programs when available. Other commenters suggested CMS align with the HEDIS® measurement cycle.

Response: We agree with aligning with existing programs/measurement cycles when possible. We are finalizing our proposal to align the MMC QRS components with those used in the Marketplace QRS. We will continue to consider opportunities for alignment and burden reduction in the development of the MMC QRS.

Comment: A few commenters supported a phased in option so that all three summary indicators do not have to be initially considered but would be phased in by the end of a set period of time. This approach is proposed to ensure that stakeholders are given adequate lead time to fully understand the measure specifications, data collection methodology and reporting strategy.

Response: As discussed above, states will not be required to implement a MMC QRS until 3 years after CMS issues guidance specifying the measures and methodologies for the MMC QRS, which in turn first requires consultation

with states and other stakeholders through a public notice in the **Federal Register** and opportunity to comment. This timeframe is designed to provide sufficient time for CMS to develop and for states to implement a robust MMC QRS.

Comment: While most commenters supported alignment with the summary indicators utilized by the Marketplace QRS, several commenters suggested that CMS replace the term “affordability” with “efficiency” because affordability may be viewed as meaning a “lower capitated rate or lower out of pocket expenses.” Other commenters simply believed the term affordability would be confusing.

Response: We appreciate the commenters support for alignment with the Marketplace QRS summary indicators. In order to maintain ongoing alignment with any future revisions to the Marketplace QRS summary indicators, in the final rule we are replacing the names of the current Marketplace QRS summary indicators (clinical quality management, member experience, and plan efficiency, affordability, and management) with a cross-reference to the Marketplace QRS regulation at 45 CFR 156.1120. This will allow the MMC QRS to adapt to changes in the Marketplace QRS and allow for ongoing alignment. We understand commenters’ concerns regarding the potential for confusion around the term affordability, however, we have eliminated reference to this term in the regulation text.

Comment: A few commenters believed that while a MMC QRS can encourage transparency and even strengthen the oversight process, a poorly designed or executed MMC QRS could result in beneficiaries with inaccurate or untimely information.

Response: We agree with the commenters and look forward to additional input from stakeholders throughout the public engagement and notice and comment process.

Comment: One commenter emphasized the importance of member surveys accounting for the significant cultural and language diversity among Medicaid beneficiaries as well as the number of children and underserved populations enrolled in Medicaid.

Response: We agree that the diversity of the populations served by Medicaid can present challenges in conducting member experience surveys. CMS, through the multi-stakeholder engagement process for the development of the MMC QRS, will solicit feedback on survey methods that are effective in reaching the diverse populations served by Medicaid.

Comment: One commenter asked CMS to publish results more than once annually allowing for a more ‘real time’ availability of information.

Response: CMS will consider such comments during the stakeholder engagement and public notice and comment process that will be utilized for the development of the MMC QRS.

Comment: One commenter asked if CMS intends to provide enhanced FFP for MMC QRS-related activities since the development and implementation of the MMC QRS is expected to require significant administrative resources from states.

Response: Under § 438.358(c)(6) of the final rule, assistance with the quality rating of MCOs, PIHPs, and PAHPs is an optional EQR-related activity. As such, consistent with § 438.370(a) of the final rule, expenditures for an EQRO’s assistance with the quality rating required under § 438.334 with respect to a MCO are eligible for the 75 percent match rate. Consistent with § 438.370(b), expenses associated with quality rating of a PIHP or PAHP are eligible for the regular administrative match rate (50 percent), regardless of whether the activities are performed by the state, an EQRO, or another contractor or state agent.

After consideration of the public comments, we are finalizing with modification our proposal that states contracting with MCOs, PIHPs, and PAHPs develop and implement a MMC QRS. Section 438.334(a) requires states contracting with MCOs, PIHPs, or PAHPs to adopt either the MMC QRS developed by CMS or an alternative MMC QRS, and implement such MMC QRS within three years of the date of a final notice published in the **Federal Register**. Section 438.334(b) has been redesignated as paragraph (d) and revised to describe the collection of data from each MCO, PIHP and PAHP to issue a quality rating and to specify that the state must issue a quality rating annually for each contracted MCO, PIHP, and PAHP. New paragraph (b) provides for CMS to develop a MMC QRS, through public notice and comment that aligns with the summary indicators of the Marketplace QRS developed per 45 CFR 156.1120. Section 438.334(c) has been revised to affirm that states may adopt an alternative MMC QRS, contingent upon CMS approval, that utilizes different performance measures and/or applies a different methodology from that described in paragraph (b), provided that the ratings generated by the alternative MMC QRS yield information regarding MCO, PIHP, and PAHP performance which is substantially

comparable to that yielded by the MMC QRS. We have also modified paragraph (c) to include requirements for a state public engagement process prior to submitting a proposal for, or modification to, an alternative MMC QRS and requirements for applications to CMS for approval of alternative MMC QRS. We have removed proposed paragraph (d), which would provide an option for states to elect to rely on the MA Five-Star Rating for MCOs, PIHPs, and PAHPs serving exclusively dual eligible beneficiaries.

(f) Comprehensive State Quality Strategy (New §§ 431.500, 431.502, 431.504, 431.506, and 438.340)

Under the existing regulations at § 438.202(a), states contracting with MCOs or PIHPs have been required to maintain a written strategy for assessing and improving the quality of services offered by all MCOs and PIHPs. We proposed adding a new subpart I to part 431 that would require a comprehensive quality strategy (CQS) that applied to services provided through all delivery systems, including a FFS delivery system, not just those provided through an MCO or PIHP. We also proposed additional CQS elements which would apply to states that contract with an MCO, PIHP, PAHP, or PCCM entity (described in proposed § 438.3(r)) to deliver Medicaid services.

(1) Basis and Scope (New § 431.500)

We proposed that each state be required to have a comprehensive quality strategy to address and support efforts to strengthen quality in a state's Medicaid managed care program (inclusive of MLTSS programs, where applicable), as well as other types of delivery systems for Medicaid services. In proposed § 431.500(a) we described the statutory basis of the proposed new subpart I, including the authority to adopt standards for a quality strategy established in section 1932(c) of the Act for MCOs, and in section 1902(a)(4) of the Act for PIHPs. We relied as well on section 1902(a)(4) of the Act because development of a comprehensive quality strategy for all service delivery systems would promote efficient and proper administration of the state plan. We also proposed to rely on section 1902(a)(6) of the Act, for purposes of the proposed reporting requirement; section 1902(a)(19) of the Act; and section 1902(a)(22) of the Act.

In paragraph (b), we proposed that the scope of this new section establish parameters for states to develop a comprehensive quality strategy to monitor the delivery of quality health care to Medicaid beneficiaries. This

would include states contracting with MCOs, PIHPs, or PAHPs, those utilizing a PCCM arrangement, and those that deliver services through FFS. We solicited comments on our proposal for a comprehensive quality strategy.

We received the following comments on proposed § 431.500.

Comment: One commenter noted that, as recognized by CMS in its revised interpretation of the EQR matching rate, provisions in section 1932(c) of the Act regarding quality are specific to MCOs with a contract subject to the requirements in section 1903(m) of the Act. In light of this, the commenter requested that the comprehensive quality strategy be made optional and that the state retain the discretion in determining elements of the comprehensive quality strategy including the ability to have the strategy apply to its managed care program only.

Response: We disagree with the commenter's view that the fact that section 1932(c) of the Act applies only to MCOs means quality requirements cannot be imposed on other managed care entities, such as PIHPs and PAHPs, or for other delivery systems. As noted above, section 1902(a)(4) of the Act allows for such methods of administration as are found by the Secretary to be necessary for the proper and efficient operation of the Medicaid State plan. Based upon this authority, the current regulations already apply quality provisions set forth in section 1932(c) of the Act to PIHPs. We believe that this authority also authorizes the Secretary to require states to draft and implement a comprehensive quality strategy addressing all Medicaid delivery systems utilized in the state. However, as discussed in section I.B.6.b(2)(f)(2) of the preamble below, we are not finalizing the proposed provisions in part 431, subpart I. We are finalizing the extension of the managed care quality strategy to states contract with PAHPs and PCCM entities (as described in § 438.310(c)(2) of this final rule); see discussion in section I.B.6.b(2)(f)(5) of the preamble below.

(2) State Comprehensive Quality Strategy (New § 431.502)

The current regulations at § 438.202(a) identify responsibilities for the managed care quality strategy for states contracting with MCOs and PIHPs. Proposed § 431.502(a) set forth a general rule requiring a comprehensive quality strategy in all states addressing all Medicaid delivery systems.

In paragraph (b)(1), we proposed that the strategy include the state's goals and objectives for continuous quality improvement, which would be required

to be measurable and take into consideration the health status of all Medicaid-covered populations in the state. Under the proposal states would be required to take into account a variety of data (such as population health status, service utilization and expenditure information, quality of life issues, quality metrics, etc.) when developing such goals. In paragraph (b)(2), we proposed that states be required to identify the specific quality metrics and performance targets that they plan to use to measure performance and improvement, which would be linked to the goals identified in paragraph (b)(1). Further, we proposed that states be required annually to publish these quality metrics and performance standards on their Web site.

We received the following comments on proposed § 431.502.

Comment: Many commenters expressed support for the proposed comprehensive quality strategy requirements, specifically the extension of the comprehensive quality strategy requirements beyond managed care to include Medicaid FFS, which they believed would help to: (1) Improve the health of the broader Medicaid population by encompassing all Medicaid services regardless of delivery system; (2) advance state efforts to measure and improve the quality of care provided to children and adults in Medicaid; (3) improve monitoring and oversight of FFS delivery systems, which one commenter noted still serves more than a quarter of Medicaid beneficiaries, including those who are often the most vulnerable beneficiaries with significant health care needs; (4) promote transparency and quality of care; and (5) avoid the risk of creating standards that vary by delivery system. One commenter believed that a CQS would support comparisons of quality of care across different delivery models. Another commenter supported measuring quality of care in an effort to achieve optimal outcomes and publicly reporting performance results in an understandable way. Another believed that the evaluation of a CQS would supply invaluable data in states that are newly transitioning to managed care as well as in states that are moving more populations into managed care.

A few commenters expressed support for the proposed CQS but were concerned that requiring every state to develop a strategy, including its own quality standards, and its own list of measures would add a potentially heavy burden for states, increase the number of measures and disparate activities, and diminish the likelihood that quality

efforts would result in improved outcomes. Several commenters noted that while flexibility would let states design their activities to meet their own needs, it would also mean that there would be little, or no, alignment between states. A few commenters recommended that having a single common set of topics and related measures from which to choose would lead to a more unified approach to measurement and greater opportunities for collaborative improvement work. One commenter expressed concern that, if state-established goals and objectives are not strictly aligned with CMS and/or NCQA accreditation standards, the result could be duplicative or misaligned requirements. While understanding of the need for state flexibility, this commenter recommended CMS establish parameters to avoid this outcome.

Other commenters did not support the proposed comprehensive quality strategy. Some of these commenters pointed to the challenges of incorporating a small or shrinking FFS population into a comprehensive quality strategy. One commenter noted that the populations served by FFS often are small and disparate, which would make it difficult for a state to develop an effective strategy. Others noted that the populations in FFS may be eligible for a limited set of benefits (such as family planning services) or may be eligible for a limited period of time (for example, medically needy beneficiaries eligible only during part of a budget period after meeting a spenddown amount in accordance with § 435.831, or individuals prior to initial enrollment in a managed care plan). Some commenters pointed out that many performance measures and performance improvement programs may not apply to FFS beneficiaries, or may prove impractical to collect based on the limited sample size or the poor fit between the measure and the population. One commenter sought guidance on how a state should incorporate goals and objectives relating to a shrinking FFS population.

One commenter recommended allowing states with more than 80 percent of their Medicaid beneficiaries in managed care to be exempted from any requirement to develop a comprehensive quality strategy, while another recommended that states be provided an option to include FFS delivery systems in their quality strategy, but not be required to do so. This commenter noted that a voluntary approach would allow each state to direct limited resources to quality activities which the state determines

will have the most impact and which are best suited to meet future program growth. Another commenter believed that the inclusion of a very small population of FFS beneficiaries would detract from a state's ability to focus on measuring the quality of care provided to enrollees in managed care.

A few commenters noted that states, which currently do not generally have in place performance measurement or improvement activities for the FFS population, would have to invest additional resources to meet the comprehensive quality strategy requirement. One of these commenters believed that this change would push states to reconsider the use of FFS. Another believed that to include the FFS population in the comprehensive quality strategy, states essentially would have to develop an organizational structure and staff similar to that of an accredited MCO. While one commenter believed that its state could include FFS in the overall quality strategy with existing staff and resources (other than implementing a consumer survey and performance improvement plan), several commenters believed that states would need time and resources to build a solid structure to achieve quality measurement and improvement in FFS. These commenters recommended that CMS provide support to states in building the requisite capacity, including an enhanced match for all quality activities and sufficient lead time to prepare for the development and implementation of a comprehensive quality strategy. Another commenter noted that a comprehensive quality strategy will require extensive review and updating by CMS, which may be difficult to maintain.

One commenter expressed general opposition to the proposed comprehensive quality strategy, noting that the variety of changes proposed, including the expansion to additional managed care programs, additional elements to be included in the CQS, and the requirement to update the plan every 3 years instead of every 5 years, would require significantly more work than what is presently required.

Two commenters requested clarification regarding the application of the comprehensive quality strategy to FFS beneficiaries and certain small populations (such as dual eligibles).

Response: We appreciate the commenters' thorough consideration of this proposal. While most commenters believe that a comprehensive quality strategy could offer valuable information about, and promote improvements in, the quality of care provided by state Medicaid programs,

specifically regarding the beneficiaries served by FFS, we recognize that the proposed requirement could pose significant logistical and resource challenges for states, many of which may lack the infrastructure and expertise necessary to develop and implement a quality strategy that addresses quality of care for beneficiaries in FFS, which is different from the strategies appropriate for managed care. We also appreciate that shrinking FFS populations and FFS populations that receive a limited benefit package pose challenges to the development and implementation of a comprehensive quality strategy addressing all delivery system models.

After considering the entirety of the comments regarding the proposed comprehensive quality strategy, we are convinced that the time and resources required to develop and implement a comprehensive quality strategy would be higher than we estimated in the proposed rule, and could hamper other state quality efforts. Therefore, we are withdrawing proposed subpart I of part 431 in its entirety. We will, however, retain the requirement for a managed care quality strategy, described in § 438.340 of the final rule (see discussion in section I.B.6.b(2)(f)(5) below). We are retaining the requirement in § 438.340 of the final rule that states contracting with MCOs, PIHPs, and PAHPs, as defined in § 438.2, or with a PCCM entity described in § 438.310(c)(2) of the final rule (describing PCCM entities with shared savings or other financial incentives tied to improved quality outcomes)—will be required to draft and implement a quality strategy consistent with § 438.340. Since we are retaining the requirement for a managed care quality strategy applicable to multiple managed care contractual arrangements in § 438.340, we are revising § 438.310 in the final rule to reflect the basis and scope for this broader applicability of the Medicaid managed care quality strategy.

We strongly encourage states to report on the CMS Child and Adult Core Measure Sets for Medicaid and CHIP, and to explore other ways to measure, improve, and report on the quality of care in FFS. States interested in expanding the scope of their quality improvement efforts to FFS beneficiaries may wish to consult our November 22, 2013 SHO letter, Quality Considerations for Medicaid and CHIP Programs (SHO #13-007, available at <http://www.medicaid.gov/Federal-Policy-Guidance/downloads/SHO-13-007.pdf>) as well as the preamble to the proposed rule (80 CFR 31098).

Comment: One commenter noted that CMS requires development of a quality strategy in section 1915(b) and 1915(c) waivers, and in all section 1115(a) demonstrations. This commenter agreed that states should have quality strategies in place, but advocated for consolidation of the separate and independent quality-related requirements that relate to the different federal program authorities. The commenter believed that although a comprehensive quality strategy has the potential for added efficiency, CMS's history of expanding the scope of state reporting on quality measures has not been accompanied by an effort to consolidate and streamline requirements across the various federal authorities.

Response: We appreciate the commenter's concern about the interaction of the various quality requirements required by different Medicaid statutory authorities. The quality strategies required under other authorities (including sections 1915(c) and 1115(a) of the Act) are outside the scope of this rulemaking. Managed care authorized under section 1915(b) waivers are subject to the requirements of part 438, including the quality strategy requirements, unless explicitly waived. As also discussed, we are withdrawing the proposed requirement for a mandatory comprehensive quality strategy covering FFS delivery systems.

Comment: One commenter recommended that CMS also develop a national comprehensive quality strategy that states could default to in the absence of their own or if their strategy had not been updated in more than 3 years.

Response: We have developed and updated a robust Quality Strategy, which is aligned with the HHS National Quality Strategy, and we encourage states to align their quality strategies with ours and the HHS National Quality Strategy (as appropriate). We do not believe it would be appropriate for states to have the option to default to a national quality strategy, given that section 1932(c)(1) of the Act explicitly requires states to develop and implement their own quality strategy for Medicaid MCOs contracting with the state. Therefore, we reject the commenter's recommendation.

Comment: Two commenters recommended that the elements of a comprehensive quality strategy incorporate the three aims of the National Quality Strategy, including the specific recommendation that the list of minimum requirements for the comprehensive quality strategy would include at least four of the six priorities

and four or more of the nine levers of the National Quality Strategy.

Response: We appreciate the commenters' support for the National Quality Strategy. While we are withdrawing the proposed comprehensive quality strategy, we encourage states to consider how their quality programs can align with the National and CMS Quality Strategies, and how the concepts in these strategies can support state activities and initiatives. While we are continuing the requirement for a Medicaid managed care quality strategy in § 438.340, we decline the commenters' recommendation to require states' specifically include components of the National and CMS Quality Strategies. The national documents are designed to address a broad array of public health and coverage programs; state Medicaid managed care quality strategies are much more specific documents which must focus on each state's unique managed care program(s), populations, and benefits. We do not believe it would be appropriate to place a requirement as described by the commenters on states given the unique and specific nature of a state Medicaid managed care quality strategy.

Comment: One commenter stated that there should be transition of care standards for all Medicaid beneficiaries transitioning between Medicaid delivery systems, and that this should be included in the quality strategy.

Response: Section 438.62(b)(3) as proposed would require that states describe their transition of care policy in their comprehensive quality strategies. While we are withdrawing the proposal for a comprehensive quality strategy in part 431, subpart I to include FFS delivery systems, we are adding a cross reference to § 438.62(b)(3) in § 438.340 of the final rule to retain the requirement to include a transition of care policy in the managed care quality strategy under the final rule.

Comment: A number of commenters recommended additional elements for comprehensive quality strategies, such as: (1) Identification and reduction of preventable events, including adverse drug events; (2) drug utilization review; (3) advanced care planning; (4) examination of payment rates and health care worker wages as they relate to quality and access; (5) for LTSS, consideration of the need for workforce training and incentives to have a career in health care and LTSS (for example, wages and benefits, and conditions of work); (6) adoption of the principles set forth in the finalized HCBS regulation for MLTSS; (7) person-centered

planning and service delivery, including person-centered goals and activities; (8) pediatric quality improvement; and (9) consideration of all populations served by Medicaid when reviewing network adequacy and availability of service standards.

Response: We thank the commenters for their recommended additions to the elements of a proposed comprehensive quality strategy. As we are withdrawing our proposal for a comprehensive quality strategy, but retaining the requirement for a managed care quality strategy in § 438.340, we will respond to these suggestions in that context. Many of the recommended additions are addressed elsewhere in this rule or in other existing Medicaid regulations, including: § 438.3(g) (relating to provider-preventable conditions); § 438.3(s) (relating to drug utilization review); §§ 438.3(o), 438.70, 438.71, 438.208, 438.214, and 438.816 (relating to MLTSS and person-centered planning); and proposed § 438.358(b)(3) and (b)(4) (relating to validation of network adequacy and availability of services). While we agree that the workforce plays an important role in the availability and quality of services, we do not believe that workforce-related assessments and efforts represent an appropriate mandatory element for each state's quality strategy. Regarding children's health, by requiring that the state consider the health status of all populations served by its managed care plans, the quality strategy necessarily encompasses pediatric quality improvement. Finally, we note that while § 438.340 establishes the minimum standards for a quality strategy, states may include additional items at their discretion. Stakeholders also can use the state's public engagement process to recommend additional, state-specific elements for the quality strategy.

Comment: A number of commenters expressed support for the requirement that a comprehensive quality strategy's goals and objectives be measurable, noting that some states' current goals and objectives lack metrics to demonstrate measurable results. Several of these commenters noted the benefit of measurable goals and objectives specifically for FFS as a way to help improve monitoring and oversight.

Response: We appreciate the commenters' support. We believe that it is important for states to be able to measure and assess their progress towards defined quality goals in an objective manner. While we are withdrawing the proposed comprehensive quality strategy, which would have addressed services

delivered FFS, we continue to encourage state efforts to measure and improve quality of care for services furnished by FFS providers.

Comment: Regarding the reference in proposed § 431.502(b)(1) to “all populations,” a number of commenters suggested that CMS explicitly identify key populations served by Medicaid, including: (1) People with disabilities and older adults; (2) children, with particular attention to those with special health care needs; (3) pregnant women; and (4) relevant population segments from the “Bridges to Health” model¹¹ article. Commenters believed that specifying broad population segments would help to ensure that no major population segment is overlooked in comprehensive quality strategies. A few also noted that quality measurement and performance improvement strategies differ for children and adults, for pregnant women compared to the general adult population, and for healthy children compared to children with special health care needs.

Response: As noted, we are withdrawing the proposal for a comprehensive quality strategy that includes FFS delivery systems. While we share the commenters’ belief that all populations enrolled in managed care must be considered in a state’s quality strategy, we do not believe it would be appropriate to highlight certain populations or population segments in the regulations and not others, particularly given that the populations enrolled in managed care vary from state to state. Section 438.340 of the final rule incorporates the requirement that a state’s goals and objectives for its managed care program must consider the health status of all populations served by the state’s managed care plans. The language is intentionally flexible to accommodate differences between the managed care populations in different states. We agree that performance measurement and improvement approaches may differ by population, and encourage states to take these differences into consideration when developing or revising a quality strategy.

Comment: A number of commenters recommended that CMS ensure that “health status” is understood broadly to include: Mental health, with a specific focus placed on what mental health comprises; functional status; quality of life in the community; and an

individual’s well-being. One commenter noted that if we are to improve health, reduce disparities, and curb costs, we must look more broadly at health and well-being. Another noted that historically, mental health has not been treated as part of overall health due to stigma, and noted that it is important for CMS to do all it can to ensure the outdated paradigms of treating mental health separately from overall health is changed. Several commenters recommended CMS modify proposed § 438.340(b)(2) to read, “The State’s goals and objectives for continuous quality improvement, which must be measurable and take into consideration the health status and quality of life of all populations served by the Medicaid program.”

Response: We thank the commenters for this opportunity to clarify the meaning of health status. We believe that health status includes physical health, behavioral health (which we broadly define to include mental health and substance use disorders (SUDs), including use of tobacco, alcohol, and other drugs), and functional status. We note that while a state must take into consideration the health status of all populations served by its managed care plans when developing its goals and objectives, the goals and objectives identified in states’ quality strategies are not required to address all facets of health status. For example, a state may identify several different needs based on the health status of its populations, but then elect to set goals for only some of those needs. States will need to describe the rationale for their choices in the quality strategy.

Comment: A few commenters recommended that comprehensive quality strategy efforts should specifically include a pediatric quality strategy that is appropriate for all subpopulations of children, including children with medical complexity. They, along with other commenters, stated that CMS should require states to specifically consider pediatric quality improvement in any comprehensive quality strategy and use a range of pediatric measures that capture the needs of all subpopulations of children, including children with medical complexity. Some commenters recommended that performance measurement address all subpopulations of children, including children with special health care needs. Another commenter noted that children’s health care presents distinctive challenges for quality measurement, and that any effort to measure quality of care should take into account the unique features of pediatric

health care and recognize the importance of pediatric development, dependency, demographics, and disparities. One commenter stated that this rulemaking presents an opportunity for CMS to focus on health child development and the needs of children with special health care needs.

Response: We appreciate the commenters’ support for the delivery of quality care to children, including those with special health care needs. Managed care plays an important role in the delivery of services to children. As noted above, we do not believe it is appropriate to identify specific populations in the regulations for inclusion in states’ quality strategies. Rather, the language in § 438.340 is broad, and requires that states’ quality strategies take into consideration the health status of all populations served by managed care, including children. Should we elect to identify a common set of national QAPI performance measures or PIPs, under the authority of § 438.330(a)(2), we will consider ones that focus on children. Therefore, we decline to require the quality strategy include additional child-specific components, or to require states to create a child-specific quality strategy.

Comment: A number of commenters recommended either performance measurement topics or specific performance measures for inclusion in comprehensive quality strategies, including: (1) Timeliness of access to providers both within and outside of a plan’s network; (2) person-centered planning and service goals; (3) rebalancing and *Olmstead* planning goals and objectives; (4) workforce issues; (5) subpopulations’ access to care in other delivery systems, and elements that take into account the needs of especially vulnerable patient populations; (6) alignment of metrics with Medicare ACO programs, specifically the Medicare Shared Savings Program (Shared Savings Program) and Pioneer ACO program, where applicable; (7) HIV-specific quality and outcome measures; (8) a combination of process and outcome measures; (9) children’s quality measures; (10) pregnant women exposed to intimate partner violence; and (11) metrics related to quality of life.

Response: We appreciate the commenters’ recommendations for performance measurement topics and specific performance measures. Should we elect to identify a common set of national QAPI performance measures or PIPs, we will use the notice and comment period described in § 438.330(a)(2); performance measure identified through this process will be

¹¹ Bell, KM., Jencks, SF., Kambric, RT., Lynn, J., & Straube BM. (2007, June). *Using population segmentation to provide better health care for all: the “Bridges to Health” model. The Milbank Quarterly*. Retrieved 21 July 2015, from <http://www.ncbi.nlm.nih.gov/pubmed/17517112>.

incorporated into a state's quality strategy per § 438.340(b)(3). We will consider these recommendations during that process, and encourage commenters to participate in potential future subregulatory guidance processes.

Comment: Several commenters supported the requirement that states publish a selection of quality metrics and performance outcomes at least annually on the state's Medicaid Web site, but recommended that the regulation be strengthened by also requiring: (1) Public reporting of comparative quality information on state Web sites in a user-friendly format and following established practices for health literacy; (2) quality standards and measurements on states' Web sites; and (3) states to publish all quality metrics and performance outcomes at least annually. These commenters also recommended that CMS should: (1) Provide clearer guidance to states to ensure consistent and timely availability of performance measurement data, which is necessary to promote broad discussion among state policy makers, advocates, and consumers; and (2) encourage states to publish quality "scorecards" that report both statewide and MCO-specific performance results on various quality measures.

Response: We thank the commenters for their support and recommendations. There are several places in the proposed rule where we addressed the public availability of data on quality of care: (1) The quality strategy will include the state's quality metrics and performance targets for its managed care plans (proposed § 438.340(b)(1), finalized at § 438.340(b)(3)(i)); (2) the annual EQR technical reports (proposed and finalized at § 438.364) will include information from the mandatory EQR-related activity of network adequacy validation (finalized at § 438.358(b)(1)(iv)); and (3) while not identical to a quality scorecard, states will be required to operate a MMC QRS for their managed care plans (§ 438.334).

We encourage states to report comparative quality information in a user-friendly format and in accordance with health literacy practices required by the state or identified in the state's quality strategy.

Through our work on the CMS Child and Adult Core Measure Sets for Medicaid and CHIP, we actively engage with and provide guidance to states to support the collection, analysis, and reporting of these performance measures. While we may issue additional guidance in the future, we believe that the guidance provided through such direct technical support to

individual states is the most useful approach.

Finally, while we encourage states to report on all of the performance measures identified in their quality strategies on an annual basis, we understand that this may not be feasible and thus provide states with the flexibility to identify which measures and outcomes they will report on annually. We note that states will report publicly on all the measures and outcomes in the quality strategy at least once every 3 years in accordance with the evaluation of the effectiveness of the quality strategy (proposed § 431.504(b)(1), finalized at § 438.340(c)(2)(i) and (ii)).

Comment: One commenter recommended that CMS require plans to achieve minimum performance levels in all CMS Child and Adult Core Measure Sets for Medicaid and CHIP to advance the quality and value of programs.

Response: We disagree with the commenter's recommendation. While we have an important oversight responsibility for Medicaid managed care plans, we do not believe it would be appropriate to establish national minimum performance levels. Performance is influenced by many factors, including population demographic characteristics and availability of health care providers; a national minimum would not account for state variation in these and other factors. It is the states that have a direct relationship with the managed care plans, and it is the contracts between the state and managed care plans that provide states with leverage to set minimum performance levels and to incentivize managed care plan performance, as many already do.

Comment: A few commenters suggested ways to improve the CMS Child Core Set measures. They recommended that CMS replace less impactful measures with validated measures coming out of the Pediatric Quality Measures Program and other sources relevant to the populations served, and that CMS ensure there is a pathway for much needed pediatric quality of care and outcomes measures.

Response: We appreciate commenters' support for the CMS Child Core Set measures. The development and maintenance of the CMS Child Core Set measures is outside the scope of this regulation. We encourage interested parties to learn more about the Measure Applications Partnerships (MAP), a multi-stakeholder partnership HHS uses to identify measures for federal health programs, managed by the NQF. Additional information on the MAP can be found online at <http://www.quality>

forum.org/setting_priorities/partnership/measure_applications_partnership.aspx.

Comment: A number of commenters encouraged us to use this rule-making as an opportunity to achieve greater integration and use of the CMS Child Core Set and the lessons learned from the Pediatric Quality Measures Program. Commenters also recommended that CMS require that states either include the CMS Child and Adult Core Measure Sets for Medicaid and CHIP, including the clinical and the non-clinical measures, in their quality improvement programs or use them as a basis for selecting metrics. Several commenters recommended that CMS move away from voluntary reporting to require a minimum subset of the CMS Child and Adult Core Measure Sets for Medicaid and CHIP.

Response: We appreciate the support from commenters for the CMS Child and Adult Core Measure Sets for Medicaid and CHIP. We believe that the use of the measure sets over the last few years has been beneficial for both CMS and for states. We do not have the authority to mandate the use of the CMS Child and Adult Core Measure Sets for Medicaid and CHIP. However, we do strongly encourage states to use these measure sets as a starting point for their own measure selection process. We do not believe it would be appropriate to limit states to selecting measures only from the CMS Child and Adult Core Measure Sets for Medicaid and CHIP, as there are other nationally validated or endorsed measures which may be appropriate for a state's quality efforts. We anticipate that, should we elect to identify national performance measures under the authority in § 438.330(a)(2), these would include measures from the CMS Child and Adult Core Measure Sets for Medicaid and CHIP. We will continue to work with states to improve collection and reporting of the CMS Child and Adult Core Measure Sets for Medicaid and CHIP.

Comment: One commenter recommended that CMS require states to collect and analyze some measures from the CMS Child and Adult Core Measure Sets for Medicaid and CHIP annually, while allowing other measures to be collected and analyzed on a less frequent basis.

Response: Adjusting the reporting timeframe for the CMS Child and Adult Core Measure Sets for Medicaid and CHIP is outside the scope of this rule. We also note that, unless required as a national QAPI measure under § 438.330(a)(2), state reporting on the CMS Child and Adult Core Measure Sets for Medicaid and CHIP remains

voluntary. As such, while we encourage states to report on all CMS Child Core Set and CMS Adult Core Set measures annually, states have the discretion to report on one or more of the measures on a less than annual basis.

Comment: A few commenters noted that, while it is important and useful to receive public input on which topics should be pursued in large scale improvement activities and which measures should be used to track improvement, hospitals and other health care organizations already respond to a vast disparate array of mandates and requests for data and participation in quality improvement activities. The result is a resource intensive effort that leads to confusion and undermines the production of robust information on actual performance improvements. Several commenters recommended that CMS direct Medicaid programs to adopt the set of improvement areas identified in the Institute of Medicine's Vital Signs report. The commenters recommended that having a single common set of topics and related measures from which to choose will lead to a more unified approach to measurement and greater opportunities for collaborative improvement work.

One commenter stated that the process for states to include additional quality measures is not clear. The commenter submitted that physicians are already overburdened with multiple quality reporting systems that use different measures and methodologies. The commenter recommended that CMS ensure standardization and harmonization of quality measures and methodologies across reporting programs to reduce administrative burdens and simplify compliance.

Response: We appreciate the effort hospitals, providers, and other health care organizations make to measure and improve the quality of care. We support efforts to align quality measurement and improvement efforts, as we strive to publicly report on the CMS Child and Adult Core Measure Sets for Medicaid and CHIP, which are identified annually based on recommendations of the multi-stakeholder NQF MAP. We encourage hospitals, other providers and health care organizations, consumer groups, and other stakeholders to comment on the managed care quality strategy proposed in their states to ensure that the strategy developed reflects the variety of perspectives of parties affected by the Medicaid program and promotes harmonization of quality measures and methodologies across reporting programs. As noted above, we believe it is important that states have

flexibility to identify the performance measures and improvement topics most appropriate for their Medicaid programs. Therefore, we will retain the state flexibility afforded under the final rule for states in developing their managed care quality strategy at § 438.340.

Comment: One commenter stated that state reporting on a standardized set of metrics and performance outcomes to both CMS and the public would facilitate the transition to value-based purchasing, and enable accurate comparisons of quality performance across plans. The commenter noted the importance of ensuring alignment between the standards to which both states and their contracted managed care plans are held.

Response: We appreciate the commenter's support for the use of standardized measures and value-based purchasing. We agree that this would support performance comparisons across plans. We believe that, in regards to the Medicaid managed care requirements, this rule does align to the extent possible the standards to which states and plans are subject.

Comment: One commenter recommended that instead of allowing states to develop their own metrics for a comprehensive quality strategy, states should be required to rely on the metrics used in the MMC QRS to be established by CMS per § 438.334(b).

Response: While we support alignment between quality efforts, we decline the commenter's recommendation, as states need flexibility to select metrics appropriate to the goals, objectives, and initiatives it has identified for its Medicaid managed care program. Further, while both the MMC QRS under § 438.334 and the managed care quality strategy under § 438.340 require performance measurement, they have a different purpose, and thus different performance measures may be appropriate.

Comment: A number of commenters recommended that CMS require that states' quality strategies include a plan to assess, address, and reduce health disparities in the state. They stated that addressing health disparities should be a top priority in quality measurement and improvement and recommended that quality measures be reported stratified by such demographic factors as age; race; ethnicity; sex; primary language; population; region or geography; MCO or other managed care plan provider; disability status; or other risk factors to the extent possible to identify populations that continue to be at risk of adverse outcomes. Some commenters suggested that states also

should collect and evaluate data stratified by sexual orientation, gender identity, and health status. Two commenters recommended that states track quality data and outcomes on persons with mental illness and substance use disorders that cycle through the criminal justice system, state psychiatric hospitals, and Medicaid. Another commenter recommended that reducing disparities in access should address both health services and LTSS.

Commenters recommended that stratifying quality data by the key factors called for in the Affordable Care Act would sharpen quality improvement interventions, identify groups that continue to be left behind, and provide critical information on whether managed care is helping to resolve the longstanding inequities in our health care system. They noted that HHS has produced reports with recommendations on how to improve data collection for health disparities in Medicaid and CHIP, and that support from the Adult Medicaid Quality Grants Program helped states build their capacity to collect and report data stratified by key demographic categories. One commenter recommended that states include the metrics developed by the Agency for Healthcare Research and Quality (AHRQ) for its Quality and Disparities Report, or another established institution, to track health disparities.

One commenter cited section 1311(g) of the Affordable Care Act, which requires insurers to have an incentive program to, among other things, reduce health and health care disparities, and noted that requiring the comprehensive quality strategy to address disparities would assure that consumers in the Medicaid program who might be victim of such disparities receive no less attention than their counterparts in the Marketplaces. Other commenters noted that the Affordable Care Act requires any federally conducted or supported health care or public health program, activity or survey to collect and report data stratified by race, ethnicity, sex, primary language, geography, and disability status to the extent practicable. Commenters noted that while HHS has moved to implement this mandate for national Medicaid population health surveys and to incorporate it into Medicaid claims data based updates, states have just begun to address the issue of health disparities in quality measurement in Medicaid managed care.

Some commenters recommended inclusion of additional language in § 438.340 to ensure that the state's

quality strategy include a “plan to identify, evaluate and reduce health disparities through its quality improvement strategy, including efforts to expand the collection and reporting of performance data stratified by race, ethnicity, sex, primary language, geography and disability status and actions taken to reduce health care disparities.”

Response: We agree that it is important for states, and their managed care plans, to work to reduce health disparities for their beneficiaries and are adding an element to the quality strategy required under § 438.340 to require that states’ quality strategies address health disparities based on race, ethnicity, sex, primary language, and disability status, consistent with the factors identified in section 3101(a)(1)(A) and (B) of the Public Health Services Act, as amended by section 4302 of the Affordable Care Act, as recommended by commenters, as well as by age, which we believe is important given the populations served by Medicaid. We understand that states may face significant challenges in collecting data and analyzing disparities based on these factors, and therefore decline to include the other factors recommended by commenters, which are beyond our legal authority to require states to collect and analyze. We note that in the proposed rule we inadvertently omitted a requirement at former § 438.204(b)(2) that states provide certain specified demographic information to managed care plans about their Medicaid enrollees at the time of enrollment. We are retaining this provision in § 438.340(b)(6) of the final rule.

In response to these comments, we are: (1) Retaining the requirements in proposed § 431.502(a) at § 438.340(a) of the final rule, with modification to specify that it applies to all Medicaid services provided by the MCO, PIHP, PAHP, or PCCM entity (described in § 438.310(c)(2)); (2) retaining the requirements from proposed § 431.502(b) within § 438.340(b) of the final rule, with non-substantive revisions for clarity; (3) adding a new element at § 438.340(b)(3)(i) of the final rule to describe quality metrics and performance targets used to measure performance; (4) adding a reference to the description of a state’s transition of care policy consistent with § 438.62(b)(3) at § 438.340(b)(5); and (5) adding an element focused on identifying, evaluating, and reducing health disparities based on age, race, ethnicity, sex, primary language, and disability status, to the extent practicable, as § 438.340(b)(6). We also

are retaining at § 438.340(b)(6) a requirement formerly at § 438.204(b)(2) requiring states provide specified demographic information to MCOs, PIHPs, and PAHPs for each Medicaid enrollee at the time of enrollment. See section I.B.6.b(2)(f)(5) for additional discussion of § 438.340 of the final rule. (3) Comprehensive quality strategy development, evaluation, and revision (new § 431.504)

In § 431.504, we proposed to extend the current regulations at § 438.202(b), (d) and (e) (relating to states’ responsibility to obtain public input into the state quality strategy, to evaluate the effectiveness of the strategy, and to submit the strategy to CMS for review) to the comprehensive quality strategy which would have been required under the proposed rule, as opposed to applying specifically to the quality strategy required for states contracting with managed care plans. We also proposed modest revision of the current regulation as follows.

We proposed at § 431.504(a) to add the State Medical Care Advisory Committee and tribes (through tribal consultation), as appropriate, to the existing list of persons and entities from which the state would obtain input when developing the quality strategy, and that this input be obtained prior to submitting the comprehensive quality strategy to CMS, to ensure that stakeholder concerns have been taken into consideration at an early phase in the quality strategy development process.

In paragraph (b), we proposed to revise the existing requirement in § 438.202(d) that states review and update their strategy “as needed” but with a requirement to do so at least once every 3 years. We encouraged states to view the comprehensive quality strategy as a living document, which should be updated on a regular basis to account for changes in population, delivery systems, emerging information system technology, and benefit design. We also proposed to improve clarity by using “review and update” instead of “conduct reviews . . . and update” in the regulation text.

We proposed moving the evaluation of the effectiveness of the quality strategy into a new paragraph (b)(1) and, in paragraph (b)(2), we proposed that states make the results and findings of this effectiveness evaluation publicly available on the state’s Medicaid Web site. The language from the current § 438.202(e)(2) relating to the submission of regular reports on the implementation and effectiveness of the strategy also was included in proposed § 431.504(b)(1) and (b)(2). We proposed

that states post these on their Medicaid Web site, rather than submitting such reports to CMS as required under the current regulation.

In paragraph (c)(1), we proposed revision of the existing language in § 438.202(e)(1) that the state submit a copy of its initial strategy to CMS to clarify that submission is for the purposes of receiving CMS comment and feedback before adopting the comprehensive quality strategy in final. In paragraph (c)(2), we proposed that states submit a copy of the revised strategy whenever significant changes are made. We also proposed that states include their definition of “significant changes” within the body of the quality strategy. Finally, in paragraph (d), we proposed that states make their final comprehensive quality strategy available on the state’s Medicaid Web site.

We received the following comments in response to proposed § 431.504.

Comment: Many commenters offered general support for the comprehensive quality strategy processes proposed under § 431.504. One commenter expressed support for allowing states flexibility to provide updates to the quality strategy when there are major programmatic changes (that is, changes affect a significant portion of the covered population or major changes in payment methodology), and to require that they do so at least once every 3 years.

Response: We appreciate commenters’ support for the proposed comprehensive quality strategy development, evaluation, and revision standards. While we are withdrawing the proposal for a comprehensive quality strategy, we are retaining this proposed provision for states’ managed care quality strategies in § 438.340, with minor modification (see section I.B.6.b(2)(f)(5) for additional discussion of § 438.340 of the final rule).

Comment: A number of commenters expressed general support for CMS’ efforts to integrate MCAC and tribes into the quality strategy process, and recommended the identification of additional specific organizations or stakeholder groups, including: Dental Quality Alliance (DQA), as a part of the development of any quality strategy that includes the delivery of dental services in Medicaid; health care workers; managed care plans; the LTSS community; key disability advocacy organizations; physicians; individuals in nursing facilities waiting for community transitions; and local multi-payer, multi-stakeholder Regional Health Improvement Collaboratives (RHICs). One commenter recommended that CMS direct states to create

mechanisms to facilitate more robust and ongoing engagement with direct care workers who provide Medicaid-funded services to help set and achieve state quality goals, especially in the area of LTSS.

Response: We appreciate the commenters' interest in ensuring that states obtain input from a variety of interested parties in the development of a quality strategy but are declining the specific suggestions. The proposed rule would have required states to obtain the input of the MCAC, beneficiaries, and other stakeholders as appropriate. As noted, we are not finalizing our proposal to require development of a comprehensive quality strategy in all states to address all delivery systems, including FFS, and we believe the proposed language is appropriately flexible and necessary to reflect the broad range of stakeholders that may need to be included in the public consultation process, depending upon the populations served in the state's Medicaid managed care program, the benefits offered by the plans, and the quality initiatives in the state. The current language is broad enough to include the various entities identified by the commenters, but does not require that states include specific organizations or interests, which may or may not be appropriate in a given state, as long as the full range of interests and perspectives is represented. We are retaining the public engagement requirement from proposed § 431.504(a) in § 438.340(c)(1), with clarification that states must consult with tribes, in accordance with the state's tribal consultation policy, if the state enrolls Indians in its MCOs, PIHPs, or PAHPs.

Comment: Many commenters recommended that CMS provide further details about the public engagement process, including whether states must or are encouraged to: (1) Provide adequate notice of a public comment period, including prominently on the state Web site; (2) conduct well-publicized public hearings to educate stakeholders on the details of the proposed comprehensive quality strategy and give them the opportunity to provide direct feedback; (3) post a detailed and comprehensive draft comprehensive quality strategy for comment for at least 30 days; (4) accept public comments via in multiple modalities, including electronically, by phone and through the mail; and (5) submit to CMS a detailed response to stakeholder comments collected, including reasons for altering or not altering the draft in response to those comments.

Other recommendations for additional guidance include requiring states: (1) To conduct statewide meetings of stakeholders that include representation from the breadth of affected individuals (for example, individuals with disabilities, LTSS consumers and their family caregivers, people with limited English proficiency, and representatives from the LGBT community); (2) to make their quality strategy available on the state Medicaid Web site for public comment and review; (3) to establish and publicize a Web site that facilitates public comment on and recommendations for the quality strategy; (4) to adopt the National Council on Disability's guidance to states on stakeholder involvement. One commenter recommended that CMS set a minimum comment period of 60 days for comprehensive quality strategy creation and revisions.

Finally, many commenters recommended that the comprehensive quality strategy undergo a public comment process that meets the same requirements as the public notice and comment process for the section 1115(a) demonstration projects.

Response: While we appreciate the commenters' interest in clarification of the process states should use to solicit input from MCAC, beneficiaries, and other stakeholders, we believe it best to leave this process to state discretion, particularly in light of our decision not to finalize a requirement that states develop a proposed comprehensive quality strategy addressing delivery systems other than managed care and states' historic experience soliciting public input into managed care quality strategies. We expect states to utilize their Medicaid Web site, as well as any other state standard practices, when soliciting public comment on their Medicaid managed care quality strategy. We do not believe that the extensive public notice process utilized for section 1115 demonstrations is appropriate for developing or updating quality strategies, which must be fully compliant with federal law and regulations, while section 1115(a) demonstrations involve the use of waivers and/or expenditure authorities to operate a state's Medicaid program in a manner that deviates from what is normally allowable under statute in order to test innovation.

Comment: One commenter expressed concern regarding the amount of time required to coordinate with a state's waiver programs, managed care plans, advisory committees, and CMS for effective feedback and implementation.

Response: We appreciate the commenter's interest in ensuring

sufficient time is allowed for effective feedback and implementation. We understand that this effort will involve time and resources from a state, which is part of why we are establishing a 3-year lifecycle for state quality strategies. The proposed language differs very little from the language in the existing regulations, issued in 2003, adding only MCAC and tribal consultation in accordance with the State's Tribal consultation policy, as appropriate, to the existing public input process, and requiring additional public input before revising an existing quality strategy. We do not believe that this process will pose a significant additional burden on states.

Comment: Two commenters recommended that the review and update of the quality strategy should include data on waitlists, including the numbers of individuals that received services in home and community settings of choice and numbers of individuals that moved into a more restrictive setting while waiting for their choice of home and community setting, numbers of people locating the housing they wanted, numbers of people that learned about the community they want to live in, numbers that learned to use public transit, the effectiveness and impacts of waiting list strategies and policies, and other items related to person-centered planning and the services utilized while individuals were on waiting lists.

Response: This final rule does not alter quality strategy or monitoring requirements for Medicaid home and community based services waivers and state plan amendments. Sections 1915(c), (i), and (k) have unique quality assurance and oversight processes. Given this, we decline to accept this recommendation, but encourage states to consider if any of the data identified by commenters would be useful to the states' programs. We agree that it is important for states to monitor and assess the delivery of LTSS; at § 438.340(b)(9) we are finalizing a cross-reference to § 438.208(c)(1) of this part, which requires states to implement mechanisms to identify persons in need of LTSS or with special health care needs.

Comment: A few commenters recommended that states review and update their comprehensive quality strategies more frequently (either annually or no less often than once every 2 years) rather than once every 3 years. One commenter urged that each state's quality strategy be reviewed, updated, opened for input and comment annually, because in the commenter's view a 3 year cycle is too long.

Response: We appreciate the recommendation from the commenters. We are sensitive to the balance between maintaining an up-to-date quality strategy and the investment necessary to develop and implement a strategy. It is also important to allow sufficient time to determine if the strategy had the desired effect. We believe that a 3-year life cycle for a quality strategy strikes the appropriate balance. We note that states may elect to revise their quality strategy more frequently.

Comment: One commenter recommended that CMS permit states to align the timing for updates to their quality strategy with changes in the National Quality Strategy and the CMS Quality Strategy. The commenter recommended that CMS identify opportunities to do this, and if necessary, provide flexibility around the 3-year update requirement.

Response: We appreciate the commenter's support for alignment between state comprehensive quality strategies and the National and CMS Quality Strategies. While we encourage states to align their managed care quality strategies with the National and CMS Quality Strategies, alignment may not always be the most appropriate approach to support state-targeted quality efforts, and therefore alignment is not required under the final rule. States do have flexibility to update their strategies more frequently than the once every 3 years specified under the rule, which would allow states to pursue alignment with national quality strategy efforts, including CMS quality efforts.

Comment: A few commenters recommended CMS must approve a state's quality strategy before it can be adopted as final.

Response: Proposed § 431.504(c) and (d), which are now redesignated to § 438.340(c)(3) and (d) of the final rule, require states to submit an initial quality strategy to CMS for comment and feedback prior to finalizing the strategy, and to make the final quality strategy available on the state's Web site required under § 438.10(c)(3). We do not believe it is feasible for us to review and approve all aspects of every state's strategy prior to implementation. However, state quality strategies must conform to the regulations, and are subject to oversight and implementation of corrective measures if they are not compliant. We will provide technical assistance to a state when a managed care quality strategy does not fulfill a regulatory requirement, so that the state can come into compliance.

Comment: Another commenter requested that CMS ensure it has sufficient resources to conduct an

adequate and thorough review of state quality strategies. The commenter believed that appropriate review of these strategies by CMS is important for achieving long-term quality goals of the Medicaid and CHIP programs.

Response: We appreciate the commenter's support for the important role of CMS review in quality improvement and oversight activities for Medicaid and CHIP. We believe that any concerns about the adequacy of our capacity to provide meaningful comment and review of states' quality strategies should be alleviated by the withdrawal of the proposed comprehensive quality strategy and the finalization of only the managed care quality strategy requirements. We believe that we have sufficient capacity to review states' managed care quality strategies, as we currently do under existing regulations.

Comment: A few commenters stated that CMS should require states to post their comprehensive quality strategy on the state Medicaid Web site no later than 10 days after submission to CMS.

Response: We thank the commenters for this recommendation; however, we are not adopting it. The version of the quality strategy submitted to us by a state to CMS represents an interim document. While we encourage states to post this version of the quality strategy to their Web sites, as a means of updating the public on the status of the development of the quality strategy, we do not believe it would be appropriate for us to require the state to post it. We do require states to post the final quality strategy online.

Comment: A commenter requested clarification regarding the nature of the evaluation of the effectiveness of the quality strategy. The commenter asked whether it is intended to be a formal evaluation plan that quantifies the progress and outcomes of programs described in the quality strategy, or a reevaluation of the effectiveness of the programs prior to revision of the quality strategy. The commenter also requested clarification of the structure of the required report and the need for an external evaluator.

Response: We appreciate the commenter's interest in the quality strategy evaluation. Under current regulations, states are required to submit regular reports on the implementation and effectiveness of their quality strategy. Historically, this has not always occurred on a consistent or regular basis, or in a transparent manner. The final rule provides for a standalone report focusing on the progress states have made in reaching goals and objectives identified in their

quality strategy. This would include an analysis of how the identified performance measures and PIPs contributed, or did not contribute, to the state's progress. We defer to states to determine whether the analysis required is best conducted by an internal or external evaluator.

Comment: One commenter recommended CMS clarify the meaning of "update" in proposed § 431.504(b). The commenter recommended that CMS clarify whether the term refers to adjusting to different quality initiatives or modifying current quality initiatives.

Response: We appreciate this opportunity to clarify this requirement, finalized at § 438.340(c)(2). At least once every 3 years, a state must examine their quality strategy, evaluate the effectiveness of that strategy, and use that information, combined with feedback from the state's EQRO per § 438.364(a)(4), to update its quality strategy to better drive improvement over the next 3 years. In some cases, this may mean identifying new goals and objectives or new quality initiatives to supplement or replace existing initiatives, while in other cases a state may make small adjustments to ongoing efforts. As the exact nature of the update will be dependent on the unique circumstances in a state and the findings of its quality strategy evaluation efforts, we decline to modify the regulatory text to more specifically define "update." However, we are adding § 438.340(c)(2)(iii) to clarify that the update should take into consideration any recommendations offered by the state's contract EQRO under § 438.364(a)(4).

Comment: Several commenters recommended that CMS further define "significant changes" which would trigger a revision of the quality strategy. Another commenter recommended CMS clarify whether or not adjusting state targets for performance measures on an annual basis would be considered a significant change or not.

Response: We appreciate the need to understand what would constitute a "significant change." Consistent with the language in the proposed rule, we believe this is best determined by the state; however, in recognition of the importance of this definition and consistent with our proposal, we are finalizing our proposal to require the state to include its definition for a "significant change" in the quality strategy (see § 438.340(b)(11) of the final rule).

Comment: One commenter stated that updates to the comprehensive quality strategy should not automatically trigger an evaluation of the document's

effectiveness or stakeholder consultation, as would be the case under proposed § 431.504(b). To ensure that states can treat their strategy as a “living document,” the commenter recommended CMS clarify that not all updates will trigger a review of the strategy’s effectiveness or the extensive stakeholder consultation envisioned under the proposed rule.

Response: We agree with the commenter that not all changes would trigger an evaluation of the effectiveness of the quality strategy or the solicitation of public input. The effectiveness evaluation must occur once every 3 years; it is not triggered solely by a revision to the quality strategy. The solicitation of public input is triggered by the once every 3 year update and by revisions due to significant changes as defined in a state’s quality strategy. As we are withdrawing the proposal for a comprehensive quality strategy, but retaining the requirement for a managed care quality strategy, we will adjust this language in § 438.340 to reflect this policy.

Comment: One commenter recommended that the comprehensive quality strategy be posted on the state’s Web site and urged CMS to require an annual publication and an archive of previous iterations of the state’s quality strategy on the state Web site.

Response: We thank the commenter for supporting the posting of the comprehensive quality strategy on a state’s Medicaid Web site. We retain this requirement for the managed care quality strategies under § 438.340(d) of the final rule. While we understand the interest and potential usefulness of an online archive of previous quality strategies, it may be administratively burdensome to require states to post and maintain these documents online. We believe posting the most current state managed care quality strategy online ensures access and transparency for the public, and decline the commenters’ recommendation.

Comment: One commenter recommended that CMS pick 2 or 3 states to serve as a pilot project, to determine if the comprehensive quality strategy and its costs result in any actual benefit.

Response: We appreciate the commenter’s recommendation. While we are withdrawing the proposed comprehensive quality strategy, and do not intend to create a pilot program, states can elect to create a comprehensive quality strategy. Such a strategy also may be required under a section 1115(a) demonstration.

Comment: A few commenters recommended allowing states between 2

and 5 years to develop a comprehensive quality strategy as envisioned in the proposed rule. Commenters recommended that CMS collaborate with states and/or medical directors to: (1) Support implementation of the comprehensive quality strategy; (2) develop a framework; (3) develop policies and procedures to support the comprehensive quality strategy; and (4) provide an adequate phase-in for the development and deployment of the comprehensive quality strategy. One commenter recommended that CMS provide adequate technical assistance to achieve the desired results.

Response: We appreciate the concern for adequate support and time for states to implement a comprehensive quality strategy. We are withdrawing the proposal for a comprehensive quality strategy, and therefore believe that existing resources will be sufficient to assist states in future revisions of their managed care quality strategies. Given that we are retaining the managed care quality strategy, which exists under current regulations, we believe that a state must come into compliance with the revised quality strategy provisions no later than July 1, 2018.

We are moving the requirements in proposed § 431.504 to § 438.340(c) and (d) to reflect the retention of only the managed care quality strategy in the final rule, with revisions discussed above and for clarity.

(4) Applicability to Medicaid Managed Care Programs (New § 431.506)

To reduce the burden on states contracting with managed care entities and to ensure that the comprehensive quality strategy addresses all populations, we proposed to cross-reference the elements of the managed care quality strategy applicable to states that contract with MCOs, PIHPs, PAHPs, and certain PCCM entities to deliver Medicaid services. Under proposed § 431.506, states contracting with one of these managed care entities would be able to create a managed care quality strategy by incorporating the part 438 elements into the larger, comprehensive quality strategy.

We received the following comments in response to our proposed § 431.506.

Comment: Several commenters expressed support for this section, specifically: (1) The application to managed care programs as defined in § 438.2 to include the full range of applicable waivers; (2) incorporating the managed care quality strategy elements into the larger comprehensive quality strategy and CMS’ offer of technical assistance; and (3) the ability to

compare performance across delivery systems.

Response: We thank the commenters for expressing support for the inclusion of the managed care quality strategies in the comprehensive quality strategy. Consistent with our decision to withdraw the requirements for a comprehensive quality strategy, we are withdrawing this section.

After consideration of the public comments on part 431 subpart I, we are striking this proposed section, consistent with our decision to withdraw the proposed requirement for a comprehensive quality strategy. Since this paragraph only cross-referenced § 438.340 but did not include any additional requirements for a comprehensive or managed care quality strategy, none of this language will be retained in § 438.340 in the final rule.

(g) Managed Care Elements of State Comprehensive Quality Strategies (New § 438.340, Formerly § 438.204)

Section 438.204 of the current regulations identifies the minimum elements of a managed care state quality strategy, including: (1) MCO and PIHP contract provisions that incorporate the standards in existing part 438 subpart D; (2) procedures for assessing the quality and appropriateness of care and services furnished to all enrollees under the contract; providing information about the race, ethnicity and language of beneficiaries to MCOs and PIHPs at the time of enrollment; and regular monitoring and evaluation of MCO and PIHP compliance with the standards in subpart D; (3) specification of any national performance measures identified by CMS; (4) arrangements for annual, external independent reviews of quality outcomes, and timeliness of, and access to, services provided by each MCO and PIHP; (5) appropriate use of intermediate sanctions for MCOs; (6) an information system sufficient to support initial and ongoing operation and review of the state’s quality strategy; and (7) standards, at least as stringent as those under the applicable subpart D of the regulations.

Consistent with our proposal in part 431 subpart I, we proposed to title this section “managed care elements of the state comprehensive quality strategy”. We also proposed to extend the quality strategy requirements to states contracting with PAHPs. Consistent with the current structure of § 438.204 (that is, a list of the elements required in a quality strategy), we proposed to move the quality strategy elements specific to managed care to proposed § 438.340 (those applicable to managed care and FFS were moved to proposed

§ 438.502). We also proposed to remove some of the existing quality strategy elements.

In paragraph (a), we proposed that states include in their comprehensive quality strategy the network adequacy and availability of service standards and examples of evidence-based clinical practice guidelines that its managed care plans follow. We proposed that the content of existing § 438.204(b)(1) was captured in proposed part 431 subpart I. We proposed deleting reference to the information previously found in §§ 438.204(b)(2) and (b)(3).

In § 438.340(b), we proposed that the state's goals and objectives developed under proposed § 431.502(b)(i) incorporate a description of quality metrics and performance targets that the state will use to assess Medicaid managed care quality, including any performance measures required by the state in accordance with proposed § 438.330(c) and any PIPs required by the state in accordance with proposed § 438.330(d). Proposed § 438.340(b) would replace § 438.204(c) of the current regulations. We proposed redesignating current § 438.204(d) and (e) at § 438.340(c) and (d), respectively, and to expand the external review element in proposed § 438.340(c) to PAHP contracts as well. We proposed to eliminate the text previously found in § 438.204(g) as redundant with proposed § 438.340(a). Finally, in paragraph (e), we proposed that states address how they would assess the performance and quality outcomes achieved by each PCCM entity, to conform to other changes made in this part.

We received the following comments in response to proposed § 438.340.

Comment: Several commenters expressed broad support for the proposed comprehensive quality strategy requirements and the managed care elements of the comprehensive quality strategy.

Response: We appreciate the commenters support for the managed care quality strategy elements. We retain these items in this final rule.

Comment: One commenter asked whether CMS will provide states with a reporting template for the comprehensive quality strategy. Another commenter referenced guidance that CMS provided to states last year in the form of questions to assure that each state submitted appropriate required information. This commenter recommended that CMS continue this standardized format, as it will be easier for CMS to review and easier for states to compare their answers with answers from other states. Several commenters

requested that CMS clarify the relationship between the state-chosen quality metrics described in § 431.502(b)(2) and the state-selected metrics described in § 438.330(a)(2). They were not clear as to whether or how metrics selected in the CMS public comment process described in § 438.330(a)(2) would apply to Medicaid FFS in a state.

Response: We appreciate the support for our previous technical assistance to states regarding the managed care quality strategy. While we do not intend to release a template for the quality strategy, we plan to issue a revised quality strategy toolkit which will assist states in complying with the quality strategy standards in § 438.340. Because we are withdrawing the proposed comprehensive quality strategy, there is no need to reconcile how the measures identified under the authority of proposed § 438.330(a)(2) would apply to FFS in a state. However, while we are withdrawing proposed § 431.502, we do retain the requirement in proposed § 431.502(b)(2) (relating to specific quality metrics and performance targets, including those to be posted on the state's Web site) in § 438.340(b)(4) of the final rule. Should we elect to identify any performance measures under § 438.330(a)(2), states must require those measures be included in their plans' QAPI programs, and in turn must be reflected in the state's quality strategy. Under § 438.340(b)(3)(i), if CMS identifies measures under § 438.330(a)(2), a state could rely on the measures identified by CMS under § 438.330(a)(2) or use a mix of nationally identified and state-selected metrics.

Comment: Two commenters expressed concern that CMS did not propose to include in § 438.340 the current provision under § 438.204(b)(2) that requires states to identify for plans the race, ethnicity, and primary language spoken by Medicaid beneficiaries. One commenter stated that removing the current reporting requirement for states to provide plans with relevant identifying information will impact the provision of culturally competent care to Medicaid beneficiaries because immediate knowledge of a person's race, ethnicity, and primary language are especially important for case managers who are coordinating care and identifying appropriate physicians for beneficiaries. Another commenter believes that the provision is necessary for quality improvement activities aimed at reducing health disparities. The commenter said that states should be required to collect this information at

the time of enrollment and share it with the MCOs. The commenters recommended that CMS include the requirement in current § 438.204(b)(2) in the final rule.

Response: We agree with the commenters that information about a beneficiary's race, ethnicity, and primary language are important to ensuring appropriate care and services for beneficiaries. In response to the comments, under § 438.340(b)(6) of the final rule, states will be required to include in their quality strategy a plan to address health disparities on the basis of age, race, ethnicity, sex, primary language, and disability status. We also agree with commenters that the current communication requirement is an important element; therefore, we are also including at § 438.340(b)(6) of the final rule the current requirement that states provide key demographic information to the MCO, PIHP, or PAHP for each of their Medicaid enrollees at the time of enrollment.

Comment: With regard to proposed paragraph § 438.340(a), one commenter stated concern that proposed § 438.340 includes a focus on adherence to clinical guidelines, which may not best serve individual patients whose situations require more individualized care. The commenter urged CMS not to rely on adherence to treatment guidelines as a measure of quality for all patients.

Response: We appreciate this opportunity to clarify the reference to clinical practice guidelines in proposed § 438.340(a) (finalized at § 438.340(b)(1)). Each state's quality strategy is required to include examples of these guidelines, but does not require adherence to these guidelines. We did not propose and do not intend to rely on adherence to clinical practice guidelines as a measure of quality for all beneficiaries for exactly the reason presented by the commenter.

Comment: Several commenters agreed with CMS that network adequacy and availability of service standards are useful quality measures, and expressed support for including these access metrics. A few commenters encouraged CMS to require that states must consider all populations served by Medicaid when reviewing network adequacy and availability of service standards.

Response: We appreciate the commenters' support for the inclusion of network adequacy and availability of services standards in the quality strategy. Section 438.68(c) of the final regulation requires that states take into consideration a number of factors in developing their network adequacy standards, including anticipated

enrollment, characteristics and health care needs of specific Medicaid populations enrolled in managed care plans. The availability of services standards in § 438.206 require that states ensure that their managed care plans maintain a network of providers sufficient to meet the need for all covered services under the contract for all enrollees, including persons with disabilities. We believe that this language is sufficient to ensure that all populations are addressed in these standards, which are then incorporated into the quality strategy.

Comment: One commenter encouraged CMS to have similar quality improvement requirements for Medicaid and Medicare.

Response: As a part of the development of the proposed rule, we compared the quality improvement requirements for Medicaid with those of Medicare. We believe that we have aligned these standards as much as possible considering the distinct and different natures of these programs.

Comment: Several commenters expressed support for proposed § 438.340(b). One commenter encouraged CMCS to be thoughtful and balanced in the selection of quality measures to ensure actual quality improvement and reduce unintended consequences. One commenter recommended that CMS include measures and steps being taken to keep people in their communities in the least restrictive environment possible. Another commenter recommended that CMS also include CMS Child Core Set measures, and recommended that all measures be properly vetted by providers and payers and endorsed by an independent entity such as the NQF. The commenter believes these actions would encourage and foster clear expectations, more precise specifications and accountability.

Response: We thank the commenters for their support of proposed § 438.340(b) (§ 438.340(b)(2) in the final rule). While the identification of specific performance measures is outside of the scope of this rulemaking, § 438.330(a)(2) provides for a public notice and comment process through which we can engage states and other stakeholders in the identification of national performance measures and PIP topics, which would be incorporated into a state's managed care quality strategy in accordance with § 438.340(b)(2).

Comment: Two commenters suggested that we remove the requirement in proposed § 438.340(b)(2) that states include in their quality strategy interventions that they propose to

achieve improvement. The commenters believe that states should proposed broad PIP topics, but not specific interventions, which instead should be based on a barrier analysis conducted by each managed care plan.

Response: We understand that states today take a variety of approaches to the PIPs conducted by their managed care plans, ranging from leaving the determination up to the plan to specifying topics, interventions, and metrics. We did not intend to limit this flexibility through this language, and proposed § 438.340(b)(2) does not require that states prescribe specific interventions. Rather, proposed § 438.340(b)(2), finalized without substantive revision at § 438.340(b)(3)(ii), requires only that states include a description in their quality strategies of any interventions that the state elects to require, if any. If a state does not specify any specific interventions, § 438.340(b)(2) only requires the state to describe the PIPs to be implemented in accordance with § 438.330(d).

Comment: One commenter suggested that there may be misalignment between the date of the quality strategy and the interventions, "which by necessity should be additive and/or refreshed over time and perhaps before the quality strategy is updated."

Response: We do not agree with the comment. The quality strategy is not a static document, but must be updated at least once every 3 years and whenever a "significant change" is made. To the extent to which new strategies emerge or a given strategy is no longer appropriate for a state, we would expect the state to update its strategy accordingly.

Comment: One commenter requested that CMS cross-reference § 438.350 in § 438.340(c) to make clear that § 438.340(c) is specifically referring to EQR and does not establish an additional requirement which must be included in a state's quality strategy.

Response: We have added the requested cross-reference.

Comment: One commenter expressed "qualified" support for the proposed inclusion of appropriate use of intermediate sanctions in proposed § 438.340(d).

Response: This element of the managed care quality strategy exists under current regulations in § 438.204(e). We appreciate the commenter's support for this item, which we will retain without medication in this final rule.

After consideration of the public comments, we are finalizing this section as proposed, with the following

modifications: (1) The inclusion of language from proposed §§ 431.502 and 431.504 with modification as discussed in sections I.B.6.b(f)(2) and (3) of this preamble; (2) renumbering of paragraphs to address the addition of the language from proposed §§ 431.502 and 431.504; (3) modifying § 438.340(b)(6) to retain the requirement, previously at § 438.204(b)(2), that states provide plans with specific demographic information about enrollees; (4) adding a cross-reference to § 438.350 to paragraph (b)(4) (paragraph (c) in the proposed rule); and (5) adding cross-references to other sections in part 438 which identify information that must be included in a state's quality strategy. We are also revising the title of this section to "Managed care State quality strategy" to reflect the content of this section in the final rule.

(h) External Quality Review (§ 438.350)

In § 438.350, we proposed to modify the title of the section that identifies the state's responsibilities related to EQR to clarify that these responsibilities are specific to the EQR process. In addition to proposing the application of EQR to PAHPs, consistent with our proposal discussed in § 438.310, we proposed a minor restructuring of § 438.350 and a few substantive changes. We proposed to redesignate existing paragraphs (a) through (f) as (a)(1) through (a)(6). In paragraph (a)(3), we proposed that information from Medicare or private accreditation reviews is a permissible source of information for use in the EQR, in addition to information gathered from the EQR-related activities as described in § 438.358. We also proposed clarification in (a)(4) that the information gathered from each EQR-related activity is for use in the EQR and resulting EQR technical report. Finally, in paragraph (b), we proposed to add that if a state chooses to perform an EQR on a PCCM entity, the standards laid out in paragraphs (a)(2) through (6) would apply.

We received the following comments in response to our proposal to revise § 438.350.

Comment: Several commenters offered general support for the changes under 438.350.

Response: We appreciate the commenters' support for the proposed revisions to this section, which we are finalizing with some revisions, discussed below.

Comment: One commenter supported use of information from Medicare or private accreditation review as a source of information for use in the EQR.

Response: We are retaining this flexibility in § 438.350(a)(3) of the final rule, consistent with section 1932(c)(2)(B) of the Act, which we are finalizing as proposed except for a non-substantive revision discussed below.

Comment: A few commenters requested that CMS take action in the regulations to more clearly eliminate and/or reduce the overlap that is inherent in the new quality assurance requirements of the proposed rules and the existing EQR requirements, to promote the efficient use of resources.

Response: We appreciate commenters' concern regarding overlap between the new and existing EQR requirements and believe we accounted for this in aligning quality related activities in the managed care quality strategy components, the MMC QRS, and expanded use of accreditation information in EQR. Specifically, consistent with section 1932(c)(2)(B) of the Act, § 438.360 of the final rule provides states with the option to use information from either a private accreditation or Medicare review in place of information which would otherwise be generated by the activities required under § 438.358. Consistent with section 1932(c)(2)(C) of the Act, § 438.362 of the final rule provides states with the option to exempt MCOs from EQR activities under specific circumstances. Beyond these areas, we believe that the quality requirements, while interrelated, are distinct and each are necessary to ensure appropriate and thorough oversight and monitoring of quality, access and timeliness of care for beneficiaries enrolled in Medicaid managed care plan.

Comment: A few commenters stated that CMS should not force states to outsource quality review to another vendor which may diffuse oversight and accountability. One commenter noted that as the primary payer, the state has a vested interest in high-quality health care and should be able to conduct reviews of its contracted vendors using standards established by CMS.

Response: We share the commenter's view that states have an interest in the provision of high quality care; but disagree with the characterization of the EQR process. Section 1932(c)(2) of the Act requires the annual external independent review conducted by a qualified independent entity. CMS is bound by statute to require states to contract with an EQRO to conduct the annual EQR as an independent review of the quality of the care provided; therefore we reject this comment. We note that under §§ 438.356(a)(2) and 438.358(a)(1) of the final rule states enjoy considerable flexibility regarding the entities that can conduct the EQR-

related activities described in § 438.358(b) and (c), which provide the data used for the annual EQR.

Comment: A commenter recommended that PCCMs and other FFS providers be evaluated on similar metrics to the extent practicable to permit comparison among and between models providing Medicaid benefits. Several commenters recommended that CMS amend paragraph (b) of this section to stipulate that a PCCM entity be required to undergo EQR if it has a state contract that provides for shared savings, incentive payments or other financial reward for improved quality outcomes, with the option for exemption when states provide written evidence that EQR would be inappropriate. One commenter noted disagreement with the proposed language which allows states to have sole discretion over whether EQR should be required for such PCCM entities. The commenters recommend that the regulation should presume that PCCM entities with a financial stake in quality outcomes would be subject to EQR.

Response: While we appreciate the commenter's interest in allowing comparison among and between care delivery models, we disagree that FFS providers should be subject to an EQR. The EQR assesses a Medicaid managed care plan; it is not designed or intended to evaluate the quality of care offered by individual providers. Similarly, while we do not agree that EQR activities generally are appropriate for PCCMs, we do agree that it is appropriate for the PCCM entities described in § 438.3(r) of the proposed rule and § 438.310(c)(2) of the final rule, specifically, PCCM entities whose contract with the state provides for shared savings, incentive payments or other financial reward for improved quality outcomes.

Proposed § 438.3(r) required that PCCM entities whose contract with the state provides for shared savings, incentive payments or other financial reward for improved quality outcomes be subject to EQR under this section. While the language in proposed § 438.350(b), and its associated preamble, described EQR as an option for these PCCM entities, this was an error. Consistent with proposed § 438.3(r), we intend that EQR of these PCCM entities be mandatory, with no flexibility for states to opt out of this requirement. Therefore, in the final rule we are striking proposed § 438.350(b) and adding a reference to PCCM entities (described in § 438.310(c)(2)) to the introductory text for § 438.350 to require the annual EQR of select PCCM entities, which were described in § 438.3(r) of

the proposed rule but are now described in § 438.310(c)(2) of the final rule.

We are also revising § 438.358(b) to clearly identify which mandatory EQR-related activities apply to PCCM entities (described in § 438.310(c)(2)). Specifically, we are redesignating proposed paragraph (b) as (b)(1) and proposed paragraphs (b)(1) through (b)(4) as paragraphs (b)(1)(i) through (b)(1)(iv). We are also adding a new paragraph (b)(2), which specifies that performance measure validation (in paragraph (b)(1)(ii) of the final rule) and the compliance review (in paragraph (b)(1)(iii) of the final rule) must be conducted on PCCM entities (described in § 438.310(c)(2)). PCCM entities (described in § 438.310(c)(2)) are not subject to the PIP validation activity (paragraph (b)(1)(i) of the final rule) as they are not required to conduct PIPs. PCCM entities (described in § 438.310(c)(2)) are not subject to the validation of network adequacy activity (paragraph (b)(1)(iv) of the final rule) as they are not subject to the network adequacy standards identified in § 438.68.

Comment: A few commenters recommended that CMS revise paragraph (a)(3) of this section to read: "The information used to carry out the review must be obtained from the EQR-related activities described in § 438.358 or, if applicable, from a Medicare or private accreditation review as described in § 438.360."

Response: We believe that the recommended revision does not alter the intent of this paragraph but may increase clarity; therefore, we accept the recommended revision.

Comment: A commenter stated that quality assurance that addresses the six characteristics of high performance care, (that is, safe, effective, efficient, personalized, timely and equitable), not only quality monitoring, needs to be in place. The commenter noted that several of these characteristics can only be assessed by querying patients and families; therefore, the commenters recommended that MCOs should be required to measure patient experience directly.

Response: We appreciate the commenter's interest in requiring direct measurement of a beneficiary's experience toward the aims of high performance care. We anticipate that states will be required to measure beneficiary experience of care for the MMC QRS under § 438.334 of the final rule. EQR also includes, as an optional activity described in § 438.358(c)(2), the administration or validation of consumer or provider surveys of quality of care, and some states utilize the

Consumer Assessment of Healthcare Providers and Systems (CAHPS®) survey as a part of their performance measurement programs. We believe these provisions relating to measurement of patient experience are sufficient and are not revising § 438.350 in response to the comment.

Comment: A commenter recommended CMS add a component to the EQR that would review state requirements, similar to the process defined for MCOs at § 438.350. The commenter states that requiring and making publicly available the results of any such review will promote transparency and accountability.

Response: We believe the commenter is requesting that states undergo an EQR, similar to the one conducted by an EQRO on an MCO. However, we disagree with this suggestion. Section 1932(c)(2) of the Act establishes the requirement for an annual external independent review of an MCO; we are responsible for overseeing a state's compliance with the requirements of the Medicaid program. CMS provides oversight of states' Medicaid managed care programs through the contract and rate certification review and approval processes. We also provide quality oversight through several existing and new activities, including: (1) Quality strategy review, consistent with final rule § 438.340(c)(1)(iv); (2) review of the annual EQR technical reports published by states under § 438.364(c); (3) review of EQRO contracts under § 438.370(c); and (4) through our work with states on the collection and reporting of the CMS Child and Adult Core Measure Sets for Medicaid and CHIP. Given our role in oversight of state Medicaid programs, we decline the commenter's recommendation, and make no changes to this section.

Comment: A commenter recommended CMS consider sanctions for poor performing plans based on EQR, poor performance reflected in the state's quality plan measures, HEDIS measures and/or member survey responses.

Response: While section 1932(e) of the Act, as effectuated by part 438 subpart I, requires that states contracting under section 1903(m) of the Act have authority to utilize intermediate sanctions to address managed care plan noncompliance, we have parallel authority under section 1903(m)(5) of the Act to impose intermediate sanctions and civil money penalties. While the regulations provide that such sanctions generally would be imposed when recommended by the state, we retain the authority to do so under § 438.730(g)(1). We would be open to

exercising this authority where determined appropriate in a case where we determine the state has not acted where it should have concerning an MCO not complying with the EQR process.

After consideration of the public comments, and to clarify the application of this section to PCCM entities described in § 438.310(c)(2) of the final rule, we are: (1) Deleting paragraph (b) and instead adding PCCM entity described in § 438.310(c)(2) to the list of impacted entities throughout this section; (2) not finalizing the proposed restructuring of section (a); and (3) revising final rule paragraph (c) of this section to clarify that the information used to carry out the annual EQR must be obtained from the EQR-related activities or, if applicable, from a Medicare or private accreditation review. This revision clarifies that the EQR of PCCM entities whose contract with the state provides for shared savings, incentive payments or other financial reward for improved quality outcomes (consistent with § 438.3(r) of the proposed rule and § 438.310(c)(2) of the final rule) is mandatory.

(i) External Quality Review Protocols (§ 438.352)

We did not propose any changes to § 438.352. This section sets forth the parameters for the EQR protocols. Protocols are detailed instructions from CMS for personnel to follow when performing the EQR-related activities. Protocols must specify: (1) The data to be gathered; (2) the source of the data; (3) the activities and steps to be followed in collecting the data to promote its accuracy, validity, and reliability; (4) the proposed methods for valid analysis and interpretation of the data; and (5) all instructions, guidelines, worksheets and any other documents or tools necessary for implementing the protocol. Under section 1932(c)(2)(A)(iii) of the Act, the Secretary, in coordination with the National Governors' Association, contracts with an independent quality review organization to develop such protocols.

We received the following comments on § 438.352.

Comment: Two commenters supported the unaltered continuation of this section. One commenter requested that CMS specify which entity develops the protocol: the state; the state's contractor; CMS; or CMS's contractor. The commenter suggested noting in the regulation that CMS will obtain input from states prior to finalizing the protocols. Another commenter suggested that if states are required to

use these protocols, CMS should make this requirement explicit in § 438.350 or § 438.352.

Response: We did not propose revisions to § 438.352, which is finalized as published in the proposed rule, except to make one small technical revision for clarity, noted below. However, we note that, in accordance with section 1932(c)(2)(A)(iii) of the Act, the Secretary, in coordination with the National Governors' Association (NGA), contracts with an independent quality review organization to develop the protocols. This process ensures state involvement in the EQR protocol development process. The Secretary is responsible under the statute for issuing the protocols; we are revising the introductory language in § 438.352 of the final rule to clarify that the protocols are issued by the Secretary but are developed by the Secretary in coordination with NGA. We also note that the requirement that states use the EQR protocols is stated in § 438.350(e), as finalized in this rulemaking, which provides that information provided to the EQRO for EQR must be obtained through methods consistent with the EQR protocols established under § 438.352. We are also revising § 438.350(e) to clarify that the Secretary issues the EQR protocols.

After consideration of the public comments, we are making a technical correction to this section to clarify that the Secretary develops the protocols in consultation with NGA and that the protocols are issued by the Secretary.

(j) Qualifications of External Quality Review Organizations (§ 438.354)

We proposed two modifications to § 438.354, which sets forth the competence and independence standards that an entity must meet to qualify as an EQRO. First, we proposed additional text, consistent with our overall proposal, to expand EQR to PAHPs. Second, in paragraph (c)(3)(iv), we proposed that an accrediting body may not also serve as an EQRO for a managed care plan it has accredited within the previous 3 years. This is due to our proposal that an EQRO be allowed to use the results of an accreditation review to perform the final EQR analyses; the financial relationship between a managed care plan and its accrediting body should not influence the results of the EQR (or the information that is included in the resulting EQR technical report). We also proposed a corresponding redesignation of existing paragraph (c)(3)(iv) to (c)(3)(v).

We received the following comments in response to our proposal to revise § 438.354.

Comment: A few commenters expressed general support for these proposals.

Response: We thank the commenters for their support and are finalizing the proposed revisions to § 438.354 with some modifications, discussed below.

Comment: A few commenters recommended adding language to the independence protections at § 438.354(c) to ensure that an organization with ties to an MCO, PIHP, or PAHP may not qualify as an EQRO to review competitors in the same service area. Other commenters recommended that the independence provision also list controlling relationships with PCCM entities as a disqualifying factor for EQROs, and suggest that similar additions may also be appropriate for other EQR sections. One commenter opposed allowing accrediting bodies to serve as EQROs, and stated that there was inherent possible conflict in having one sector both define the metrics of MCO quality and the same sector validating its quality results.

Response: We agree that an EQRO with ties to an MCO, PIHP, or PAHP should not be permitted to review competitors of said MCO, PIHP, or PAHP that operate in the same service area, as this could undermine the fact or appearance of independence and impartiality. We are revising paragraph (c)(3)(i), redesignated as paragraph (c)(2)(i) in the final rule, of this section to reflect this recommendation, with the modification of state instead of service area. We preliminarily note that we inadvertently neglected to add PCCM entities (described in § 438.310(c)(2) of the final rule) to the regulation text at proposed § 438.354(c). We agree with the commenters that EQROs selected to review a PCCM entity must meet the same independence requirements as EQROs reviewing an MCO, PIHP, or PAHP; this was our intent under the proposed rule. We are therefore correcting this oversight throughout § 438.354(c) of the final regulation, as the qualifications for EQROs apply equally to the entities reviewing a PCCM entity (described in § 438.310(c)(2)) in accordance with § 438.350 of the final rule.

Regarding the concerns about an accrediting body serving as an EQRO, we share the commenter's interest in ensuring impartiality, though we are uncertain what is meant by the statement that the accrediting body sector "define[s] the metrics of MCO quality." Section 1932(c)(2)(iii) of the

Act requires CMS to contract with an independent quality review organization, such as NCQA, to develop these protocols; however, consistent with § 438.352, the EQR protocols are to be developed by the Secretary in coordination with the National Governor's Association. These protocols are ultimately issued by the Secretary, not by an accrediting body. Second, to ensure independence, proposed paragraph (c)(3)(iv) would require that the EQRO have not, within the previous 3 years, conducted an accreditation review of any MCO, PIHP, or PAHP contracted by the state. We believe that these provisions ensure that the same entity is not developing the EQR protocols and conducting EQR for plans it has accredited. We believe this sufficiently addresses the commenter's concern, and are finalizing paragraph (c)(3)(iv) as paragraph (c)(2)(iv) with nonsubstantive edits.

Comment: A few commenters recommended adding the phrase "or expected" to paragraph (c)(3)(v) of the proposed rule, so that paragraph would require that an EQRO not have a present, or known or expected future, direct or indirect financial relationship with an MCO.

Response: We did not propose revisions to the current regulation text at § 438.354(c)(iv), redesignated at § 438.354(c)(v) in this rulemaking and are not making any changes in the final rule. We also disagree with the addition of "expected" to the description of financial relationships. The current regulation already prohibits use of entities with a known future financial relationship with a managed care plan from serving as an EQRO. Introduction of the word "expected" would serve to infuse an element of speculation and uncertainty that we do not believe could be clearly defined, applied, or enforced.

After consideration of the public comments, we are adding PCCM entity described in § 438.310(c)(2) to the list of managed care plans in § 438.354(c) and adding a provision that an EQRO with ties to an MCO, PIHP, PAHP or PCCM entity (described in § 438.310(c)(2)) cannot qualify to review competitors of its MCO, PIHP, PAHP, or PCCM entity operating in the same state. We are also making a technical clarification to paragraph (c), which does not alter the meaning of the rule, by redesignating proposed paragraphs (c)(1) and (c)(2) as paragraphs (c)(1)(i) and (c)(1)(ii), respectively. This redesignation necessitates the redesignation of paragraph (c)(3) as (c)(2).

(k) State Contract Options for External Quality Review (§ 438.356)

Our proposed revisions to § 438.356 would provide additional clarification to the existing EQRO contracting process. We proposed changing the title of this section to clarify that it is specific to EQR contracting. In paragraph (a)(2), we proposed adding that other entities, in addition to or instead of an EQRO (such as the state or its agent that is not an MCO, PIHP, or PAHP) may conduct the EQR-related activities to comport with this same flexibility afforded to states in § 438.358. In paragraph (e), we proposed the addition of a cross-reference to paragraph (a), with the addition of "with an EQRO" to make clear that the contract subject to the open, competitive process is the state's contract with the EQRO. We also, in paragraph (e), proposed to update the cross-reference to the part of 45 CFR that governs grants to state governments from part 74 to part 75, to reflect changes that occurred after the existing regulations were finalized.

We received the following comments in response to our proposal to revise § 438.356.

Comment: One commenter offered general support for the proposed revisions in § 438.356.

Response: We appreciate the commenter's support.

Comment: Two commenters supported the addition that other entities, in addition to or instead of any EQRO, may conduct EQR-related activities as set forth in § 438.356(a)(2). One commenter noted that this flexibility is critical so that states can tailor their EQR processes to accommodate the differing structure of state Medicaid programs and their capacity needs.

Response: We appreciate the commenters support for this provision, which is actually a clarification of existing policy regarding the entities able to conduct the EQR-related activities described in § 438.358. As discussed in the proposed rule, § 438.358(a) provides that other entities (specifically the state or its agent that is not an MCO or PIHP) were already able to conduct the EQR-related activities described in § 438.358(b) through (d). Therefore, the revision of § 438.356(a)(2) does not represent a change in policy but instead ensures that this existing flexibility is described clearly and consistently in the regulation. It is important to note that EQR-related activities conducted by a non-EQRO on any managed care plan are only eligible for the 50 percent match rate described in § 438.370(b).

Comment: One commenter appreciated the additional flexibility in allowing other entities instead of an EQRO to conduct EQR-related activities, but also cautioned against potential conflicts of interest that may arise.

Response: We appreciate the commenter's concern. It is important to note that while other entities may conduct the EQR-related activities, and that these entities are not subject to the competence and independence requirements of an EQRO (described in § 438.354), the EQR-related activities produce information used in the annual EQR. The EQR may only be conducted by a qualified EQRO, and only a qualified EQRO may produce EQR results. This ensures that an independent and competent EQRO reviews the information produced by EQR-related activities (regardless of the entity that conducts the activities) and evaluates the quality, timeliness, and access to the care furnished by the managed care plan.

Comment: One commenter noted that the proposed revisions in § 438.356 would provide more options for EQR contracting with the exception of the EQR Technical Report which must be done by an EQRO.

Response: We disagree that the proposed revisions in § 438.356 provide more options for EQR contracting. The proposed revisions to § 438.356(a)(2) do not represent a change in policy, but instead reflect the flexibility that already exists in § 438.358(a). We agree that this flexibility does not extend to the EQR technical report. To ensure that the EQR technical report reflects an independent analysis of the quality, timeliness, and access to the care furnished by the managed care plan, only a qualified EQRO may produce an annual EQR technical report.

Comment: One commenter noted that some states have contracted with the same EQRO for an extended period of time without a rebid of the contract. The commenter recommended that CMS specify in § 438.356(e) that contracts should be rebid at a regular interval.

Response: We did not propose changes to paragraph (e) to require rebidding and are not making such a revision in the final rule. We believe that there may be both advantages and disadvantages to a state retaining the same EQRO for an extended period with or without a rebidding process. Provided that the entity is qualified and independent, we believe that it is appropriate for states to retain the degree of flexibility afforded under the current regulations to engage or to not engage in a rebidding process.

Comment: Several commenters supported the proposed revisions and specifically mentioned their support for the requirement that states follow an open, competitive procurement process. Commenters noted that 45 CFR part 75 requires that requests for proposals (RFPs) be publicized, but does not specify that states post RFPs on the state Medicaid Web site. Commenters recommended that the public should have a role in providing input on the RFPs. Some commenters requested that CMS specify in § 438.356(e) that notwithstanding state law, the state agency shall post its RFPs on the state Web site and provide a reasonable public comment period prior to beginning the bidding process. Some commented that the public comment period should be at least 30 days prior to beginning the bidding process.

Response: We appreciate commenters support for the proposed revision, and specifically for the open and competitive procurement process. We disagree with requiring states to post RFPs online for public comment prior to the bidding process, which we believe would be inconsistent with general contracting practices.

After consideration of the public comments, we are finalizing this section as proposed.

(l) Activities Related to External Quality Review (§ 438.358)

This section sets forth the activities that produce information that the EQRO must use to conduct the EQR, to draw conclusions regarding access, timeliness, and quality of services provided by managed care plans, and to draft the final EQR technical report. Under the 2003 final rule, there were three mandatory and five optional EQR-related activities. The three mandatory EQR-related activities are: (1) Validation of performance improvement projects; (2) validation of performance measures; and (3) determination of compliance with the standards set forth in subpart D. The five optional activities are: (1) Validation of encounter data; (2) administration or validation of surveys; (3) calculation of additional performance measures; (4) conduct of additional PIPs; and (5) conduct focused studies of quality of care. Under paragraph (d) of this section, EQROs are permitted to provide technical assistance if the state directs. We proposed several changes to this section, including the addition of text to be consistent with our proposal to extend EQR to PAHPs.

We proposed separating the current paragraph (a) into two paragraphs, the first of which would retain the language

in the current general rule. Our proposed paragraph (a)(2) would clarify that the information resulting from the performance of the EQR-related activities will be used in accordance with § 438.350(a)(3) to complete the EQR. In paragraph (b), we proposed minor technical changes to make clear that the mandatory activities will be performed for each MCO, PIHP, and PAHP. In paragraphs (b)(1) and (b)(2), we included reference to the proposed CMS-identified measures and PIPs, which may be developed by CMS, in consultation with the states and other stakeholders, through the public process as described in the proposed § 438.330(a)(2). In paragraph (b)(3), we proposed that the mandatory compliance review would consist of an evaluation of the MCO, PIHP, and PAHP standards proposed in subpart D, and because we proposed moving the QAPI program standards to subpart E (as described in the proposed § 438.330), we reference that section as well. This does not propose any significant change from what comprises the current compliance review activity.

We proposed the addition of a new mandatory EQR-related activity in paragraph (b)(4), the analysis of which would be included in the annual EQR technical report in accordance with § 438.364. This proposed EQR-related activity would validate MCO, PIHP, or PAHP network adequacy during the preceding 12 months to comply with the state standards developed in accordance with § 438.68. An assessment of compliance with § 438.206 (availability of services) would occur as part of the mandatory compliance review described in § 438.358(b)(3); however, because the methods that are frequently used to do so are limited to the review of policies and procedures and onsite interviews of personnel, we proposed that this EQR-related activity would go beyond the compliance activity by directly evaluating and validating network adequacy on an annual basis. While the specifics of this activity would be identified in a new EQR protocol, we envision the inclusion of steps such as measurement of how effectively a plan is meeting a state's specific access standards (for example, time and distance standards), direct testing to determine the accuracy of network information maintained by managed care plans, and telephone calls to providers that either assess compliance with a specific standard, such as wait times for appointments, or assess the accuracy of provider information, such as whether a provider is participating in a plan.

Finally, in paragraph (d), we proposed a minor technical change by clarifying that technical assistance may be provided by the EQRO to assist managed care plans in conducting activities that would produce information for the resulting EQR technical report.

We received the following comments in response to our proposal to revise § 438.358.

Comment: Many commenters expressed general support for the changes under § 438.358; a few commenters expressed strong support.

Response: We thank the commenters for their support for this section as proposed, and note that we are finalizing this section with modification, as described below.

Comment: A commenter stated that the identification by CMS of national performance measures and PIPs would be additional work for the contracting managed care plans, the state, and its EQRO.

Response: We appreciate the commenter's concerns about the possible burden associated with the identification by CMS of national performance measures and PIP topics. We note that CMS has the authority today to identify and require these items, but to date has not chosen to exercise this authority. Under § 438.330(a)(2), if we elect to identify these items, we will utilize a public notice and comment process and engage states and stakeholders in the selection of these national performance measures and PIP topics; therefore, states, plans, and EQROs will have an opportunity to make recommendations regarding the measures and topics, which should reduce the additional burden these items will impose, as well as time to collect data and report on such measures.

Comment: A few commenters requested that CMS amend § 438.358(b) to include PCCMs.

Response: We agree that a technical correction would clarify the application of EQR-related activities under this section to certain PCCM entities (described in § 438.310(c)(2) of the final rule). Consistent with revisions to §§ 438.310(c)(2) and 438.350 of the final rule, we are modifying § 438.358 to reflect the requirement that PCCM entities described in § 438.310(c)(2) must undergo an annual EQR, which requires the information generated by the activities under this section. Specifically, we are renumbering paragraphs (b)(1) to (b)(4) as paragraphs (b)(1)(i) to (b)(1)(iv), and adding a new paragraph (b)(2) to specify that PCCM entities (described in § 438.310(c)(2))

must undergo the EQR-related activities described in paragraphs (b)(1)(ii) (validation of performance measures) and (b)(1)(iii) (compliance review).

Comment: Many commenters raised questions about or proposed methodologies for how to conduct the validation of network adequacy, including: (a) Direct test standards; (b) validation based on the managed care plan's submission required under § 438.207; and (c) surveys of beneficiaries as part of the validation of network adequacy. One commenter requested clarification on how network adequacy will be assessed in situations where access to services and providers is less available overall, particularly for linguistic and physical access.

Response: We thank the commenters for their questions and suggestions. The methodology for each EQR-related activity will be contained in an EQR protocol, which will be developed in accordance with § 438.352 in a process that is outside of this rulemaking. Therefore, we will not include methodological details recommended by commenters in regulation.

Comment: Several commenters requested that CMS not adopt the proposed network adequacy validation activity. A few commenters believed it was duplicative of the accreditation process. One commenter recommended that CMS delete the new mandatory activity because it is already covered as part of the EQR compliance reviews and state monitoring requirements described in § 438.66(b)(10).

Response: We understand commenters' concerns. Network adequacy validation is a key quality oversight and monitoring activity. The proposed rule differs from the current accreditation review and/or the EQR compliance review in that it would require direct annual assessment of network adequacy for compliance with state network standards, versus the policy and procedure reviews, site visits, and interviews that occur once every 3 years under accreditation surveys or EQR. The methodology for this new activity will be defined in a forthcoming EQR protocol issued under § 438.352. Finally, as an annual EQR-related activity, the data produced will be included in a state's annual EQR technical report, which will increase the accessibility of this information. Since we do not believe this would be duplicative of existing quality efforts, this new mandatory activity will remain in the final rule.

Comment: A few commenters stated that the creation of a new mandatory activity for validating network adequacy would not be necessary for states with

existing managed care delivery models, and would be unnecessary, duplicative and an administrative burden for MCOs and states experienced in managed care. One noted that this activity would be unnecessary in states with regular network oversight, and recommends that this mandate not apply to states that perform regular network oversight, and that it be written more broadly to allow for existing oversight mechanisms rather than prescribing the use of the EQRO.

Response: We understand the commenters' concern and interest in avoiding duplication of activities. States will have an opportunity for input on the protocol that is developed for this activity. The activity will supplement, but not duplicate, existing state oversight activities. Consistent with § 438.358(a), states may conduct the EQR-related activities; if the state conducts its validation consistent with the forthcoming new EQR protocol, then that information can be used for the annual EQR. We believe it is important to continue with the existing mandatory compliance review activity that includes managed care plan network adequacy assessment from a policy and operations perspective so that states have a nationally accepted standard that plans meet at a minimum. To reduce duplication of effort, states can provide information from an accreditation review (in place of information generated by the EQR-related activities in § 438.358 provided that the information is comparable as discussed in § 438.360) to EQROs for the annual EQR process. States that have existing network adequacy review methodologies in place will have the opportunity to demonstrate how they are consistent with EQR protocols, and will be able to submit recommendations through the public comment process in the development of the new EQR protocol. The new activity will also be eligible for 75 percent administrative match per § 438.370. Therefore, we reject the commenters' view that this activity would create significant administrative burden for the state, but acknowledge a phased-in approach should be considered for implementing the new activity most effectively.

Comment: A commenter was concerned about loopholes that can distort information on the adequacy of a MCO provider network. The commenter suggested that CMS require surveys be conducted by the MCO to determine the status of their provider networks.

Response: We appreciate the commenter's concern. We understand that network development and

maintenance are important activities for managed care plans, and that gaps and challenges exist in measuring the adequacy of a provider network. As discussed earlier, details of the network adequacy validation methodology will be provided in a forthcoming EQR protocol, the development of which is outside the scope of this regulation. There will be an opportunity for public feedback during the development of the EQR protocols.

Comment: A few commenters recommended that CMS not require the validation of network adequacy be an annual activity.

Response: We disagree with the commenters' recommendation. We believe that one way this activity distinguishes itself from other network monitoring activities is its annual nature. Network changes can occur at any point in time and a less frequent cycle would provide less timely and useful information for action by a managed care plan or a state.

Comment: A commenter noted annual reviews—while helpful—are always retrospective and should only be a supplement rather than a replacement for routine monthly network adequacy analyses.

Response: We appreciate the commenter's observation about the timing of the EQR process. By adding a mandatory EQR-related activity for network adequacy validation, we are neither recommending nor requiring alteration of a state's existing network oversight processes. Instead, annual network validation is a tool that can help to improve oversight of managed care plan networks, and make that information more accessible to the public. We see this activity working in harmony with other monitoring activities to help ensure beneficiaries have timely access to high quality services.

Comment: A commenter noted that states will need time to adjust their EQRO contracts to reflect the new required mandatory activity.

Response: We understand that states will require time to adjust their EQRO contracts. This new activity will phase in after the release of the EQR protocol for the validation of network adequacy, which will provide states with time to do so. Depending on a state's reporting cycle, we expect that all states contracting with MCOs, PIHPs, and PAHPs will conduct and report on this activity within 2 years of the release of the EQR protocol.

Comment: A commenter stated that the addition of a new, mandatory EQR-related activity would increase its EQRO budget to include this additional work.

However, the commenter also stated that the additional burden to the state for the new validation activity would be offset by use of deeming requirements which would reduce necessity for the compliance review and performance measure validation, two existing EQR-related activities.

Response: We understand that, for states that elect to have their EQRO conduct the validation of network adequacy EQR-related activity, this will increase the cost of the EQRO contract. We note that in this situation, the network adequacy validation of MCOs, PIHPs, and PAHPs would be eligible for the 75 percent match rate under § 438.370(a).

Comment: A few commenters noted that while they are in favor of requiring states to validate quality information reported by MCO, PIHP, or PAHPs, they recommend that CMS develop stronger oversight to ensure that states are validating data and not simply relying on independently reported quality metrics.

Response: We appreciate the commenters' concern about the importance of validated performance measure data. One of the mandatory EQR-related activities is the validation of performance measures, described in proposed paragraph § 438.358(b)(2) and finalized as § 438.358(b)(1)(ii). This activity must be conducted in a manner consistent with the protocols established under § 438.352, and we believe that it is reasonable to allow states the flexibility in paragraph (a)(1) of this section to either conduct this EQR-related activity themselves, or to have an agent that is not an MCO, PIHP, PAHP, or PCCM entity (described in § 438.310(c)(2)), or an EQRO conduct the activity.

Comment: Multiple commenters requested the creation of additional new EQR-related activities: (a) Full review and accounting of grievances and appeals; (b) requiring states or EQROs to collect data directly from enrollees, in the form of focus groups or beneficiary surveys; and (c) a review and analysis of home care provider and other direct care workers' wage adequacy, opportunities for training and skill development, and their role in potential plan quality improvement.

Response: We understand the value of information on grievances and appeals, beneficiary surveys, and on home care providers and other direct care workers; however, disagree with adding the requested items as mandatory EQR-related activities. States are required under § 438.66(b)(2) to have a monitoring system in place for oversight of managed care plans' appeal and

grievance systems. States are also required to use information from member grievance and appeals logs to improve performance of their managed care plans (§ 438.66(c)(2)). We allow, as an optional EQR-related activity in paragraph (c)(2) of this section, the administration or validation of consumer or provider surveys of quality of care. Beneficiary surveys are a component of the current QHP QRS; in § 438.334(a) we propose to align the MMC QRS with the QHP QRS components. Finally, under current regulations and under § 438.358(c)(5) of this final rule, states have the flexibility, as an optional EQR-related activity, to elect to conduct a focus study related to home care providers, other direct care workers, or grievances and appeals. As such, states have an EQR mechanism for these types of analyses if they determine such an analysis would be appropriate for the state's program.

Comment: A commenter recommended that CMS add a general provision in which states could propose optional EQR activities that could qualify for enhanced match for CMS review and approval that align with its quality strategy.

Response: We appreciate the commenter's request for state flexibility; however, we do not have the authority to provide enhanced match for state-specific activities. The 75 percent match rate authorized by section 1903(a)(3)(C)(ii) of the Act applies to independent external reviews conducted under section 1932(c)(2) of the Act, which further requires, in paragraph (2)(A)(iii), the use of protocols developed by the Secretary. Therefore, states can only claim the 75 percent match under § 438.370 for EQR-related activities described in § 438.358 conducted by an EQRO consistent with the protocols issued per § 438.352. Additional optional EQR-related activities not identified in § 438.358 would not have an associated EQR protocol under § 438.352, and therefore, could not be eligible for the 75 percent match. Therefore, we reject this recommendation.

Comment: A commenter stated that CMS should strengthen the requirements of the EQR program, including requiring provider input and verification of provider issues in trying to assist members as they move through the system.

Response: We believe this final rule strengthens the requirements of the EQR, which will improve the quality of, timeliness of, and access to care for Medicaid beneficiaries. We appreciate the role that providers offer in assisting beneficiaries to navigate the system and

in providing quality care to beneficiaries, however, we decline to add an EQR-related activity focused on the role of providers. However, we will consider this recommendation with all other public comments during the next revision to the EQR protocols under § 438.352.

After consideration of the public comments, we are finalizing this section as proposed, with several technical revisions: (1) We are modifying § 438.358 to reflect that states require an annual EQR for PCCM entities described in § 438.310(c)(2), consistent with § 438.350 in the final rule; (2) we are clarifying in (a)(2) that the information produced by the EQR-related activities must be used in the annual EQR under § 438.350, and that the information produced by the activities must at a minimum include the elements described in § 438.364(a)(1)(i) through (iv); and (3) we are modifying (b)(4) of this section to reflect that the network adequacy validation should examine compliance with the requirements set forth in § 438.14(b), which addresses network requirements for managed care plan contracts involving Indians, Indian health care providers (IHCPs), and Indian managed care entities (IMCEs).

(m) Non-Duplication of Mandatory Activities (§ 438.360)

This section is based on section 1932(c)(2)(B) of the Act, which provides the option for states to exempt MCOs from EQR-related activities that would duplicate activities conducted as a part of a Medicare review conducted of an MA plan or a private accreditation survey. In 68 FR 3586 (published January 24, 2003), to avoid duplication of work, states were given the option of using information about contracted MCOs or PIHPs obtained from a Medicare or private accreditation review to provide information which would otherwise be gathered from performing the mandatory EQR-related compliance review, but not for the validation of performance measures or PIPs. In addition, for MCOs or PIHPs that exclusively serve dual eligible beneficiaries, states may use information obtained from the Medicare program in place of information otherwise gathered from performing the mandatory EQR-related activities of validating performance measures and validating PIPs.

We proposed giving states the option to rely on information obtained from a review performed by Medicare or a private accrediting entity to support performing the three existing mandatory EQR-related activities: (1) The validation of PIPs; (2) the validation of

performance measures; and (3) the compliance review. For further discussion of this proposed change, see section I.b.6.b.2.m of the June 1, 2015 proposed rule (80 FR 31098).

We proposed in paragraph (a) that the state may use information about an MCO, PIHP, or PAHP obtained from a Medicare or private accreditation review within the past 3 years to support collection of information that would be obtained by completing one or more of the three existing EQR-related mandatory activities. We did not propose extending this option for non-duplication to the fourth, newly proposed EQR-related mandatory activity for validation of network adequacy, as neither we nor private industry have enough experience to know how well it would line up with current accreditation standards.

Because of our proposal to extend the non-duplication option to three mandatory activities, we proposed to combine and streamline the content in the current § 438.360(b) and (c), as it would no longer be necessary to separately address plans serving only dual eligibles. In paragraph (b)(1), we proposed clarifying that the Medicare or private accreditation review standards must be substantially comparable to the standards for the three EQR-related activities to be eligible for non-duplication. Finally, we retain that states identify whether they opt to deem portions of any of the EQR-related activities under this option, and include the reasons for doing so, in the comprehensive quality strategy. This redesignated the previous § 438.360(b)(4) and (c)(4) to paragraph (c).

We received the following comments in response to our proposal to revise § 438.360.

Comment: Multiple commenters expressed support for the expansion of nonduplication to the mandatory EQR-related activities of validation of PIPs (proposed § 438.358(b)(1)) and performance measures (proposed § 438.358(b)(2)). They indicated that this would improve efficiency and alignment, reduce redundancies, generate financial and time savings, and reduce the overall administrative burden on plans and states.

A number of other commenters expressed opposition to the expansion of nonduplication to either the mandatory EQR-related activities of validation of PIPs (proposed § 438.358(b)(1)), performance measures (proposed § 438.358(b)(2)), or both. Concerns that were submitted include: (1) Use of proprietary private standards in EQR that can't be publicly compared

to the CMS EQR Protocols; (2) questions about the independence of validation tests from private accreditors when accreditation survey or a HEDIS audit paid for by the plan could represent a potential conflict of interest; and (3) a potential for increased time lag in use of information from private accreditation within the previous 3 years, in lieu of mandatory EQR activities under EQR to validate performance measures and PIPs annually.

Several commenters recommended that CMS revert to the current nonduplication provision, with the added requirement that information from an authorized private accreditor used in lieu of an EQR-related activity must come from entities that meet the independence and competency standards in § 438.354, except § 438.354(c)(3)(iv) (which relates to accreditation).

Response: We thank the commenters for their careful consideration of the proposed expansion of nonduplication to the validation of performance measures and PIPs. Section 1932(c)(2)(B) of the Act provides states the option to not conduct EQR-related activities which would be duplicative of review activities conducted as a part of the accreditation process or Medicare external review. This applies even if private accreditation standards are not publicly available and even when the information is generated by an accreditation review paid for by a Medicaid managed care plan. We note that paragraph (c) of this section requires a state to document its rationale for the use of the nonduplication provision in its quality strategy, and that the quality strategy, consistent with § 438.340, is a public document; this affords the public an opportunity to review and comment on the state's determination and rationale. It also provides a forum for the public to comment on any impartiality concerns.

Paragraph (b)(1) of the proposed rule, finalized as paragraph (a)(2) of this section, requires that for the state to rely on information from a Medicare review or private accreditation, the standards for that review must be comparable to the standards for the EQR-related activities, consistent with the EQR protocols issued per § 438.352. We intend to provide guidance on comparability for the mandatory EQR-related activities in § 438.358 (b)(1) to (b)(3) through future EQR protocols required under § 438.352. This will address concerns raised relating to the transparency, timeliness and independence of accreditation results, and how the information from an

accreditation review may be used in the annual EQR.

Finally, § 438.358(a)(1) of the final rule allows a state, its agent that is not an MCO, PIHP, or PAHP, or an EQRO to conduct the mandatory and optional EQR-related activities. This allows an entity that does not meet the independence and competency standards in § 438.354 to conduct these activities. Given this flexibility, we do not believe the standards in § 438.354 should apply to accreditation entities whose information is used under this section. Furthermore, section 1932(c)(2)(B) of the Act refers to accreditation by a private independent entity such as those described in section 1852(e)(4) of the Act; we do not believe we have the authority to impose additional restrictions based on the standards in § 438.354.

We are finalizing this section with revision to clarify that nonduplication is to be used at the state's discretion and consistent with guidance issued by the Secretary under § 438.352.

Comment: Several commenters noted that it is unclear if the accreditation referred to in this section would be specific to a plan's Medicaid line of business. Concern was raised as to how the validations of PIPs and performance measures applied to a population covered in the private market can be considered duplicative of validation of these measures for a Medicaid-specific population. Several commenters noted that in the previous rule-making that finalized the current regulations, HHS justified excluding these activities from the non-duplication provision because the private accreditation review often encompasses an MCO or PIHP's private market line of business. HHS stated that the population served by private market insurance is dissimilar to the population served by Medicaid, and that EQR should only evaluate performance measures and PIPs specific to the Medicaid population. The commenters stated that it is not clear what has changed to justify this proposed policy change.

Response: We thank commenters for noting historical reference to why use of private accreditation standards were not previously included for validation of performance measures and PIPs. Since publication of the 2003 final rule, at least two private accrediting entities have made available standards specific to the Medicaid line of business. We will issue guidance to states regarding the comparability of accreditation information to the information generated by the mandatory EQR-related activities in § 438.358(b)(1)(i) through (b)(1)(iii) through future EQR protocols

issued per § 438.352. If the information generated by the accreditation review is not comparable to the information generated by an EQR-related activity, then the state must ensure that activity is applied to the managed care plan. Nonduplication provides a mechanism to reduce administrative burden to managed care plans and states while still ensuring relevant information is available to EQROs for the annual EQR. We are finalizing this section with modification to clarify that nonduplication is to be used at the state's discretion and consistent with guidance issued by the Secretary under § 438.352.

Comment: A number of commenters expressed concern over the interaction between the state review and approval process (including the use of accreditation) and nonduplication. These commenters believe that: (1) Private accreditation should not be allowed to be substituted for EQR-related activities; (2) states should not be allowed to deem plan compliance with EQR based on accreditation; and (3) accreditation should not undermine or effectively replace independent EQR or other quality assurance efforts. Several expressed concern that nonduplication weakens the EQR process. Other commenters stated that the expansion of nonduplication appears to directly contradict and undermine other proposed changes intended to strengthen the EQR process.

Response: As discussed in section I.B.6.b.(2)(d) of the preamble, we are withdrawing the proposed state review and approval process in § 438.332 (though we are retaining this section to require the availability of information regarding the accreditation status of a managed care plan). States currently have flexibility to require managed care plans to be accredited or not, and this flexibility will remain. Section 1932(c)(2)(B) of the Act grants states the option to not duplicate, through EQR-related activities, activities that are conducted as a part of an accreditation process or Medicare review. The expansion of nonduplication to the mandatory EQR-related activities of validation of PIPs (§ 438.358(b)(1)(i)) and performance measures (§ 438.358(b)(1)(ii)) for all Medicaid managed care MCOs, PIHPs, and PAHPs, not just those serving only dual eligibles, will provide additional flexibility to states to reduce administrative burden. We do not believe it undermines changes which strengthen the EQR process as information from a private accreditation review may only be used if it is comparable to the information generated

by an EQR-related activity; if it is not comparable, the activity must occur.

Comment: One commenter expressed concern that the use of nonduplication could pose a challenge to an EQRO's ability to conduct an effective performance analysis of a managed care plan.

Response: We disagree. States which exercise the nonduplication option are required under § 438.360(b) of the final rule to ensure that the information obtained from the accrediting organization in lieu of conducting the EQR-related activity is provided to the EQRO and included in the analysis and report required under § 438.364.

Comment: One commenter recommended that CMS allow states to deem accreditation as sufficient for state quality purposes, which would reduce the burden on plans and states, avoid duplication of effort, and avoid measure fatigue. Another encouraged CMS to streamline EQR by allowing NCQA accreditation to demonstrate EQR compliance when the requirements are similar. This approach would reduce the burden on states and plans.

Response: We agree with the commenter on aligning quality measurement and improvement opportunities and reducing burden to states and managed care plans where appropriate. However, private accreditation does not cover the full range of quality activities required under the regulations. Therefore, we disagree that accreditation alone should be sufficient to deem a plan fully compliant with all quality regulations. For example, per § 438.364(a)(3) of the final rule, EQROs will need to provide recommendations for improving the quality of health care services furnished by each MCO, PIHP, or PAHP, as well as for how the state can target goals and objectives in the quality strategy to better support improvement in the quality, timeliness, and access to health care services furnished to Medicaid beneficiaries. Under § 438.364(a)(5), the EQRO is tasked with providing an assessment of the degree to which each MCO, PIHP, or PAHP has addressed the recommendations made by the EQRO during the previous year's EQR. These activities, which are specific to Medicaid managed care plans under the regulations, are not accounted for in private accreditation survey processes at this time.

Comment: A few commenters requested CMS create a process to review and formally recognize accreditation standards as they map to EQR requirements, or to work with states to develop a managed care plan checklist which could be used to deem

compliance. Several commenters requested clarification of how states will apply the “substantially comparable” standard in § 438.360(b)(1).

Response: Given the number of accreditation standards available, and the frequency with which they may change, we do not believe a crosswalk would be the most efficient means of supporting nonduplication. Instead, we intend to provide guidance to states on comparability for the mandatory EQR-related activities in § 438.358 (b)(1) to (b)(3) through future EQR protocols required under § 438.352. States will continue to have flexibility within that guidance to determine which activities are duplicative. Technical assistance will be available to states through the quality strategy, which will, under § 438.360(c) of the final rule, identify the state’s use of nonduplication and the related rationale. We believe the EQR protocols are the best vehicle to provide comparability guidance, given that such guidance must be specific to the details in each protocol, and thus should be revised any time the protocols undergo revision. We are revising this section to reflect that the standards of the Medicare or accreditation review must be comparable (rather than substantially comparable) to those enumerated in the EQR protocols. We believe it is appropriate to remove the qualifier “substantially” in light of the future comparability guidance.

Comment: One commenter requested additional information regarding which type of Medicare review would be acceptable to replace the EQR mandatory activities and the names of the private accreditation agencies that are certified to do a comparable review of activities.

Response: The comparability guidance to be included in forthcoming EQR protocols issued per § 438.352 will be applicable to both Medicare reviews and private accreditation. While CMS may recognize accrediting agencies for accreditation of QHPs in the Marketplace and for MA organizations (§ 422.157), there is no similar provision in the statute providing for us to formally recognize accrediting entities for Medicaid managed care plans. Therefore, we intend to issue comparability guidance for the mandatory EQR-related activities in § 438.358 (b)(1) to (b)(3) through future EQR protocols required under § 438.352 which would be applicable to multiple accreditation standards.

Comment: A few commenters requested clarification of what would happen if a state requires other performance measures that are not part of HEDIS, and recommended that if

states require LTSS or any other non-HEDIS measures, the state should be responsible for contracting with an EQRO to separately validate all the required non-HEDIS measures. Some commenters expressed concern that accreditation data may not include information related to LTSS. Relatedly, a few commenters requested guidance on how to address areas where Medicaid quality standards and accreditation standards do not overlap.

Response: We appreciate this opportunity to clarify the application of the nonduplication provision. Information from a Medicare or accreditation review can be used in place of information generated by the EQR-related activity when the standards for the reviews are comparable to the standards for the EQR-related activity. If the standards are not comparable, then the EQR-related activity must occur. A state that chooses to utilize nonduplication and forwards information from an accreditation review to a contracted EQRO for the annual EQR must ensure the completion of any EQR-related activities (or components of those activities) which are not addressed by the information from the accreditation review. Therefore, if an accreditation review did not validate LTSS or other non-HEDIS measures required by the state under § 438.330(b)(2) of this subpart, this EQR-related activity would need to be completed for these measures.

Comment: One commenter requested clarification of how nonduplication will occur in light of any CMS-specific performance measures required under § 438.330(a)(2). The measures accreditation entities use to examine performance might not align with the measures that are required by CMS; how would this lack of alignment be handled under the nonduplication option?

Response: If there is a part of an EQR-related activity whose standards are not comparable to the standards of a Medicare or accreditation review, the state is required to complete that part of the EQR-related activity. In the scenario provided, if the measures identified by CMS per § 438.330(a)(2) were not included in the accreditation review, then the state would be required to conduct the performance measure validation activity (§ 438.358(b)(1)(ii)) for these measures.

Comment: One commenter believed that it is important to retain flexibility for MCO products serving sub-populations to select non-standard measures that apply to the population being served.

Response: This section would not limit the ability of a managed care plan

serving sub-populations to select non-standard measures that are specific to the population served. However, we note that the plan would still be subject to measurement standards required by CMS and the state.

Comment: A few commenters recommended that CMS allow nonduplication for the new EQR-related activity of network adequacy validation (proposed § 438.358(b)(4)) for plans that are already accredited with a CMS-recognized accreditation body such as NCQA. Another commenter supported and applauded CMS for not extending nonduplication to the new network adequacy validation EQR-related activity.

Response: Nonduplication can only be used in situations in which the standards for the Medicare or accreditation review are comparable to the standards for the EQR-related activity established through the EQR protocols. Since the EQR protocol for the new network adequacy validation activity (proposed, § 438.358(b)(4), finalized as § 438.358(b)(1)(iv)) is pending and its standards are undefined, we decline the recommendation to allow nonduplication for the new EQR-related activity.

Comment: Several commenters recommended that, to avoid duplicative efforts and requirements, CMS should explore other opportunities for deeming based on accreditation. They recommend exploring opportunities for deeming: Within the proposed rule; within state oversight, management, and report requirements; and between federal programs. Alternatively, they suggested that CMS should require states to work with plans to identify duplication based on accreditation and then work towards a process for deeming.

Response: We appreciate commenters’ interest in reducing duplicative efforts. However, the authority for states to rely on private accreditation for quality-related provisions under section 1932(c)(2)(B) of the Act is limited to mandatory EQR-related activities.

Comment: Commenters recommended that CMS map each of the quality requirements and program monitoring activities under this rule to ensure plans are only required to be reviewed once for the same requirement or activity.

Response: We have reviewed the quality requirements and program monitoring activities under this rule and believe that, while they may be interrelated, they are not duplicative.

Comment: One commenter recommended that, in cases where a state uses information from an accreditation

review in place of information generated by the compliance review in proposed § 438.358(b)(3), CMS should require the state to conduct additional direct testing of some aspect of a managed care plan's compliance each year.

Response: We appreciate the commenter's interest in the use of direct testing as a means of supplementing the information from a Medicare or accreditation review used, under this section, in place of the EQR-related review of a managed care plan's compliance (finalized at § 438.358(b)(1)(iii)). However, the intent of the nonduplication provision is to decrease duplication of effort when activities are comparable; requiring a state that utilizes nonduplication to conduct additional compliance review work as compared to a state that conducts the EQR-related activity appears to undermine the statutory intent. Therefore, we decline the commenter's recommendation.

Comment: One commenter requested clarification regarding the use of nonduplication; the proposed rule states it is optional, but it is unclear if this will remain optional or become highly recommended or required.

Response: The nonduplication provision is optional for states. Under section 1932(c)(2)(B) of the Act, states must be permitted to rely information from a Medicare or private accreditation review, but whether or not to exercise the option is left to each state.

Comment: One commenter supported the expansion of nonduplication for the validation of performance measures, but expressed concern about the use of nonduplication for PIP validation if the PIP does not align with a state's approach and selected topics.

Response: Section 438.358(b)(1)(i) of the final rule requires validation of the PIPs required under § 438.330(b)(1). If the project(s) validated as a part of the accreditation review do not fully align with those required under § 438.330(b)(1), then the accreditation review would not be comparable to the EQR-related activity finalized at § 438.358(b)(1)(i), and the state would be required to ensure the completion of this activity.

Comment: One commenter expressed concern regarding duplication between annual state Medicaid network adequacy assessment and the annual EQR-related activity of network adequacy validation for MCOs operating in combination with FIDESNPs and D-SNPs and exclusively serving dually eligible beneficiaries.

Response: While the details of the validation of network adequacy EQR-related activity will be determined

through the EQR protocol process, we intend this activity to be distinct from other network monitoring activities which may be undertaken by the state. In the event that the state's network monitoring activities closely align with the EQR protocol for the network adequacy validation activity, we note that a state, its agent that is not an MCO, PIHP, or PAHP, or an EQRO are all eligible entities to conduct the mandatory EQR-related activities.

Comment: A few commenters sought clarification of the permitted time for using accreditation information and the allowable time period for collecting PIP and performance measure data.

Response: Nonduplication is an option for states when the standards of the Medicare or private accrediting entity review used to obtain the data are comparable to the standards for the EQR-related activity, as described in the associated EQR protocol. This comparability would apply to timeframes, as well as processes. Therefore, if the only information available from a Medicare or accreditation review was 2 or more years old, it would not be comparable to the information generated by the performance of an annual EQR-related activity.

Comment: One commenter asked if CMS intends to update the EQR protocols to incorporate data from a Medicare or private accrediting entity review.

Response: We do not intend to update the EQR protocols to incorporate data from a Medicare or private accrediting entity review. The EQR protocols are developed for the EQR-related activities in § 438.358 independently of Medicare or accreditation review standards. For nonduplication to be an option for a state, the Medicare or accreditation review standards must be comparable to the EQR protocols, not vice versa. States have flexibility to then define within their managed care quality strategy which comparable standards are selected for nonduplication and the justification for selecting those standards. We intend to provide guidance on comparability for the mandatory EQR-related activities in § 438.358(b)(1) to (b)(3) through future EQR protocols required under § 438.352.

Comment: One commenter requested clarification on the guidelines provided in the proposed rule to ensure the alternative review mechanism is valid and reliable.

Response: While CMS is responsible for determining the validity and reliability of the Medicare or accreditation review, the standards for these reviews are set outside of the

Medicaid program. We will issue guidance in the EQR protocols to address when such reviews may be considered comparable to the EQR-related activity.

Comment: One commenter agreed with the use of NCQA accredited plans that already use HEDIS measures.

Response: We do not intend to promote or require that states contract with NCQA accredited plans that already use HEDIS measures. Rather, we used NCQA accredited plans in the proposed rule as an example of a situation in which a plan's performance measures may have already been validated as a part of the accreditation process. States have flexibility to determine which, if any, accreditation to require of managed care plans, and maintain flexibility in choosing if accreditation information will be used as part of the EQR process.

After consideration of the public comments we are finalizing this section with modification to clarify that nonduplication must operate consistent with guidance issued by the Secretary under § 438.352. We are also reorganizing this section so that the general rule, including qualifying conditions, is finalized as paragraph (a) and paragraph (b) contains the requirement that if a state uses information from a Medicare or accreditation review to support an EQR-related activity, this information must be provided to the EQRO. Paragraph (c) is revised to reflect that the state's use of and rationale for nonduplication must be included in the managed care quality strategy, in light of the withdrawal of the proposed comprehensive quality strategy.

(n) Exemption From External Quality Review (§ 438.362)

This section is based on section 1932(c)(2)(C) of the Act, which provides that a state may exempt a MCO from undergoing an EQR if the MCO has a current Medicare contract under part C of Title XVIII or under section 1876 of the Act, and, for at least 2 years, has had in effect a Medicaid contract under section 1903(m) of the Act. We proposed the removal of PIHPs, as they are not entities that fall under section 1903(m) of the Act. We also proposed to update the phrase "Medicare+Choice" to "Medicare Advantage" (MA).

We received the following comments in response to our proposal to revise § 438.362.

Comment: Two commenters agree with allowing a state to exempt a MCO from undergoing an EQR if the MCO has a current Medicare contract. One commenter also supported the

requirement that the MCO must have a Medicaid contract in effect for at least 2 years, and noted that this requirement is already in place.

Response: We thank the commenters for their support of these provisions, which implement section 1932(c)(2)(C) of the Act.

Comment: Several commenters supported the proposal to limit exemptions to MCOs.

Response: We appreciate commenters' support; we are finalizing this provision such that its application is limited to MCOs as proposed.

Comment: One commenter disagreed with allowing MCOs to be exempt from the EQR process. The commenter notes that EQR has been an asset for the state when reviewing MCO policies and procedures, and would likely continue to use EQR even if the requirement for it were removed. Another commenter requested that CMS not allow more than two consecutive exemption periods for a MCO. The commenter notes that this recommendation will balance the goal of aligning requirements across MA and Medicaid managed care while ensuring that the specific health care needs of the Medicaid managed care population are met.

Response: Section 1932(c)(2)(C) of the Act allows states to deem compliance with EQR for certain plans with a Medicare contract under section 1876 of the Act or MA (Medicare Part C). Neither the statute nor § 438.362 requires states to exempt plans from EQR; this is provided only as an option for states. It is up to the state, not a managed care plan or CMS, to determine whether or not to exempt a plan from EQR. The state has discretion to require all their managed care plans to undergo EQR, even those that appear eligible for an exemption under this section. Although we did not propose to limit the duration of a plan's exemption from EQR, a state may elect to set such a limit. We recognize the importance of understanding which plans states have exempted from EQR, and for how long the plan has been exempt, and we encourage states to post this information on their Web site. We will consider proposing in future rulemaking, to require that states do so.

Comment: One commenter asked CMS to clarify whether a state may exempt an MCO from undergoing an EQR if the MCO has a current Medicare contract in a different state.

Response: No, a state may not exempt an MCO from undergoing an EQR if the MCO's current Medicare contract is in a different state. Per paragraph (a)(2) of this section, one of the criteria that must be satisfied for a state to exempt a MCO

from EQR is that the MCO's current Medicare contract and its current Medicaid contract must cover all or part of the same geographic area within the state.

Comment: One commenter asked CMS to clarify who determines if an MCO is performing acceptably with regard to the quality, timeliness, and access to health care services the MCO provides to Medicaid beneficiaries, and what review standards are used for this determination.

Response: The state determines if a specific MCO is performing acceptably, using standards established by the state. Given that the EQR examines the quality, timeliness, and access to health care services provided by an MCO, the state should examine EQR data to determine if the MCO has performed acceptably during the most recent 2 consecutive years.

Comment: One commenter opposed the removal of the exemption option for PIHPs.

Response: Section 1932(c)(2)(C) of the Act limits the exemption option to Medicaid MCOs that have a current Medicare contract under part C of Title XVIII or under section 1876 of the Act and has had a contract in effect under section 1903(m) of the Act for at least the last 2 years. By its own terms, this language does not apply to PIHP contracts, which are not under section 1903(m) of the Act. While we could elect to use the authority under section 1902(a)(4) of the Act to expand this option to PIHPs (as it did in the 2003 final rule) and PAHPs, these delivery systems are unique to Medicaid and do not exist under either Medicare Part C or under section 1876; therefore, there is not a scenario under which either PIHPs or PAHPs would be eligible for an exemption.

After consideration of the public comments, we are finalizing this section with minor wording revisions.

(o) External Quality Review Results (§ 438.364)

This section sets forth the information, or final deliverables, that annually result from the EQR. We proposed several changes to this regulation to assist CMS and the states in meaningfully assessing the performance of each managed care plan. For more discussion, see section I.B.6.b.2.o of the June 1, 2015 proposed rule. Previously, the EQR activities in § 438.358(b)(1) and (2) only refer to validation of the data. While we continue to believe that data validation is important and should remain a core function of the EQR process, a statement of validation alone is insufficient to

provide insight into plan performance on quality, timeliness, and access to care. Therefore, under § 438.364(a)(1) we proposed that each EQR technical report include performance measurement data for any collected performance measures and implemented PIPs (in accordance with each EQR activity conducted in accordance with § 438.358(b)(1) and (2)).

In paragraph (a)(3), we proposed the inclusion of recommendations for how states can target the goals and objectives in the comprehensive quality strategy to better support improvement in the quality, timeliness, and access to health care services furnished to Medicaid beneficiaries. In paragraph (a)(4), we proposed deleting the language that allows the state alone to decide the appropriate methodology of comparative information about managed care plans, as we believe this should be a determination made by the state in conjunction with CMS (via the Protocols, as described in § 438.352).

In paragraph (b)(1), we proposed that states contract with a qualified EQRO to produce the final EQR technical report (that is, we clarified that there is no other entity which may produce the EQR technical report) and we proposed that this report be completed and available for public consumption no later than April 30th of each year. We also proposed that states may not substantively revise the content of the final EQR technical report without evidence of error or omission, or upon requesting an exception from CMS.

Paragraph (b)(2) proposed that states maintain the most recent copy of the EQR technical report on the state's Medicaid Web site, proposed under § 438.10(c)(3). We also proposed to separate out the existing language for states to make the information available in alternative formats for persons with disabilities in a new paragraph (b)(3). As part of this proposal, we replace the phrase "sensory impairments" with "disabilities".

We received the following comments in response to our proposal to revise § 438.364.

Comment: Many commenters generally agreed with the proposed changes to this section of the rule.

Response: We appreciate the support for the proposed revisions and note that we are finalizing this section with modifications, as described below.

Comment: A few commenters requested clarification on the April 30th technical report production date. One commenter requested the option to produce a report 90 days following the end of a contract year, and another

commenter suggested alignment with the HEDIS measure audit and reporting timeframes.

Response: The April 30th deadline will align with the timeframe needed for the annual reporting of managed care data by the Secretary each September 30th as prescribed by section 401 of the Children's Health Insurance Program Reauthorization Act (CHIPRA) of 2009 (Pub. L. 111-3) and section 2701 of the Affordable Care Act. The EQR technical reports must be published on the state's Medicaid Web site by this date, annually. We note that this timeframe is consistent with current subregulatory guidance, and do not believe this will require significant modification of existing state practices. However, states are responsible for establishing timeframes in their EQRO contracts which allow the states to meet this reporting deadline.

Comment: A commenter requested that states be required to share a draft EQR technical report with the managed care plans prior to finalization, and that the EQRO should be required to give consideration to plan comments. If the EQRO does not agree to amend the report based on managed care plan comments, then the plan comments should be included as a mandatory addendum to the report. This would align with the procedures used by federal audit agencies such as the HHS OIG and the GAO.

Response: The EQR technical report is a tool to assist state oversight of managed care plans. Given this, we believe it is appropriate to defer to the states as to if and when to share the draft EQR technical report with managed care plans, and preserve this flexibility in the final rule. We note that the EQR technical report represents the independent analysis of a state's managed care plan(s) by a qualified EQRO. Under this final rule, states may not substantively revise the content of the final EQR technical report without evidence of error or omission. Given this, we do not believe it would be appropriate to require EQROs to include comments from managed care plans as an addendum to the EQR technical report, and decline this recommendation. However, we note that the final rule is sufficiently flexible to allow a state to take up the commenter's recommendations if it chooses to do so.

Comment: A commenter recommended that states be allowed to revise the final EQR technical reports.

Response: We believe that states should only revise the final EQR technical report when there is evidence of error or omission. Information provided to the EQRO in accordance

with § 438.350(a)(2) is obtained through methods consistent with the protocols established under § 438.352. Unless inaccuracies are identified in the reports, we believe these reports should not be edited by the state prior to publication since they represent an independent assessment of the quality, timeliness, and access to care provided by the managed care plans. In the case of inaccurate information, states can and should work with the EQRO per § 438.364(b) to ensure presentation of accurate information prior to publication. We note that the preamble to the proposed rule, but not the associated regulation text, said that states wishing to make additional revisions to their EQR technical reports (other than those due to error or omission) could seek an exception from CMS. This statement was inaccurate; we do not intend to develop an exception process. Under § 438.364(b) the final rule, states may not substantively revise the content of the EQR technical report without evidence of error or omission.

Comment: A few commenters recommended CMS require plans to maintain an archive of past EQR technical reports on their Medicaid Web site; some recommended this archive contain the reports from at least the previous 5 years.

Response: While we encourage states to maintain an online archive of prior year EQR technical reports, in the final rule we are only requiring states to post their new EQR technical reports by April 30th of each year. We encourage interested parties to view the reports annually. We also note that states must keep these reports consistent with state record-keeping policies and consistent with § 431.17(b)(2) and (c).

Comment: Several commenters recommended that CMS broaden the transparency requirements related to EQR technical reports. One commenter requested transparency for any information that would be useful to stakeholders including, but not limited to quality standards and measurements. Another commenter requested more robust reporting of quality measures. A few commenters recommended the final rule add a requirement that EQR technical reports account for all violations identified by the state or EQRO during the compliance review and detail corrective actions taken. One commenter recommended CMS should support states in complying with this requirement through technical assistance and resources.

Response: We believe that the transparency of information provisions related to the quality and delivery of services to beneficiaries through a

managed care delivery system provided under the proposed regulations, and finalized in this rulemaking, provide the information which is critical to ensuring plan accountability and enabling consumers to make informed decisions about their health care, without imposing undue administrative burden on states. Specific to EQR results, § 438.364(a)(2)(iii) of the final rule requires that EQR technical reports include the validated performance measurement data for any performance measures or PIPs finalized under § 438.358(b)(1)(i) and (ii). Section 438.364(b)(2) of the proposed rule, finalized as § 438.364(c)(2)(i), requires that EQR technical reports be posted on the state's Web site by April 30th of each year. Under the proposed rule, and finalized in this rule-making, the annual EQR technical report will include information from the new EQR-related activity of network adequacy validations (finalized as § 438.358(b)(1)(iv)).

There are additional provisions intended to improve transparency outside of the EQR process being finalized with this rulemaking, including a requirement that states operate a Web site (§ 438.10(b)(3)) which will include, at a minimum: The enrollee handbook (§ 438.10(g)); the provider directory (§ 438.10(h)); network adequacy standards (§ 438.68(e)); plan accreditation status (§ 438.332 of the final rule); quality ratings for managed care plans (§ 438.334); managed care quality strategies (§ 438.340); and EQR technical reports (§ 438.364(c)). We believe that these items will ensure that the public has access to a state's quality standards, more robust quality measurement data, and information on network adequacy.

Regarding the recommendation that EQR technical reports include information concerning violations uncovered during the compliance review and any corrective actions taken, we note that in accordance with section 1932(c)(2)(A)(iii) of the Act, the Secretary, in consultation with the National Governors' Association (NGA), will contract with an independent quality review organization to develop and revise protocols to guide states and EQROs in conducting EQR. We will include a review of public comments to CMS-2350-P, including this section, in the next EQR protocol review and revision process, at which time we will consider this recommendation. We are therefore finalizing this section as proposed, with modifications described below.

Comment: A commenter recommended that states should retain the sole authority to determine the

methodology for comparative information about plans in the EQR technical report (§ 438.364(a)(4)) because the commenter believes states are in the best position to understand these variations across their managed care program and draw any meaningful comparisons between plans.

Response: We agree that states are in the best position to understand the variations across their managed care program(s) and have discretion in establishing standards for performance beyond the minimum standards identified in the final rule. However, to assure a consistent approach to comparing plans, CMS, working in conjunction with the NGA as prescribed in section 1932(c)(2)(A)(iii) of the Act, will develop protocols for the methodology. CMS will assess options for state flexibility in comparative reporting during the EQR protocol review and revision that will follow this rulemaking. We are revising proposed § 438.364(a)(4), redesignated at paragraph (a)(5) in the final rule, to reflect that the methodology for plan comparison will be included in the EQR protocols developed in accordance with § 438.352.

Comment: A commenter stated they are concerned that only requiring plans to make the “findings on access and quality of care” available on request to interested parties, including enrollees/prospective enrollees, participating providers, and beneficiary advocacy groups does not provide adequate transparency.

Response: We agree with this commenter that only requiring plans to make the findings on access and quality of care available on request would be insufficient. However, proposed § 438.364(b) also requires states to post the most recent annual EQR technical report(s) on the state’s Web site no later than April 30th of each year. Additionally, individuals can request this information from the state, and the state shall make the information available upon request, including in alternative formats for persons with disabilities. We are finalizing these requirements as § 438.364(c)(2).

Comment: A commenter opposed the proposed changes to § 438.364, believing that they were redundant with state requirements to post the state’s quality improvement strategy on its Web site, including evaluation results for both performance measures and PIPs. In addition, the commenter stated stakeholders and consumers are far more likely to access the state quality strategy than the technical report.

Response: The commenter has misinterpreted the proposed rule. While

the quality strategy and EQR both will be publicly posted online, each serve a distinct purpose. The state quality strategy will set forth a blueprint for state goals, objectives, and quality measurement approaches to improve care delivery and health outcomes for Medicaid beneficiaries; the EQR technical report(s) provide analysis and public reporting of quality, timeliness, and access to care for contracted MCOs, PIHPs, PAHPs, and PCCM entities described in § 438.310(c)(2).

After consideration of the public comments, we are finalizing this section with modification to reflect the application of EQR per § 438.350 to PCCM entities described in § 438.310(c)(2) and with nonsubstantive modification to improve clarity.

(p) Federal Financial Participation (§ 438.370)

This section sets forth the matching rates for expenditures for EQR, including the production of EQR results and the conduct of EQR-related activities when performed by a qualified EQRO or other entity. In the proposed rule, we proposed to revise the regulations to reflect the fact that the enhanced 75 percent EQR match rate provided for under section 1903(a)(3)(C)(ii) of the Act is only authorized for reviews conducted under section 1932(c)(2) of the Act. Section 1932(c)(2) of the Act provides that each contract under section 1903(m) with a Medicaid MCO must provide for EQR conducted by a qualified independent entity. PIHPs do not have contracts under section 1903(m) of the Act. Thus, the statute does not provide a basis for paying the 75 percent match rate for EQR conducted in connection with these entities.

In the 2003 final rule, we used the authority of section 1902(a)(4) of the Act to extend EQR to PIHPs. We determined that, because we were extending the performance of EQR under section 1932(c)(2) of the Act to PIHPs, such review could be considered to be performed “under” section 1932(c)(2) of the Act, even though it was not “required” by section 1932(c)(2) of the Act itself for purposes of qualifying for the enhanced federal match rate of 75 percent. In re-examining this issue in connection with this rulemaking, we believe that, in context, “under section 1932(c)(2),” as used in section 1903(a)(3)(C)(ii) of the Act, means review performed “under to” that provision, (that is, review required by that provision). Because that provision by its clear terms provides for and requires review only for MCOs that contract under section 1903(m) of the

Act, we proposed in paragraph (a) that only EQR or EQR-related activities performed by EQROs for MCOs with contracts under section 1903(m) of the Act are eligible for the 75 percent match.

In paragraph (b), we proposed clarifying that EQR and EQR-related activities performed on entities other than MCOs (including PIHPs, PAHPs, primary care case management arrangements, or other types of integrated care models) would be eligible for a 50 percent administrative match, regardless of what type of entity performs the review (that is, the state, its agent that is not an MCO, PIHP, or PAHP, or an EQRO).

Finally, in paragraph (c), we proposed that states submit their EQRO contracts to CMS prior to claiming the 75 percent match. Although section 1932(c)(2) of the Act does not require review and approval by CMS of EQRO contracts, we believe the reason for doing so remains the same as it is today—to allow CMS to determine if the EQRO contract complies with the EQR-related provisions of this rule (for example, by confirming that contracting entities meet the standards set forth in § 438.354 for qualified EQROs), and, if so, which activities under the contract are eligible for the 75 percent match.

We received the following comments in response to our proposal to revise § 438.370.

Comment: Several commenters disagreed with CMS’ statutory interpretation and recommended that CMS continue to allow PIHPs to be eligible for the 75 percent FFP match rate. Commenters stated that the extension of enhanced FFP match rate for PIHPs has been uncontroversial for more than a decade, and that CMS used authority under section 1902(a)(4) of the Act elsewhere in the proposed regulation to implement methods of administration necessary for the proper and efficient operation of the plan.

One commenter stated that what the commenter called our “narrow reading” of section 1903(a)(3)(C)(ii) of the Act to only include those contracts “required” by section 1932(c)(2) of the Act, is not compelled by the statute, but is “an arbitrary change of policy.” The commenter stated that EQR of PIHPs could be construed to be provided for under section 1932(c)(2) of the Act because this section requires each contract “under section 1903(m)” with a Medicaid MCO to provide for annual external independent review, and while PIHPs do not enter into contracts that are subject to the contract requirements in section 1903(m)(2)(A) of the Act, they likely do meet the broad definition of

“MCO” in section 1903(m)(1) of the Act, and their contracts thus could be considered to be “contracts under section 1903(m)” for purposes of review being deemed to be under section 1932(c)(2) of the Act, and thus for purposes of the availability of a 75 percent match rate under section 1903(a)(3)(C)(ii) of the Act. The commenter went on to state that, while PIHPs are not required to comply with the requirements in section 1903(m)(2)(A) of the Act that apply to comprehensive risk contracts as defined in that section, the commenter erroneously believed that PIHPs would be subject to the reporting requirements in section 1903(m)(4) of the Act and to the sanctions under section 1903(m)(5) of the Act, and they thus in this sense also would be contracts “under section 1903(m).” The commenter correctly noted that CMS, through its regulations, applies all the same EQR requirements for PIHPs as for the entities designated as MCOs in its regulations but erroneously stated that CMS’ authority to apply these requirements was derived from the authority provided in section 1903(m) and 1932(c)(2) of the Act. The commenter stated that CMS, in the commenter’s view, lacks authority to not apply those requirements to PIHPs that do not meet the statutory definition of an MCO. The commenter recommended that CMS clarify that the enhanced matching rate for EQR is available to both the entities it designates by regulation as MCOs and PIHPs, under the authority specified in sections 1932(c)(2), 1903(m) and 1903(a)(3)(C)(ii) of the Act.

Others stated on fairness grounds that all entities subject to EQR, including PIHPs, PAHPs and PCCM entities, should be eligible for the 75 percent FFP match rate. These commenters noted that it appears contradictory to expand EQR to PAHPs and PCCM entities while not providing the enhanced FFP match rate for EQR review of these entities. Two commenters recommended that CMS either apply the 75 percent match rate for all entities subject to EQR or eliminate the requirement to review PIHPs and the proposed requirement to review PAHPs in the same manner. Commenters noted that the implications of this proposed policy change would be substantial and stated that an enhanced match rate would support States in conducting the variety of new quality requirements proposed in this regulation.

Response: While we believe that EQR review of PIHPs and PAHPs is an important part of states’ quality oversight and improvement programs, after reviewing the comments and the

legal rationale, we continue to believe that the 75 percent matching rate under section 1903(a)(3)(C)(ii) of the Act can only reasonably be interpreted to be authorized in the case of review of an MCO that has a contract that complies with the requirements in section 1903(m)(2)(A) of the Act. While it is true that PIHPs would likely technically meet the definition of MCO in section 1903(m)(1) of the Act, this does not make a PIHP contract a “contract under” section 1903(m) of the Act. Meeting the definition of MCO is only one of the several requirements that applies to a section 1903(m) of the Act contract (see section 1903(m)(2)(A)(i) of the Act). Contracts with PIHPs are not in any sense entered into “under” section 1903(m) of the Act, but as noted above, and in the preamble to the 2003 rule extending the EQR requirement to PIHPs, under regulations implementing authority in section 1902(a)(4) of the Act. As noted above, it is also incorrect that PIHPs are subject to the requirements in section 1903(m)(4) and (5) of the Act, because paragraph (m)(4) applies only to an MCO, which we have always defined in regulations as an entity subject to section 1903(m)(2)(A) requirements, and paragraph (m)(5) only applies to a contract “under this section” (that is, subject to the requirements in section 1903(m)(2)(A) of the Act).

Comment: Several commenters stated that CMS should provide the 75 percent match rate for EQR activities of FFS Medicaid, in addition to all managed care programs. One commenter noted that this would align with other quality requirements in the proposed regulation that encompass all Medicaid delivery systems.

Response: The 75 percent match rates authorized in section 1903(a)(3)(C)(ii) of the Act applies only to the independent external reviews conducted under section 1932(c)(2) of the Act, which does not address reviews of FFS delivery systems. Further, we are not requiring states to conduct EQRs of FFS delivery systems under the final rule. We note that we are not requiring any specific quality assurance or improvement activities for FFS under this final rule, as we are withdrawing the proposed comprehensive quality strategy (§§ 431.500–431.506 of the proposed rule). Accordingly, costs associated with a voluntary EQR of FFS delivery systems will be matched at the regular 50 percent administrative match.

Comment: One commenter requested that CMS clarify which EQR activities will be eligible for the matching funds.

Response: All EQR-related activities described in § 438.358 are eligible for

the 75 percent match rate provided that they are conducted on an MCO by an EQRO which satisfies the requirements of § 438.354. The production of the EQR technical report, as described in § 438.364, for the EQR of MCOs is also eligible for the 75 percent match rate described in § 438.370(a). EQR-related activities conducted on entities other than MCOs, or by an entity which does not satisfy the requirements of § 438.354 are eligible for the 50 percent match rate described in § 438.370(b).

Comment: One commenter requested that CMS clarify the FMAP rate for EQR and EQR-related activities performed on PCCM entities.

Response: The EQR (including EQR-related activities and the production of EQR results) of PCCM entities (described in § 438.310(c)(2)) is eligible for the 50 percent match rate described in § 438.370(b).

Comment: Given the proposed requirement to develop a comprehensive quality strategy for all Medicaid beneficiaries, one commenter recommended that the same FFP that is provided for EQRO activities should be applied to quality management reviews for populations outside of managed care.

Response: Per section 1903(a)(3)(C)(ii) of the Act, only independent external reviews conducted under section 1932(c)(2) of the Act are eligible for the 75 percent match rate; the quality strategy is not a component of the independent EQR. Quality strategy expenditures are eligible for the 50 percent administrative match rate.

Comment: One commenter recommended that prior to finalizing the regulations regarding EQR, CMS should solicit input from all states regarding this regulatory provision.

Response: We agree that CMS should solicit input from states regarding this statutory provision, and have done so through the **Federal Register** notice and public comment period. The proposed rule was published in the **Federal Register** on June 1, 2015; the public comment period closed on July 27, 2015.

Comment: One commenter noted CMS’ proposal that states submit their EQRO contracts to CMS prior to claiming the 75 percent match and commented that they already do this.

Response: We understand and appreciate that many states already work closely with CMS regarding their EQRO contracts, and submit these contracts to CMS for review prior to claiming the 75 percent match rate. While the current regulation text does not expressly require CMS approval of these contracts, EQRO contracts have

been subject to CMS review under the authority of the Secretary to ensure compliance with the statute, to determine if they satisfy the requirements for the 75 percent match rate. This addition of § 438.370(c) will formalize the EQRO contract review process, in a manner consistent with current policy and practice.

After consideration of the public comments, we are finalizing this section without modification. In addition, we are making a technical conforming change to § 433.15(b)(10) to cross-reference § 438.370(a) of this chapter (75 percent) and § 438.370(b) (50 percent).

c. State Monitoring Standards (§ 438.66)

In the proposed rule, we relied on the authority in section 1902(a)(4) of the Act to establish methods of administration for the proper and effective operation of the state plan to strengthen our state monitoring standards at § 438.66, noting that many of these practices are already employed by states. We also proposed a minor change in the title of this regulation section to clarify that the monitoring required here is a state activity.

In paragraph (a), we proposed that the state have a monitoring system for all of its managed care programs, using the term monitoring to include oversight responsibilities. In paragraph (b), we proposed that the state's monitoring system address, at a minimum, specific aspects of the managed care program that include: Administration and management; appeal and grievance systems; claims management; enrollee materials and customer services; finance, including MLR reporting; information systems, including encounter data reporting; marketing; medical management, including utilization management; program integrity; provider network management; quality improvement; the delivery of LTSS; and other items of the contract as appropriate. We noted that research has highlighted these program areas as critical for state success.

In § 438.66(c), we proposed that states use data collected from its monitoring activities to improve the performance of its managed care program. While we expect that many states already take this approach, our proposal would set out a baseline standard for all managed care programs. We also provided a list of activities for which data should be used for performance improvement. This list encompassed the areas that we believe are fundamental to every managed care program and for which data is readily available. We did not propose an exhaustive list in § 438.66(c) of the performance areas about which data

may be used in improvement efforts to provide flexibility for the state to collect and use additional data they find useful and pertinent for its program.

In § 438.66(d), we proposed to establish a new standard for states to conduct readiness reviews of MCOs, PIHPs, PAHPs and PCCM entities prior to the effective date of new or modified managed care programs, although experience has shown that states employ this practice today. As proposed in paragraph (d)(1)(i) through (v), readiness reviews would have to be conducted: Prior to the start of a new managed care program; when a new contractor enters an existing program; or, when the state adds new benefits, populations or geographic areas to the scope of its contracted managed care plans. We proposed in paragraph (d)(2)(i) and (ii) that these readiness reviews would have to commence at least 3 months before the state implements any of those program changes, so that states ensure that critical MCO functions are operational far enough in advance for successful implementation. In paragraph (d)(2)(iii), we proposed that the results of those readiness reviews would have to be submitted to us to enable us to determine if the contract or contract amendment is approved, which would permit both CMS and the state to review the findings, discuss any possible issues, and arrive at a mutual understanding of expectations. In paragraph (d)(3), we proposed that the readiness reviews would consist of both a desk review of documents and an on-site visit that includes (at a minimum) interviews with staff and leadership that manage key operational areas. We did not propose to define the key operational areas but noted that we plan to rely on states to reasonably identify those areas in light of the areas which are identified in proposed paragraph (d)(4). Finally, we proposed in paragraph (d)(4) to require four broad areas for inclusion in the readiness review and outline subcomponents within each area. The broad areas include: (1) Operations and administration; (2) service delivery; (3) financial management; and (4) systems management.

We noted that these standards reflect our current guidance. For example, our guidance for MLTSS programs under section 1915(b) waivers and section 1115(a) demonstration projects set forth MCO readiness to implement LTSS as a key element under adequate planning; likewise under Special Terms and Conditions for new or expanding managed care programs under these waiver and demonstration authorities,

states conduct readiness reviews of their contracted managed care plans. Additionally, managed care plans participating in the Capitated Financial Alignment Demonstration have to undergo an extensive readiness review process before the enrollment of dual-eligible beneficiaries will be permitted.

Finally, to address the fragmented program information we currently receive about states' managed care programs and to help improve our oversight efforts, we proposed in § 438.66(e) that states provide an annual program assessment report to us. In this proposal, states would have to submit these to us no later than 150 days after the end of the managed care plan's period of performance. We requested comment on whether 150 days is enough time after the end of a program year for the state to provide the type of information we proposed. In paragraph (e)(1), we proposed flexibility for states which already have to provide an annual report under section 1115(a) demonstrations to submit that report for this purpose if the information in the annual report is duplicative of the information specified here.

In proposed paragraph (e)(2), we identified the areas on which information and an assessment would have to be submitted by the state in the report. We proposed that the report include information about, and assessments of eight specific areas of the managed care program detailed in paragraph (e)(2). We took the opportunity to emphasize that states providing LTSS through managed care plans would also have to include areas specific to MLTSS in this assessment noting these could include alignment of payment rates and incentives/penalties with the goals of the program, any activities the managed care plans have undertaken to further the state's rebalancing efforts, and the satisfaction of enrollees with their service planners. In paragraph (e)(3), we also proposed that this annual program assessment would have to be posted publicly and provided to the Medical Care Advisory Committee and, if applicable the LTSS stakeholder group specified in § 438.70.

We received the following comments in response to our proposal to revise § 438.66.

Comment: Many commenters supported the new standards for a state's monitoring system at § 438.66(b). Several commenters noted that CMS will need to release sub-regulatory guidance following the final rule to further assist states with implementing the new areas of state monitoring. Several commenters also recommended that CMS provide ongoing technical

assistance to states regarding the new areas for state monitoring to ensure the highest level of quality care for enrollees.

Response: We thank commenters for their support of § 438.66(b). We understand commenters' concerns regarding additional CMS guidance and will be available to offer states technical assistance regarding any of the new areas of state monitoring and performance. After the publication of the final rule, we will assess the appropriate areas where additional CMS subregulatory guidance may be needed.

Comment: Many commenters supported the areas of state monitoring identified at § 438.66(b)(1) through (14) but recommended additional areas. In total, commenters recommended more than 20 new areas of monitoring that states should be required to address in the monitoring system, such as state monitoring related to specific areas of access to care or state monitoring related to specific types of care.

Response: We appreciate the thoroughness of commenters' recommendations regarding areas for state monitoring. However, we decline to add additional mandatory areas of monitoring for states to address in their state's monitoring system. We believe that the current list at § 438.66(b)(1) through (14) is comprehensive and includes areas related to provider network management and availability and accessibility of services. We also believe that the current standard at § 438.66(b)(14) is clear that all other provisions of the contract, as appropriate, should be included in the state's monitoring system. We also note that states will have the ability to expand their monitoring systems beyond the current list specified to account for state-specific issues. Therefore, we do not believe it is necessary to add new areas to the list at § 438.66(b).

Comment: A few commenters stated that the new requirements at § 438.66(b) were too burdensome on states and included duplicative reporting areas. Commenters recommended that CMS remove § 438.66(b) or reduce the number of areas that require state monitoring.

Response: We disagree with commenters and decline to remove § 438.66(b) from the regulatory text. We believe that states should have robust and comprehensive state monitoring systems that are inclusive of the requirements found at § 438.66(b)(1) through (14). The areas specified in § 438.66(b) represent the minimum core aspects of a managed care program that a state needs to monitor both as the

direct contractor with the managed care plan and the agency charged with administering the Medicaid program.

Comment: Many commenters recommended that CMS include specific requirements at § 438.66(b) for states to monitor provider rates and the timeliness and accuracy of paid claims.

Response: We believe that state monitoring of the timeliness and accuracy of paid claims is included at § 438.66(b)(3) related to claims management. We decline to add specific state monitoring requirements regarding provider rates in this section, as this does not fit our general approach at § 438.66(b). We have included the adequacy of provider rates in the requirements at § 438.4(b)(3) for actuarial soundness.

Comment: Several commenters recommended that CMS include at § 438.66(b)(4) specific state monitoring requirements regarding the activities of the beneficiary support system described at § 438.71.

Response: We agree with commenters that we should clarify that the activities of the beneficiary support system are included at § 438.66(b)(4), as we believe that these activities are an extension of enrollee customer service. We believe this clarification to the regulatory text is important since the beneficiary support system at § 438.71 is a new requirement, and we want to ensure that states include its performance in the state's monitoring system. To be consistent with the addition at paragraph (b)(4), we will also include the performance of the beneficiary support system at § 438.66(c)(11) to ensure that the state is using the data collected to improve the effectiveness and performance of the beneficiary support system appropriately. We are modifying the regulatory text to adopt this recommendation accordingly.

Comment: Several commenters recommended that CMS include at § 438.66(b)(10) specific state monitoring requirements regarding the provider directories described at § 438.10(h).

Response: We agree with commenters that we should clarify that provider directories are included at § 438.66(b)(10), as we believe that provider directories are an extension of provider network management. We believe this clarification to the regulatory text is important since the provider directory requirements at § 438.10(h) are new, and we want to ensure that states include these new requirements in the state's monitoring system. We are modifying the regulatory text to adopt this recommendation.

Comment: Many commenters recommended that CMS include at

§ 438.66(b)(11) specific state monitoring requirements regarding the network adequacy standards described at § 438.68. Several commenters also recommended that CMS include specific references to § 438.206 and § 438.207 regarding availability and accessibility.

Response: We agree with commenters that § 438.66(b)(11) should be clarified by adding network adequacy standards, as we believe these standards are an extension of the availability and accessibility requirements already listed. We believe this clarification to the regulatory text is important since the network adequacy standards at § 438.68 are new, and we want to ensure that states include these new standards in the state's monitoring system. We are modifying the regulatory text to adopt this recommendation. However, we decline to include specific references to §§ 438.206 and 438.207, as such references are unnecessary and not consistent with the format of this section. We believe it is clear that the requirement to monitor the availability and accessibility of services is inclusive of the requirements at §§ 438.206 and 438.207.

Comment: Several commenters recommended that CMS include more specificity at § 438.66(b)(13) regarding LTSS programs.

Response: We disagree with commenters that additional specificity is needed at § 438.66(b)(13) regarding LTSS programs. We have provided a comprehensive mandatory list of state monitoring areas at paragraphs (b)(1) through (12), that we believe apply to both LTSS and non-LTSS programs. We give states the flexibility to include additional areas of state monitoring specific to LTSS programs at paragraph (b)(13), as appropriate. We believe this flexibility should be retained to accommodate the varying scopes of LTSS programs and populations served.

Comment: Several commenters recommended that CMS include specific requirements for states to provide quarterly updates to provider, consumer, or other stakeholder groups. Several commenters recommended that CMS include requirements for states to involve their Medical Care Advisory Committee or the LTSS stakeholder group described at § 438.70 in their state monitoring systems. Other commenters recommended that CMS require states to post public notice regarding their state monitoring systems. Commenters also recommended that CMS include a public comment period for state monitoring systems.

Response: We require states to deliver their managed care program assessment

reports to both the Medical Care Advisory Committee and the LTSS stakeholder group at § 438.66(e)(3)(ii) and (iii). We believe this meets commenters' recommendations to involve such groups in the state monitoring process. We decline to add requirements that states update these groups on a quarterly basis, as we find this recommendation to be too prescriptive. While we encourage states to include and update such stakeholder groups as often as feasible, this standard should ultimately be left to state discretion. We also decline to add specific public notice and public comment requirements, as it is unclear to us why this would be beneficial. States are required to monitor all provisions of their contracts, as appropriate. These state monitoring requirements do not require specific public notice or public comment periods, as the final report described at § 438.66(e) will be public and posted on the state Medicaid Web site, as specified at § 438.66(e)(3)(i).

Comment: One commenter recommended that CMS include a specific requirement for states to maintain a minimum ratio of state staff to enrollees to strengthen contract oversight and state monitoring.

Response: We disagree with the commenter and decline to adopt a requirement for states to maintain a minimum ratio of state staff to enrollees. We find this recommendation to be overly prescriptive, as states need the flexibility to monitor their programs in the most efficient and effective manner. States must weigh a variety of internal and operational considerations when determining the appropriate number of state staff dedicated to state monitoring and contract oversight.

Comment: Several commenters recommended that CMS add specific standards under each state monitoring area to ensure that states are implementing meaningful and effective state monitoring systems. One commenter recommended that CMS add more specificity regarding PCCM entity requirements, as PCCM entities do not perform activities related to all of the areas listed at § 438.66(b).

Response: We disagree with commenters and decline to add specific standards under each state monitoring area listed in paragraph (b), as we believe this would be overly prescriptive and not appropriate. While we believe in requiring states to implement and maintain a state monitoring system, states should retain the flexibility to determine the specific performance standards that are most meaningful and appropriate for their

respective programs. We also decline to add specificity regarding PCCM entities, as we included the appropriate regulatory text at § 438.66(b) to specify that state systems must address all aspects of the managed care program, including the performance of each PCCM entity (if applicable) in at least the areas listed. If PCCM entities do not perform activities related to all of the areas listed, we would not expect the state to include such areas in their managed care state monitoring system.

Comment: Several commenters recommended that CMS include requirements at § 438.66(c) for states to provide the data collected from its monitoring activities to the Medical Care Advisory Committee and LTSS stakeholder group described at § 438.70 on a quarterly basis. A few commenters also recommended that states collect data from stakeholder groups to improve performance. A few commenters recommended that CMS include requirements to collect data from the state DUR board and specific DUR activities. A few commenters also recommended that CMS clarify that all data collected from a state's monitoring activities should be posted publicly to improve transparency.

Response: We disagree with commenters that CMS should include requirements at § 438.66(c) for states to provide the data collected from state monitoring activities to the Medical Care Advisory Committee or the LTSS stakeholder group on a quarterly basis. We already require states to deliver their annual managed care program assessment reports to both the Medical Care Advisory Committee and the LTSS stakeholder group at § 438.66(e)(3)(ii) and (iii). We believe this is the appropriate requirement, and states will have the authority to provide additional data updates as feasible. We also decline to add requirements for states to collect data from stakeholder groups; if the state wants to collect qualitative data from such groups, they have the option to do so, under state law. In addition, we do not believe we need to include requirements for states to collect data from their DUR board and DUR activities, as we believe this is already appropriately included at § 438.66(b)(8). States have the ability to use DUR data as appropriate and meaningful to improve the performance of their managed care programs. We also disagree with commenters that all data collected should be posted publicly. While we believe in transparency, not all data collected would be appropriate for public posting. Instead in this final rule, we have required that states post their final managed care program

assessment report described at § 438.66(e) on the state Medicaid Web site for public access, as specified at § 438.66(e)(3)(i).

Comment: One commenter recommended that CMS remove § 438.66(c)(2) and (3) regarding member grievance and appeal logs and provider complaint and appeal logs, as it is not appropriate for managed care plans to provide these logs to the state. The commenter recommended that CMS include summary data instead.

Response: We disagree with the commenter that member grievance and appeal logs and provider complaint and appeal logs should be withheld from the state. We believe that states should require these logs as part of their state monitoring system. We do not believe that summary data is a sufficient substitute for the actual logs, as there may be additional details available to the state in the logs that is not present in the summary data to support sufficient oversight of the managed care plans. We further believe that member grievance and appeal logs and provider complaint and appeal logs can provide states with valuable information about potential problems that would warrant additional investigation. We are aware that many states use the various logs to identify potential problems with network adequacy, timely access to care, gaps in care coordination, and ineffective utilization management. The other advantage of these logs is that they serve as a real-time feedback system for monitoring program activity. We encourage states and managed care plans to collaborate in making the member grievance and appeal logs and provider complaint and appeal logs as useful as possible for early identification of potential problems, including ensuring that data collected is structured to facilitate review and analysis.

Comment: Several commenters recommended additional requirements for CMS to include that would require states to use data collected from monitoring activities at § 438.66(c), including provider satisfaction surveys, direct testing of network adequacy standards, assessments related to care experience, and specific LTSS outcomes, such as quality of life indicators.

Response: We appreciate commenters' recommendations at § 438.66(c). We agree with commenters that provider satisfaction surveys could be included and are modifying the regulatory text to add "or provider" after "enrollee" at § 438.66(c)(5) so that states use data collected from the results of any enrollee or provider satisfaction survey.

While we decline to include direct testing of network adequacy standards in § 438.66(c), we note that we are finalizing the mandatory EQR-related activity of network adequacy validation at § 438.358(b)(1)(iv) of this rule. While the specifics of this activity will be identified in a new EQR protocol, this activity will provide additional review of a state's network adequacy standards. States have the flexibility to conduct direct testing or other appropriate methods to monitor network adequacy. To the extent that states are assessing network adequacy and availability of care using direct testing methods, we anticipate that the results of such testing would be included in the annual report, which addresses the availability and accessibility of covered services. We believe that assessments related to care experience is adequately included at § 438.66(c)(5) regarding enrollee satisfaction surveys. We also decline to add specific LTSS outcomes, such as quality of life indicators, as we believe this should be left to state discretion depending on the scope of the LTSS program and the populations served.

Comment: Many commenters raised concerns and points in opposition to proposed § 438.66(d)(1) related to the requirement for states to assess the readiness of each managed care plan and recommended that CMS make appropriate revisions to reduce uncertainty, excessive state burden, and excessive costs. Specifically, many commenters found the criteria listed at paragraphs (d)(1)(i) through (v) to be excessively burdensome on states and recommended that CMS consider the scope of changes in a managed care program before requiring a comprehensive readiness review. Many commenters stated that minor and frequent program changes are common, such as minor eligibility or benefits changes, and recommended that CMS revise the readiness review requirements to accommodate such minor program changes. Several commenters also recommended that CMS remove the new geographic requirement at paragraph (d)(1)(v), as it is also common for managed care plans to add a county to their service area, and such a change should not trigger a comprehensive readiness review. In addition, many commenters recommended that states be allowed the flexibility to determine the frequency of the readiness review, the events that would trigger a readiness review, and the exact timing of such readiness reviews.

Several commenters also suggested that CMS remove these requirements entirely, as states should determine the

best approach regarding readiness reviews without federal intervention. Several commenters recommended that CMS allow an exemption for mature managed care programs and only enforce paragraph (d)(1) on new managed care programs. A few commenters recommended that CMS phase in the readiness review requirements to ensure states have the budget and staff to accommodate the new federal standards. Finally, a few commenters supported paragraph (d)(1) as proposed and stated that such standards would prevent states from fast tracking the implementation of managed care programs without ensuring a comprehensive review process.

Response: We appreciate the commenters' concerns and recommendations and agree that CMS should reconsider § 438.66(d)(1) as currently proposed. While we disagree with commenters that we should remove paragraph (d)(1) in its entirety, we agree that paragraph (d)(1)(iv) and (v) should be removed from the regulatory text to reduce burden and allow state flexibility to consider whether the addition of new benefits or the expansion of coverage to new geographic areas should trigger a comprehensive readiness review. We agree with commenters that such program changes may be minor or infrequent and that states are in the best position to determine the impact and scope of such changes. We are modifying the regulatory text to adopt these recommendations.

However, we believe that paragraphs (d)(1)(i) through (iii) should be finalized as proposed, as we believe it is necessary for states to assess the readiness of each managed care plan when the state is implementing a new managed care program, when the managed care plan has not previously contracted with the state, or when the managed care plan will be providing or arranging for the provision of covered benefits to new eligibility groups. We believe that all three of these scenarios represent major changes to a state's Medicaid program and believe that states should assess the readiness of each managed care plan accordingly. We clarify here that new eligibility groups does not include minor changes in program eligibility as a result of ongoing program maintenance. The intent of paragraph (d)(1)(iii) is to trigger a comprehensive readiness review when a new and distinct eligibility group is being added to the managed care plan. We decline to adopt commenters' recommendation to add an exemption from paragraph (d)(1) for mature managed care programs, as we do not

believe that such an exemption would be appropriate given the removal of paragraphs (d)(1)(iv) and (v).

Comment: Many commenters recommended revisions at § 438.66(d)(2)(i) regarding the timeframe for the readiness review to be conducted at least 3 months prior to the implementation date. Several commenters recommended that CMS allow state flexibility on the appropriate amount of time needed to complete a readiness review prior to the change described at paragraph (d)(1). Another commenter recommended that CMS revise the 3-month requirement to 15 working days. One commenter recommended that CMS revise the 3-month requirement to 3 weeks. A few other commenters recommended that CMS revise the 3-month requirement to 180 calendar days. Several other commenters recommended that CMS clarify whether the readiness review has to be completed or started 3 months prior to the change described at paragraph (d)(1). One commenter recommended that CMS establish an exceptions process for the 3-month timeframe when extenuating circumstances occur, such as the withdrawal of a managed care plan.

Response: We appreciate the opportunity to clarify the requirement at § 438.66(d)(2)(i). We clarify that the state must start the readiness review at least 3 months prior to the effective date of the event described at paragraph (d)(1). However, there is no requirement that the readiness review be completed 3 months prior to the event described at paragraph (d)(1). We encourage states to complete the readiness review as soon as feasible but recognize the challenge of completing all elements of the readiness review, especially onsite reviews. States must ensure that the readiness review is completed in sufficient time to resolve or mitigate problems identified through the readiness review to ensure smooth implementation as described at paragraph (d)(2)(ii). We decline all commenters' recommendations to either lengthen or shorten the 3-month timeframe, as we believe it is the appropriate amount of time for states to begin their readiness review activities. While we decline to add an exceptions process for extenuating circumstances, we are available to provide technical assistance and intend to work closely with states when such circumstances occur, such as the withdrawal of a managed care plan.

Comment: Many commenters disagreed with § 438.66(d)(2)(iii) regarding the readiness review submission to CMS for CMS to make a

determination regarding the contract or contract amendment approval under § 438.3. Commenters recommended that CMS remove the readiness review contingency for contract approval, as many commenters stated concerns regarding CMS delays and CMS capacity to review and approve such readiness reviews. One commenter recommended that CMS specify the exact readiness review documentation needed by CMS to approve the contract. Several commenters recommended that CMS add timeframes regarding CMS approval. Specifically, several commenters recommended that CMS approve such readiness reviews within 30 calendar days of receipt. One commenter recommended that CMS revise the reference from § 438.3 to § 438.3(a) to add more specificity.

Response: We appreciate the thoroughness of commenters' recommendations but decline to revise the requirements at § 438.66(d)(2)(iii). While we understand commenters' concerns regarding the timing of contract approval, we believe that the CMS review of state readiness review documentation will assist us with approving the contract or contract amendment. We decline to specify the exact readiness review documentation needed, as this could vary greatly depending on the event described at § 438.66(d)(1). We also decline to add timeframe requirements for CMS review and approval of state readiness review documentation. The readiness of managed care plans to meet the assurances required under the contract and federal regulations are an integral source of information to support approval of the contract. The provisions at § 438.66(d)(2)(i) through (iii) require the state to start this process in a sufficient amount of time for the state to have sufficient assurances from the plan, and thereby, provide sufficient assurances to CMS that the contractors are able to meet their obligations under the contract. Finally, we agree with the commenter that we should revise the reference from § 438.3 to § 438.3(a) to add more specificity regarding contract approval. We are modifying the regulatory text to adopt this recommendation.

Comment: Several commenters recommended that CMS revise § 438.66(d)(3) to add more specificity regarding onsite reviews. Several commenters recommended that CMS require states to interview advocacy groups, stakeholder groups, and consumers when conducting onsite reviews. A few commenters recommended that onsite reviews be made optional to reduce administrative

burden on both states and managed care plans.

Response: We disagree with commenters that we should add a requirement at § 438.66(d)(3) to require states to interview advocacy groups, stakeholder groups, and consumers when conducting onsite reviews. It is not entirely clear to us what value this would add regarding the readiness of managed care plans. While we encourage both states and managed care plans to work with and involve advocacy groups, stakeholder groups, and consumers when designing and implementing their managed care programs, we do not believe that we should add a requirement for states to interview such groups as part of the onsite readiness review. We have reevaluated the requirement for onsite reviews and have determined that onsite reviews for events described at paragraph (d)(1)(iii), regarding new eligibility groups, should be optional and at the state's discretion. However, we believe that onsite reviews should remain a requirement for events described at paragraphs (d)(1)(i) and (ii), when the state is implementing a new managed care program or when the managed care plan has not previously contracted with the state. We are modifying the regulatory text to adopt this recommendation.

Comment: Many commenters recommended that CMS allow states complete discretion at § 438.66(d)(4) to decide which criteria a state's readiness review should include, or states should only be required to include the criteria that are directly impacted by the change described at paragraphs (d)(1). A few commenters recommended that CMS include requirements for states to review the operations of the managed care plan's DUR board and the member advisory committee. One commenter also recommended that CMS include requirements for states to review the managed care plan's claims processing system.

Response: We appreciate commenters' recommendations but disagree that § 438.66(d)(4) should be left only to state discretion. While we believe that states will have the expertise to appropriately review each area specified at § 438.66(d)(4), we believe it is necessary for states to review, at a minimum, the areas specified to ensure the managed care plan is adequately prepared to meet the requirements and obligations specified in the contract. If a managed care plan is unable to perform any of the activities described in § 438.66(d)(4), there is a high likelihood that beneficiaries will not be able to receive the benefits and services

to which they are entitled. Ensuring that managed care plans are capable of meeting their obligations under the contract is not only good contract management; it is an essential component of protecting beneficiaries. We also decline to add specific requirements for states to review the operations of the managed care plan's DUR board and member advisory committee, as we believe such requirements are included at paragraph (d)(4)(i) for the member advisory committee and paragraph (d)(4)(ii) for the DUR board. Finally, we note that the review of a managed care plan's claims processing system is included at paragraph (d)(4)(iv).

Comment: A few commenters recommended that CMS include requirements at § 438.66(d) to include specific readiness review areas for LTSS programs, including state LTSS experience, alignment of rates and goals for the program, rebalancing efforts, and satisfaction of enrollees.

Response: We have included specific state monitoring requirements for LTSS programs at § 438.66(b)(13) and (c)(12). However, we do not believe it is necessary to include specific LTSS readiness review areas, as the current requirements specified at § 438.66(d) would apply to both LTSS and non-LTSS managed care programs. Many of the examples listed by commenters would be appropriately assessed at paragraphs (d)(4)(i) and (ii) regarding the operations, administration, and service delivery areas of the readiness review. We believe that states can appropriately tailor readiness review requirements at § 438.66(d) for managed LTSS programs and populations, as needed.

Comment: Many commenters opposed the requirement at § 438.66(e)(1) for states to submit a report on each managed care plan 150 days after each contract year. Several commenters recommended that CMS eliminate the report at paragraph (e)(1) in its entirety. Commenters stated that the report is duplicative of other CMS required reporting and would be very burdensome on states to prepare. One commenter recommended that CMS allow dashboard reporting instead of the annual report. Many commenters stated that 150 days was not enough time to prepare each report and recommended that CMS allow more time. Commenters recommended 180 days and 8 months as alternative timeframes. A few commenters recommended that CMS shorten the timeframe. Commenters recommended 30 days, 90 days, and 120 days as alternative proposals. Finally, one commenter recommended that CMS

reconsider the proposal for the reports to be an annual requirement and instead recommended that each report be completed once every 5 years.

Response: We disagree with commenters that we should eliminate the report at § 438.66(e)(1) in its entirety, as we believe the report will provide valuable and timely information on and an assessment of the operation of the managed care program in each state. We also believe that the annual report will improve transparency for consumers, providers, and other stakeholders interested in the operations of the managed care program. The contracts with managed care plans under the managed care program are some of the largest (financially) and most complex relationships for a state. We believe that the level of oversight required under this annual report is consistent with expectations for a business relationship of this scope and complexity. We note, as specified at final paragraph (e)(1)(ii) (proposed at paragraph (e)(1)), that annual reports submitted under the authority of section 1115(a) of the Act will be deemed to satisfy the annual report requirement. We also decline to allow dashboard reporting instead of an annual report, as it is unclear to us what dashboard reporting includes. To provide a consistent format across all programs, we believe the annual report is an appropriate requirement. To respond to commenters concerned about the amount of state burden to prepare and develop this report and to better clarify the timing of the requirements under this paragraph, we are finalizing regulatory text at paragraph (e)(1)(i) to include language that specifies that the initial report will be due after the contract year following the release of CMS guidance on the content and form of the report.

We agree with commenters' concerns that 150 days might not be enough time to collect the necessary data and produce the report on each managed care plan. Therefore, we will adopt commenters' recommendation to lengthen the amount of time states have to submit the annual managed care program assessment report to CMS from 150 days to 180 calendar days. We believe that by lengthening the amount of time states have to prepare each report, states will have access to cleaner, more accurate, and more complete data. We are modifying the regulatory text to adopt this recommendation. Finally, we decline to revise the annual report requirement in favor of a report submitted once every 5 years. This recommendation is not consistent with our general approach to improve state

monitoring requirements, nor is it consistent with the approach of CMS to generally require an annual report at the end of each program or contract year.

Comment: Many commenters recommended revisions at § 438.66(e)(2) regarding the areas of the managed care program assessment report. Several commenters recommended that CMS shorten the list at paragraphs (i) through (ix) to reduce state burden. Several commenters recommended that CMS lengthen the list to include all areas listed at § 438.66(b) and (c). One commenter specifically recommended that CMS remove paragraph (e)(2)(ii) related to including encounter data reporting by each managed care plan. The commenter stated that paragraph (e)(2)(ii) seemed to violate HIPAA regulations. Other commenters recommended that CMS include an assessment of the state's network adequacy standards, the beneficiary support system, and structures for engagement of consumers, providers, advocates, and other stakeholders.

Response: We disagree with commenters that we should shorten the list of areas that states must include in their annual managed care program assessment report for each managed care plan at § 438.66(e)(2). We carefully balanced all areas listed at § 438.66(b) and (c) and included what we believe to be the most appropriate and meaningful areas to include in an annual report. We also decline to remove paragraph (e)(2)(ii) regarding reporting of encounter data, as we disagree that this requirement violates any HIPAA regulations. We clarify that states must provide information on and an assessment of the operation of the managed care program on the areas listed at paragraph (e)(2). It is not our intention to require the publication of actual encounter data; rather, it is the intent of paragraph (e)(2)(ii) that states assess each managed care plan's performance in this area. As stated elsewhere, we believe that encounter data are the basis for any number of required activities, including rate setting, risk adjustment, quality measurement, value-based purchasing, program integrity, and policy development. CMS and states have engaged in many efforts to improve the quality, timeliness, and use of encounter data. This portion of the annual report provides the opportunity to report on the status of those evolving efforts.

We agree with commenters that states should include information on and an assessment of the state's beneficiary support system. We believe this is important to not only report on the activities of the beneficiary support

system, but we also believe that including the beneficiary support system will enhance and improve performance over time. To be consistent with our preamble discussion and regulatory text revisions at § 438.66(b)(4) and paragraph (c)(11), we are modifying the regulatory text at paragraph (e)(2) to include the beneficiary support system. We will designate the beneficiary support system at paragraph (e)(2)(ix) and move the current regulatory text at paragraph (e)(2)(ix) related to LTSS to paragraph (e)(2)(x).

Finally, we will clarify the current regulatory text at paragraph (e)(2)(vi) and include network adequacy standards, as we agree with commenters that network adequacy standards are an extension of the availability and accessibility of covered services. We are modifying the regulatory text to adopt this recommendation. We decline to add specific requirements for states to include structures for engagement of consumers, providers, advocates, and other stakeholders, as we find this to be a duplicative requirement. We have included requirements throughout part 438 to include stakeholder engagement, such as the LTSS stakeholder group required at § 438.70, the managed care plan's member advisory committee at § 438.110, and the requirement listed at § 438.66(e)(3) for states to provide the annual managed care program assessment report for each managed care plan to both the Medical Care Advisory Committee and the LTSS stakeholder group. We believe that structures for engagement of consumers, providers, advocates, and other stakeholders are appropriately included throughout part 438.

Comment: Many commenters supported and recommended revisions at § 438.66(e)(3). One commenter recommended that CMS remove the requirement to post the annual managed care program assessment report on the state's Medicaid Web site at § 438.66(e)(3)(i), as the information contained in the report would not promote or improve enrollee choice and could be misconstrued. Several commenters recommended that the annual report be posted for public comment before submission to CMS. A few commenters recommended that managed care plans be allowed to review the report before being posted on the state's Medicaid Web site. Finally, a few commenters recommended that the annual report be provided to the Medical Care Advisory Committee at paragraph (e)(3)(ii) and the LTSS stakeholder group at paragraph (e)(3)(iii)

before being posted on the state's Medicaid Web site.

Response: We disagree with the commenter that we should remove the requirement at § 438.66(e)(3)(i) to require the state to post the annual managed care program assessment report on the state's Medicaid Web site. We believe that the annual report should be posted publicly to improve transparency and allow enrollees, providers, and other stakeholders to assess the information contained in each managed care report. We clarify for commenters that the requirements at paragraph (e)(3) do not prohibit a state from posting the annual report for public comment. We encourage states to work with enrollees, providers, and other stakeholders to ensure that the report is meaningful and inclusive of stakeholder feedback. We also clarify for commenters that the requirements at paragraph (e)(3) do not prohibit a state from allowing the managed care plan to review the report before public posting. We expect that states and managed care plans will need to work together to ensure that each report is accurate and complete. Finally, we clarify for commenters that the requirements at paragraph (e)(3) do not prescribe the order of events in posting the annual report on the state's Medicaid Web site and providing the annual report to the Medical Care Advisory Committee and LTSS stakeholder group. We clarify here that states may provide the report to stakeholder groups prior to posting the report on the state's Medicaid Web site but it is not a requirement under this section.

After consideration of the public comments, we are modifying the regulatory text at § 438.66(b)(4) and § 438.66(c)(11) to include the activities and performance of the beneficiary support system in a state's monitoring system. We are also modifying the regulatory text at § 438.66(e)(2) to include the beneficiary support system in the state's annual managed care program assessment report. We will designate the beneficiary support system at § 438.66(e)(2)(ix) and move the regulatory text at § 438.66(b)(10) to include specific state monitoring requirements regarding provider directories. We are also modifying the regulatory text at § 438.66(b)(11) and § 438.66(e)(2)(vi) to clarify and include specific state monitoring requirements regarding network adequacy standards and to clarify that network adequacy standards must be included in the state's annual managed care program assessment report. We are modifying the regulatory text at § 438.66(c)(5) to add "or provider" after enrollee to clarify

that states should use data collected from the results of any enrollee or provider satisfaction survey.

We are modifying the regulatory text to remove § 438.66(d)(1)(iv) and (v) to reduce burden and allow state flexibility to consider whether the addition of new benefits or the expansion of coverage to new geographic areas should trigger a comprehensive readiness review. In addition, we are modifying the regulatory text at § 438.66(d)(2)(iii) to revise the reference from § 438.3 to § 438.3(a) to add more specificity regarding contract approval. We are also modifying the regulatory text at § 438.66(d)(3) to make onsite reviews for events described at § 438.66(d)(1)(iii), regarding new eligibility groups, optional and at the state's discretion. We are also modifying the regulatory text at § 438.66(d)(1)(iii) to correct a typo and change the word "provisions" to "provision."

Finally, we are modifying the regulatory text at § 438.66(e)(1) to lengthen the amount of time states have to submit the annual managed care program assessment report to CMS from 150 days to 180 calendar days. We are also finalizing regulatory text at § 438.66(e)(1)(i) to include language that specifies that the initial report will be due after the contract year following the release of CMS guidance on the content and form of the report. We will also finalize at § 438.66(e)(1)(ii) the regulatory language proposed at paragraph (e)(1) that specifies that annual reports submitted under the authority of section 1115(a) of the Act will be deemed to satisfy the annual report requirement. We are also finalizing a technical correction at paragraph (e)(2) for clarification regarding the areas of the program report. We are finalizing all other sections as proposed.

d. Information Requirements (§ 438.10)

In the preamble to the proposed rule, we described our concerns that current § 438.10 pertaining to information standards is not sufficiently clear or direct and does not reflect current technology advances that provide access to information more quickly and less expensively. For that reason, we proposed to replace the entire existing regulation section with a more organized and clear set of standards for beneficiary information. Electronic communications are becoming typical, and we proposed to explicitly permit both states and managed care plans to make beneficiary information available in electronic form, subject to certain standards. We noted that electronic information needs to be disseminated in

a manner compliant with Section 504 of the Rehabilitation Act. In addition, we indicated that providing for electronic information delivery would further our goal of aligning Medicaid managed care beneficiary information dissemination practices with those of the private insurance market. We also proposed to remove the distinctions among MCO, PIHP and PAHP information requirements. We proposed that regardless of the scope of the managed care plan's benefits, the information that should be provided to potential enrollees and enrollees is the same for all types of plans.

We also proposed to move the current definitions in paragraph (a) to § 438.2 because those terms ("potential enrollee" and "enrollee") are used throughout this part. We noted the differences in these definitions: "potential enrollee" refers to a beneficiary that has been determined eligible for Medicaid but is not yet enrolled in a managed care plan, while "enrollee" refers to a beneficiary who is a member of a specific MCO, PIHP, PAHP, PCCM or PCCM entity. In proposed paragraph (a), we revised the definition of "prevalent" and added a definition of "readily accessible" for use in this section. The term "prevalent" is currently defined in § 438.10(c)(1); we proposed to amend the current definition of "prevalent" to clarify that the non-English languages that are relevant are those spoken by a significant number or percentage of potential enrollees and enrollees in the state that are LEP, consistent with standards used by the Office for Civil Rights in enforcing anti-discrimination provisions related to individuals with limited English proficiency.

We proposed to add a definition of "readily accessible" to clarify parameters for the provision of electronic information. We noted that states, MCOs, PIHP, PAHPs, and PCCM entities should consult the latest section 508 guidelines issued by the U.S. Access Board or W3C's Web Content Accessibility Guidelines (WCAG) 2.0 AA (see <http://www.access-board.gov/sec508/guide/index.htm> and <http://www.w3.org/TR/WCAG20/> for additional information.)

In paragraph (b), we clarified that the standards in this section apply to all managed care programs regardless of authority because the distinctions among managed care programs that operate under the state plan and waivers or demonstration projects are immaterial for purposes of beneficiary educational materials that are provided in a managed care program. We noted that this section incorporates those

statutory standards of section 1932(a)(5)(B) through (D) of the Act and expands upon them to encompass additional information for all beneficiaries based on our authority under section 1902(a)(4) of the Act to adopt standards and standards that are necessary for the proper and efficient operation of the state plan.

In proposed paragraph (c), we specified basic standards for information in managed care programs. Several of the standards (that is, paragraphs (c)(1) through (c)(6)) were proposed to be applicable to the state as part of its responsibility for ensuring delivery of critical program information to beneficiaries. Paragraphs (c)(1), (c)(6) and (c)(7) were proposed to apply to MCOs, PIHPs, PAHPs, and PCCM entities; however, PCCMs would need to comply only with paragraph (c)(1).

In paragraph (c)(1), we proposed the fundamental standard that each state, enrollment broker, MCO, PIHP, PAHP, PCCM and PCCM entity provide all information in an easily understood and readily accessible manner and format. Such manner and formats include the use of TTY/TDY and American Sign Language interpreters. The proposed regulation is similar to the current regulation at § 438.10(b)(1) but would also include PCCM entities consistent with the provisions discussed in section I.B.6.e. of this final rule. Except for PIHPs and PAHPs, this language implemented the statutory provision in section 1932(a)(5)(A) of the Act for all enrollment, informational and instructional materials. We relied on section 1902(a)(4) of the Act authority to extend such standards on PIHPs, PAHPs, and PCCMs for the proper and efficient operation of the State plan to ensure that enrollees and potential enrollees receive information in a form and manner that they can understand. In paragraph (c)(2), we proposed that states must use the beneficiary support system proposed under § 438.71 to provide education and choice counseling to all beneficiaries. We proposed in paragraph (c)(3) that states would need to operate a Web site for information about the state's managed care program and could link to the Web sites of managed care plans for some of the information. We noted that all states already operate a Web site and that this proposal would merely codify existing practices. In paragraph (c)(4), states would be required to develop standardized managed care definitions and terminology, and model enrollee handbooks and notices for use by its contracted managed care plans. The suggested list of definitions and terminology had been adapted from the

standards for a uniform glossary that private market insurers must include as part of their summary of benefits and coverage (SBC) in 45 CFR part 147. We proposed in paragraph (c)(5), that states would need to ensure, through their managed care contracts, that MCOs, PIHPs, PAHPs, and PCCM entities provide the information outlined in this section.

In proposed paragraph (c)(6), we identified the standards for providing information electronically. Specifically, electronic information would have to be compliant with language, formatting, and accessibility standards; be in a prominent place on the state's, MCO's, PIHP's, PAHP's, or PCCM entity's Web site; and be able to be retained and printed. Additionally, all information would be made available to enrollees and potential enrollees in paper format upon request at no cost and provided within 5 calendar days. We noted that these standards are consistent with those for QHPs operating in the Marketplace; thus, we believed that by finalizing them we further our goal of alignment across insurance affordability programs.

In proposed paragraph (d), we addressed federal standards for the language and format used for beneficiary information, and largely carries over existing standards from current paragraph (c). However, we proposed to add three new standards, which we believed were important beneficiary standards and recognize the cultural and linguistic diversity of Medicaid beneficiaries. The first two changes, proposed in paragraph (d)(2) and (d)(3), would have materials for potential enrollees disseminated by the state, as well as enrollee materials disseminated by MCOs, PIHPs, PAHPs or PCCM entities, to be available in prevalent languages and include taglines in each prevalent non-English language and large print explaining the availability of written materials in those languages as well as oral interpretation in understanding the materials. We also proposed, based on guidance from the American Printing House for the Blind, Inc., that large print must be no smaller than 18 point font. We also proposed in paragraph (d)(3) that written materials must also be made available in alternative formats and auxiliary aids and services must be made available upon request of the potential enrollee and enrollee at no cost. The third change we proposed was in paragraph (d)(3)(i), where we listed the 'materials' which each MCO, PIHP, PAHP or PCCM entity would have to make available in each prevalent non-English language in its service area under our proposal. To

determine the types of materials to which this standard should apply, we consulted guidance provided by HHS regarding access to programs and services for persons with LEP. See section I.B.6.d of the proposed rule for discussion of this topic. We proposed that provider directories, enrollee handbooks, appeal and grievance notices and other notices that are critical to obtaining services be considered vital documents, and therefore would have to be made available in each prevalent non-English language in its service area. The current standard for oral interpretation services would remain mostly unchanged in paragraphs (d)(4) except for adding a clarification that interpretive services include the use of auxiliary aids (such as TTY/TDY) and American Sign Language. Currently, under paragraphs (b)(5)(i) and (ii), states have to notify enrollees of the availability of interpretation and translation services and how to access them. We proposed to add a new paragraph (d)(5)(ii) clarifying that potential enrollees and enrollees must be also be notified that auxiliary aids and services are available upon request and at no cost for enrollees with disabilities. This proposed addition would clarify that interpretive services are not limited to LEP potential enrollees and enrollees. We proposed to redesignate current paragraph (d)(5)(ii) as (d)(5)(iii).

We proposed in paragraph (d)(6) to establish a standard that the availability of alternative formats for beneficiary materials must include a large print tagline and information on how to request auxiliary aids and services, including the provision of materials in alternative formats. Auxiliary aids would include but are not limited to the use of TTY/TDY and American Sign Language interpreters. We also proposed, based on guidance from the American Printing House for the Blind, Inc., that large print must be no smaller than 18 point font.

In paragraph (e), we proposed the information that must be provided to potential enrollees. We proposed in paragraph (e)(1) to provide flexibility to the states to provide this information in paper or electronic format to ease the administrative burden and cost of mailing paper materials to potential enrollees. Proposed paragraphs (e)(1)(i) and (ii) would maintain current timeframes for the provision of the information.

In paragraphs (e)(2)(i) through (x), we proposed a minimum list of topics that the state would need to provide in the information sent to potential enrollees including disenrollment rights, basic

features of managed care, populations excluded from enrollment, service area of each managed care plan, covered benefits, provider directory information, cost sharing, network adequacy standards, care coordination services available, and quality indicators for each MCO, PIHP, PAHP, and PCCM entity.

The next paragraphs of proposed § 438.10 focused exclusively on information standards for managed care plan enrollees—that is, once they have selected and enrolled in a managed care plan. Paragraph (f) proposed general standards for both the state and managed care plans regarding enrollee information; paragraph (g) proposed the minimum content of enrollee handbooks; and paragraph (h) proposed the minimum content of provider directories. The products of the standards proposed in these paragraphs would provide enrollees with a substantial and valuable source of information on most aspects of how to access care and fully utilize the benefits of their managed care enrollment.

Proposed paragraph (f) set forth basic standards applicable to information that must be disclosed to enrollees of MCOs, PIHPs, PAHPs, and PCCMs. In proposed § 438.10(f)(1), we proposed to redesignate an existing regulatory standard in current § 438.10(f)(5); that standard is that the managed care plan must make a good faith effort to provide notice of the termination of a contracted (that is, in-network) provider to each affected enrollee within 15 days of receipt or issuance of the termination notice. For purpose of these standards, an affected enrollee is one who received his or her primary care from the provider or was seen on a regular basis by the provider. In paragraph (f)(2), we proposed to redesignate an existing regulatory standard in current § 438.10(f)(1); the state must notify all enrollees of their right to disenroll and clearly explain the process for doing so and, if enrollment is restricted for 90 days or more, provide this notice at least 60 calendar days in advance of each enrollment period. We proposed to add “calendar” before “days” to eliminate potential ambiguity. Lastly, in proposed paragraph (f)(3), MCOs, PIHPs, PAHPs, and, when appropriate, PCCM entities, would have to provide, upon request, copies of any physician incentive plans in place as specified in § 438.3(i).

The regulatory standards proposed in paragraphs (g), (h), and (i) address enrollee handbooks, provider directories, and formularies because we believe these are foundational tools to help enrollees utilize the benefits and services available to them from their

managed care plan. We declined to propose regulatory standards for other types of plan-enrollee communications, recognizing that those decisions are best made at the state level based on the maturity and structure of each state’s managed care program.

Proposed paragraph (g) outlined minimum content standards for the enrollee handbook; we attempted to align with private market insurance standards by reflecting similarities to the SBC in both content and appearance. In paragraph (g)(1), each MCO, PIHP, PAHP or PCCM entity would have to provide an enrollee handbook to each enrollee within a reasonable time after receiving the enrollment notice from the state. While the information proposed to be included in the handbook (in proposed paragraph (g)(2)), which already exists in current § 438.10, we noted that it is currently not well organized or all in one section for easy reference. Proposed paragraph (g)(2) listed all of the existing elements in one paragraph for easy reference. Taken together, these elements would be referred to as a “handbook” consistent with how the term is typically used in Medicaid managed care. While some minor grammatical revisions have been made for clarity, we noted that the elements remained the same as in current regulation. We also proposed to correct a reference in § 438.100(b)(2)(iii) to “§ 438.10(f)(6)(xii),” which was redesignated as “§ 438.10(g)(2)(ii)(A) and (B).

Paragraph (g)(3) proposed to clarify the circumstances under which the MCO, PIHP, PAHP, or PCCM entity would be considered to have provided the information in paragraph (g)(2). We proposed mail, email if enrollee consent was obtained, Web site with paper and electronic notification, auxiliary aids and services at no cost (upon request), and any other method that can reasonably be expected to result in the enrollee receiving the information. We proposed this last method to provide flexibility for communication methods not commonly used, such as alternative communication devices for persons with disabilities, and other technological advances in communication not yet widely available. In proposed paragraph (g)(4) we affirmed the current standard that enrollees be notified 30 days in advance of any significant change to any of the information in paragraph (g). Consistent with other proposed revisions throughout § 438.10, we proposed to delete the standard that this notice be written and let the provisions of paragraphs (c) and (d) control regarding

the standards for the use of written and electronic communications. Proposed paragraph (h) specified the minimum content standards for provider directories. We noted that the content and accuracy of provider directories have long been an issue of contention between states, managed care plans and stakeholders and that the move to electronic provision of this document should improve the accuracy of the information. We also noted that even web-based provider directories can be out of date quickly without accurate information from participating providers to the managed care plans.

Paragraphs (h)(1)(i) through (viii) proposed all of the elements that exist currently in § 438.10(f)(6)(i) but expanded on them in four key ways. In addition to name, address, telephone number, and open panel status, we proposed to add four additional elements: A provider’s group/site affiliation; Web site URL (if available); the provider’s cultural and linguistic capabilities; and the accessibility of the provider’s office to enrollees with physical disabilities. Paragraphs (h)(2)(i) through (v) proposed five provider types that would have to be included in the directory, if applicable under the contract: Physicians; hospitals; pharmacies; behavioral health; and LTSS. In paragraph (h)(3), we proposed that paper provider directories must be updated at least monthly and electronic directories within 3 business days of receiving updated provider information. Lastly, to align managed care with both QHPs and MA, in paragraph (h)(4), we proposed that provider directories be made available on the MCO’s, PIHP’s, PAHP’s, or if applicable, PCCM entity’s Web site. The current rule for MA plans (§ 422.111(h)) requires such plans to post provider directories online. Additionally, in a recent final rule (80 FR 10873), HHS finalized a requirement for QHPs in a federally facilitated Marketplace to post provider directories in a machine readable format specified by the Secretary. Therefore, to improve transparency and provide an opportunity for third party aggregating of information, we proposed that MCOs, PIHPs, PAHPs, and if applicable, PCCM entities, must post provider directories on their Web sites in a machine readable file and format specified by the Secretary.

We also proposed a new paragraph (i), Information for all enrollees of MCOs, PIHPs, PAHPs, and PCCM entities—Formulary. This proposed paragraph would have MCOs, PIHPs, PAHPs, and PCCM entities provide their medication formularies electronically or on paper, if requested. Under paragraphs (i)(1) and

(i)(2), the formulary must display all covered medications, both generic and brand name, and have the tier of each medication. We proposed this paragraph because understanding how medications are covered by the managed care plan is important information for enrollees, particularly for those with chronic conditions or on-going needs. Additionally, we proposed that formulary drug lists be made available on the MCO's, PIHP's, PAHP's, or if applicable, PCCM entity's Web site in a machine readable file and format as specified by the Secretary for the same reasons discussed in the proposed rule in connection with provider directories. Machine readable files with formulary drug lists would provide the opportunity for third parties to create resources that aggregate information on different plans. We noted this would increase transparency by allowing software developers to access this information and create innovative and informative tools to help enrollees better understand formulary drug lists across specific plans.

We received the following comments in response to our proposal to revise § 438.10.

Comment: We received many comments supporting the reorganization of § 438.10. Commenters believed the proposed Information Requirements section was easier to use, more comprehensive, and added needed consistency on many covered topics. Commenters were particularly supportive of the new proposed sections on enrollee handbooks, provider directories, and formularies and believed they will provide critically needed information for potential enrollees and enrollees.

Response: We appreciate the supportive comments and will finalize § 438.10 with the organizational structure proposed.

Comment: We received a few comments requesting that CMS define LEP consistent with the definition by the Office for Civil Rights' Guidance to Federal Financial Assistance Recipients Regarding Title VI Prohibition Against National Origin Discrimination Affecting Limited English Proficient Persons, 68 FR 47311 (Aug. 8, 2003).

Response: We agree and will add to § 438.10(a) the definition for LEP published by HHS Office for Civil Rights to § 438.10(a), in the Guidance to Federal Financial Assistance Recipients Regarding Title VI Prohibition Against National Origin Discrimination Affecting Limited English Proficient Persons, 68 FR 47311, 47313 (Aug. 8, 2003).

Comment: We received many comments on the proposed definition of "prevalent" in § 438.10(a) for the purpose of determining the non-English languages for written materials that require translation. Some commenters wanted specific thresholds for states to use when determining which non-English languages should be represented when translating vital documents. Other commenters did not want CMS to adopt specific thresholds as existing guidance (for example, HHS Guidance to Federal Financial Assistance Recipients Regarding Title VI Prohibition Against National Origin Discrimination Affecting Limited English Proficient Persons 68 FR 47311 (Aug. 8, 2003) and Executive Order 13166, "Improving Access to Services for Persons with Limited English Proficiency") provides sufficient information on how states can determine the most appropriate non-English languages spoken in their state. Other commenters believed the proposed definition was confusing since there are currently no specific published standards by the Office of Civil Rights.

Response: We agree with commenters that existing guidance provides a solid foundation and that the reference to standards by the Office of Civil Rights was unclear. That reference is not being finalized and this regulation will be interpreted consistently with other regulations on similar or the same topic. We believe that states, with their experience in setting their own thresholds in this area, are capable of applying the regulation standard that is being finalized in a reasonable and responsible manner.

Comment: A few commenters suggested that the proposed definition of "readily accessible" in § 438.10(a) could be improved by including W3C's Web Content Accessibility Guidelines (WCAG) 2.0 AA and Section 504 of the Rehabilitation Act.

Response: We agree with the commenters and are finalizing the definition of "readily accessible" as meaning compliance with modern accessibility standards. Examples of such standards include Section 504 of the Rehabilitation Act and W3C's Web Content Accessibility Guidelines (WCAG) 2.0 AA and successor versions. The regulation text, by using the phrase "modern accessibility standards" is designed to flexibly adapt with changes and updates to accessibility.

Comment: A few commenters suggested we clarify "easily understood" in § 438.10(c) by including a specific grade reading level. The commenters believed that all states should use the same grade level for consistency.

Response: We understand that selecting a grade level is a common component of states' methodologies for determining if a document can be easily understood by the intended audience. We believe using a specific grade level is a reasonable approach but acknowledge that there is variation among states as to which level is most appropriate. Therefore, we decline to add a specific grade level in the final rule, leaving that decision to the state.

Comment: We received many comments supporting the requirement for states to have Web sites dedicated to managed care and the specified information to be included. We received a comment suggesting that proposed § 438.10(c)(3) be reorganized for more appropriate grammatical flow, as well as a suggestion that a reference to proposed § 438.66(e) be added to make § 438.10(c)(3) a more complete list of items that states must post on their Web site. We also received several comments recommending that the Web site proposed in § 438.10(c)(3) be available to the public and not limited to potential enrollees or enrollees only. The commenters believe that the information could be very valuable to others such as those assisting beneficiaries. Lastly, we received a few comments recommending that we add a timeframe by which states must update the information on their Web sites to ensure that the sites were maintained in a timely fashion.

Response: We appreciate the supportive comments; we agree that § 438.10(c)(3) could be clearer and that the information required in this paragraph is appropriate for public viewing. We are modifying § 438.10(c)(3) in the final rule to include a reference to § 438.10(i) which was erroneously omitted in the proposed rule. We are not finalizing the references to §§ 438.68(e), 438.364(b)(2), and 438.602(g) to remove unnecessary cross references; those regulations are clear in imposing the requirement that identified information be posted on the Web site required under § 438.10(c). We are also not finalizing "(b)(2)" in "§ 438.364(b)(2)" as the availability of information requirement will be finalized at § 438.364(c). Minor revisions have been made to improve grammatical flow. As to the suggestion for adding a timeframe, we do not believe one is necessary. We believe our intent is clear that we expect states to maintain their Web sites as accurately as possible. Given that most, if not all, states already maintain Web sites that contain some of the required information and will likely utilize links directly to the managed care plan rather

than uploading documents for much of the information, we believe that attempting to identify an attainable and reasonable time frame that would be applicable for all of the required information would not be possible. We believe utilizing links directly to the managed care plans' Web site will be the most efficient way to provide access to the current version of certain required documents.

Comment: Several commenters recommended that CMS provide the definitions for the terms proposed in § 438.10(c)(4)(i), as well as model enrollee handbooks and member notices proposed in paragraph (c)(4)(ii). Some commenters suggested including adding "habilitation services and devices," "rehabilitation services and devices," "orthotics and prosthetics," "behavioral health services," "continuity of care," "care coordination," and "health risk assessment" to the list in § 438.10(c)(4)(i). Commenters believed this would result in consistent practices across the states.

Response: We appreciate these suggestions and clarify that the list of terms in § 438.10(c)(4)(i) is a minimum and states should add any additional terms they consider appropriate. We are adding "and devices" to "habilitation services" and "rehabilitation services" in the final rule for consistency with terminology used for essential health benefits. While we understand that having CMS provide standard definitions and model handbooks and notices would provide some consistency, we believe that there is sufficient variation between states' program design, covered benefits, and localized use of terminology to warrant leaving this responsibility with the states.

Comment: One commenter requested that CMS clarify if the model handbooks proposed may be customized by the managed care plans. Another commenter questioned if the state would provide the model handbook translated into the prevalent languages.

Response: Managed care plans should work with the states in which they contract for clarification on the level of customization permitted and translation of the model handbook. We do not believe that such specificity is necessary in § 438.10.

Comment: We received many comments recommending that enrollees be required to affirmatively elect to receive electronic communications, or "opt-in," while other commenters believed enrollees should not have to affirmatively elect to receive electronic communications, or "opt-out."

Response: We understand the commenters' recommendations regarding the use of electronic communications. However, we do not believe that requiring every enrollee to actively elect to receive electronic communications would be feasible or necessary. When an email address is provided by the enrollee, we believe it is reasonable for the states and/or managed care plans to use it for contacting the enrollee unless the enrollee requests not to receive communications at that email address. An enrollee's request to receive information on paper and/or in a prevalent language should be noted in the enrollee's record so that future distribution of information is handled consistent with the enrollee's preference.

Comment: A few commenters suggested that the time frame of 5 calendar days in § 438.10(c)(6)(v) for providing information requested on paper was not feasible due to the steps involved in printing on-demand, storing printed materials offsite, and producing alternative formats. Suggestions for alternatives ranged from 5 business days to 10 calendar days.

Response: We understand the concerns raised by the commenters and believe that 5 business days, rather than 5 calendar days, will provide sufficient additional time for mailing the materials while still fulfilling the beneficiary's request in a timely manner. Therefore, we are finalizing § 438.10(c)(6)(v) with a timeframe of 5 business days.

Comment: We received a few comments that suggested that § 438.10(c)(7) should be revised to reference each MCO, PIHP, PAHP, and PCCM entity having a system, rather than a mechanism, to help enrollees and potential enrollees understand the requirements and benefits of the managed care plan or PCCM entity. They believed the term "system" more appropriately described the intent of this paragraph.

Response: We do not agree that "system" would be more appropriate as it may imply more infrastructure than is intended. We do, however, concede that "a mechanism" is probably too limiting as managed care plans utilize many ways to assist enrollees in understanding the requirements and benefits of the plan. Therefore, we will finalize § 438.10(c)(7) making mechanism plural.

Comment: A few commenters suggested that the provision in § 438.10(d)(2) to "make available oral and written information in each prevalent non-English language" was unclear due to the requirement in

paragraph (d)(3)(ii) that stated oral interpretation services must be provided for all languages, not just prevalent non-English languages. Some commenters also suggested that we add "competent" each time oral interpretation or written translation is addressed.

Response: We agree with the commenter that § 438.10(d)(2) could be clearer and are modifying § 438.10(d)(2) to add "in all languages" after oral interpretation; we are also revising paragraph (d)(2) to finalize it to require "oral interpretation" and "written translation" be available in the applicable languages so that the requirement is clearer. We believe these changes more accurately refer to the language assistance available to LEP enrollees. We also corrected "written information" to "written translation" in § 438.10(d)(5)(i). While we agree that only competent interpreters and translators should be utilized, we do not believe it is necessary to add it throughout part 438 nor to list specific criteria for determining competence. It is implicit in the regulation requirement that the provision of oral interpretation and written translation serve their purpose; that is only possible if the services are competently provided. Incompetent translation or interpretation services will not satisfy the regulation requirement. Information is available on determining competence of interpreters and translators in the HHS Guidance to Federal Financial Assistance Recipients Regarding Title VI Prohibition Against National Origin Discrimination Affecting Limited English Proficient Persons as well as at www.lep.gov.

Comment: Commenters were very supportive of the proposed inclusion of requiring taglines on written materials. We received many comments recommending that the proposed requirement in § 438.10(d)(2) for taglines in written materials for potential enrollees to be revised to require 15 taglines for consistency with QHP requirements.

Response: We appreciate the commenters' suggestion to adopt the QHP standard of 15 taglines; however, we decline to revise § 438.10 to adopt such a requirement. We believe that the experience of states and managed care plans in determining the prevalent languages within the state, as well as utilization data of interpreter and translation services by their enrollees, will result in a determination of the appropriate number of taglines. We encourage states and managed care plans to assess the language needs in their state and add taglines in additional languages beyond the languages

determined as prevalent. We also believe states and managed care plans should collaborate with their state-based exchanges and the QHPs in their market to determine if sharing taglines could be an effective option. Additionally, to reduce duplication, the requirement for including taglines on written materials that are critical to obtaining services proposed in paragraph (d)(3)(i) has been added to paragraph (d)(3) and we are not designating separate paragraphs as (d)(3)(i) and (ii).

Comment: We received many comments suggesting that we add denial and termination notices to the list of written materials in § 438.10(d)(3) and paragraph (d)(3) must be made available in prevalent languages and include taglines. Commenters believed that while there are many documents that are important to fully utilize a managed care program, denial and termination notices are critical enough to warrant being specifically mentioned. One commenter suggested that the list in § 438.10(d)(3) and (d)(3)(i) specify each document that should be considered critical.

Response: We agree with the commenters on the importance of denial and termination notices and are finalizing § 438.10(d)(3) to include denial and termination notices in the list of specifically identified documents that are subject to the translation requirements. We do not believe that the lists in § 438.10(d)(3) can be made exhaustive in regulation as each state and managed care plan produces different types of documents, so we emphasize here that each state must exercise due diligence in determining which documents are critical to obtaining services.

Comment: We received a few comments recommending that CMS require that all materials for potential enrollees and enrollees be consumer tested prior to use. The commenters believe this would improve comprehension and understanding of the materials.

Response: We agree that consumer testing is a valuable tool available to states and managed care plans and encourage them to utilize it. States and managed care plans have extensive experience producing written materials for their populations and some already use consumer testing on their written materials; therefore, we do not believe adding a new provision on this issue is necessary.

Comment: Some commenters recommended that the notices to potential enrollees more clearly explain the opportunity enrollees have to change plans during the initial 90 days

without cause. Commenters believed this information was often not clearly or prominently included in notices.

Response: We agree that the opportunity to disenroll from an enrollee's current managed care plan without cause during the initial 90 days of enrollment is an important right and states need to be diligent about including the information in a clear way in appropriate notices. Notices should already explain this disenrollment right under current § 438.56(f). We take this opportunity to remind states of the provisions in § 438.56 and encourage them to review their notices to ensure that a full and clear explanation of this right and easy to follow instructions for exercising it if the enrollee so chooses, are included.

Comment: We received some comments recommending that the notices to potential enrollees more clearly explain the length of the enrollment period, since disenrollment rights can be limited to for cause reasons during this period. Commenters believed states were not consistently explaining the significance of this period to enrollees.

Response: We agree that enrollees need to understand the length of the enrollment period and what opportunities for disenrollment will be available to them during that period. To address this, we are modifying § 438.10(e)(2)(iii) in the final rule to require that the length of the enrollment period and that all disenrollment opportunities be described in the informational notices.

Comment: A few commenters recommended that § 438.10(e)(2)(vi) be revised to include the managed care plan's formulary in addition to the provider directory. Commenters believe reviewing a managed care plan's formulary is an important component of the plan selection process and potential enrollees should not have to request this information separately.

Response: We understand the commenters' concern and agree. Therefore, we are revising § 438.10(e)(2)(vi) in the final rule to include the formulary.

Comment: We received numerous comments recommending that CMS define "regular basis" as used in § 438.10(f)(1) for notice to enrollees of a terminated provider. Some commenters suggested that enrollees who had received services from a provider within the last 12 months should be notified of the provider's termination from the network. They were especially concerned that "regular basis" may not capture female enrollees that only see

an OB/GYN once a year for preventive services.

Response: We understand the commenters' concern. However, we believe that providers frequently notify their patients of changes in their network status; we do not believe that an additional level of specificity is necessary in this provision. We encourage plans and states to consider the frequency of services provided by a particular provider in identifying the enrollees who see that provider on a regular basis.

Comment: A few commenters recommended that CMS add a 5 day time limit for sending out handbooks as referenced in § 438.10(g)(1). Commenters believe the current provision for sending handbooks "within a reasonable time after receiving notice of the beneficiary's enrollment" is too vague.

Response: We understand the commenters' concern and believe that states and managed care plans understand the importance of getting the handbook to enrollees in a timely fashion since all parties benefit from enrollees having the information they need. There is nothing in § 438.10 that prevents a state from imposing a specific timeline on their managed care plans. Additionally, we believe with the use of electronic communications proposed elsewhere in § 438.10, the distribution of information will occur very quickly, oftentimes on the same day. We believe the option to specify a timeframe is best left to the states and will finalize § 438.10(g)(1) as proposed.

Comment: We received numerous suggestions for additional types of information that could be added to § 438.10(g)(2). Suggestions primarily included adding specific benefits and how to access them, with one commenter suggesting adding the provisions specific to Indian enrollees. A few commenters recommended additional text for § 438.10(g)(2)(vii) to add clarity about the freedom of choice allowed for family planning services and devices.

Response: We appreciate the suggested topics to enhance § 438.10(g)(2) but found most of them duplicative of an existing provision. Paragraph (g)(2) states that this information must include at a minimum. We expect states to comprehensively represent each of the required topics plus any others that they believe would enhance an enrollee's understanding of how to effectively use the program. To make this clear for family planning, we have added that managed care plan handbooks must include an explanation that enrollees do

not need a referral before choosing a family planning provider.

Comment: Commenters generally supported the proposal to strengthen provider directory requirements proposed in § 438.10(h) and agreed that provider data needs to be as accurate as possible to be useful. Commenters recommended a different timeframe for updates than the 3 business days from receipt as proposed in § 438.10(h)(3). Many commenters explained that information included in the directory is obtained from numerous sources and must be validated prior to acceptance, thus making the 3 business day time frame impossible. Many commenters suggested aligning with Marketplace and MA requirements and require monthly updates.

Additionally, many commenters expressed confusion over the provision of paper directories; specifically, whether we were proposing in § 438.10(h)(3) that they be sent routinely or only upon request. Commenters also explained that using the same data source file for the electronic and paper directories would be more efficient but would require the same updating timeframe for electronic and paper formats. One commenter proposed that printing on demand from the on-line directory be deemed acceptable.

Response: We appreciate the information provided by the commenters and agree that consistency with guidance applicable to QHPs and MA would be the most prudent approach. While this extends the timeframe originally proposed for electronic directories, we believe supporting accuracy is more productive than retaining an unrealistic timeframe. We encourage managed care plans to work to shorten the monthly timeframe while maintaining their directories as accurately as possible.

Regarding questions about paper directories, we clarify that paper directories need only be provided upon request and that we encourage plans to find efficient ways to provide accurate directories within the required time frames. We encourage innovative methods such as single data source files or printing the on-line directory to provide accurate paper directories within the required timeframe to enrollees that request them. To adopt these revisions and clarifications, we will be finalizing § 438.10(h)(3) to reflect that paper directories are only upon request and that paper directories must be updated monthly and electronic provider directories must be updated within 30 calendar days after the receipt of updated provider information.

Comment: Several commenters suggested additional information for inclusion in the list of information in the provider directory proposed in § 438.10(h)(1). Suggestions included provider gender; subspecialties/areas of practice; hospital privileges; age limitations; hours of operation; expected period of open or closed panel status; utilization management criteria; and provider-tiering and associated cost sharing differentials. Commenters believed this information would make the directory more comprehensive and useful.

Response: We appreciate these suggestions and believe many of them could provide useful information. We consider the list proposed in § 438.10(h) a minimum and encourage states and plans to consider the suggested additions and include them as appropriate and feasible.

Comment: We received several comments on the proposed provision in § 438.10(h)(1)(viii) requiring information on the accessibility of provider offices for people with physical disabilities. Some commenters wanted the proposed requirement expanded to include more information, other commenters wanted the proposed requirement narrowed to include less information about internal accessibility, and some believed the state should be required to obtain the information either through licensing or the screening requirement proposed in § 438.602. Many commenters clarified that information about internal office accommodations is not collected on most credentialing applications nor via any other uniform mechanism. Commenters also expressed concerns about legal liability issues around reporting an office's accessibility features.

Response: We understand the various commenters' concerns about the challenges of collecting this information but continue to believe that providing accessibility information is critical, particularly as the number of managed LTSS programs increases. To provide more flexibility for how the information is displayed in the directory, we have revised § 438.10(h)(1)(viii) from "is accessible" to "has accommodations." We believe this is broad enough for states to consider all of the possible accommodations including wide entries, wheelchair access, accessible exam tables and rooms, lifts, scales, bathrooms, grab bars, or other equipment. We expect states and managed care plans to present the information in the directory with sufficient specificity to be useful to readers.

Comment: We received numerous comments suggesting additional provider types for inclusion in § 438.10(h)(2). We received one comment requesting clarification on the appropriateness of including personal care aids and providers who frequently do not have a business phone or address.

Response: We appreciate the suggestions and clarify that the list in § 438.10(h)(2) is a minimum; states and managed care plans should collaborate on any additional provider types to be included. States and plans should design the directory to be of maximum use for their program's enrollees and expand the list in § 438.10(h)(2) as appropriate. For LTSS providers, we appreciate the sensitive nature of the services provided by certain types of LTSS providers and the lack of formal business information associated to them. We use the term "LTSS providers" broadly in § 438.10(h)(2) and expect states and plans to exercise judgment when determining whether to include certain LTSS provider types in the directory. To make this clear, we are adding "as appropriate" after "LTSS provider" in the final rule.

Comment: One commenter requested clarification on whether links could be used rather than including the networks of large subcontractors, such as pharmacy benefit managers.

Response: We appreciate the opportunity to clarify that no provision in § 438.10(h) would prohibit using links for large subcontracted networks in the on-line directory. However, a mechanism will have to be in place to provide the linked information in paper directories.

Comment: We received several comments on proposed § 438.10(h) including: Penalizing plans if there were errors in the directories because providers often fail to notify the plan of changes; the administrative burden and costs associated with strengthened provider directory requirements; requiring that managed care plans honor what is listed in the provider directory even if it erroneous; that plans, states, and CMS be required to monitor data for accuracy; that plans be held to a 97 percent accuracy rate; that plans exclude from the directory any providers that cannot be contacted; that plans verify data with providers monthly; and that plans be required to have mechanisms for enrollees to report inaccurate data.

Response: We thank the commenters for their suggestions but decline to adopt these suggestions in the final rule. We understand the concern about managed care plans being held

accountable for errors in directories beyond their control and encourage managed care plans to work with their providers to ensure that their directories are as current and accurate as possible. We encourage managed care plans to facilitate multiple methods for providers to submit data changes and for enrollees to report inaccuracies. We urge states and managed care plans to develop innovative mechanisms to audit and verify the accuracy of their data and facilitate easy means for enrollees to report inaccurate data. Similarly, we understand the concern underlying the comments that managed care plans should honor what is listed in their directories even if there are errors as enrollees rely on directories to access providers and needed services; and we encourage that practice. We understand that there may be some administrative burden associated with maintaining accurate and timely directories, but believe it is necessary for enrollees to be fully informed about provider networks. We also believe that enrollees reasonably expect their managed care plan to make available an accurate provider directory, especially when the enrollee is expected to take action based on the information supplied by the managed care plan.

Comment: We received many comments about the proposal in § 438.10(h)(4) requiring directories to be available in a machine readable format. Some commenters supported the provision that the format be specified by the Secretary and many recommended aligning with the format selected by the Marketplace. Other commenters suggested allowing states to select the format, a few suggested removing the requirement completely, and a few expressed concern over CMS providing sufficient implementation time for this provision.

Response: We appreciate the comments on this proposed provision and understand the commenters' concerns. Aligning with the Marketplace and providing sufficient implementation time will be given serious consideration given the complexity of this proposed provision. We anticipate issuing clarifying guidance on this provision when additional details on machine readable formats become available.

Comment: Many commenters expressed support for proposed § 438.10(i) as they believe having formulary information is critical to enrollees. We received some comments recommending that a specific time frame be established for updating the electronic formulary proposed in § 438.10(i). Commenters believed a

timeframe was necessary to ensure that managed care plans maintained and updated the information in a timely fashion.

Response: We agree with the commenters that having accurate information is critical for enrollees; however, revisions to a formulary are often contingent on the actions of a state and/or managed care plan's pharmaceutical and therapeutics committee. As such, there is great variation in the timing of revisions. We do not believe that we can effectively select a specific time frame that would accommodate such variation. Therefore, we are finalizing § 438.10(i) as proposed.

Comment: A few commenters suggested that pre-authorization criteria and the exception process for non-formulary drugs be included in the formulary proposed in § 438.10(i). Commenters believed this information would be useful to enrollees.

Response: We do not agree that including this information in the formulary would be helpful to most enrollees given the large volume of information and its highly technical nature. Additionally, formularies can be lengthy and adding a large amount of additional information that is not valuable to most readers does not seem beneficial. We acknowledge that states are free to include the pre-authorization criteria if they choose to, along with any other information they believe useful to the enrollee, but we do not believe adding it as a requirement to § 438.10(i) is necessary.

Comment: Some commenters suggested that information on the process for obtaining an emergency supply of a drug be required in § 438.10(i). A few commenters asked CMS to require plans to identify both the level of cost sharing for drugs in each tier for coverage as well as the actual cost the patient will incur for each drug.

Response: While we agree that this information may be useful to enrollees, we believe that information on the process for obtaining an emergency supply and cost sharing should already be in the enrollee handbook. While we do not believe we need to mandate the inclusion of such information in the formulary, states are free to include this information at their discretion.

Comment: A few commenters suggested that a managed care plan be required to notify its enrollees if it removes a drug from its formulary.

Response: Given the wide variation in formulary management practices, we decline to mandate notification to enrollees for the removal of each drug.

However, states and managed care plans are free to require and implement, respectively, such notification if they so choose.

Comment: One commenter requested that CMS revise § 438.102(b)(2) to incorporate § 438.10(g)(2)(ii)(B) that requires the managed care plan to inform enrollees through the enrollee handbook on how to obtain information from the state for accessing covered services that the managed care plan does not cover due to moral or religious reasons.

Response: We agree that § 438.102(b)(2) could be more consistent with § 438.10(g)(2)(ii)(B) and with the underlying statutory requirements (section 1932(b)(3) of the Act); we are modifying as appropriate. Additionally, we are correcting an error in § 438.102(b)(1)(ii)(A) and (b)(2) by removing the term "potential enrollees." The term "potential enrollee" should not be included in these paragraphs as § 438.102(b) addresses information that must be provided by the managed care plan. Information to potential enrollees is generally a state responsibility under § 438.10, which we discussed as part of our proposal; we are making this change to ensure that part 438, as finalized here, is internally consistent on this point.

After consideration of the public comments, we are finalizing § 438.10 as proposed with the following revisions:

- In § 438.10(a), added a definition of "limited English proficient"; and removed "consistent with standards [used by OCR]" from the definition of "prevalent"; and supplemented the examples of "modern accessibility standards" in the definition of "readily accessible".
- In § 438.10(c)(3), added a cross reference to § 438.10(i); removed references to §§ 438.68(e), 438.364(b)(2), and 438.602; and revised the text to improve its readability.
- In § 438.10(c)(4)(i), added "and devices" after "habilitation services" and "rehabilitation services".
- In § 438.10(c)(4)(ii), changed "member" to "enrollee" in front of "handbook" for consistency as "member" is not defined in this part. This correction was made throughout part 438.
- In § 438.10(c)(6)(ii), used the phrase "applicable entity's" to refer to the State, MCO, PIHP, PAHP, PCCM or PCCM entity regulated by paragraph (c)(6).
- In § 438.10(c)(6)(v), removed "State, MCO, PIHP, PAHP, or PCCM entity" as it was duplicative of the list in paragraph (c)(6); moved "is informed" for grammatical flow; used "applicable

entity” to refer to the applicable regulated entity; and changed “5 calendar days” to “5 business days” for mailing information requested on paper.

- In § 438.10(d)(2), added “interpretation” after “oral” and “translation” after “written” for clarity.

- In § 438.10(d)(3), added “denial and termination notices” to the list of documents that must be translated upon request; and rearranged some parts of the paragraph to improve readability.

- In § 438.10(d)(5)(i), revised “written information” to “written translation” for accuracy and consistency.

- In § 438.10(d)(5)(iii), replaced “those services” with a specific cross references for better clarity.

- In § 438.10(e)(1)(i), added “managed care” to references to voluntary and mandatory programs for clarity.

- In § 438.10(e)(2), added “all of” to clarify that items (i) through (x) are required.

- In § 438.10(e)(2)(iii), added requirement that notices to potential enrollees must include information on the length of the enrollment period and all disenrollment opportunities available to them.

- In § 438.10(e)(2)(vi), added “and formulary” and “and (i)” to information that must be provided to potential enrollees.

- In § 438.10(g)(2) replaced “member” with “enrollee” and in paragraph (ii)(A), added “by the MCO, PIHP, PAHP, or PCCM entity” at the end of the sentence for clarity.

- In § 438.10(g)(2)(ii)(B), replaced “those services” with a specific cross reference for better clarity.

- In § 438.10(g)(2)(vii), added a requirement that freedom of choice of family planning providers be included in the handbook.

- In § 438.10(g)(2)(xi)(E), and (h)(1)(viii), made revisions for grammatical flow.

- In § 438.10(h)(1)(vii), changed “spoken” to “offered” to recognize sign language and added a reference to cultural competence training to add consistency to the way the information is presented in the provider directory.

- In § 438.10(h)(1)(viii), changed “is accessible” to “has reasonable accommodations” for clarity.

- In § 438.10(h)(2)(v), added “as appropriate” after “LTSS providers” to acknowledge that certain types of providers may not be suitable for display in a provider directory.

After consideration of public comment, we are amending § 438.102(b)(2) to be consistent with § 438.10(g)(2)(ii)(B) and the underlying statutory requirements.

e. Primary Care Case Management (§§ 438.2, 438.3, 438.330, 438.340, and 438.350)

PCCM services have a unique status in the Medicaid program. PCCM services are considered a state-plan covered benefit through section 1905(a)(25) of the Act. Section 1905(t) of the Act defines PCCM services, the providers that may furnish them, and the standards for a PCCM contract—one of which is that the state’s contract with the PCCM complies with applicable sections of 1932 of the Act (the managed care rules in the statute). A PCCM, as defined in section 1905(t)(2) of the Act, is considered a managed care entity under section 1932(a)(1)(B)(ii) of the Act. Current regulatory standards in part 438 have minimal standards that PCCM programs have to meet; they generally mirror the statutory standards specified in section 1932 of the Act.

Current regulations reflect the prevailing PCCM program design that existed in 1998. At that time, virtually all PCCM programs were intended to layer a ‘gatekeeper’ model on top of states’ FFS programs. Each primary care provider who acted as a PCCM was paid a small monthly fee (typically less than \$5.00) per beneficiary in recognition of the provision of PCCM services, in addition to any direct service payment the provider might also receive from the state, to coordinate access to primary care services and manage referrals to specialty care for Medicaid beneficiaries. The Medicaid provider was not held accountable for quality or health outcomes for that enrollee. We believe the current regulatory structure still works reasonably well for these ‘gatekeeper’ PCCM programs, which generally are very small and remain exclusively focused on individual primary care providers.

Over the past 8 years, however, states have determined that they need additional tools to better manage utilization of Medicaid services. In the proposed rule in section I.B.6.e, we discussed the history of the PCCM model, noting the evolution of PCCM entities and the fact that there current regulations in part 438 do not explicitly address them. We noted that typically, a more robust PMPM fee has been paid to these entities, depending upon the scope of activities under the contract; however, these payments are not considered risk-based capitation payments subject to the actuarial soundness standards of § 438.4 through § 438.7 because the entities are not responsible for the provision of medical services under the state plan. Rather, the state continues to pay for medical

services on a FFS basis. As these PMPM fees are not subject to the actuarial soundness standards, federal review and approval of these payments has been limited. Therefore, we proposed to adopt a term for these more intensive care case management entities: PCCM entities. Our proposed term reflects our view that these entities are PCCMs subject to the statutory minimum standards for PCCMs but by distinguishing these entities from the traditional PCCM model—one based on the use of individual providers to act as gatekeepers—we proposed to exercise our authority under section 1902(a)(4) of the Act to adopt additional standards for those PCCM entities that provide more intensive case management and care coordination, measure performance outcomes and quality improvement activities, and receive higher reimbursement.

We proposed to also distinguish the PCCM programs that are considered managed care, and therefore, subject to the specified standards of part 438, from other health care delivery systems, such as integrated care models, patient-centered medical homes, and ACOs, which would remain outside the purview of the regulatory changes to part 438 we proposed. We also noted that SMDLs issued in 2012 outlined new flexibilities for states to implement integrated care models that fall on the spectrum between unmanaged FFS and full-risk managed care. SMDL #12-002, available at <http://www.medicaid.gov/Federal-Policy-Guidance/downloads/SMD-12-002.pdf>, specifically highlighted that primary care case management is a state plan service, which does not necessarily have to be a managed care delivery system.

Notwithstanding the guidance in those SMDLs, we noted that states continue to seek clarification on the attributes of a PCCM program that make it “managed care” and they perceive that there are additional burdens if the program is considered a managed care program. We clarified in the proposed rule that states may operate PCCM programs—under the rubric of integrated care models, ACOs or other similar terms—without triggering the standards of part 438 (which include additional contractual obligations) as long as enrollees’ freedom of choice is not constrained and any willing and qualified provider can participate—that is, where traditional FFS rules for provider participation remain in place. For such programs that use FFS provider participation, only the statutory standards in section 1905(t) of the Act that apply to PCCM contracts will apply, and not our further

interpretations and applications of the provisions of section 1932 of the Act. We requested comment on this proposal and our underlying analysis; further, we requested comment on whether we should consider further rulemaking to better explain these differences.

Specifically, we proposed in § 438.2 to update definitions for primary care case management and PCCM. We proposed to modify the existing definition in § 438.2 for a “primary care case management system” as a system under which a state contracts either with an individual (PCCM) to provide case management services or when a state contracts with an entity to furnish case management services or a defined set of functions that go beyond case management services. We also proposed to remove the reference to an “entity” under the existing definition of “primary care case manager” as an “entity” that provides primary care case management services is defined in the proposed new definition of “PCCM entity” that would permit a broader scope of functions to be provided than those focused on primary care case management services; these include such activities as intensive case management, development of enrollee care plans, execution of contracts and/or oversight responsibilities for the activities of FFS providers, provision of payments to FFS providers, enrollee outreach and education, operation of a customer service call center, provider profiling and quality improvement and measurement, coordination with behavioral health providers, and coordination with LTSS providers. We believe these functions are included in the range of functions that current PCCM programs cover.

We also proposed throughout the proposed and final rule and in the revisions to part 438, to include a reference to a PCCM entity wherever there was an existing standard on PCCMs. We also identified those standards that only apply to PCCM entities when they undertake certain responsibilities on behalf of the state. We proposed to move § 438.3(k) to § 438.3(q) which implements the statutory provisions in section 1905(t) of the Act for PCCM contracts.

In addition, we proposed a new § 438.3(r) to have states obtain our approval of PCCM entity contracts. This proposed paragraph also specifies new standards that we propose elsewhere in this rule. For PCCM entities that have the same administrative responsibilities and financial incentives as MCOs, PIHPs, and PAHPs, states which hold their PCCM entities accountable for provider behavior and quality outcomes

would have to monitor and evaluate the performance of their networks accordingly. We noted that those PCCM entity contracts which provide for shared savings or other payment incentives—the same financial incentives that managed care plans have—should be held to higher standards in terms of enrollee information and quality improvement.

We also proposed changes to the following sections to effectuate these new standards related to PCCM entities that were also discussed in proposed § 438.3(r) in section I.B.2. of the proposed rule: §§ 438.10; 438.330; 438.340; and 438.350. However, we did not propose to subject traditional PCCMs to these standards because PCCMs are not responsible for the activities that PCCM entities are responsible for under our proposed framework. In § 438.10, we proposed to treat PCCM entities like MCOs, PIHPs and PAHPs in areas including oral and written translation standards; general and miscellaneous enrollee information standards; and enrollee handbook and provider directory content standards. In §§ 438.330, 438.340 and 438.350, we proposed small modifications in each section, as follows, to propose new standards for PCCM entities:

- In § 438.330, we proposed that states assess the performance of each PCCM entity to detect over- and underutilization of services; measure performance using standard measures; and conduct a program review.
- In § 438.340, we proposed that the state’s quality strategy, consistent with the guidance provided in SMDL #13–007, describe how the state is assessing the performance and quality outcomes achieved by each PCCM entity.
- In § 438.350, we proposed, based on inquiries received by states with PCCM entities, that the state may have their EQRO perform an EQR of each PCCM entity. Since EQRs of MCOs, PIHPs, and PAHPs focus on the operation of the managed care plan, we believe that applying similar review principles to PCCM entities is reasonable and appropriate.

We received the following comments in response to our proposal to revise §§ 438.2, 438.3, 438.330, 438.340, and 438.350.

Comment: Many commenters supported the distinction between PCCMs and PCCM entities at § 438.2. Several commenters recommended that CMS clarify whether the definition of a PCCM entity includes ACOs, integrated care models, or patient-centered medical home (PCMH) programs. Commenters also recommended that CMS clarify whether the regulations

throughout part 438 apply to ACOs, integrated care models, or PCMH programs. A few commenters recommended that CMS define ACOs for both the Medicare and Medicaid programs. One commenter recommended that CMS establish and define a new entity that delivers comprehensive specialty services across the whole state, or a specific and defined geographic region.

Response: We clarify that the definition of PCCM entity does not include ACOs, integrated care models, or PCMH programs. As discussed in the proposed rule (80 FR 31163), states operating ACOs, integrated care models, or PCMH programs are outside of the purview of Medicaid managed care and are not bound by 42 CFR part 438. We decline to define ACOs for both the Medicare and Medicaid programs, as this is not within the scope of this rule. We also decline to establish and define a new entity that delivers comprehensive specialty services across the whole state, or a specific and defined geographic region. If an organization is providing comprehensive services under a risk contract across the whole state, or a specific and defined geographic region, it must meet the requirements at section 1903(m) of the Act, and the organization is a MCO. If an organization is providing a more limited set of specialty benefits or services under a contract with the state and on the basis of risk-based, capitation payments that do not use state plan payment rates, such an organization is a PAHP. We are available to provide technical assistance to states to determine the appropriate regulatory framework for models under consideration.

Comment: A few commenters recommended that CMS modify the definition of PCCM at § 438.2 to include a clinical nurse specialist (CNS), a registered nurse (RN), and other licensed practitioners, including occupational therapists (OT) and a broader range of primary care providers.

Response: We decline to accept commenters’ recommendations to include a CNS, a RN, and other licensed practitioners, including OT and a broader range of primary care providers in the definition of PCCM, as we lack the statutory authority to do so. Section 1905(t)(2) of the Act defines “PCCM” and that definition is limited to a physician, a physician group practice, or an entity employing or having other arrangements with physicians, or at state option, a nurse practitioner, a certified nurse-midwife, or a physician assistant.

Comment: Many commenters supported the distinction between PCCM and PCCM entity contract requirements at § 438.3(q) and (r). A few commenters recommended that CMS clarify the additional requirements for PCCM entity contracts that provide incentive payments or other financial rewards for improved quality outcomes. One commenter recommended that CMS clarify the difference between program level PCCM entity incentive payments and PCCM entity individual primary care physician incentive payments.

Response: We clarify for commenters that consistent with proposed § 438.3(r), if the state's contract with the PCCM entity provides for shared savings, incentive payments, or other financial rewards for improved quality outcomes, the state must comply with the requirements at § 438.330(b)(2), (b)(3), (c), and (e), § 438.340, and § 438.350. As discussed in the proposed rule (80 FR 31164), states pursuing models that rely on measurable quality improvements as the basis for validation of payment must articulate a quality strategy that describes the state's overall goals and interventions. It is unclear to us why the commenter views program level PCCM entity incentive payments and PCCM entity individual primary care physician incentive payments differently. Generally, PCCM entity incentive payments are shared among individual primary care physicians within the PCCM entity and can vary based on individual primary care physician performance. Such terms would be specified in the contract between the PCCM entity and individual primary care physicians and would not be appropriate for us to clarify in regulation.

After consideration of the public comments, we are finalizing all sections discussing PCCMs and PCCM entities as proposed.

f. Choice of MCOs, PIHPs, PAHPs, PCCMs, and PCCM Entities (§ 438.52)

As noted in our proposed rule in section I.B.6.f., one of the key principles in federal statute and regulations is that enrollees—to the maximum extent possible—have a choice of more than one managed care plan. Section 1932(a)(3) of the Act requires that choice be an element of a mandatory managed care program for MCOs and PCCMs. In the 2002 final rule at current § 438.52, an application of that standard exists for PIHPs and PAHPs.

We proposed modifications to § 438.52(a) to clarify current standards regarding the choice of two entities. Under the current regulation, states

must give enrollees a choice of at least two MCOs, PIHPs, PAHPs, or PCCMs if enrollment with such an entity is required to receive Medicaid benefits. In paragraph (a)(1), we proposed to remove the reference to PCCM and provide that states that enroll beneficiaries in an MCO, PIHP or PAHP must give those beneficiaries a choice of at least two MCOs, PIHPs or PAHPs. As background, in the proposed rule, we proposed to separate PCCMs that are an individual physician (or physician assistant or certified nurse mid-wife) or a physician group practice from an entity or organization that employs such providers and performs services on the state's behalf in addition to basic primary case management services. That proposal underlies the proposed amendments here for how the statutory choice standards would be implemented for PCCMs and PCCM entities. In paragraph (a)(2), we proposed that in a primary care case management system, as currently defined in § 438.2, beneficiaries must be permitted to choose from at least two PCCMs employed by or contracted with the state. In paragraph (a)(3), we proposed that beneficiaries who must enroll in a PCCM entity may be limited to one PCCM entity, but beneficiaries must be permitted to choose from at least two PCCMs employed by or contracted with the PCCM entity.

We received the following comments on proposed § 438.52(a).

Comment: A few commenters supported § 438.52(a) as proposed, while other commenters recommended that CMS revise the requirements at paragraphs (a)(1) and (3). A few commenters recommended that CMS exclude PIHPs and PAHPs from the requirement at paragraph (a)(1) for a state to offer enrollees a choice of at least two managed care plans. Commenters stated that PIHPs and PAHPs provide a very narrow scope of services and should therefore be exempt from the choice requirement. A few commenters also recommended at paragraph (a)(1) that CMS allow the option for a single statewide MCO. A few commenters recommended that CMS require choice for PCCM entities at paragraph (a)(3) consistent with the requirement to offer choice for MCOs, PIHPs, and PAHPs at paragraph (a)(1). Commenters stated that PCCM entities and PCCM entity operations take on similar characteristics of MCOs, and therefore CMS should treat PCCM entities more like MCOs than traditional PCCMs for enrollee choice.

Response: We thank commenters for their support and recommendations at § 438.52(a) but decline to adopt

commenters' recommendations. Section 1932(a)(3)(A) of the Act requires states to permit an individual to choose a managed care entity from not less than two such entities for both MCOs and PCCMs. This statutory directive means that enrollees must have choice between at least two MCOs, as specified in paragraph (a)(1), and between at least two PCCMs, as specified in paragraph (a)(2). Consistent with our authority at section 1902(a)(4) of the Act, we included PIHPs and PAHPs in this choice requirement, *see* 67 FR 41020. Therefore, we decline to allow states to implement a single statewide MCO in a mandatory enrollment program, as this is statutorily prohibited. In addition, we disagree with commenters and decline to adopt recommendations to exclude PIHPs and PAHPs from the choice requirement. By definition, PIHPs and PAHPs cover a more limited set of services than MCOs but still limit enrollees to a network of providers to obtain those services. We maintain that enrollee choice is important for PIHPs and PAHPs.

While we understand commenters' concerns regarding choice for PCCM entities, that is, that choice would be operationalized at the PCCM level as is the case for PCCMs, we decline to require choice at the PCCM entity level. While PCCM entities and MCOs may share similar characteristics, such as quality improvement activities for providers, the operation of a customer service call center, or claims processing, we believe that PCCM entities are fundamentally different in that they are focused solely on care coordination activities and arranging for the provision of services outside of the PCCM entity. In other words, enrollees are not bound by a provider network to obtain services that the PCCM under the PCCM entity may coordinate with as those services are rendered FFS. We also believe that PCCM entity models vary greatly by state, and we recognize that a blanket choice requirement at the PCCM entity level could be disruptive to mature and successful programs already in operation.

Comment: Several commenters recommended that CMS include at § 438.52(a) the requirement that at least one managed care plan must provide the full range of reproductive health services covered in the State plan, to the extent that such reproductive health services fall within the scope of the services covered under the managed care plan's contract.

Response: We appreciate commenters' recommendations to include this requirement but decline to do so, as we believe it is duplicative and

unnecessary. Consistent with § 438.206(a), each state must ensure that all services covered under the State plan, including the full range of reproductive health services covered in the State plan, are available and accessible to enrollees of managed care plans. Further, consistent with § 438.206(b)(4), if the managed care plan's network is unable to provide necessary services covered under the contract to a particular enrollee, the managed care plan must adequately and timely cover these services out of network.

After consideration of public comments, we are finalizing § 438.52(a) as proposed without modification.

Section 1932(a)(3)(B) of the Act provides an exception to the standard that an enrollee have the choice of at least two MCOs, or PCCMs, if applicable, for states with rural areas. This exception is reflected in the current regulations at § 438.52(b), wherein the exception to choice was extended to PIHPs and PAHPs. We proposed two significant changes to the implementation of the rural area exception. First, as a consequence of our proposal to change the implementation of the enrollee choice standards, we proposed to eliminate the rural exception for PCCMs.

We proposed to change the definition of a rural area for purposes of the state option to contract with one MCO, PIHP, PAHP, or PCCM under mandatory Medicaid managed care programs. The current definition of a rural area at § 438.52(b)(3) is any area other than an "urban" area as specified in the Office of Management and Budget's (OMB) delineation of Metropolitan Statistical Areas (hereinafter OMB Bulletin). We noted that the OMB Bulletin produces geographic distinctions focused on a core population center that has a high degree of social and economic integration with adjacent territories as measured by commuting ties, which can include less densely populated areas within a Metropolitan Statistical Area (MSA). Further, OMB has consistently warned against the non-statistical use of the delineations within the OMB Bulletin, noting that: "Metropolitan and Micropolitan Statistical Area Standards do not produce an urban-rural classification, and confusion of these concepts can lead to difficulties in program implementation [for programs that rely on such distinctions]." See for example 75 FR 37236 (June 28, 2010).

Because we have encountered a number of states seeking to contract with one MCO, PIHP, PAHP, or PCCM system in sparsely populated counties that are classified as part of an MSA that

cannot meet the current regulatory definition for a rural area, we proposed changes to this standard.

We proposed to adopt Medicare's county-based classifications to set network adequacy standards under the MA program. As noted in the proposed rule, Medicare establishes population and density parameters based on approaches taken by the Census Bureau in defining "urbanized areas" and OMB's delineation of "metropolitan" and "micropolitan" areas. These parameters are then used to set nationwide county designations as "large metro," "metro," "micro," "rural," or "Counties with Extreme Access Considerations (CEAC)." The county designations are published annually in the MA Health Services Delivery (HSD) Reference file, which is accessible at the MA Applications page at <http://www.cms.gov/Medicare/Medicare-Advantage/Medicare-AdvantageApps/index.html?redirect=/MedicareAdvantageApps/>. We proposed that a county with a designation other than large metro or metro would fall under the definition of a rural area for purposes of the rural exception to choice. We believe that the Medicare county designations would be easy for states to research and for us to confirm a county's classification as rural. In addition, we believe that a number of states that were barred from exercising the rural exception to choice under the existing standard would see greater flexibility with the proposed change. We believe that the modification to the definition of a "rural" area for purposes of exercising the exception to choice of managed care plans addresses past challenges faced by some states. However, consistent with the key principle in favor of managed care plan choice outlined earlier, we continue to encourage the provision of such choice to beneficiaries where feasible.

We noted that we considered adopting the geographic distinctions used by the Office of Rural Health Policy (ORHP) within the Health Resources and Services Administration (HRSA) for purposes of determining a provider's eligibility for grant funding available through that agency. ORHP's definition of a rural area identifies lower population counties or census tracts within a county that otherwise fall under OMB's delineation of MSAs. Census tracts are defined at the zip code rather than county level, so it is possible for a county to include multiple census tracts of different population densities. If we were to adopt ORHP's approach, we would need to establish a review standard for a county that as a whole did not qualify as rural and states would

have the burden of researching the nature and scope of the census tracts to meet the standard.

We received the following comments in response to our proposal to revise § 438.52(b).

Comment: Several commenters supported the rural exception provided at § 438.52(b)(1), which allows a state to limit a rural resident to a single managed care plan consistent with section 1932(a)(3)(B) of the Act. A few commenters opposed § 438.52(b)(1) and stated that the needs of rural areas should be balanced with adequate enrollee choice. A few commenters recommended that CMS waive mandatory managed care requirements or require states to provide a FFS option for rural residents that are limited to a single managed care plan. A few commenters also recommended that CMS include specific network adequacy and timely access to care requirements for states that limit rural residents to a single managed care plan.

Response: We decline to adopt commenters' recommendations as they are not consistent with the requirements at section 1932(a)(3)(B) of the Act, which permits states the option to limit a rural resident to a single MCO if states comply with the requirements we have codified at § 438.52(b)(2). Through our authority under section 1902(a)(4) of the Act, we extended the rural exception to PIHPs and PAHPs. We also decline to waive mandatory managed care requirements or require states to provide a FFS option for rural residents that are limited to a single managed care plan, as section 1932(a)(3)(B) of the Act explicitly references managed care programs with mandatory enrollment. Finally, we decline to add specific network adequacy and timely access to care requirements for states that limit rural residents to a single managed care plan, as such requirements are already applied broadly for all states and managed care plans at § 438.68 and § 438.206(c)(1).

Comment: Several commenters provided recommendations for revisions at § 438.52(b)(2). One commenter recommended that CMS permit states to waive the requirement for choice of primary care providers at § 438.52(b)(2)(i). One commenter opposed § 438.52(b)(2)(ii)(B)(1) regarding the requirement that a provider be given the opportunity to become a participating provider under the same requirements for participation in the managed care plan's network as other network providers of that type. The commenter stated that managed care plans must be given absolute discretion to manage their provider

networks and exclude providers as appropriate.

A few commenters recommended that the requirements at paragraph § 438.52(b)(2)(ii)(C) regarding moral or religious objections be included broadly for all enrollees and not be limited only to enrollees of rural areas that have been limited to a single managed care plan. Finally, several commenters recommended that CMS include requirements at § 438.52(b)(2)(ii) to specify that the single managed care plan must provide the full range of reproductive health services covered in the State Plan and recommended that CMS include specific references to § 438.62 regarding continued services to enrollees and § 438.206(a) regarding access to State plan services.

Response: We decline the commenter's recommendation at § 438.52(b)(2)(i) to waive the requirement for choice of primary care providers, as this is not consistent with the statutory language at section 1932(a)(3)(B)(i) of the Act, which requires states limiting a rural resident to a single MCO to offer the individual the choice of not less than two physicians or case managers. We also decline to remove § 438.52(b)(2)(ii)(B)(1) and clarify for the commenter that such requirements do not limit the managed care plan's discretion to manage their provider networks and exclude providers as appropriate. The regulatory text at § 438.52(b)(2)(ii)(B)(1) and (2) provide that such providers must meet all of the same requirements for participation in the managed care plan's network as other network providers of that type and if the provider does not meet the necessary requirements to join the managed care plan's network, the enrollee can be transitioned to a participating provider within 60 calendar days after being given an opportunity to select a provider who participates in the managed care plan's network.

We remind commenters that paragraph § 438.52(b)(2)(ii)(C) related to moral or religious objections is not limited to enrollees of rural areas that have been limited to a single managed care plan. Within part 438, we have included the appropriate references for moral and religious objections at §§ 438.10(e)(2)(v)(C), 438.10(g)(2)(ii)(A) and (B), and 438.100(b)(2)(iii) for all enrollees of managed care plans. We did not accept the suggestion to add requirements at § 438.52(b)(2)(ii) to specify that the single managed care plan must provide the full range of reproductive health services covered in the State plan or include specific references to § 438.62 regarding

continued services to enrollees or § 438.206(a) regarding access to State plan services, as we find these recommendations to be duplicative of existing requirements. The requirements at §§ 438.62 and 438.206(a) are applicable for all enrollees of managed care plans; therefore, specific references are not required at § 438.52(b)(2)(ii). Consistent with § 438.206(a), each state must ensure that all services covered under the State Plan, including the full range of reproductive health services covered in the State Plan, are available and accessible to enrollees of managed care plans. Further, consistent with § 438.206(b)(4), if the managed care plan's network is unable to provide necessary services covered under the contract, to a particular enrollee, the managed care plan must adequately and timely cover these services out of network for the enrollee.

Comment: Many commenters supported § 438.52(b)(3) regarding the definition and criteria of rural area. A few commenters recommended that CMS allow states the option to use the definition and criteria of rural area that best meets the state's specific needs and circumstances. Other commenters recommended that CMS retain OMB's definition and criteria of rural area. A few commenters recommended that states be allowed to use the rural distinctions used by the ORHP within HRSA. One commenter recommended that CMS include specific criteria for managed care plans in metro areas that serve small and complex populations. The commenter recommended that CMS include such areas in the definition and criteria of rural area for purposes of granting a rural exception and allowing the state to limit those enrollees to one single managed care plan. Several commenters recommended that CMS add requirements at § 438.52(b)(3) to ensure that states utilizing the rural exception have demonstrated that no additional managed care plans will serve the specific rural area. Finally, one commenter recommended that CMS clarify that if more than one managed care plan is currently serving a rural area, the state cannot implement a rural exception until the end of the next contract end date.

Response: We decline to revise the definition and criteria of rural area at § 438.52(b)(3), as we believe the Medicare county-based classifications better reflect our intent for the provision and permits more flexibility for states pursuing the rural exception. We also decline commenters' recommendations to give states the option of which rural area definition to use, or to allow states the option to still utilize the OMB

criteria or the rural distinctions used by the ORHP within HRSA. As discussed in the preamble to the proposed rule at 80 FR 31165, we considered ORHP's approach but concluded that applying the census tract unit of measure, which is determined at the zip code level, would be difficult to apply in this context as the usual unit of measure for managed care service areas is county-based.

We believe that a consistent approach is necessary to ensure that the rural exception is applied uniformly across all managed care programs and populations. We disagree with the commenter that we should add specific criteria for managed care plans in metro areas that serve small and complex populations and include such areas in the definition and criteria of rural area for purposes of granting a rural exception and allowing the state to limit those enrollees to one single managed care plan. This recommendation is not consistent with the language in section 1932(a)(3)(B) of the Act, which provides the exception for an individual residing in a rural area. The recommendation is also not consistent with the requirement in section 1932 of the Act that states are expected to maintain enrollee choice in non-rural areas regardless of the populations served. We also decline to add requirements at § 438.52(b)(3) to ensure that states utilizing the rural exception have demonstrated that no additional managed care plans will serve the specific rural area. This recommendation is operational in nature, and we believe it is unnecessary to include in the regulatory text. Finally, we note and clarify that if multiple managed care plans are currently being offered in a rural area, it is our expectation that states continue to allow choice. It would not be appropriate for states to pursue the rural exception if multiple managed care plans meet the state's requirements and are willing to serve in specific rural areas.

After consideration of the public comments, we are finalizing § 438.52(b) as proposed with a modification with the correct reference to "County with Extreme Access Considerations" in the regulatory text at paragraph (b)(3).

We did not receive comments on proposed § 438.52(c) and (d) and will finalize those provisions as proposed without modification.

g. Non-Emergency Medicaid Transportation PAHPs (§ 438.9)

As states' managed care programs have matured, states have used PAHPs for a broader scope of services than was initially considered when the Medicaid managed care rules were finalized in

2002. With that in consideration, we proposed additional provisions throughout part 438 to address PAHPs providing medical services (as currently defined in § 438.2) which were discussed throughout the proposed rule. However, we noted that we understand that states may also use a PAHP structure to deliver only NEMT services when they are not using the state plan brokerage option authorized through section 1902 of the Act or providing NEMT through Medicaid FFS or as an administrative activity. We also noted that we did not believe that states and PAHPs providing only NEMT services should have to comply with the full scope of PAHP provisions included in part 438. Therefore, we proposed to amend the existing § 438.8 to include only the specific provisions applicable to NEMT PAHPs.

First, we proposed to change the section number of § 438.8 to § 438.9 because of additional sections added to the beginning of the subpart. Second, in an effort to avoid duplicative information, we proposed to delete the existing language in paragraphs (a) and (b) as all the PIHP and PAHP provisions listed in the existing paragraphs are specified throughout the regulatory text of part 438 and, therefore, it was unnecessary to include a separate section listing the standards applicable to PIHPs and PAHPs. We proposed a new paragraph (a) which defines an NEMT PAHP as an entity that provides only NEMT services to enrollees under contract with the state on a pre-paid capitated basis or other payment arrangement that does not use state plan payment rates. If a state chooses to use a PAHP to provide NEMT services along with any other ambulatory medical service, that PAHP would then be considered a traditional PAHP as defined in § 438.2 and all the PAHP provisions throughout part 438 would apply. Lastly, in paragraph (b), we list the specific provisions in part 438 that would apply to NEMT PAHPs in the same way they apply to any other PAHP. The provisions that apply include contracting provisions, actuarial soundness standards, information standards, anti-discrimination provisions, certain state responsibility provisions, certain enrollee rights and responsibilities, certain PAHP standards, enrollee right to fair hearings, and certain program integrity standards.

We received the following comments in response to our proposal to revise § 438.8 to include only the specific provisions applicable to NEMT PAHPs and to change the section number from § 438.8 to § 438.9.

Comment: A few commenters recommended that CMS require NEMT PAHPs to comply with all of the same requirements as PAHPs throughout part 438. A few commenters specifically recommended that CMS require NEMT PAHPs to comply with the grievance and appeal requirements in subpart F of this part. A few commenters recommended that CMS reevaluate the new requirements proposed for NEMT PAHPs, as the new requirements will limit providers and drive up costs with little benefit to Medicaid enrollees.

Response: We carefully considered the requirements for both NEMT PAHPs and PAHPs throughout part 438. We believe that the proposed list at § 438.9(b) achieves the appropriate balance of enrollee protections and administrative efficiency for states and NEMT PAHPs. We maintain that an internal grievance and appeal system does not seem appropriate given the scope of NEMT PAHP contracts. Enrollees receiving services from NEMT PAHPs will continue to have direct access to the state fair hearing process to appeal adverse benefit determinations.

Comment: A few commenters recommended that CMS include a requirement for audited financial reports at § 438.9(b)(1).

Response: We clarify for commenters that audited financial reports are included at § 438.3(m) as a standard contract requirement. Section 438.9(b)(1) requires NEMT PAHPs to comply with all contract provisions in § 438.3, including the audited financial reports at § 438.3(m), except for the specific provisions in § 438.3 listed in § 438.9(b)(1). For clarity, we will finalize paragraph (b)(1) with specific references to the provisions in § 438.3 that do not apply to NEMT PAHP contracts.

Comment: One commenter recommended that CMS clarify whether states must comply with the NEMT PAHP requirement at § 438.9(b)(5) related to the state's responsibilities in § 438.56 regarding disenrollment.

Response: We clarify that § 438.9(b)(5) related to the state's responsibilities in § 438.56 regarding disenrollment would only apply to NEMT PAHPs if the state allows enrollee disenrollment from the NEMT PAHP. We note that consistent with section 1915(b)(4) of the Act, many states selectively contract with one NEMT PAHP, or broker, per geographic region and would not be required to comply with § 438.56.

Comment: Some commenters recommended that § 438.9(b) be amended to make the Indian specific

provisions in § 438.14 applicable to NEMT PAHPs.

Response: We appreciate the commenters observation and have added the provisions of § 438.14 to § 438.9(b) in a new paragraph (b)(10).

Comment: We received one comment recommending that NEMT PAHPs be added in proposed § 438.818. The commenter believed that since NEMT PAHPs were included in proposed § 438.242, they should also be included in proposed § 438.818.

Response: We agree and acknowledge that not including a reference to § 438.818 in the proposed § 438.9 was an oversight. Proposed § 438.9(b)(5) has been revised accordingly.

After consideration of the public comments, we are finalizing § 438.9 as proposed with the addition of specific references to § 438.3 in § 438.9(b)(1), § 438.818 in § 438.9(b)(5), and the addition of the provisions of § 438.14 in § 438.9(b)(10).

h. State Plan Requirements (§ 438.50)

Section 438.50 governs state plan requirements for programs with mandatory managed care enrollment and currently has a reference to "managed care entities." Although defined in the statute, "managed care entities" is an undefined term in the regulation. Because this provision only applies to MCOs and PCCMs as referenced later in § 438.50, we proposed to replace the term "managed care entities" with "MCOs, PCCMs, or PCCM entities, as applicable."

In addition, we proposed to delete paragraphs (e) and (f), which addressed priority and default enrollments for managed care programs operated under section 1932(a) of the Act. These processes, along with other general standards for enrollment, that are applicable to all authorities for managed care programs are provided in the proposed new § 438.54.

We received the following comments in response to our proposal to revise § 438.50.

Comment: One commenter recommended that CMS modify proposed § 438.50(b)(4), pertaining to the public process in both the design and implementation of a managed care program under section 1932(a) of the Act, to set specific standards to include the perspectives of families and, in particular, families of children with special health care needs. Specifically, the commenter stated that states should be required to consult with pediatricians, pediatric medical subspecialists, and pediatric surgical specialists in the public process when

such populations are covered under the managed care program.

Response: We agree that states should engage with appropriate stakeholder groups for public input in the design, implementation, and on-going monitoring of their managed care programs, but to anticipate every appropriate stakeholder for the populations covered under a managed care program in regulation is not feasible. We encourage states to review the covered populations and benefits in their programs and ensure that their stakeholder engagement is sufficiently robust. We decline to revise this provision.

Comment: One commenter requested clarification as to why CMS excluded PIHPs and PAHPs from proposed § 438.50 and encouraged CMS to require that states not be allowed to require enrollment in PIHPs or PAHPs.

Response: Section 438.50, as proposed and finalized here, implements section 1932(a) of the Act, which only addresses MCOs and PCCMs. PIHPs and PAHPs cannot be utilized for programs authorized using section 1932(a) authority. We clarify that § 438.52 permits mandatory enrollment into PIHPs or PAHPs.

Comment: We received one comment recommending that as non-MCO entities provide an increasing number of services comparable to MCOs, (for example, ACOs), CMS should require these entities to operate on a level playing field with existing market participants for requirements such as network requirements, actuarial soundness, solvency and reserves, and quality improvement. The commenter believes it helps reduce administrative barriers to ensure that families and individuals have the most seamless possible transition between coverage types.

Response: We decline to revise this provision to address ACOs. We believe we have addressed this issue by including PCCM entities in § 438.50 and many other sections of this rule. Additionally, we added PAHPs to many provisions of the regulation where the PAHPs had previously been excluded. We believe this creates a more consistent application of the provisions and increases transparency, accountability, and beneficiary protections. ACOs or other integrated care models that do not meet the definition of a MCO, PIHP, PAHP, PCCM, or PCCM entity is not governed by 42 CFR part 438.

After consideration of the public comments, we are finalizing § 438.50 as proposed without modification.

7. Implementing Statutory Provisions

a. Encounter Data and Health Information Systems (§§ 438.2, 438.242 and 438.818)

As explained in the proposed rule at I.B.7.a, sections 6402(c)(3) and 6504(b)(1) of the Affordable Care Act reorganize, amend, and add to sections 1903(i)(25) and 1903(m)(2)(A)(xi) of the Act by adding provisions related to routine reporting of encounter data as a condition for receiving federal matching payments for medical assistance. Section 1903(i)(25) of the Act mandates that, effective March 23, 2010, federal matching payments to the states must not be made for individuals for whom the state does not report enrollee encounter data to us. Further, section 1903(m)(2)(A)(xi) of the Act specifies that an MCO must report “patient encounter data” for contract years after January 1, 2010, to the state in a timeframe and level of detail specified by the Secretary. We noted in the proposed rule that the data that must be collected and reported under these provisions is the same, but the population of covered by section 1903(i)(25) of the Act, compared to the population covered by section 1903(m)(2)(A)(xi) of the Act, included enrollees of PIHPs and PAHPs.

Since effective monitoring of all programs from which enrollees receive services is a critical function, we proposed to expand the contract standards that apply the provisions of section 1903(m)(2)(A)(xi) of the Act to PIHPs and PAHPs by utilizing authority under section 1902(a)(4) of the Act to ensure the proper and efficient operation of the state plan by ensuring provision to the state of information that the state must provide to CMS.

We proposed to add the following:

- A definition of enrollee encounter data in § 438.2;
- Additional MCO, PIHP, and PAHP contract standards defining enrollee encounter data submission and maintenance standards;
- Clarifications to better align the basic elements of a health information system with the Affordable Care Act; and
- Standards on the state to report accurate, complete, and timely enrollee encounter data to us as a condition for receiving federal matching payments on its MCO, PIHP, and PAHP contract expenditures.

In § 438.2, we proposed to define enrollee encounter data as the information relating to the receipt of any item(s) or service(s) by an enrollee under a contract between a state and a

MCO, PIHP, or PAHP that is subject to the standards of §§ 438.242 and 438.818.

We proposed to revise § 438.242 to clarify and align the basic elements of a MCO, PIHP, or PAHP health information system with the Affordable Care Act. The size and scope of today’s Medicaid programs need robust, timely, and accurate data to ensure the highest financial and program performance, support policy analyses, and maintain ongoing improvement that enables data-driven decision making. In August 2013, we released SMDL #13–004 that issued guidance to states on the Transformed Medicaid Statistical Information System (T–MSIS) <http://www.medicaid.gov/Federal-Policy-Guidance/Downloads/SMD-13-004.pdf>. We also indicated that we intended to review whether managed care entities provide timely and accurate encounter data to facilitate the transition to T–MSIS. Future guidance and revisions to the CMS EQR protocols will reflect this ongoing effort. In paragraph (a), we proposed, relying on section 1902(a)(4) of the Act, to include PAHPs in the existing requirement for managed care plans to maintain a health information system meeting certain standards. This aligns with our other proposals to extend existing standards throughout this part to PAHPs because the services they provide are important and they must be held as fully accountable as MCOs and PIHPs; enrollees of PAHPs must be afforded the same protections as MCO and PIHP enrollees. Additionally, we proposed to change the reference to having sufficient data to achieve the objectives of “this subpart” to “this part” to emphasize the critical role data plays in achieving the objectives throughout part 438. We also proposed making this same change in paragraph (b)(4) (redesignated from (b)(3)).

In § 438.242(b)(1), we proposed a specific reference to the new standard in section 6504(a) of the Affordable Care Act, which would mandate that state claims processing and retrieval systems be able to submit data elements to us deemed necessary for Medicaid program integrity, oversight, and improvement. Existing paragraphs (b)(1) through (b)(3) were proposed to be redesignated, respectively, as paragraphs (b)(2) through (b)(4); in paragraph (b)(2), we also proposed to add “all” to clearly indicate that data collected by the state would have to include all services furnished to an enrollee. For similar reasons, we proposed to add “including capitated providers” in paragraph (b)(3)(i) as this is currently a data weakness for many states, MCOs, PIHPs, and PAHPs. Utilization data from capitated providers is frequently less

robust, or in some cases non-existent. This data is equally as important as the data from providers paid on a FFS basis and must be incorporated and utilized in all MCO, PIHP, and PAHP functions.

We proposed a new § 438.242(c) to add standards for enrollee encounter data that would have to be incorporated in all MCO, PIHP, and PAHP contracts. Contracts would have to specify that enrollee encounter data must: Include rendering provider information; include all information that the state is required to produce under § 438.818; and be submitted to the state in a format consistent with the industry standard ASC X12N 835, ASC X12N 837, and NCPDP formatting. In paragraph (c)(2), we also proposed that MCOs, PIHPs, and PAHPs submit data at a level of detail to be specified by CMS. To retain flexibility to adapt to changes in coding and payment practices over time, we anticipate issuing guidance in the future. At a minimum, we expect the initial guidance to address standards for MCOs', PIHPs', and PAHPs' submissions to the state: Enrollee and provider identifying information; service, procedure and diagnosis codes; allowed/paid, enrollee responsibility, and third party liability amounts; and service, claim submission, adjudication, and payment dates.

We proposed to add a new § 438.818 entitled Enrollee Encounter Data to implement the standard for enrollee encounter data reporting by the state to CMS. We proposed that federal matching payments would not be available for states that do not meet established data submission benchmarks for accuracy, completeness, and timeliness. Timeliness and frequency of reporting encounter data is a key issue in terms of alignment between the managed care delivery system and the FFS Medicaid delivery system. We released guidance in 2013¹² that clarified the data elements, reporting structure for, and frequency of enrollee encounter data in the Medicaid Statistical Information System (MSIS). States must submit data monthly for all FFS and managed care services as required by section 1903(r) of the Act.

In addition to receipt of data in a timely manner, we noted that receipt of data that is accurate and complete is integral to our administration and oversight of state Medicaid programs. This means that encounter data submitted to us must represent all services received by an enrollee regardless of payment methodology, including services sub-capitated by a

MCO, PIHP, or PAHP to a provider. In proposed § 438.818(a), we restated the statutory provision prohibiting FFP unless the state meets the standards for submitting sufficient and timely encounter data. Proposed paragraph (a)(1) would require that the submission of encounter data be compliant with current HIPAA security and privacy standards and in the format needed by the MSIS or any successor format. MSIS and T-MSIS are the repositories of all encounter data for the Medicaid program and although submission of data to MSIS has been a standard for years, states have not always invested the resources needed to ensure the quality of the submissions. We proposed these changes to support efforts currently underway to improve the accuracy, timeliness, and completeness of submissions. We proposed in paragraph (a)(2) that the state validate enrollee encounter data before each submission to us. States may use various methods to ensure the accuracy and completeness of the encounter data, including the protocol defining the optional EQR activity for Encounter Data Validation.¹³ We expect that if a state chooses a different method, it would ensure that there is sufficient analytic rigor in the chosen method.

We proposed § 438.818(a)(3) to reinforce the importance of complying with all MSIS encounter data reporting standards as a condition for receipt of FFP and noted that encounter data is just one piece of a complete MSIS submission. To maximize our ability to fully integrate and utilize all MSIS data for comprehensive analysis and oversight, we emphasized that encounter data needs to be fully compliant.

In § 438.818(b) and (c), we proposed to review each encounter data submission for accuracy and potentially defer or disallow payment to a state if it is determined that the enrollee encounter data set is not complete, accurate, and timely. If, after review of an encounter data submission, we determine that it does not comply with established criteria, we proposed to provide the state with a reasonable opportunity to make the submission compliant. Further, if the state is unable to make the submission compliant within the time allowed, we proposed to defer and/or disallow FFP for the MCO, PIHP, or PAHP contract in question. We interpreted the statute as providing for a per-enrollee disallowance for a failure to report enrollee encounter data. We

believe it is more accurate to calculate the deferral and/or disallowance amount based on the enrollee and the specific service type of the non-compliant data. Using this methodology, only the portion of the capitation payment attributable to that enrollee for the service type of the non-compliant data would be considered for deferral and/or disallowance under sections 1903(i)(25) and (m)(2)(A)(xi) of the Act. For example, if the non-compliant encounter data is for inpatient hospital services, then only the inpatient hospital portion of the capitation payment for that enrollee would be subject to deferral and/or disallowance. We proposed that any reduction in FFP would be effectuated through the processes outlined in § 430.40 and § 430.42. In § 438.818(d), we proposed that within 90 calendar days of the effective date of the final regulation, states would have to submit to us a detailed plan of their procedures to ensure that complete and accurate data are being submitted timely. We indicated our intention to work with the states to develop a comprehensive and workable procedure and would review and approve the states' plans for compliance.

We received the following comments in response to our proposal to revise §§ 438.2, 438.242 and 438.818.

Comment: Some commenters expressed support for proposed § 438.242. Commenters believed it added important detail on the responsibilities of the MCOs, PIHPs, and PAHPs to submit complete encounter data to the state.

Response: We thank the commenters for their support.

Comment: We received one comment requesting that proposed § 438.242(b)(2) be amended to include a requirement that a managed care plan's system be capable of collecting, reporting and analyzing data stratified by race, ethnicity, sex, primary language, gender identity, sexual orientation, geography and disability status.

Response: Most of the data elements suggested by the commenter are not required to be provided by Medicaid applicants. Section 435.907(e) of this chapter provides that the state may only require information relevant to an eligibility determination. Section 438.242(c)(3) requires managed care plans to submit all of the data that the state is required to report to CMS under § 438.818 and there are fields in TSIS for race, ethnicity, sex, and disability status, if supplied by the applicant. However, it is not appropriate to mandate submission of data elements that the state may not have a way to

¹² <http://www.medicare.gov/Federal-Policy-Guidance/Downloads/SMD-13-004.pdf>.

¹³ <https://www.medicare.gov/Medicaid-CHIP-Program-Information/By-Topics/Quality-of-Care/Quality-of-Care-External-Quality-Review.html>.

collect unless volunteered by the applicant.

Comment: One commenter requested that CMS add “in all circumstances, without exception” to “Collection and maintenance of sufficient enrollee encounter data to identify the provider who delivers any item(s) or service(s) to enrollees” as proposed in § 438.242(c)(1) to emphasize the importance of submitting the rendering provider data.

Response: While we agree that submitting this data is required, we do not believe it is necessary to add additional emphasis to § 438.242(c)(1). We believe the proposed provisions in § 438.242(c) are sufficiently clear to convey that all managed care plan contracts must provide for the submission of this data.

Comment: A few commenters stated that data is not always available to managed care plans because providers do not supply it. The commenter stated that this issue is particularly acute with providers that are paid an all-inclusive or bundled rate and providers paid on a capitated basis.

Response: We understand the commenters’ concern, particularly for providers paid via capitation by the managed care plans; we added a specific reference to this in proposed § 438.242(b)(3)(i). We do not have the ability to place requirements directly on providers in part 438. However, managed care plans have the ability to, and should, address the issue through their contracts with providers to ensure that the plan meets its obligations under the contract terms required by § 438.242.

Comment: A few commenters requested clarification on “frequency and level of detail” in proposed § 438.242(c)(2). Some commenters requested that CMS specify the data elements required for encounter data submissions. One commenter suggested we include the five EPSDT screening elements, while another commenter suggested adding number of hours worked, travel time, and overtime for home care workers.

Response: We thank the commenters for the opportunity to clarify this issue. Encounter data is critical for states to be able to effectively and efficiently operate their managed care programs and to report to CMS. The encounter data are the basis for any number of required or voluntary activities, including rate setting, risk adjustment, quality measurement, value-based purchasing, program integrity, and policy development. We have engaged in many efforts with states to improve the quality, timeliness, and use of

encounter data. The data elements required in a state’s submission to MSIS/T–MSIS are already defined and states are aware of the required elements. These data elements form the minimum requirement that States must collect from managed care plans under proposed § 438.242(c)(3) to ensure compliance with § 438.818.

However, § 438.242(c)(2) implements section 1903(m)(2)(a)(xi) of the Act, which we believe was intended to broadly support program integrity, program oversight, and administration before expending federal dollars. As proposed, § 438.242(c)(2) did not include specific elements to ensure that we have the ability to respond appropriately to new and emerging program integrity concerns, new methods of fraud waste and abuse, and changing oversight concerns. We believe that this flexibility is particularly important as new, more complex and vulnerable populations transition to managed care and as more federal Medicaid funding is flowing through managed care programs.

Additionally, we recognize that states need additional and different data elements, beyond the minimum required for submission under § 438.818, for other program activities (for example, rate setting, risk adjustment, quality measurement, and value-based purchasing). To make the flexibility we intended clearer and to provide the parameters and substantive standards for identification of the frequency and level of detail for these information submissions, we will revise § 438.242(c)(2) to state that this information must be specified by CMS and the state based on program administration, oversight and program integrity needs. For this reason, we decline to add a specific set of data elements to § 438.242(c)(2).

For EPSDT screenings, we are not aware of any reason why they would not be included in the encounter data submission to the state, if they are reported by the provider to the managed care plan. We note that there are no fields in T–MSIS for number of hours worked, travel time, and overtime for home care workers so the state would not be required to submit that data to MSIS/T–MSIS. Consequently, these data would not be covered by § 438.242(c)(3). The managed care plan, by contract, may be required to submit that data to the state; managed care plans should consult their contract and the state to determine the reporting requirements for that information, if appropriate. We note that § 438.242, as finalized in this rule, imposes a minimum requirement that the state must include and ensure

through its contracts with managed care plans; states may impose additional requirements to serve state needs.

Comment: A few commenters suggested that CMS not require pricing information on encounter data, particularly when the provider is paid on a capitated basis.

Response: We appreciate the complexity of attaching pricing information to encounters from capitated providers, but states need to work with their managed care plans to establish a methodology for consistent submission of these types of encounters. Encounters from capitated providers are too frequently not collected by states despite the fact that they often represent a high volume of services rendered. Including the paid amount on encounter data provides important information to the state and CMS and enables multiple types of useful analysis not previously available. Additionally, this information is increasingly more important as CMS and states apply more data-driven, analytic methods to value-based purchasing efforts and rate development. Per service pricing information may not be available when providers are paid on a capitated basis but at least the amount of the capitation payment should be available.

Comment: One commenter suggested that states share the required data elements and validation process for encounter data with managed care plans and their subcontractors so they can ensure that the data they submit will meet the requirements.

Response: We agree that sharing information on the state’s validation activities could be helpful and encourage states and managed care plans to collaborate on the most effective way to disseminate the information.

Comment: One commenter suggested that states be able to use a proprietary file format if the ASC 12N X835 did not supply sufficient information to managed care plans on the state’s adjudication of encounter data.

Response: We thank the commenters for the opportunity to clarify the requirements in § 438.242(c)(4). We believe that the accuracy, timeliness, and consistency of encounter data will improve, if states and managed care plans use standards that have been developed and are maintained by Standard Setting Organizations (as defined at 45 CFR 160.103). The use of common standards for the submission of an encounter also facilitates the development of guidance and third party tools to support the submission, processing and auditing of encounter data. We also believe that the accuracy,

timeliness, consistency, and efficiency of encounter data submissions can be best achieved by linking the requirements to similar requirements on providers and managed care plans for routine business transactions, such as electronic claim submission and electronic remittance advice.

The standards identified in § 438.242(c)(4) have been developed and are maintained through Standards Setting Organizations. We would also note that there has been significant work to make these standards applicable to encounter data reporting. The ANSI ASC X12 has specifically developed the Post Adjudicated Claims Data Reporting standard for purposes of reporting encounter data. These standards were developed with broad support from the payer and provider community. Additionally, many states have modified definitions of data elements in the ASC X12N 837 standard while maintaining the formatting for purposes of submitting encounter data. This approach has allowed states to collect all necessary claim and remittance data from managed care plans. Although we believe that using a single standard such as the Post Adjudicated Claims Data Reporting is preferable, using the general formats identified in § 438.242(c)(4) will facilitate managed care plans and states moving toward greater standardization.

Managed care plans, providers, and states are required to use the HIPAA compliant versions of the standards identified in § 438.242(c)(4) for routine electronic business transactions. Because the standards are used for routine and necessary business transactions, the standard code sets needed to make the standards workable are also routinely updated. We believe that the more closely the encounter data requirements align with other existing business transactions, the easier it will be to collect high-quality encounter data.

We take this opportunity to clarify that § 438.242(c)(4) requires the use of a standard format. It does not require the use of a specific transaction (for example, a HIPAA compliant Health care claims or equivalent encounter information transaction). If states are using the standard format and modifying the definitions of particular data elements within the format, CMS would find this consistent with the requirements in § 438.242(c)(4). Many states have been able to use the standard formats to collect adjudicated data, therefore we decline to allow the use of proprietary formats.

Comment: Many commenters recommended that CMS supply

standardized formats for encounter data submissions to the state and to CMS. We received one comment suggesting that CMS require managed care plans' network providers to also submit additional information using the ASC 12N X275 format (Additional Information to Support a Health Care Claim or Encounter).

Response: We proposed, and finalized in this rule, specific standardized formats for managed care plans to use in proposed § 438.242(c)(4). We believe that the development and maintenance of the standard formats would be best accomplished through an appropriate Standard Setting Organization with the broad input of all impacted parties. The use of a Standard Setting Organization would also allow for the development of standards that would be applicable to a wider set of plan business needs beyond Medicaid. The standardized formats required for states to submit encounter data to CMS is dictated by MSIS/T-MSIS and has been repeatedly communicated to states. We encourage managed care plans and providers to use standard, electronic transaction to the greatest extent possible. However, dictating the use of particular electronic business transactions between managed care plans and providers is outside the scope of this regulation.

Comment: We received some comments expressing support for proposed § 438.818. Commenters believed it added important detail on the responsibilities of the state to supply high quality data to CMS.

Response: We thank the commenters for their support of § 438.818.

Comment: Several commenters recommended that states make encounter data available to stakeholder groups, advisory groups, and the public.

Response: We are not finalizing a requirement for encounter data to be made public. While we proposed in § 438.602(g)(2) that states would make all data submitted under proposed § 438.604, including encounter data, available upon request or on the state's Web site, we have decided not to require that encounter data be made publicly available in the final rule. After consideration of comments received on the proposed provisions of § 438.602(g)(2), we believe that the proposed rule was overly broad in the types of information that would need to be on the state's Web site or made available upon request. We are finalizing section § 438.602(g) specifying the minimum list of the types of information to be made publicly available on the state's Web site and are not specifying information that must be available upon request.

Comment: Some commenters recommended that CMS provide more resources and/or funding to states to implement the proposed provisions in § 438.818. Commenters believed the provisions would require a significant amount of resources and expertise that some states will have problems accessing.

Response: We understand the commenter's concerns; however, the proposed provisions in § 438.818 are not substantially new in terms of state responsibility. Section 4753 of the Balanced Budget Act of 1997, adding section 1903(r) of the Act, required states to have mechanized information retrieval systems that provided for electronic transmission of encounter data consistent with MSIS. Proposed § 438.818 simply adds provisions for implementing section 1903(i)(25) of the Act. We have been providing technical assistance to states on encounter data submission to MSIS/T-MSIS for many years. Despite this, some states have not or could not make the investment of resources previously to comply with MSIS/T-MSIS requirements; as proposed and finalized, § 438.818 will require them to make that investment. We are obligated to implement the statutory requirements in section 1903(i)(25) of the Act to condition FFP on the provision of this data by the state; we believe that states' administration of their managed care programs will benefit in numerous ways from receiving more timely, accurate, and complete encounter data.

Comment: One commenter noted that as managed care plan contracting moves to a more value-based approach, one incentive for providers to participate is to limit the amount of reporting and submissions. The commenter recommended that CMS engage with states and managed care plans about the tension between encounter data submission and value-based purchasing.

Response: We assume that these comments are applicable to both §§ 438.242 and 438.818 Value-based purchasing, which is frequently focused on outcomes, may require additional alternative types of data and the use of different methods to document the provision of services and evaluate the quality of services. In many circumstances, value-based purchasing has required more extensive data exchanges between providers and managed care plans to ensure the distribution of adequate information about an enrollee's care. Value-based purchasing may, overtime, require the health care community to develop different methods and systems for documenting the provision of services

than the claims-based approach used today. We will work with stakeholders to monitor the information needs associated with value-based purchasing; however, the predominant method for documenting the provision of health care services today is the use of claims data. We note that § 438.242(c)(2) permits changes in the frequency and level of data when necessary for program administration, oversight and program integrity, not necessarily to support transitions to different purchasing models if data other than encounter data is collected. States that transition to other purchasing models should be careful to assure that their contracts with managed care plans support the states' needs for data.

Comment: One commenter suggested that any assessment of "sufficient and timely" encounter data as proposed in § 438.818(a) should also provide consideration for value based purchasing initiatives and how states can document expenditures for value and outcomes that may not be captured in encounter data.

Response: We understand the commenter's concern and agree that certain outcomes, particularly a reduction in undesirable services (for example, readmissions), may not be readily apparent in encounter data. However, we believe that complete encounter data can demonstrate these improvements through analysis, making compliance with the proposed provisions even more critical. Better, more complex, analysis requires more complete, timely, and accurate data.

Comment: One commenter stated that burdensome reporting requirements could cause some health care providers to not contract with managed care plans and affect network adequacy.

Response: We are unclear why the commenter believes the proposed requirements in either §§ 438.242 or 438.818 would pose an unreasonable burden on providers. The data required is no more than required on a claim in a standardized format, which most other health insurance issuers require for all product lines. We acknowledge that there is more variation in billing practices for LTSS providers, but many states with managed LTSS programs have developed policies to address consistent code sets and standards for their use.

Comment: We received several comments requesting clarification of terms used in proposed § 438.818. Commenters questioned the meaning of "validate" and "completeness" in proposed § 438.818(a)(2).

Response: We thank the commenter for the opportunity to clarify this

requirement. The requirement in in § 438.818(a)(2) was intended to capture two different types of validation. First, it was intended to require states to review and confirm that the information that the state received from managed care plans under § 438.242(c) was complete and accurate. That is, the encounter data supplied to the state under § 438.242(c) was a true representation of the encounter data held by the managed care plan after the adjudication of all providers claims, for all services, for all enrollees under the managed care plan's contract with the state. We agree that this validation requirement could be clearer and we are finalizing a new paragraph § 438.242(d), which states the State shall review and validate that the encounter data collected, maintained, and submitted to the State by the MCO, PIHP, or PAHP, meets the requirements of this section. The State shall have procedures and quality assurance protocols to ensure that enrollee encounter data submitted under paragraph (c) is a complete and accurate representation of the services provided to the enrollees under the contract between the State and the MCO, PIHP, or PAHP.

The second type of validation intended under § 438.818(a)(2) was to require states to validate the data to CMS through MSIS/T-MSIS as complete and accurate. Submission of encounter data by managed care plans to the state consistent with the requirements in § 438.242 enables the state to submit data to CMS that is complete and accurate; under these regulations, states are responsible for reviewing the data and making sure that the regulation standards are met before submitting the data to CMS. Section 438.818 also requires that states submit all of the data elements required by MSIS/T-MSIS, for all of the services, for all of the enrollees enrolled in the states' managed care plans. We will clarify these requirements by modifying § 438.818(a)(2) to state that states must ensure that enrollee encounter data is validated for accuracy and completeness as required under § 438.242 before submitting data to CMS. States shall also validate that the data submitted to CMS is a complete and accurate representation of the information submitted to the State by the MCOs, PIHPs, or PAHPs.

In finalizing § 438.242(d) and § 438.818(a)(2), we eliminated the text, "States may use the EQR activity required in § 438.358 for the validation of encounter data to meet this requirement." We eliminated this language for two reasons. First, the validation of encounter data is an

optional activity under § 438.358 and it is not a required activity. Second, the use of an EQR to validate the encounter data reported by a managed care plan can be an important component of states' procedures and quality assurance protocols to ensure that enrollee encounter data submitted is a complete and accurate representation of the services. However, an annual validation alone is probably not adequate. Many states have been developing procedures and protocols to ensure that their data is complete and accurate, including evaluating the value of submitted claims against the managed care plan's general ledger, random sampling of claims within managed care plans' systems, and other types of reconciliation. States have found that performing validation activity on a monthly or quarterly basis has improved the data collection efforts. We support and encourage states' efforts to improve encounter data. CMS anticipates continuing to work with states and to publish guidance and best practices based on states' experiences.

Comment: We received several comments requesting clarification of other terms used in proposed § 438.818. Commenters questioned the meaning of "fully comply" in proposed § 438.818(a)(3), "compliance issues" in § 438.818(c) and "reasonable opportunity" as used in the preamble for § 438.818(c).

Response: We do not intend a unique meaning to "fully comply" in proposed § 438.818(a)(3) with the caveat that we acknowledge that states are currently in varying stages of compliance with MSIS/T-MSIS requirements and are working with CMS to document any deficiencies. For those states, "fully" will be considered to be within the parameters approved by CMS at the time of submission. "Reasonable opportunity" was used in the preamble in reference to proposed § 438.818(c) where we proposed, if, after review of an encounter data submission, we determine that it does not comply with established criteria, we propose to provide the State with a reasonable opportunity to make the submission compliant. States currently receive feedback from CMS on their MSIS/T-MSIS submissions and are expected to correct any noted deficiencies and resubmit corrected data. As the final rule is implemented, additional guidance will be provided clarifying additional details. "Compliance issues" simply refers back to § 438.818(b) which states CMS will assess a State's submission to determine if it complies with current criteria for accuracy and completeness; "compliance issues" would be anything that causes us to

determine that the submission is not compliant with current criteria for accuracy and completeness.

Comment: We received a few comments raising the issue of the expense of data validation. Commenters believed that CMS should provide additional funding to states for validation activities; allow the enhanced FFP rate of 75 percent apply to any vendor that performs data validation; and allow managed care plans to have policies and procedures for ensuring accuracy and completeness and only require that EQROs review those policies and procedures.

Response: We understand the commenters' concerns regarding the expense of data validation. However, we believe that States should generally already be taking steps to ensure the accuracy and completeness of encounter data. The ability to collect accurate, timely, and complete encounter data is critical to the effective operation of a managed care program. We are aware that many states have been devoting resources and efforts to improve their data collection efforts. CMS supports these efforts and is available for technical assistance. We acknowledge that the validation processes used by states need to accommodate the monthly submission schedule for T-MSIS. Given that MSIS/T-MSIS submissions are subject to deferral or disallowance of FFP under section 1903 of the Act, we do not believe that a policy review alone is sufficient. The enhanced FFP rate of 75 percent in section 1903(a)(3)(C)(ii) of the Act is only designated for work performed by an EQR in reviewing MCO performance (see § 438.370). We do not have the authority to extend that provision to other entity.

Comment: We received one comment requesting clarification on whether the validation for accuracy and completeness had to be performed by an entity outside of the state Medicaid agency.

Response: It was not our intent to imply that the validation for accuracy and completeness under § 438.242(d) and § 438.818 had to be done outside of the state Medicaid agency. States can perform their own data validation for accuracy and completeness if they choose.

Comment: We received some comments requesting that CMS specify the standards states should use to determine accuracy and completeness of encounter data. One commenter recommended that CMS work with states to determine mutually agreeable standards. One commenter believed that standards for accuracy and

completeness should be customized by state to account for programmatic differences. One commenter requested clarification on whether the three tiers of edits applied by T-MSIS would meet CMS' expectations for quality, accuracy, and completeness.

Response: We understand the commenters' request for more specificity on this important provision. However, we do not believe CMS should set specific standards for accuracy and completeness under § 438.242(d). We believe states understand the importance of encounter data and will set sufficiently stringent standards under § 438.242(d) to complete successful MSIS/T-MSIS submissions, as well as to fulfill other programmatic data needs. For MSIS/T-MSIS submissions, deferrals and/or disallowances will be based on the results of evaluative processes to assess timeliness, accuracy, and completeness including but not limited to system edits. If it is determined that additional guidance on the evaluative processes or edits is needed after the release of this final rule, we will provide it.

Comment: We received one comment requesting that CMS prohibit states from applying FFS claims edits to encounter data and to require states to report how many encounter records they deny based on those edits.

Response: We understand the commenter's concern and agree that some FFS claims edits may not be appropriate to apply to encounter data and encourage states to review the edits that it applies to encounter data to ensure that they are appropriate. However, we decline to add that level of specificity to § 438.242 or require denial rate reporting in § 438.818.

Comments: We received many comments suggesting the amount of time states and managed care plans will need to comply with proposed §§ 438.242 and 438.818. Suggestion ranged from 1 to 5 years, while other commenters recommended a "phased in" approach.

Response: We understand the commenters' concerns but maintain that states have historically been required to collect encounter data under § 438.242. This final rule provides greater detail and clarification on this requirement. Similarly, we believe that sufficient time has been allowed for states to come into compliance with MSIS/T-MSIS submissions. States have been working with us to comply with TMSIS requirements utilizing established design and testing processes. As such, we acknowledge that the submission of an implementation plan by the state as proposed in § 438.818(d) may not be a

productive mechanism given states' current progress in achieving milestones toward full production status. To date, some states have completed sufficient testing and have already moved into the production phase of TMSIS submissions. Therefore, to help states keep their IT resources focused on full TMSIS compliance and eliminate unnecessary burden, we will not finalize § 438.818(d) and, instead, continue to utilize established processes.

Comment: We received several comments on the difficulty of collecting encounter data on LTSS due to the lack of standardized coding. Some commenters recommended that CMS create codes for states to use while others suggested that states be exempt from proposed §§ 438.242 and 438.818 for MLTSS programs. One commenter recommended that states have flexibility in how they are required to submit data for non-state plan services and services that are more administrative. The commenter believed data on those types of services are dissimilar enough to the traditional types of encounter data reported that additional flexibility was warranted.

Response: We understand there are some challenges with standardized coding for certain services, particularly for LTSS. However, we do not create billing codes; rather, we endorse the use of industry established codes, which we believe exist for the majority of covered services. Additionally, T-MSIS allows for each state to maintain a list of non-standard codes used in their data; codes submitted and on the state's approved list will not generate an error when submitted to T-MSIS. We do not believe that exempting states with MLTSS plans from submitting any encounter data is an appropriate solution. The requirements in § 438.242, as proposed and finalized here, provide states the flexibility to work with managed care plans and providers of LTSS services to ensure that claims submitted to managed care plans and encounter data submitted to the state meets the needs of the program. States need to understand the types of services and amount of services provided to individuals receiving LTSS, just as with any other Medicaid service. The text in § 438.242 provides states the ability to collect the data consistent with their needs. Therefore, we decline to make the recommended modifications.

Comment: We received numerous comments on requesting clarification on "sufficient and timely" in proposed § 438.818(a). Some commenters suggested that states should be able to define it for themselves while many

commenters stated that the expectation should never be for 100 percent compliance.

Response: We do not believe it would be appropriate for each state to set its own standard for submission of encounter data. We believe since all encounter data submitted by states is stored in MSIS/T–MSIS, it is more appropriate that the criteria be consistent to the extent possible. States will be notified as additional implementation details become available. To avoid ambiguity and clarify our intent, we will remove “sufficient and timely;” we do not want imply that our goal for T–MSIS is less than 100% compliance or that timeliness is the only criteria for encounter data.

Comment: A few commenters requested clarification on the process that CMS will use for submission and review of encounter data under § 438.818.

Response: The processes for submission and review of encounter data under § 438.818 are already established in the procedures for MSIS/T–MSIS. We did not intend to imply there would be separate or different processes as result of this rule. If there are changes in MSIS/T–MSIS procedures, states will be notified.

Comment: We received several comments on the challenges that states face in submitting data to MSIS, such as changing data dictionary values and formats. Commenters believe that CMS should not assume that having problems completing a successful MSIS submission indicates poor quality encounter data. Some commenters also believed that any deferrals or disallowances should be based on the actual quality of the data, not the state’s ability to complete a successful MSIS submission.

Response: We understand the commenters’ concerns. We agree that states’ effort to collect complete and accurate data from managed care plans is distinct from their MSIS/T–MSIS submissions. However, we are limited in our ability to accept and/or evaluate encounter data outside of MSIS/T–MSIS. We acknowledge that challenges exist in submitting to MSIS/T–MSIS and we continue to utilize states’ experiences to determine needed enhancements to these systems. Additional details of the deferral and disallowance processes will be shared with states as they become available.

Comment: We received one comment suggesting that submission of encounter data not be required more frequently than quarterly.

Response: We do not agree that a revision of that nature is appropriate for either § 438.242 or § 438.818. As states operate their managed care program and pursue delivery system reforms, timely and accurate data is increasingly critical. Thorough and useful program monitoring should utilize the most current data available. As such, we believe a monthly schedule for T–MSIS, as currently exists, is appropriate. We also believe that most states are already collecting encounter data from managed care plans monthly or more frequently.

Comment: We received one comment recommending that CMS rely on financial analysis rather than encounter data.

Response: We do not agree with the commenter that financial analysis alone is sufficient. We acknowledge that financial analysis is an excellent tool for evaluating encounter data and encourage all states to utilize it, but we do not consider it a suitable replacement for the submission of encounter data.

Comment: We received one comment requesting that CMS provide greater clarity on when deferral is appropriate, when a disallowance is appropriate, and when either may be appropriate as they are applied in proposed § 438.818(c).

Response: A reduction in FFP warranted by a state’s failure to comply with § 438.818 would be effectuated through the processes outlined in § 430.40 and § 430.42 and we are finalizing § 438.818(c) with additional language to make that clear. Additional details on the specific standards to be used to determine the necessity for a deferral or disallowance will be provided through sub-regulatory guidance.

Comment: We received several comments recommending that any measure of accuracy and completeness by CMS as proposed in § 438.818(b) be done at the aggregate level only, not at the individual record level. Commenters believed that CMS must recognize some of the inherent challenges with encounter data that will be unique to certain programs, such as MLTSS.

Response: We do not agree that evaluation should be done only at the aggregate level. We acknowledge the challenges in collecting certain types of data consistently, particularly in MLTSS programs, but believe that analysis at the individual record level is the most appropriate and necessary to fulfill statutory intent in section 1903(i)(25) of the Act, which provides that payment of FFP shall not be made with respect to any amounts expended for medical assistance for individuals for whom the State does not report enrollee encounter

data (as defined by the Secretary) to the MSIS in a timely manner (as determined by the Secretary). This requirement also applies to payments for assistance for beneficiaries in Medicaid FFS and enrollees in a Medicaid managed care plan.

Comment: We received many comments on the deferrals and disallowances provisions proposed in § 438.818(c). Some commenters suggested that CMS should delay imposing a deferral and/or disallowance for a specified period of time; suggestions ranged from 2–5 years. A few commenters suggested removing proposed § 438.818(c) completely; others suggested replacing it with CMS providing additional technical assistance for non-compliant submissions; and one commenter suggested that deferrals and disallowances not be taken if the enrollee did not receive any services. One commenter believed that payment should not be retracted from the managed care plans when a deferral and/or disallowance are taken as a result of an error by the state.

Response: We appreciate the comments received on this important provision and remind commenters that this provision was added to implement section 1903(i)(25) of the Act. We understand the significance of this provision and states will be provided adequate advance notification as more details of the implementation process become available. To the comment regarding enrollees that have not received services, and thus, have no encounter data to report, it was never our intent to penalize a state for not submitting data that does not exist due to the enrollee not receiving services. Processes to accommodate this will be addressed in the implementation process. The retraction of capitation to a managed care plan as a result of a deferral and/or disallowance of FFP is outside the scope of this rule and should be addressed by the state in its managed care plan contracts.

Comment: We received one comment recommending that CMS specify the standards and processes it will utilize to determine deferrals and disallowances so that the information can be added to the managed care plans’ contract.

Response: States will be provided adequate advance notification as more details of the implementation process become available. States are free to include the information in their managed care plan contracts as they deem appropriate.

After consideration of the public comments, we are adopting §§ 438.242 and 438.818 as proposed, with the

following changes. In § 438.242(b)(4), we removed “as required in this part” to make our intention clearer that all collected data must be available to the state and CMS. In § 438.242(c)(2), text was added to clarify and establish the standards and parameters for identifying the frequency and level of data. In § 438.242(d), we are finalizing different regulation text to require state review and validation of all collected encounter data. In § 438.818(a)(2), we are finalizing different regulation text to clarify that the validation required in § 438.242(d) must be completed before the data is submitted to CMS and that states must validate that the data submitted to CMS is a complete and accurate representation of the data submitted to the state. In § 438.818(c), clarifying language addressing deferrals and disallowances was added. The proposed text in § 438.818(d) is not being finalized, as explained above.

b. Standards for Contracts Involving Indians, Indian Health Care Providers and Indian Managed Care Entities (§ 438.14)

This section implements section 5006(d) of the American Reinvestment and Recovery Act of 2009, which created section 1932(h) of the Act governing the treatment of Indians, Indian health care providers and Indian managed care entities, participating in Medicaid managed care programs. We had previously provided guidance on this statutory provision in a SMDL on January 22, 2010 (SMDL #10-001, ARRA #6) <http://www.medicaid.gov/Federal-Policy-Guidance/downloads/SMD10001.PDF>. To ensure the proper and efficient operation of the state plan, we proposed to expand the standards that apply the provisions of section 1932(h) of the Act to PIHPs and PAHPs through the authority under section 1902(a)(4) of the Act.

We proposed in paragraph (a) to define the following terms: “Indian,” “Indian health care provider (IHCP),” and “Indian managed care entity (IMCE)” consistent with statutory and existing regulatory definitions with minor modifications to extend the definitions, as applicable, to PIHPs and PAHPs.

In paragraph (b), we proposed that each MCO, PIHP, PAHP, PCCM, and PCCM entity’s contract had to comply with the provisions of (b)(1) through (5):

- In (b)(1), we proposed that each MCO, PIHP, PAHP, and PCCM entity’s contract must demonstrate sufficient IHCPs in the managed care network and that Indian enrollees be able to obtain services from them;

- In (b)(2), we proposed that IHCPs be paid for covered services provided to Indian enrollees who are eligible to receive services from such providers whether the IHCP participates in the managed care network or not;

- In (b)(3), we proposed to permit any Indian who is enrolled in a non-Indian MCO, PIHP, PAHP, PCCM, or PCCM entity and eligible to receive services from a participating IHCP to choose that IHCP as his or her primary care provider, as long as that provider has capacity to provide the services;

- In (b)(4), we proposed to permit Indian enrollees to obtain services covered under the MCO’s, PIHP’s, PAHP’s, or PCCM entity’s contract, from out-of-network IHCPs; and

- In (b)(5), we proposed that in any state where timely access to covered services cannot be ensured due to few or no IHCPs, a MCO, PIHP, PAHP, and PCCM would be considered to have met the standard for adequacy of IHCP providers if either Indian enrollees are permitted to access out-of-state IHCPs, or the state deems the lack of IHCP providers to justify good cause for an Indian’s disenrollment from both the MCO, PIHP, PAHP, or PCCM entity and the state’s managed care program in accordance with § 438.56(c).

Proposed § 438.14(c) outlined payment standards to implement section 1932(h) of the Act. Paragraph (c)(1) specified that when an IHCP is enrolled in Medicaid as a FQHC but is not a participating provider with a MCO, PIHP, PAHP, or PCCM entity, it must be paid FQHC payment rates, including any supplemental payment due from the state. Where the IHCPs is not enrolled in Medicaid as a FQHC, paragraph (c)(2) would have the MCO, PIHP, PAHP, or PCCM entity payment be the same payment as it would receive using a FFS payment methodology under the state plan or the applicable encounter rate published annually in the **Federal Register** by the Indian Health Service, regardless of its contracting status with the MCO, PIHP or PAHP. Paragraph (c)(3) proposed that when the amount a IHCP receives is less than the amount required in paragraph (c)(2), the state must make a supplemental payment to the IHCP to make up the difference between the amount paid by the managed care plan and the amount required in paragraph (c)(2).

Paragraph (d) would implement the statutory provision permitting an IMCE to restrict its enrollment to Indians in the same manner as Indian Health Programs may restrict the delivery of services to Indians, without being in violation of the standards in § 438.3(d).

This proposed rule has tribal implications and is therefore, subject to the CMS Tribal Consultation Policy (December 2015) <http://www.cms.gov/Outreach-and-Education/American-Indian-Alaska-Native/AIAN/Downloads/CMSTribalconsultationpolicy2015.pdf>. Consistent with this policy, after the proposed rule was published on June 1, 2015, CMS issued a Dear Tribal Leader Letter soliciting advice and input from tribes and held a second All Tribes Call on June 25 to present an overview of the rule and the tribal specific provisions. On July 15, 2015, CMS attended the Tribal Technical Advisory Group meeting to discuss the proposed rule provisions and solicit tribal advice and input.

We solicited comment on the overall approach to this provision, including as to whether these proposals are adequate to ensure that Indian enrollees have timely and integrated access to covered services consistent with section 5006 of the ARRA. We solicited comment on how to facilitate a coordinated approach for care for Indian enrollees who receive services from a non-participating IHCP and who need Medicaid covered services through a referral to a specialty provider. Also, we solicited comment on the potential barriers to contracting with managed care plans for IHCPs and what technical assistance and resources should be made available to states, managed care plans, and IHCPs to facilitate these relationships.

We received the following comments in response to our proposal to revise § 438.14.

Comment: A few commenters expressed concern that meaningful tribal consultation had not occurred given that the proposed rule has tribal implications and is subject to the CMS Tribal Consultation Policy. Commenters believed that it was critical that CMS work directly with the TTAG and other tribal entities to ensure that the final rule reflects suggestions received through that engagement about minimizing any disruption to services for individual AI/ANs or tribes as a whole. Commenters believed the All Tribes’ Calls conducted prior to release of the proposed rule did not constitute acceptable tribal consultation, particularly for a proposed rule that affects tribal interests. Commenters recommended that CMS should ensure that the tribal community be given further opportunity to consult, review, and respond to provisions in the proposed rule before publication of the final rule.

Response: We complied with its Tribal Consultation Policy (Policy) in

the development of this proposed rule. We held an All Tribes' Call on May 7, 2014, prior to development of the proposed rule to obtain advice and input on Tribal issues surrounding Medicaid managed care, consistent with the Policy. In an effort to preserve the federal government's deliberative process privilege, however, CMS does not consult with outside parties, including tribes, on the specifics of a proposed rule. Nevertheless, prior to the publication of the proposed rule, CMS staff attended the February 2015 TTAG face-to-face meeting to solicit advice and input on Medicaid managed care issues in general and to understand the tribal implications. After the proposed rule was published on June 1, 2015, CMS issued a Dear Tribal Leader Letter soliciting advice and input from tribes and held a second All Tribes Call on June 25, 2015, to present an overview of the rule and the tribal specific provisions. We considered the tribal comments that were submitted to the proposed rule consistent with the process identified in the proposed rule in the **Federal Register** (80 FR 31098). The All Tribes Calls were intended to provide information and answer questions to facilitate the formal submission of comments to the proposed rule. In addition, on July 15, 2015, we attended the TTAG meeting to discuss the proposed rule provisions and solicit tribal advice and input.

Comment: Several commenters requested that CMS clarify that section 1932(a)(2)(C) of the Act (adding section 1932(h) of the Act), which does not permit mandatory enrollment of Indians in a managed care program, cannot be waived through a section 1915(b) or 1115(a) demonstration waiver. The Balanced Budget Act (BBA) of 1997 allowed states to impose mandatory managed care programs through a State plan amendment, but Congress specifically prohibited states from mandating Indians into managed care through section 1932(a)(2)(C) of the Act. Commenters believed that CMS has interpreted the Indian managed care protections in section 1932(a)(2)(C) of the Act too narrowly by applying them only to managed care programs authorized under section 1932(a) of the Act. The commenters believe that interpretation is not consistent with Congressional intent, which they believe was to exclude Indians from mandatory enrollment into managed care under all authorities. Other commenters were supportive of CMS' past practice of not permitting mandatory enrollment of Indians into managed care under section 1115(a)

demonstrations and referred to that practice as not permitting a waiver of section 1932(a)(2)(C) of the Act.

Response: We appreciate the opportunity to clarify the scope of section 1932(a)(2)(C) of the Act pertaining to enrollment of Indians into Medicaid managed care programs and the relation of that provision to other authorities for Medicaid managed care programs. Section 1932(a)(1) of the Act provides the ability for states to operate a mandatory Medicaid managed care program under the state plan subject to special rules at section 1932(a)(2) of the Act, and the Indian enrollment provisions are found at section 1932(a)(2)(C) of the Act. That paragraph explicitly provides that a state may not require under paragraph (1)—that is, section 1932(a)(1) of the Act—the enrollment of an individual who is an Indian unless the managed care entity contracted with the state is the Indian Health Service, an Indian health program operated by an Indian tribe or tribal organization under the Indian Self-Determination Act, or an urban Indian health program operated under Title V of the Indian Health Care Improvement Act. Because section 1932(a)(2)(C) of the Act refers to the state option to authorize a Medicaid managed care program under section 1932(a) authority, the prohibition on mandatory enrollment of Indians into a Medicaid managed care program can only be read as limited to that authority.

Many states use section 1115(a) demonstration authority to operate Medicaid managed care programs. For managed care programs operated under either section 1915(b) or 1115(a) authorities, tribal consultation must be conducted in accordance with the approved Tribal Consultation state plan, and as approval of waivers is at the discretion of the Secretary, we verify that the required processes were followed to solicit robust tribal input before determining whether to permit states to mandatorily enroll Indians into managed care. We take this opportunity to address the statement by commenters that past practice under section 1115(a) demonstrations was a decision not to waive section 1932(a)(2)(C) of the Act. That is not correct. Section 1115(a) of the Act authorizes the Secretary to waive provisions of section 1902 of the Act and grant expenditures of FFP under section 1903 of the Act. As discussed above, section 1932(a)(2)(C) of the Act applies only to managed care programs operated under section 1932(a) of the Act. Any past decisions not to permit mandatory enrollment of Indians into managed care under section 1115(a) demonstration authority was the

result of negotiations with those specific states and tribes. We decline to formalize any past practice related to Indian enrollment into managed care under section 1115(a) demonstrations in this regulation.

However, in light of the significant comments received on the differences across managed care authorities and the parameters for mandatory enrollment of Indians, we intend to develop sub-regulatory guidance on mandatory enrollment of Indians under section 1932(a), 1915(b), and 1115(a) authorities through the tribal consultation process.

Comment: Several commenters were supportive of codifying the protections in section 1932(h) of the Act, as added by section 5006(d) of ARRA at proposed § 438.14. However, commenters stated that these statutory protections were designed to supplement, not replace the protections from mandatory enrollment in section 1932(a)(2)(C) of the Act, and remain important for American Indians and Alaska Natives who are enrolled in managed care and continue to receive services from an IHCP.

Response: We appreciate the comments in support of § 438.14 generally. The provisions of § 438.14, as finalized here, will apply to managed care programs regardless of the authority used by the state to operate its Medicaid managed care program. As described above, the prohibition on mandatory enrollment for Indians only applies to managed care programs operated under section 1932(a) of the Act. We did not receive comments on paragraph (a) that would define "Indian," "Indian health care provider (IHCP)," and "Indian managed care entity (IMCE)" consistent with statutory and existing regulatory definitions and will finalize those definitions as proposed. Upon review of proposed § 438.14, we identified a number of paragraphs that incorrectly included PCCMs or did not include PCCM entities. To correct this error, we will strike "PCCM" from § 438.14(b), (b)(2)(i), (b)(5), and (c)(3), and include a reference to PCCM "entity" in paragraphs (b) and (b)(5) in the final rule. These corrections have been made to more accurately reflect the obligations of PCCMs and PCCM entities. For example, it excludes PCCMs from network adequacy, rate negotiation, and claim payment provisions since PCCMs do not perform those functions. We believe that implementing these requirements for PCCM entities, which may have networks of providers or process claims, meet the statutory requirements in section 1932(h) of the Act that impose

these access and payment standards on PCCMs generally.

Comment: Many commenters recommended that CMS strengthen § 438.14(b) by requiring oversight and enforcement of states and contracted managed care plans to ensure compliance with the Indian-specific requirements. Commenters also stated that managed care plans are not abiding by the cost sharing prohibitions for Indians under § 447.56. In addition, commenters recommended that CMS must require that managed care plans actively and regularly provide verification to CMS that they are in compliance with § 438.14. Some commenters also suggested that the quality assessment activities required under subpart E of part 438 address compliance with the Indian-specific provisions in § 438.14.

Response: As proposed and finalized, the regulatory language in § 438.14 imposes on the state the responsibility to oversee the compliance of their contracted managed care plans with the provisions of § 438.14, which must be incorporated into the contract between the state and the managed care plan. Because the state is the direct contractor with the managed care plans, we believe it is not appropriate to require managed care plans to directly verify compliance with § 438.14 with CMS; this division of responsibility is consistent with how Medicaid operates. Regarding comments about managed care plans failure to adhere to the cost sharing protections for Indians at § 447.56, we note that § 438.108 incorporates the cost sharing provisions in §§ 447.50 through 448.82 of this chapter as a contractual requirement. In the event managed care plans are inappropriately assessing cost sharing on Indian enrollees, such non-compliance must be brought to the attention of the states as a contract compliance issue to be remedied.

In reference to comments about including § 438.14 under subpart E, we interpret those comments as equating the requirements in relation to quality assessment in subpart E with a state's general oversight of the provisions in 42 CFR part 438. The quality assessment activities in § 438.330 are developed by the state and under this rule CMS may specify performance measures and performance improvement initiatives through a public notice and comment process. There are many provisions in subpart E related to performance improvement initiatives that would impact all populations covered under a managed care contract. Due to the scope of subpart E, it is not appropriate or necessary to include a cross-reference to

the contractual requirements in § 438.14.

Comment: Several commenters suggested that in order for managed care plans and PCCM entities, to the extent the PCCM entity has a provider network, to meet the requirement at § 438.14(b)(1) that there be "sufficient" IHCPs in the networks, the regulations should be amended to require the managed care plans or PCCM entities to demonstrate sufficiency by offering network provider agreements using an Indian Managed Care Addendum to all IHCPs in their service area who request one. Commenters also requested clarification as to how CMS will determine that the IHCP network is sufficient to satisfy § 438.14(b).

Commenters responded affirmatively to CMS' request for comment as to whether there should be a contract addendum for IHCP participation in Medicaid managed care networks similar to those created for QHPs and Medicare Part D plans and recommended that its use by Medicaid managed care plans be required rather than optional. Several commenters stated that managed care plans use non-negotiable network provider agreements that require IHCPs to waive their federal rights under the Indian Health Care Improvement Act and other laws and apply licensing and provider certification requirements on IHCPs that are also inconsistent with the Indian Health Care Improvement Act.

Response: We decline to require managed care plans to offer a network provider agreement to all IHCPs as we believe we lack clear and specific statutory authority to mandate such a requirement at the federal level. The standard in § 438.14(b)(1) for the sufficiency of IHCPs in a managed care network must consider the anticipated Indian enrollment and the capacity of network IHCPs to meet the needs of that population. States would have the flexibility to specify in the managed care contract that the managed care plans must offer a provider agreement to all IHCPs in the service area or establish other measures of network adequacy similar to § 438.68 or other appropriate measures. We decline to set specific standards for sufficiency of IHCPs in managed care plan networks since § 438.14(b)(4) provides that Indian enrollees have the ability to receive care from out-of-network IHCPs. This is a consistent with our position in response to comments that we specify standards for family planning providers in § 438.68 due to the ability to receive such services from out-of-network family planning providers.

Notwithstanding out-of-network access, § 438.14(b) does require that managed care plans and PCCM entities, as appropriate, demonstrate that there are a sufficient number of IHCPs in the network unless there are no or too few IHCPs to ensure timely access to services for Indian enrollees. We appreciate the engagement and the work of the TTAG to date to develop a draft Indian Managed Care Addendum and we are committed to finalizing that addendum through subregulatory guidance to offer to managed care plans on a voluntary basis, to facilitate the network status of IHCPs. Because we do not have explicit statutory authority to require the use of an addendum by managed care plans for the provider agreements with IHCPs, we will follow an approach similar to QHPs operating under the FFM. CMS issued a Dear Tribal Leader Letter that introduced the QHP Addendum for IHCPs to facilitate QHP contracting with tribes, Urban Indian Health programs, and IHS providers, and specified that use of the addendum was encouraged by QHPs and providers but, ultimately, the addendum was optional, *see* http://www.ihs.gov/newsroom/includes/themes/newihstheme/display_objects/documents/IndianHealthEssentialCommunityProviders_Final.pdf. We recognize that some states have required the use of an addendum through Medicaid managed care contracts and we encourage states to do so to facilitate provider agreements with IHCPs and to ensure that managed care programs meet the needs of Indian enrollees.

Comment: We received several comments in support of § 438.14(b)(5)(i) that would permit an Indian enrollee who is located in a state with few or no IHCPs to access services from out of state IHCPs, as well as the provision that the state could consider the presence of few or no IHCPs as a for cause reason to disenroll from the managed care program at § 438.14(b)(5)(ii). However, some commenters recommended that § 438.14(b)(5) should only be in effect if the managed care plan's service area has no IHCPs, rather than "few" as proposed. In addition, commenters requested clarification as to the options available to an Indian were he or she to disenroll from the managed care program under § 438.14(b)(5)(ii).

Response: Section 438.14(b)(4) sets forth the procedures for demonstrating adequate access which we are directed to establish under the last sentence of section 1932(h)(2)(A)(ii) of the Act, and permits Indian enrollees to obtain covered services from an out-of-network IHCP from whom the enrollee is otherwise eligible to receive services.

Due to this flexibility for enrollees to see out-of-network IHCPs, we decline to apply the operation of the disenrollment right in paragraph (b)(5)(ii) only to instances where no IHCPs are in the managed care plan's service area. In cases where the state deems the presence of few or no IHCPs as a for cause disenrollment reason for Indian enrollees from the managed care program, a FFS delivery system would have to be maintained by the state to provide Medicaid covered services. Because Indian enrollees may see out-of-network IHCPs under § 438.14(b)(4) and out-of-state IHCPs under paragraph (b)(5)(i), we do not anticipate that states will choose to utilize the provision for disenrollment specified in paragraph (b)(5)(ii) with significant frequency; regardless, we believe it is important to include it as an option in the final rule. However, we anticipate that the use of the Indian Managed Care Addendum will facilitate the inclusion of IHCPs in managed care networks and reduce the instances of reliance on paragraph (b)(5). We will finalize paragraph (b)(5) as proposed.

Comment: We received several comments stating that managed care plans auto-assign beneficiaries to particular primary care providers in a manner that is inconsistent with the right of Indians to choose an IHCP that is participating in the managed care plan's network as their primary health care provider in section 1932(h)(1) of the Act and as proposed at § 438.14(b)(3). The administrative burden associated with correcting these issues is extremely timely and expensive, costing CMS, the states, and Tribes valuable resources and ultimately affecting the quality and timely care that a patient receives.

Response: We agree with commenters that, to the extent possible, managed care plans should support the intent of section 1932(h)(1) of the Act and § 438.14(b)(3) when auto-assigning Indians to primary care physicians. Managed care plans should review their auto-assignment algorithm to ensure that appropriate logic is included to accomplish the most appropriate PCP assignment. Additionally, managed care plans should ensure that information on the process for changing primary care providers is easily accessible and, at a minimum, in the enrollee handbook and on the managed care plan's Web site.

Comment: We received several comments supporting the payment provisions in § 438.14(b)(2) and (c)(2). However, commenters believed proposed § 438.14(c)(2) should be clearer in indicating which rate—the State plan or the published encounter rate—the IHCP is entitled to receive.

Commenters explained that in most cases, the state plan should provide for payment to IHCPs at the encounter rate, although there may be exceptions. Commenters believed this section should be revised to clarify that IHCPs should have the right to payment at either the rate set out in the state plan or the encounter rate, whichever is higher.

Response: Proposed § 438.14(c)(2) explains that the IHCP is to be paid under the reimbursement methodology outlined in the state plan when the IHCP is not an FQHC (and therefore not entitled to FQHC payment rates). We agree § 438.14(c)(2) is not clear as proposed; therefore, we will amend § 438.14(c)(2) to specify that the IHCP is entitled to receive the encounter rate published in the **Federal Register** annually by the Indian Health Service, or in the absence of a published encounter rate, the amount the IHCP would receive if the services were provided under the State plan's FFS payment methodology. We believe this revision more clearly reflects the requirements from section 1932(h)(2)(C)(ii) of the Act. Additionally, consistent with section 1932(h)(2)(C)(ii) of the Act, paragraph (c)(3) provides for the state to pay the difference should the managed care plan pay less than the required amount. As these payments from the state to a provider are required by the statute, they fall under the exception to the general rule in § 438.60 (otherwise prohibiting state payments directly or indirectly to health care providers for services covered by a managed care contract).

Comment: Some commenters noted that the provisions of section 1932(h) of the Act, as added by section 5006(d) of ARRA, which were proposed at paragraph (c)(3), require the state to make a supplemental payment to IHCPs when the amount negotiated or received by the IHCP from the managed care plan is less than the amount required under the encounter rate or the state plan; these commenters stated that such supplemental payment requirements from the state result in payment delays for the reconciliation amounts. Commenters noted that some states are considering requiring the managed care plans to pay at the required encounter or state plan rates to reduce delays in full reimbursement to IHCPs.

Response: We acknowledge that the provisions of § 438.14(c)(3) do not prohibit the state from requiring managed care plans to reimburse IHCPs at the specified encounter or state plan rate as the regulatory language specifies that the state must make a supplemental

payment to IHCPs if the amount received by the IHCP from the managed care plan is less than the amount required under paragraph (c)(2). This is consistent with section 1932(h)(2)(C)(i)(II) of the Act which stipulates that the state must pay, in a timely manner, the difference between the amount paid by the managed care plan and the amount owed to the IHCP under the state plan. States would have the option to build the required reimbursement levels into the capitation rates and require managed care plans to reimburse IHCPs at those rates through the managed care contract. All FQHC payment rules under section 1902(bb) of the Act apply in the context of IHCPs that are designated as FQHCs and this statutory provision is accommodated by the exception to the general rule on state direction of managed care plan expenditures at § 438.6(c)(1). In addition, the non-FQHC IHCP payment requirements at section 1932(h)(2)(C)(ii) of the Act are similarly accommodated by § 438.6(c)(1)(iii) because the state is permitted to set minimum (for example, the state plan rate) or maximum fee schedules (see discussion of § 438.6(c)(1)(iii) in section I.B.3.d) for a specific class of providers (for example, IHCPs).

Comment: Some commenters believed that the care coordination standards and prior authorization requirements at the managed care plan level are inconsistent with how IHCPs coordinate care, both within the system of IHCPs and with outside providers. Commenters expressed concern that this can result in a managed care plan paying twice for the same service. For example, an out-of-network IHCP is reimbursed for providing primary care services to an Indian enrollee, but the Indian enrollee is also required to see a network primary care provider to obtain a referral for specialty care, which results in another payment by the managed care plan for a duplicative primary care visit. Commenters recommended that the final rule require managed care plans to waive the requirements for referrals and prior authorizations from a network primary care provider if the enrollee receives his or her primary care through an out-of-network IHCP who adheres to the managed care plan's referral processes.

Response: We understand the commenters' concern and agree that duplicative services and payments should be avoided if possible. Thus, under our authority in section 1902(a)(4) of the Act, we have added a new requirement at § 438.14(b)(6) to clarify that MCO, PIHPs, and PAHPs must permit an out-of-network IHCP to

refer an Indian to a network provider. This provision prohibits the managed care plan from requiring the Indian to receive the referral from an in-network primary care provider under those circumstances. The goal, as evidenced by our commitment to issue an Indian Managed Care Addendum, is to create an environment for provider contracting arrangements between managed care plans and IHCPs that is cognizant of the federal protections afforded these providers while integrating IHCPs into managed care networks to ensure that Indian enrollees have access to a comprehensive and integrated service package.

Comment: One commenter raised the issue of difficulties encountered by states in conducting mandatory licensure reviews of facilities on reservations.

Response: We appreciate this comment but licensure reviews for facilities on reservations are outside the scope of this rule. It is our understanding that most states require an attestation by IHS or tribal facilities that licensure standards are met and thus, review by the state survey agencies is not necessary.

Comment: A few commenters recommended that CMS exempt American Indians/Alaska Natives (AI/ANs) from all Medicaid estate recovery requirements, or include in the draft regulations additional requirements for providing information and counseling about Medicaid estate recovery to AI/ANs, during the Medicaid application process. The commenters suggested providing detailed written information about estate recovery requirements and exemptions currently available to AI/ANs, providing counseling to the AI/AN to determine types of ownership subject to estate recovery, identifying the status of the applicant's ownership interest as exempt or not exempt from estate recovery, explaining how an estate recovery claim is calculated for a beneficiary enrolled in Medicaid managed care, obtaining the non-exempt AI/AN's written consent for estate recovery, and providing an annual summary of accrued costs to the beneficiary.

Response: This comment is outside the scope of this rule. We note that the statutory authority for Medicaid estate recovery is separate and distinct from the authority for Medicaid managed care, and that estate recovery applies to Medicaid beneficiaries age 55 and over, or permanently institutionalized, whether they are enrolled in a Medicaid MCO or not. We also note that the commenters' concerns and recommendations have been shared

with CMS by the Tribal Technical Advisory Group (TTAG) and other concerned parties, and we are currently reviewing them.

After consideration of the public comments, we are finalizing with the following revisions. Technical corrections to punctuation and text (including deletions of unnecessary citations) have been made in paragraph (a). The heading of paragraph (b) has been made more accurate by adding "and coverage." Additionally, throughout paragraphs (b) and (c) as appropriate, "and" was replaced with "or" in the lists of managed care plan types to be clear that an enrollee in any of the listed types of plans has the listed rights. Corrections related to references to a PCCM and/or PCCM entity have been made in paragraphs (b), (b)(2)(i), (b)(4), (b)(5), and (c)(3) to reflect the various activities and functions of each. We are also finalizing a new paragraph (b)(6) which permits IHCPs to refer Indians to network providers. Minor grammatical corrections have been made in paragraphs (c)(1) and (c)(3). Revisions for clarification to the applicable payment rates have been made in paragraph (c)(2). A citation has been added to paragraph (d) to clarify the definition of "Indian Health Program."

c. Emergency and Post-Stabilization Services (§ 438.114)

We proposed to revise portions of § 438.114 to make technical corrections to the existing regulations. We did not propose any changes to paragraph (a), (d), and (f).

We proposed to correct an error in the current regulations at paragraph (b) by removing paragraph (b)(2) which refers to PCCMs with a risk contract. This provision is inconsistent with the rest of our managed care regulatory structure, in that a PCCM which accepts risk for medical services—including the emergency services referenced in this section—would be considered either a PAHP or PIHP (depending on the scope of medical services at risk). Because a PCCM would never be responsible for coverage and payment of emergency services, we proposed to remove that reference from paragraph (b). A state will always be responsible for coverage and payment of emergency services if it operates a PCCM program, which is reflected in the proposed revisions to paragraph (b)(2), where we proposed to move the existing text in paragraph (b)(3) with the addition of "PCCM entities."

In paragraph (c)(1), we proposed to add PCCM entity to each reference to "MCO, PIHP, PAHP, or PCCM" for

consistency with changes discussed in I.B.6.e of the proposed rule. In paragraph (c)(2), we proposed to redesignate paragraph (c)(2)(i) as (c)(2) and delete paragraph (c)(2)(ii) for the same reason as the proposal for paragraph (b).

Currently in paragraph (e), MCOs, PIHPs, and PAHPs must follow MA guidelines when covering post-stabilization services and be paid in accordance with Medicare guidelines. However, payment for post-stabilization services to Medicaid enrollees is governed by Medicaid and State rules. We corrected this misleading provision by proposing language that ensures that hospitals providing post-stabilization services receive payment consistent with federal and state Medicaid payment standards, not based on Medicare rates. The resulting language would apply MA coverage guidelines to MCOs, PIHPs and PAHPs but Medicaid payment standards for covered post-stabilization services.

We received the following comments in response to our proposal to revise § 438.114.

Comment: Several commenters recommended that CMS clarify the coverage and payment rules at § 438.114(c) and (d). Several commenters recommended that CMS clarify that only emergency department physicians can determine if an emergency medical condition or non-emergency condition is present, not the MCO, PIHP, PAHP, or state. Commenters also recommended that CMS require MCOs, PIHPs, PAHPs, and the state to provide payment for both the medical screening and evaluation and the emergency services, regardless of provider network status. One commenter recommended that CMS require the prohibition and elimination of all triage payments. Several commenters recommended that CMS reinforce the prudent layperson (PLP) requirements of the BBA of 1997 and clarify for MCOs, PIHPs, PAHPs, and states that limiting coverage and payment for emergency services based on approved lists of emergency diagnosis codes is prohibited. Several commenters stated that MCOs, PIHPs, PAHPs, and states are denying coverage and payment of emergency services when the final diagnosis on the claim is not on the approved list of emergency diagnosis codes. One commenter recommended that CMS remove the prohibition to use an approved list of emergency diagnosis codes to assess the appropriate use of emergency services. The commenter stated that many states and managed care plans rely on such

code lists to determine appropriate payment levels for emergency room use.

Response: We decline to add explicit text that only emergency department physicians can determine if an emergency medical condition or non-emergency condition is present. Managed care plans and states maintain both medical necessity criteria and clinical standards and consult regularly with health care providers. We also decline to add coverage and payment requirements for the medical screening and evaluation. Consistent with § 438.114(c)(1)(i), managed care plans and states must cover and pay for emergency services regardless of whether the provider that furnishes the services has a contract. We also decline to prohibit and eliminate all triage payments. States and managed care plans have discretion to pay and cover medical screenings and evaluations for non-emergent conditions, including triage payments. We note that EMTALA requires screening for emergency medical conditions but does not specify or require payment for that screening.

Regarding the PLP requirements of the BBA of 1997 and the use of approved lists of emergency diagnosis codes, we remind commenters that consistent with our discussion in the 2002 managed care final rule at 67 FR 41028–41031, we prohibit the use of codes (either symptoms or final diagnosis) for denying claims because we believe there is no way a list can capture every scenario that could indicate an emergency medical condition under the BBA provisions. Section 1932(b)(2)(B) of the Act defines emergency services as covered inpatient or outpatient services that are furnished by a provider qualified to furnish these services under Medicaid that are needed to evaluate or stabilize an “emergency medical condition.” An “emergency medical condition” is in turn defined in section 1932(b)(2)(C) of the Act as a medical condition manifesting itself by acute symptoms of sufficient severity (including severe pain) that a prudent layperson, who possesses an average knowledge of health and medicine, could reasonably expect the absence of immediate medical attention to result in placing the health of the individual (or for a pregnant woman, the health of the woman or her unborn child) in serious jeopardy, serious impairment to body functions, or serious dysfunction of any bodily organ or part. While this standard encompasses clinical emergencies, it also clearly requires managed care plans and states to base coverage decisions for emergency services on the apparent severity of the symptoms at the time of presentation,

and to cover examinations when the presenting symptoms are of sufficient severity to constitute an emergency medical condition in the judgment of a prudent layperson. The final determination of coverage and payment must be made taking into account the presenting symptoms rather than the final diagnosis. The purpose of this rule is to ensure that enrollees have unfettered access to health care for emergency medical conditions, and that providers of emergency services receive payment for those claims meeting that definition without having to navigate through unreasonable administrative burdens. We note that managed care plans have a responsibility to reach out to enrollees and provide and manage care such that enrollees do not use the emergency room in place of primary care.

Comment: One commenter recommended that CMS add standards at § 438.114(c)(1)(ii) to require that payment is not denied when an enrollee has not been able to obtain non-emergency services in a timely manner.

Response: We decline to accept the commenter’s recommendation, as managed care plans must ensure timely access to care consistent with the requirements at § 438.206(c)(1). It is not appropriate to require coverage and payment of non-emergent conditions in an emergency setting when managed care plans are responsible for providing timely access to care in the appropriate setting.

Comment: A few commenters recommended that CMS continue to require the payment of post-stabilization care services at § 438.114(e) at the Medicare rate and not the Medicaid rate. One commenter recommended that CMS add “applicable state Medicaid laws and regulations” after “Title XIX of the Act and the States.”

Response: The provision at § 438.114(e) was never intended to require payment for post-stabilization care services at the Medicare rate. We only intended to require coverage of post-stabilization care services in accordance with the provisions at § 422.113(c) of this chapter but not to mandate a payment rate using Medicare standards. Consistent with section 1932(b)(2)(D) of the Act, payment for post-stabilization care services is required in accordance with Title XIX of the Act. We also decline to add “applicable state Medicaid laws and regulations” after “Title XIX of the Act and the States,” as we believe it is duplicative and does not flow with the existing regulatory text.

After consideration of the public comments, we are finalizing § 438.114 as proposed without modification.

8. Other Provisions

We received comments on sections that were not discussed in the preamble of the proposed rule. In these instances, the proposed rule restated the current regulation text without change. We have included those sections, along with the comments and responses, below.

a. Provider Discrimination Prohibited (§ 438.12)

Comment: One commenter recommended that managed care plans have on-going monthly monitoring processes to ensure compliance with state and federal provider nondiscrimination contract provisions.

Response: As for all contractual provisions, states and managed care plans should have monitoring mechanisms to ensure on-going compliance. We note that in accordance with § 438.66(b)(10), states must have a monitoring system that addresses provider network management, which includes compliance with all state and federal provider nondiscrimination contract provisions. We encourage all states and managed care plans to ensure that the appropriate processes are in place to meet this requirement.

Comment: We received one comment recommending that CMS clarify that § 438.12(a)(1) applies both to states and managed care plans. The commenter also requested that CMS clarify that excluding a provider entirely from the network is not the only prohibited form of discrimination; actions such as inferior reimbursement are also prohibited.

Response: We believe the commenter is requesting that CMS apply the provisions of § 438.12 to state FFS providers, which is outside the scope of this rule. The text of § 438.12(a)(1) is adequate to prohibit discrimination for provider participation, reimbursement, and indemnification as it specifies that an MCO, PIHP, or PAHP may not discriminate in the participation, reimbursement, or indemnification of any provider who is acting within the scope of his or her license or certification under applicable State law, solely on the basis of that license or certification. The text is significantly similar to the statutory provision it implements, which is section 1932(b)(7) of the Act, in identifying the scope of the anti-discrimination mandate.

Comment: One commenter recommended that CMS specify a time frame for managed care plans to send

the notice to providers required in proposed § 438.12(a)(1).

Response: We do not believe that level of detail is necessary in § 438.12(a)(1). States can address that in the managed care plan contract or state laws that address credentialing. We decline to amend § 438.12(a)(1) in response to this comment.

Comment: A few commenters recommended that CMS amend § 438.12 to prohibit a managed care plan from discriminating against an otherwise qualified health care provider on the basis that the provider furnishes certain services under their scope of practice, on the basis of the patients they serve, or on the basis of the professional activity or advocacy they conduct separately from their contractual relationship with the managed care plan. Another commenter recommended that managed care plans be prohibited from refusing to contract with providers because the provider offers services to which the managed care plan objects. This commenter believed that CMS should clarify that Medicaid managed care plans may not prohibit contracted providers from prescribing or providing services or treatments that are covered under the contract. Another commenter recommended that CMS include a list of the activities that are prohibited. Likewise, CMS should require that agreements between Medicaid managed care plans and participating providers reinforce this standard.

Response: We believe that the commenters' references to discrimination "on the basis that the provider furnishes certain services under their scope of practice, on the basis of the patients they serve, on the basis of the professional activity or advocacy they conduct" or "services that the managed care plan objects to" meant that the activities and services triggering the discriminatory treatment are services and activities within the scope of the provider's licensure. As such, this is already addressed in proposed § 438.12(a)(1), which clearly indicates that a managed care plan may not discriminate against a provider solely for providing services within their scope of licensure. The text in § 438.12(a)(1) is significantly similar to the specific statutory provision it implements, section 1932(b)(7) of the Act, in identifying the scope of the anti-discrimination mandate.

We disagree with the commenter that Medicaid managed care plans must allow contracted providers to prescribe or provide all services covered under the contract that are within the provider's scope of licensure. We reiterate that § 438.12 does not force

managed care plans to contract with every provider for every covered service. Section 438.12(b) explicitly limits the effect of the prohibitions in paragraph (a) and does not prohibit flexibility in reimbursements or prohibit plans from establishing measures to maintain quality and control costs. Therefore, managed care plans can contract for less than the full scope of services available from a provider and/or for less than the full scope of services covered in the managed care plan's contract with the state. It is outside the scope of part 438 to mandate specific provisions in the contract between a managed care plan and its providers. We believe § 438.12 is sufficiently broad to address many forms of discrimination but cannot include an exhaustive list of all possible types of, or basis for, discrimination. We decline to amend § 438.12 in response to these comments.

Comment: One commenter requested that CMS clarify that managed care plans are prohibited from discriminating against providers on the basis of their race, color, or national origin, language, disability, age, sex, gender identity, or sexual orientation.

Response: We appreciate the opportunity to clarify that, as provided in § 438.3(f)(1), all Medicaid managed care plan contracts must comply with all applicable federal and state laws and regulations including Title VI of the Civil Rights Act of 1964; Title IX of the Education Amendments of 1972 (regarding education programs and activities); the Age Discrimination Act of 1975; the Rehabilitation Act of 1973; the Americans with Disabilities Act of 1990 as amended; and section 1557 of the Patient Protection and Affordable Care Act. Under these identified statutes and their implementing regulations, managed care plans are prohibited from discriminating against providers (for example, rejecting a provider's participation in a plan's network) on the basis of the provider's race, color, national origin, disability, age, or sex. The Department's 1557 guidance and the final 1557 regulation provide more information on what constitutes sex discrimination. See www.hhs.gov/ocr. Other laws, such as state laws, that prohibit discrimination may also be applicable to manage care plans.

Comment: We received one comment requesting that CMS specify that written notice requirements apply to providers seeking to be included in a managed care plan network and those that are terminated from a plan network.

Response: The proposed text in § 438.12(a) is sufficiently clear in addressing existing and prospective

providers and a revision to address terminated providers is not necessary.

After consideration of the public comments, we are not amending § 438.12 in response to these comments. Please refer to section I.B.9.a of this final rule for discussion of a change to § 438.12(a)(2) related to defined terms.

b. Enrollee Rights (§ 438.100)

Comment: We received one comment asking CMS to clarify how an enrollee can address issues with a managed care plan regarding ADA accommodation or modification.

Response: We appreciate the opportunity to clarify that enrollees can avail themselves of the grievance system in a managed care plan (see § 438.400) to request an accommodation or question the failure to provide an accommodation. If that does not adequately address the concern, then the enrollee should contact the state Medicaid agency or the HHS Office for Civil Rights.

Comment: We received one comment regarding § 438.100(b)(2)(iii) stating that while the state can include this provision in an MCO contract that an enrollee has this right, it has no mechanism to enforce this provision of the proposed rule or to guarantee to CMS that the regulation is followed by providers. The commenter believed that discussions about treatment options and alternatives should be occurring between the enrollee and his provider, and it is up to providers to discuss treatment options with their patients without interference from the state or the managed care plan.

Response: We agree that discussions about treatment options and alternatives should occur between the enrollee and their provider and that the primary responsibility for discussing treatment options and alternatives rests with the provider. We appreciate the opportunity to provide guidance on this provision. We note that providers are generally under contract with the managed care plan, and the plan can include contract terms with network providers to specifically include § 438.100(b)(2)(iii). Also, when a managed care plan makes a coverage determination about treatment, § 438.100(b)(2)(iii) would apply. This provision was included in the 2002 final rule to reiterate the state's and managed care plan's responsibility to ensure that they support this right and do not have policies, procedures, or contractual provisions that infringe or impede it. This provision is a complement of § 438.102(a) about how managed care plans cannot prohibit providers from acting within the lawful scope of their practice in providing

counseling or referral services to a patient who is an enrollee but also provides necessary protections to enrollees by requiring states to ensure that information is adequately provided to enrollees in a manner appropriate to their ability to understand and their condition.

Comment: Several commenters recommended that CMS address an enrollee's right to indicate an alternative address for confidential or sensitive information. The commenters believed managed care plans should be required to notify enrollees of this option and how to exercise it.

Response: 45 CFR 164.522(b) requires health care providers and health plans to accommodate reasonable requests to receive communications by alternative means or at alternative locations. As such, all Medicaid managed care plans (and most health care providers) should already be in compliance as part of their compliance with HIPAA Privacy Rule compliance.

Comment: We received a few comments recommending that proposed § 438.100(d) should be consistent with § 438.3(f)(1), which provides a more complete list of enrollee protections.

Response: Revisions have been made to § 438.100(d) to include all laws referenced in § 438.3(f)(1).

After consideration of the public comments, § 438.100 will be finalized as proposed except for an amendment to § 438.100(d) for consistency with § 438.3(f)(1).

c. Provider-Enrollee Communications (§ 438.102)

Comment: One commenter recommended that CMS require states and managed care plans to provide all enrollees the ability to redirect communications to an alternate physical or electronic address in § 438.102.

Response: 45 CFR 164.522(b) requires health care providers and managed care plans to accommodate reasonable requests to receive communications by alternative means or at alternative locations. As such, all Medicaid managed care plans (and most health care providers) should already be in compliance as part of their compliance with HIPAA Privacy Rule compliance.

Comment: We received one comment recommending that managed care plans not be allowed to exclude any benefit covered under the state's Medicaid managed care program from their coverage, including benefits that the managed care plan objects to on moral or religious grounds. The commenter believed that since states identify the benefits to be covered by the contract as part of the procurement process,

selected managed care plans should not be able to later decide to discontinue covering a service.

Response: Section 1932(b)(3)(B) of the Act provides that a managed care plan is not obligated to furnish or pay for a particular counseling or referral services if (1) the managed care plan objects to the provision of that counseling or referral service on moral or religious grounds, and (2) provides information to the state, prospective enrollees, and to current enrollees with 90 days after adopting the policy for objections of any particular service. Therefore, we cannot remove the ability of a managed care plan to object to the coverage of referral or counseling services provided by health care professionals as described in section 1932(b)(3)(A) of the Act on moral or religious grounds through regulation. We decline to modify this section to address the commenter's suggestion.

After consideration of the public comments, we are amending § 438.102(b)(2) to be more consistent with § 438.10(g)(2)(ii)(B); see section I.B.6.d. for discussion of this revision.

d. Liability for Payment (§ 438.106)

Comment: A few commenters recommended that CMS add a new provision at § 438.106 to prohibit managed care plans from charging enrollees, or holding enrollees liable for payment, for out of network family planning services and supplies.

Response: We decline to adopt commenters' recommendations to add a new provision at § 438.106 to prohibit managed care plans from charging enrollees, or holding enrollees liable for payment, for out of network family planning services and supplies. Consistent with the current language at § 438.106, Medicaid enrollees are not held liable for covered services provided to the enrollee consistent with paragraphs (b)(1) and (2), including covered family planning services and supplies. We do not believe it is necessary to specify any covered service in this provision, as the current language is inclusive of all covered services.

After consideration of the public comments, we are not amending § 438.106.

e. Cost Sharing (§ 438.108)

Comment: A few commenters recommended that CMS add a new provision at § 438.108 to include the provisions of section 2713 of the Affordable Care Act that prohibit cost sharing for preventive health services.

Response: Section 2713 of the Affordable Care Act applies to group

health plans and health insurance issuers offering group or individual health insurance coverage and does not generally impose a requirement on Medicaid; therefore, we decline to adopt commenters' recommendations to add a new provision at § 438.108. However, we encourage states and managed care plans to adopt such practices and provide for no cost sharing for preventive health services, and we note that section 4106(b) of the Affordable Care Act established a one percentage point increase in the FMAP effective January 1, 2013, to be applied to expenditures by states that cover, without cost sharing, preventive health services that are assigned a grade of A or B by the United States Preventive Services Task Force (USPSTF) and approved vaccines and their administration, recommended by the Advisory Committee on Immunization Practices (ACIP).

We also note that effective January 1, 2014, the Affordable Care Act requires that Alternative Benefit Plans (ABPs) for beneficiaries, including individuals in the new adult eligibility group (that is, section 1902(a)(10)(A)(i)(VIII) of the Act, cover preventive health services described in section 2713 of the Affordable Care Act as part of the set of Essential Health Benefits (EHBs). The preventive health services in section 2713 include the preventive health services authorized for increased match under section 4106 of the Affordable Care Act.

After consideration of the public comments, we are not amending § 438.108.

f. Solvency Standards (§ 438.116)

Comment: One commenter recommended that CMS must take further steps to ensure that network providers are held harmless when managed care plans go bankrupt. The commenter suggested the provision of federal financing to guarantee the payment of bad debts to providers or mandating that managed care plans contribute to a funding pool to cover such debts.

Response: Section 438.116 is based on sections 1903(m)(1) and 1932(b)(6) of the Act, which requires certain types of MCOs to provide assurances to the state that its provision against the risk of insolvency is adequate to protect enrollees from financial liability, including the debts of the organization, should the managed care plan become insolvent; we extended the regulation to PIHPs and PAHPs, as well as MCOs under our authority at section 1902(a)(4) of the Act in the 2002 final rule. In addition, § 438.116(b) provides that, in

general, MCOs and PIHPs must meet the solvency standards established by the state for private HMOs, or be licensed or certified by the state as a risk-bearing entity. Solvency standards for the business of insurance are under the state's purview and section 1903(m)(1) of the Act requires that enrollees not incur financial liability in the event a managed care plan becomes insolvent. Any hold harmless protections for network providers should be addressed in the contract between the state and the managed care plan to reflect state rather than federal laws, or in the contracts between the providers and the managed care plan. For these reasons, we decline to mandate that managed care plans maintain a reserve to anticipate network provider claims in the event of insolvency. In addition, under section 1903(m)(2)(A)(iii) of the Act, federal funding for managed care programs is limited to the FFP attributable to actuarially sound capitation rates and would not extend to the additional federal financing suggested by the commenter.

After consideration of the public comment, we are not amending § 438.116.

g. Confidentiality (§ 438.224)

Comment: Several commenters recommended that CMS strengthen the language at § 438.224 to add confidentiality requirements for enrollees receiving sensitive and confidential services. Several commenters also recommended that CMS add language to protect the confidentiality of enrollee medical records, all aspects of enrollee coverage and care, and specific communications with health care providers. Commenters also recommended that CMS include a requirement for managed care plans to inform enrollees of their right to specify an alternative mailing address. A few commenters recommended that CMS include specific confidentiality requirements for family planning services and supplies. One commenter recommended that CMS add a reference to include 42 CFR part 2 regarding the confidentiality of alcohol and drug abuse patient records. One commenter recommended that CMS clarify that states are only required to take appropriate contract action and make appropriate referrals for patterns of non-compliance with potential privacy violations.

Response: We believe that the regulatory text provides for the appropriate information and references to ensure that all managed care contracts comply with the applicable privacy requirements. Section 438.224,

as a whole, is intended to ensure that managed care plans have procedures to protect the confidentiality of all enrollees, regardless of which services they receive, and includes communications between enrollees and providers. We also decline to add specific references to 42 CFR part 2, as we believe that the reference is unnecessary to include given the general context of the current provision. The requirements at § 438.224 do not preempt other state or federal confidentiality laws and regulations that apply and are more protective of enrollee privacy. We also decline to include a requirement for managed care plans to inform enrollees of their right to add an alternative mailing address, as 45 CFR 164.522(b) requires providers and plans to accommodate reasonable requests to receive communications by alternative means or at alternative locations. Finally, we clarify for the commenter that states should take appropriate contract action and make appropriate referrals for patterns of non-compliance with potential privacy violations.

After consideration of the public comments, we are not amending § 438.224.

h. Practice Guidelines (§ 438.236)

Comment: A few commenters recommended that CMS include standards at § 438.236(b)(1) to require that all practice guidelines be based on valid and reliable clinical evidence and be peer reviewed and published. One commenter recommended that CMS require practice guidelines to be based on valid and reliable clinical evidence when available, and otherwise allow a consensus of health care professionals in the particular field. One commenter recommended that CMS clearly define practice guidelines. One commenter recommended that CMS require post-approval adverse event data in adopting practice guidelines related to medication therapy.

Response: We do not agree with commenters that § 438.236(b)(1) should be revised to require that all practice guidelines be peer reviewed and published. While we encourage managed care plans to include peer reviewed and published clinical evidence in the development of practice guidelines as feasible, we are also aware that clinical practice guidelines are not always available for all areas of clinical practice. We note that managed care plans should adopt practice guidelines that are based on valid and reliable clinical evidence or a consensus of health care professionals in the

particular field under the existing rule at § 438.236(b)(1).

We decline to define practice guidelines, as we do not believe it is necessary to do so. Practice guidelines are developed by a variety of organizations in a variety of areas and are widely available for use by health care professionals. Practice guidelines assist health care professionals to apply the best evidence-based practice to clinical care. We therefore see no compelling reason for CMS to specifically define practice guidelines. We also decline to require review or use of post-approval adverse event data in adopting practice guidelines related to medication therapy, as we do not agree that such specificity is needed in the context of the regulatory language. This regulation has never specified the kinds of practice guidelines managed care plans must adopt but rather establishes criteria to be used by managed care plans in adopting guidelines. We also note that the scope of services in the managed care plan contract will determine the areas in which practice guidelines are appropriate.

Comment: One commenter recommended that CMS clarify at § 438.236(c) that only general clinical practice guidelines will be made available to the public, as licensed and proprietary clinical criteria should not be available publicly unless such criteria is relevant to a specific treatment or service and is specifically requested by the enrollee, or the enrollee's health care provider, with appropriate notice of disclosure of confidential and proprietary information. One commenter recommended that CMS require all practice guidelines to be published publicly on each managed care plan's Web site.

Response: We understand the commenter's concern regarding licensed and proprietary clinical criteria. We remind the commenter that § 438.236(c) requires each managed care plan to disseminate practice guidelines to all affected providers, and upon request, to enrollees and potential enrollees. We do not expect managed care plans to disseminate all of their practice guidelines widely (such as through public posting on a Web site), but we do expect that managed care plans make specific practice guidelines available to the applicable network providers (or out-of-network providers to whom the plan refers enrollees for covered services) for which such practice guidelines apply. We believe this is consistent with the general concept of having practice guidelines and assisting health care professionals to apply the

best evidence-based practice to clinical care. We maintain that § 438.236(c) is an appropriate minimum standard for the dissemination of practice guidelines to affected providers, potential enrollees, and enrollees; therefore, we decline to require that practice guidelines be published on each managed care plan's Web site.

Comment: One commenter recommended that CMS include requirements at § 438.236(d) for managed care plans to provide the applicable practice guidelines in all prior authorization denials to the requesting health care provider and the enrollee.

Response: We do not agree with commenters that § 438.236(d) should be revised to require managed care plans to provide the applicable practice guideline with all prior authorization denials to the requesting health care providers and enrollees. The managed care plan's denial of a prior authorization request may be based on coverage criteria other than the practice guidelines; therefore it is not appropriate to require the inclusion of practice guidelines with denials of prior authorization requests. In addition, this recommendation is duplicative of existing requirements at § 438.236(c) that the managed care plan provide practice guidelines to affected providers and the content of the managed care plan's notice of an adverse benefit determination at § 438.404(b)(2).

After consideration of the public comments, we are not amending § 438.236.

9. Definitions and Technical Corrections

a. Definitions

We proposed to redesignate and add several definitions to § 438.2 in connection with changes we proposed to specific sections and subparts. In addition, we proposed several modifications and additions to § 438.2 to address terms used throughout this part. In § 438.2 we proposed to modify existing definitions for "comprehensive risk contract," "health care professional," "health insuring organization," "managed care organization," "nonrisk contract," "prepaid ambulatory health plan," "prepaid inpatient health plan," and "risk contract." In addition, we proposed to add definitions for "managed care program," "network provider," and "state," which are terms used with some frequency in part 438 but are not currently defined.

For the existing definition of a "comprehensive risk contract" we proposed to add that the contract is

"between the State and an MCO" to make clear that only MCOs can have comprehensive risk contracts and to identify the parties to the contract.

We received the following comments in response to the proposed changes to the definition of "comprehensive risk contract."

Comment: A few commenters requested revisions to the definition for a comprehensive risk contract; specifically, commenters requested the addition of freestanding birth centers or LTSS to the list of services that could be covered by an MCO contract. Another commenter requested clarification if the revised definition to clarify that a comprehensive risk contract is between the state and an MCO has any impact on the contractual relationship the state has with PIHPs or PAHPs.

Response: We decline to add additional types of services to the definition of a comprehensive risk contract because the services covered under a comprehensive risk contract with a MCO are specified in statute at section 1903(m)(2)(A) of the Act. The revision to the definition of a comprehensive risk contract was merely to clarify the parties to the arrangement. Since we use the term "risk contract" to apply to all types of those contracts and do not use a term specific to a limited or non-comprehensive contract with a PIHP or PAHP, we clarify here for the commenter that for states that contract with PIHPs and PAHPs, the parties to the contract would be the state and the PIHP or PAHP.

After consideration of comments, we are finalizing the definition of "comprehensive risk contract" as proposed.

We proposed to revise the definition for "health care professional" to include language from the statutory definition that the physician's or provider's services are covered under the contract and to clarify that providers of services other than medical services, such as LTSS, would be included in this definition. We also proposed to delete the list of professionals in section 1932(b)(3)(C) of the Act from our regulatory definition of "health care professional" because the list was not intended to be exclusive and inclusion of this list in the regulatory definition does not clarify our intent for this definition. We requested comment on this approach.

We received the following comments on the definitions and use of "health care professional" and "provider."

Comment: Several commenters were supportive of the proposed modification to the definition of "health care professional" that would remove the list

of specific provider types from section 1932(b)(3)(C) of the Act and clarify that the term encompasses any provider whose services are covered under a managed care contract. Another commenter recommended that CMS clarify in the definition that such health care professionals must be appropriately credentialed. Other commenters suggested that CMS explicitly acknowledge behavioral health providers that are certified but not licensed, nurse practitioners, and providers of LTSS in the definition. Another commenter recommended that the definition be based on the work done by the individual, rather than their degree or title. We also received comments questioning our use of the term "provider" but not defining it in this part.

Response: In consideration of these comments, we have decided not to retain "health care professional" and instead, simplify our usage of terminology and use "provider" and "network provider" in part 438, except in § 438.210(b)(3), where we finalize the regulation with the term "individual." We believe that the existing definition of "provider" in § 400.203 generally addresses our intent in the term "health care professional." Based on § 400.203, we will define "provider" as "any individual or entity that is engaged in the delivery of services, or ordering or referring for those services, and is legally authorized to do so by the state in which it delivers the services" for purposes of part 438. This definition is broad enough to address all services under the contract without the need to maintain a specific list of specialties and is not based on title or degree. We have chosen not to incorporate the term "health care services" in the definition of "provider" for consistency with our efforts throughout part 438 to reflect the broader range of services covered in managed care, including LTSS. We believe this new definition clarifies our intent while enhancing consistency with other parts.

To the comment that recommended that a reference to "credentialing" be added, we appreciate the opportunity to clarify. Credentialing is included in the process of being a network provider and we are retaining "network provider" in this part. Therefore, there is no need to add a reference to credentialing to any other definition.

Comment: We received a comment requesting that CMS clarify whether or not the applicable definition of the term "provider" is the same as defined in § 400.203.

Response: We appreciate the opportunity to clarify the use of

“provider” within part 438. As explained in the response to comments above on “health care professional,” we will be adopting “provider” and define it as “any individual or entity that is engaged in the delivery of services, or ordering or referring for those services, and is legally authorized to do so by the State in which it delivers the services.” We will add this to § 438.2 and use the term, as appropriate, throughout part 438.

Comment: The definition for “health care professional” should not include providers of all services other than medical services. In these proposed regulations, a health care professional can render coverage and medical necessity decisions, as in § 438.210. Non-medical, unlicensed persons and paraprofessionals, such as providers of personal care services and NEMT providers, cannot render these types of decisions.

Response: We appreciate the opportunity to clarify § 438.210. The reference to “health care professional” in § 438.210(b)(3) was not intended to reference an in-or-out of network provider, but rather an employee or contractor of the managed care plan that renders authorization decision for the managed care plan. To make our intent clearer, we will replace “health care professional” with “individual” in § 438.210(b)(3). We believe that states and plans make every effort to select individuals with appropriate expertise and training for authorization decision making functions and that the use of “individual” reflects that flexibility. Additionally, paragraph (b)(3) sets a minimum standard; states are free to include additional specificity through the managed care plan contract.

Therefore, we have added a definition for “provider” in § 438.2 and are not finalizing the definition of “health care professional.” As a result of this, we are replacing proposed uses of “health care professional” throughout part 438 with the terms “provider,” “network provider,” or “individual” (specifically in § 438.210) as appropriate.

In the existing definition of a “health insuring organization,” we proposed to correct a technical error to the citation to the Omnibus Budget Reconciliation Act of 1985 from “section 9517(e)(3)” to “section 9517(c)(3)” and update the reference to statutes that have since amended the HIO-related provisions established in the 1985 statute. We did not receive comments on the definition of an HIO and will finalize as proposed.

In the existing definition of a “managed care organization” we proposed to clarify, consistent with section 1903(m) of the Act that the

Secretary determines if the conditions specified are met by an entity seeking to qualify for a comprehensive risk contract. The existing language does not identify who makes such a determination. We did not receive comments on the definition for a “managed care organization” and will finalize as proposed.

In the proposed definition of a “nonrisk contract,” we proposed language to clarify that such a contract is between the state and a PIHP or PAHP. This proposed revision was consistent with the proposed change to identify the parties subject to a “comprehensive risk contract.” We proposed to remove “medical” as the modifier for “services” in the definitions for “prepaid ambulatory health plan” and “prepaid inpatient health plan” because managed care plans may cover non-medical services such as LTSS. We also proposed to remove “agency” that follows “state” consistent with our proposal to add a definition for “state” as meaning the single state agency as specified in § 431.10. We did not receive comments on the proposals related to the definitions for “nonrisk contract,” “comprehensive risk contract,” “prepaid ambulatory health plan,” “prepaid inpatient health plan,” and “state,” and will finalize as proposed.

In the existing definition of a “risk contract,” we proposed to clarify that such a contract is between the state and MCO, PIHP or PAHP. This proposed revision is consistent with the proposed change to identify the parties subject to a “comprehensive risk contract.” We did not receive comments on the proposed modification to the definition of a “risk contract” and will finalize as proposed.

We proposed to add a definition for the phrase “managed care program,” which is currently used in several sections of this part. We proposed this term to mean a managed care delivery system operated by a state as authorized under sections 1915(a) or (b), 1932(a), or 1115(a) of the Act. We did not receive comments on the proposed addition of a definition for a “managed care program” and will finalize as proposed.

We proposed to add a definition for “network provider.” We intended this term to include all types of providers, either as an individual or through a group, and entities that order, refer, or render covered Medicaid services as a result of the state’s arrangement with an MCO, PIHP, or PAHP. We also proposed to insert “network provider” in place of “affiliated provider” as used in this part for consistency in use of terminology.

We received the following comments on the definition of “network provider.”

Comment: A few commenters noted that the proposed definition of “network provider” includes any provider that receives funding directly or indirectly, which would include out-of-network providers, and that including non-participating providers as network providers also has unintended consequences, such as including all non-participating providers in the MCOs provider directory. The commenters suggested that CMS define network provider to include only those providers under contract, and in specific areas, add reference to non-participating providers where the intent is to include them.

Response: We agree with the commenter as it was not our intention to include non-participating (or out-of-network) providers under the definition of “network provider.”

After consideration of public comments, we are finalizing the definition of “network provider” to clearly reflect that this term only applies to a provider that has a provider agreement with a managed care plan or a subcontractor of the managed care plan. To avoid any ambiguity, it is important to add subcontractor of a managed care plan because providers that have a provider agreement with a subcontractor of a managed care plan to order, refer, or render covered services are receiving Medicaid funding indirectly by virtue of the state’s contract with the managed care plan. Additionally, we are removing “health care professional” from this definition and replacing it with “provider” as discussed above in section I.B.9.a. In addition, we will replace the word “contract” with “provider agreement” and delete “managed care plan”, as that term is not defined, and insert “MCO, PIHP, or PAHP.”

We received the following comments to add or modify other definitions in § 438.2.

Comment: A few commenters recommended that CMS add a definition for ACO under 42 CFR part 438.

Response: As discussed in the proposed rule at 80 FR 31163, states contracting with ACOs under the Medicaid program are outside of the purview of this final rule and are not bound by 42 CFR part 438. We decline to define ACOs for Medicaid programs as this is not within the scope of this rule.

Comment: A few commenters recommended adding a definition for preventive health services, including but not limited to the health services

with a grade of A or B from the United States Preventive Services Task Force (USPSTF), in the general definitions of the proposed rule to harmonize it with the requirements of the Affordable Care Act.

Response: The provisions related to preventive health services in the Affordable Care Act do not specifically apply to Medicaid managed care, and therefore, we do not believe it is appropriate to include a definition for preventive health services in part 438. See also our discussion in I.B.8.e.

Comment: One commenter supported the addition of the services of “other licensed practitioners” to the definition of “primary care.” As the health care system evolves and primary care services are provided by different types of health care professionals, the commenter stated that it is necessary that the Medicaid managed care system be modernized to reflect this reality.

Response: We appreciate the commenter’s support of the revision to the definition of “primary care” at § 438.2. We acknowledge here that we neglected to describe this proposed change in the preamble but included in the proposed regulation text at 80 FR 31255. We originally proposed this revision for the reasons identified by the commenter.

After consideration of the public comments, we are finalizing the definition of “primary care” as proposed without modification.

Comment: One commenter noted that the terms “enrollee” and “beneficiary” appear to be used interchangeably in the proposed rule and asked for clarification as to whether these terms are synonymous.

Response: We appreciate the opportunity to clarify the meaning of these terms. An “enrollee” is a Medicaid beneficiary that is enrolled in a managed care plan. The term is used in the regulatory context when an individual’s enrollment into a managed care plan affords certain rights or obligations. Generally speaking for purposes of this rule, “beneficiary” is a Medicaid eligible individual that is not enrolled with a managed care plan but is also used in the managed care context to address individuals that are potential enrollees or enrollees. For example, the Beneficiary Support System is available to both potential enrollees and enrollees but the usage of both terms in the title of that system would unnecessarily complicate the title.

Comment: One commenter recommended that CMS adopt the following definition of “telemedicine”: “Telemedicine or Telehealth” means covered health care services provided to

a covered person from a health care professional who is at a site other than where the covered person is located using telecommunications technology.”

Response: We appreciate the commenter’s suggestion but decline to add a definition for “telemedicine” because, while we have included telemedicine in § 438.68(c)(1)(ix), we believe that the term has a generally accepted definition that is sufficient for purposes of that regulation.

b. Technical Corrections

We proposed to correct a limited number of technical and typographical errors identified in the June 14, 2002 final rule and the October 25, 2002 correcting amendment, as well as those identified through our review of the existing regulations in part 438.

- We proposed to update the cross-reference to cost-sharing rules in § 438.108 to reflect recent revisions to part 447.
- For purposes of consistency throughout part 438, we proposed to remove specific references to our Regional Office in § 438.806(a)(1) and replace it with a general reference to CMS. This proposed change does not represent a modification in the role of the Regional Offices; rather, we would prefer to establish workflow processes in sub-regulatory guidance rather than in regulation.
- We proposed to delete § 438.804 related the primary care provider payment increase under section 1202 of the Affordable Care Act as that provision expired at the close of CY 2014.

We did not receive comments on the proposed technical corrections and will finalize those changes as proposed.

c. Applicability and Compliance Dates

To clarify the applicability and compliance dates of various sections in this final rule, we are also finalizing new regulations text, consistent with the statement on applicability and compliance in the Effective Dates and Supplementary Information of this rule, in the following sections: §§ 438.3(v), 438.10(j), 438.62(c), 438.66(f), 438.206(d), 438.207(f), 438.208(d), 438.210(f), 438.230(c), 438.242(e), 438.310(d), 438.400(c) and 438.600(c). We are also changing the name of §§ 438.400 and 438.600 to account for the addition of regulation text on applicability and compliance dates for those provisions.

II. CHIP Requirements

A. Background

ARRA, CHIPRA and the Affordable Care Act made applicable to CHIP

several Medicaid managed care provisions in section 1932 of the Act, including section 1932(a)(4), Process for Enrollment and Termination and Change of Enrollment; section 1932(a)(5), Provision of Information; section 1932(b), Beneficiary Protections; 1932(c), Quality Assurance Standards; section 1932(d), Protections Against Fraud and Abuse; and section 1932(e), Sanctions for Noncompliance. In addition, the Affordable Care Act made applicable to CHIP and sections 1902(a)(77) and 1902(kk) of the Act related to provider and supplier screening, oversight, and reporting.

This rule implements these statutory provisions and builds on initial guidance on the implementation of section 403 of CHIPRA (section 2103(f) of the Act) provided in State Health Official (SHO) letters 09–008 and 09–013, issued on August 31, 2009 and October 21, 2009, respectively and codifies our policies. (SHO #09–008 is available at <http://downloads.cms.gov/cmsgov/archived-downloads/SMDL/downloads/SHO083109a.pdf>. SHO #09–013 is available at <http://www.medicaid.gov/Federal-Policy-Guidance/downloads/SHO102109.pdf>.) The SHO letters explained that the requirements of section 2103(f) of the Act, as amended by section 403 of CHIPRA effective July 1, 2009, apply to all CHIP managed care contracts. The provisions in this final rule both reflect and supersede this earlier guidance.

Our overarching goal for these regulations is to align CHIP managed care standards with those of the Marketplace and Medicaid where practical to ensure consistency across programs. As discussed in section I of the preamble, in this final rule, we are revising existing Medicaid regulations in order to modernize managed care contracting and service delivery while improving health care outcomes and beneficiary experience in a cost effective manner. To the extent appropriate, the final regulations for CHIP are aligned with the revisions made for Medicaid.

We recognize that CHIP has historically had few regulations related to managed care. To that end, we proposed to apply the requirements of section 2103(f) of the Act in a manner that is consistent with the goal of aligning CHIP managed care with Marketplace and Medicaid managed care rules, without imposing any additional requirements. We similarly address provisions of section 1932 of the Act applicable to CHIP under section 2107(e)(1)M) of the Act, and certain program integrity authorities applicable to CHIP under section 2107(e)(1)(D) of the Act with the goal of

alignment between programs without imposing significant new burdens on CHIP. Thus, the scope of the CHIP regulations is narrower than the revisions and amendments to the Medicaid managed care regulations. Most of the proposed CHIP regulatory changes are limited in scope to those areas specified in statute and, to the extent possible, those changes that will align the program with Medicaid and Marketplace regulations.

B. Summary of Proposed Provisions and Analysis of and Responses to Comments

In the June 1, 2015 proposed rule (80 FR 31169 through 31175), we proposed to implement provisions of the Children's Health Insurance Program Reauthorization Act of 2009 (CHIPRA) related to managed care.

We proposed adding a new subpart L to part 457 related to CHIP managed care plans. Most of the proposed regulations in this subpart are new, however we also proposed to move portions of § 457.940 and § 457.950 and all of § 457.955 from subpart I to the new subpart. This was to ensure that all information related to managed care would be contained in one subpart. We proposed to make revisions to § 457.204 related to FFP. In addition, we proposed to revise § 457.760 related to Strategic Planning, Reporting, and Evaluation.

Below we summarize the proposed provisions related to CHIP, as well as the public comments we received, and our responses to the comments. Comments related to the paperwork burden and the impact analyses are addressed in the "Collection of Information Requirements" and "Regulatory Impact Analysis" sections in this final rule.

1. Definitions (§§ 457.10, 457.902)

We proposed to move the definitions of "fee-for-service entity" and "actuarially sound principles" in § 457.902 to § 457.10, to delete § 457.902 and to add new definitions of various terms used elsewhere in the proposed regulations for CHIP, including comprehensive risk contract, EQR, EQR organization, MCO, prepaid ambulatory health plan, prepaid inpatient health plan, primary care case management, primary care case management entity, PCCM, and risk contract.

Comment: One commenter requested that we add freestanding birth centers and doula and other community health worker agencies to the definition of a comprehensive risk contract in § 457.10

Response: We decline to add additional types of services to the definition of a comprehensive risk contract in order to maintain alignment

between the definition of a comprehensive risk contract in CHIP with the definition in Medicaid. Discussion of the Medicaid definition of comprehensive risk contract can be found in section I.B.9.a of this preamble.

We have added definitions for "federally qualified HMO" and "provider" to further align with the Medicaid regulatory language and made revisions to the definition of "managed care organization" to remove references to advanced directives as there are very few adults in CHIP and very few children need an advanced directive. After consideration of the public comments, we are finalizing §§ 457.10 and 457.902 as proposed with these stated additions and revisions.

2. Federal Financial Participation (§ 457.204)

We proposed to revise § 457.204(a) to expand the regulatory statement of when we may withhold FFP to make clear that non-compliance can be based on a finding by the CMS Administrator that the state plan or state practice is in substantial non-compliance with the regulations in part 457 that implement Title XXI of the Act. In addition, we proposed to explicitly provide that substantial non-compliance includes, but is not limited to, failure to comply with requirements that significantly affect federal or state oversight or state reporting.

We received the following comments in response to our proposal to revise § 457.204.

Comment: Several commenters encouraged CMS to withhold FFP when a CHIP managed care entity is in substantial non-compliance with the state plan.

Response: Federal regulations do not directly regulate the CHIP managed care entities with which states contract. The regulations set out requirements and standards for States, including contracting standards and oversight responsibilities for the MCOs, PIHPs, PAHPs, PCCMs, and PCCM entities participating in the state's CHIP. The revised language of § 457.204 would authorize compliance actions when a state fails to comply with its oversight responsibilities under these regulations with respect to a managed care contract.

To streamline § 457.204 and make clear that compliance includes meeting requirements for state oversight, we are moving the definition of substantial non-compliance, which we proposed to include in paragraphs (a)(1) and (a)(2) to a separate (a)(3). After consideration of the public comments, we are making no additional changes to § 457.204.

3. Basis, Scope, and Applicability (§ 457.1200)

In § 457.1200, we described the statutory basis and scope of proposed subpart L. Specifically, we proposed to implement the requirements expressly set forth in section 2103(f)(3) of the Act, as added by section 403 of CHIPRA, which applies sections 1932(a)(4), 1932(a)(5), 1932(b), 1932(c), 1932(d), and 1932(e) of the Act to CHIP; section 2107(e)(1)(M) of the Act, as added by section 5006 of the American Recovery and Reinvestment Act of 2009 (Pub. L. 111-5, ARRA), which applies sections 1932(a)(2)(C) and 1932(h) of the Act, relating to protections for American Indians, to CHIP. We also proposed to implement statutory provisions related to program integrity, specifically sections 2107(b) and 2107(e)(2)(C) through (E) of the Act. Finally, the proposed regulations also rely on section 2101(a) of the Act, which provides that the purpose of Title XXI is to provide funds to states to enable them to initiate and expand the provision of child health assistance to uninsured, low-income children in an effective and efficient manner.

Comment: Commenters were supportive of the scope of the regulations and did not make any suggested revisions

Response: We thank commenters for their support.

After consideration of the public comments, we are finalizing § 457.1200 as proposed.

4. Contracting Requirements (§§ 457.950, 457.1201)

Previously, all CHIP contracting requirements, including managed care contracting requirements, were included in § 457.950. We proposed to move some provisions of § 457.950 related to managed care into new § 457.1201 and to eliminate others. We also proposed new contracting standards in § 457.1201. In some cases, we proposed CHIP-specific contracting requirements; in other cases, we proposed to adopt the Medicaid standards in § 438.3. The proposed CHIP-specific provisions at § 457.1201(a) would have states submit CHIP managed care contracts in accordance with standards that will be specified by the Secretary. We did not propose to condition FFP on CMS' prior approval of CHIP managed care contracts. This would have diverged from the proposed Medicaid regulations at §§ 438.3 and 438.806, providing increased flexibility for states under CHIP while still retaining a role for federal oversight.

Although we did not propose to adopt Medicaid rules related to rate review,

the proposed § 457.1201(a) requires that CHIP contracts submitted to CMS include the rate that will be paid to the managed care entity.

There are several standards at § 438.3 that we did not propose to adopt in CHIP, either because we do not have clear authority or because we wished to maintain flexibility, or because they are not appropriate for the CHIP population.

We received the following comments on the proposed revisions to § 457.950 and on proposed new § 457.1201.

Comment: Several commenters expressed support for the alignment of Medicaid and CHIP contract provisions as proposed. Other commenters recommended that CMS apply additional Medicaid provisions to CHIP. Specifically, commenters suggested that CMS fully align CHIP with the Medicaid contracting rules in proposed § 438.3(q)(4) through (q)(5) (related to contracting with PCCMs) and § 438.3(r) (related to contracting with PCCM entities).

Response: We agree with commenters that the contracting rules in proposed § 438.3(q)(4) through (q)(5) should apply to CHIP. In § 457.1201(l), we proposed to adopt the standards in § 438.3(q)(1) through (q)(3). The proposed rule omitted the cross reference to the standards in paragraphs (q)(4), which specifies that the contract must prohibit discrimination in enrollment, disenrollment, and reenrollment based on the beneficiary's health status or need for health care services, and (q)(5), which provides that enrollees have the right to disenroll in accordance with § 438.56(c). This was an oversight, and we are including cross references to all of 438.3(q) in the final rule. Note that existing regulations at § 457.480 already prohibit states from imposing any exclusion for covered services for pre-existing conditions, and § 438.56(c) also is applied to CHIP via cross reference at § 457.1212 of the final rule. Section 438.3(r) provides that contracts with PCCM entities that provide for shared savings must comply with § 438.330(b)(2), (b)(3), (c), and (e), § 438.340, and § 438.350. These provisions are incorporated into the final regulations for CHIP via cross-reference at § 457.1240(b), (e), and (f). Rather than cross-referencing to § 438.3(r), in proposed § 457.1201(m), re-designated at § 457.1201(n) of the final rule, provides that, if contracts with PCCM entities provide for shared savings, incentive payments or other rewards for quality outcomes, the contracts must comply with § 457.1240(b), (e), and (f).

Comment: Commenters also requested that CMS adopt for CHIP proposed

§ 438.3(e) (related to services that may be covered), § 438.3(g) (related to provider-preventable conditions), and § 438.3(s)(1), (4), (5) and (6) (related to outpatient drugs) because they believe that these provisions would provide valuable information about program operations. In particular, commenters expressed concern that exclusion of § 438.3(e) could be interpreted as prohibiting CHIP enrollees from receiving services that an MCO voluntarily provides. The commenters request clarification that CHIP enrollees will be able, at the state's option, to receive services voluntarily provided by MCOs. They recommended adopting § 438.3(e) to give states the option to require continuation of voluntarily provided services.

Response: We agree with commenters that MCOs are not precluded from providing additional services, and that the terms of § 438.3(e) are equally applicable to CHIP; we did not intend to imply that CHIP enrollees would be prohibited from receiving services that an MCO provides voluntarily. While we do not believe that it is necessary to expressly allow MCOs, PIHPs, and PAHPs to provide services that are not required under the state plan, we agree that it is confusing to have a stated standard in Medicaid and omit it in CHIP. In addition, § 438.3(e) provides clarity to states about what may be included in the capitation rate.

However, we do not agree with commenters that we should adopt the standards in § 438.3(g) and § 438.3(s)(1), (4), (5) and (6). Section 438.3(g) refers to § 447.26, which prohibits payment for provider-preventable conditions as required by section 2702 of the Affordable Care Act. Section 2702 of the Affordable Care Act does not apply to CHIP and we did not propose to exercise rulemaking authority to make it applicable to CHIP. While we encourage states to apply a prohibition on payments for provider-preventable conditions, we are not requiring it at this time. Similarly, § 438.3(s)(1), (4), and (5) refer to standards related to outpatient drugs in section 1927 of the Act. Section 1927 of the Act does not apply to CHIP, we did not propose to make it applicable, and we are not imposing these standards to CHIP managed care entities at this time.

Comment: One commenter expressed concern that the proposed standards for LTSS as outlined in § 438.3(o) and the standards for enrollees who are patients in an IMD proposed at § 438.3(t) (finalized elsewhere in this final rule at § 438.6(e)) are not included in this section. The commenter recommends that CMS apply the standards proposed

for Medicaid to CHIP so enrollees with special health care needs who do not meet the SSI criteria for disability can benefit from these services.

Response: We do not agree that adopting these standards in CHIP is appropriate. Section 438.3(o) requires that home and community based services which are provided by a Medicaid MCO, PIHP or PAHP that could be authorized under sections 1915(c), 1915(i), or 1915(k) of the Act be delivered in a setting which satisfies the requirements of § 441.301. There are no comparable statutory or regulatory provisions relating to provision of home and community based services for children eligible for a separate CHIP. Similarly, the IMD provision finalized at § 438.6(e) sets out standards for capitation payments to MCOs and PIHPs for enrollees with a short-term stay in an IMD. The exclusion of FFP for care provided to patients in an IMD in paragraph (B) following section 1905(a)(29) of the Act and § 435.1010 of the Medicaid regulations does not apply to CHIP (while status as a patient in an IMD is relevant to an eligibility determination, there is no preclusion of coverage for IMD or other services for an individual who has been determined eligible).

Comment: Several commenters requested that CMS provide sub-regulatory guidance to states to ensure compliance with new requirements.

Response: We intend to provide guidance to states regarding the new regulations.

Comment: Some commenters expressed support for CMS' approach to contract review for CHIP, which would not condition FFP on prior approval of contracts. One commenter acknowledged that CHIP may need to be treated differently than Medicaid due to statutory constraints and difference in program structure. However, several commenters recommended that CMS follow Medicaid by conditioning FFP on timely submission and prior approval of contracts. In addition, several commenters suggested that CMS coordinate the timing of submissions with the Medicaid review and submission schedule, specifically requesting that CMS require submission 90 days prior to the effective date of contracts. In addition, several commenters requested that CMS allow a single contract review process for states with separate and combination CHIP programs.

In contrast, some commenters expressed concern that the proposed contract submission requirements could cause administrative burden for states. One commenter stated that if the

provisions are adopted as proposed, CMS should only apply the submission requirements to future contracts rather than to the renewals of current contracts.

Response: We appreciate the comments on this topic. We believe having states submit the contracts, including the capitation rates, but not conditioning FFP on prior approval, strikes the appropriate balance for CHIP. As we discussed in the proposed regulation, we believe this approach, over time, will give CMS and the public important information about the administration of CHIP. Once we have learned more, we may consider adopting additional standards (including conditioning FFP on prior approval of contracts) or providing guidance on best practices for managed care contracting. We intend to specify standards for submission of the contracts in sub regulatory guidance.

Comment: A few commenters expressed concern that the requirement at proposed § 457.1201(j) that CHIP plans submit annual audited financial reports may increase costs for the plans. Commenters requested clarification in § 457.1201(j) that audited financial reports are not required to be specific to the Medicaid and/or CHIP experience only. Several commenters recommended that CMS accept submission of alternative CEO/CFO assured or certified reports.

Response: Proposed § 457.1201(j), finalized at § 457.1201(k) of this final rule, requires the MCO, PIHP, or PAHP submit annual audited financial reports specific to the CHIP contract(s). Submission of alternative certified reports is not permitted under the regulation. We disagree that audited financial reports, which will help to ensure states that plans are operating in accordance with federal requirements, will impose undue costs on plans.

Comment: One commenter stated that audits of MCOs, PIHPs, and PAHPs should be conducted in compliance with the generally accepted auditing standards as opposed to the generally accepted auditing principles.

Response: We agree that managed care plans must submit audited financial reports on an annual basis in accordance with generally accepted accounting principles as well as generally accepted auditing standards. As finalized, § 457.1201(k) cross-references § 438.3(m), which requires both standards.

Comment: Several commenters stated that the record retention and audit standards were unclear and suggested that that CMS clarify and align recordkeeping and audit standards so

that Medicaid managed care plans clearly understand their obligations. One commenter supported the 6-year minimum recordkeeping requirement, but recommended that CMS adjust the audit and inspection timeline so that Medicaid managed care plans maintain records that may be required in an audit or inspection. Some commenters recommended that CMS align the timeframes for records retention across the regulation by extending the records retention requirements proposed at § 457.1201(p) (finalized at § 457.1201(q)) for MCOs, PIHPs and PAHPs to a period of no less than 10 years.

Response: We agree with commenters that the recordkeeping requirements should align throughout the regulation. Medicaid is updating the record retention requirement in § 438.3 to 10 years to align with § 438.230(c)(3)(iii), the False Claims Act at 31 U.S.C. 3731(b)(2), and MA. Therefore, we believe it is appropriate to align § 457.1201 with the 10 year requirement. We are modifying the regulatory text to adopt this recommendation.

After consideration of the public comments, we are:

- Revising paragraph (h) (redesignated as paragraph (i)).
- Revising paragraph (j) (redesignated as paragraph (k)).
- Clarifying the cross-references in paragraph (n) related to additional rules for contracts with PCCM entities; and
- Modifying the record retention standard in § 457.1201(q).

To streamline the regulatory language and better align with the requirements set forth in Medicaid, we also are:

- Making minor editorial revisions to paragraphs (a), (b), and (c);
- Adding paragraph (e), related to services that may be covered by an MCO, PIHP, or PAHP;
- Redesignating the paragraphs following paragraph (e);
- Updating the cross-references in paragraph (f) (related to additional rules for contracts with PCCMs; and
- Updating the paragraphs of § 457.1201 to cross-reference the Medicaid definitions in § 438.3 in order to streamline the regulation text where appropriate.

Other than redesignation, we are finalizing paragraphs (o) and (p) as proposed.

5. Rate Development Standards and Medical Loss Ratio (§§ 457.940, 457.1203, 457.1205)

Currently, regulations related to CHIP managed care rate setting are in § 457.940(b)(2), (c), and (e). We proposed to move those standards to

new § 457.1203. The standards would remain substantively unchanged, although we proposed to change the term “principles of actuarial soundness” to “actuarially sound principles,” to match the term defined in § 457.902, which we proposed to move to § 457.10. We did not propose to change or move the standards unrelated to managed care rate setting in § 457.940(a), (b)(1), and (d). In addition, to align with the private market and the Medicaid managed care proposal at § 438.4(b)(9) (related to medical loss ratio), we proposed at § 457.1203(c) to adopt an MLR calculation and reporting requirement in CHIP and to require rates to be developed to meet a target MLR. We believe MLR calculation and reporting are important tools to ensure that the CHIP program is administered in an effective and efficient manner in accordance with section 2101(a) of the Act. We also proposed to align with the Medicaid proposed regulations at § 438.8 and § 438.74 at § 457.1203(c) in relation to MLR standards and state oversight.

We did not propose to adopt any of the other Medicaid standards related to rate development (§ 438.5), contract provisions related to payment (§ 438.6), or rate certification (§ 438.7).

We received the following comments in response to our proposal to revise § 457.940, and add § 457.1203 and § 457.1205.

Comment: Many commenters supported the adoption of a minimum MLR in CHIP, and some supported the application of the MLR standards for Medicaid described in § 438.4(b)(9) and § 438.74. However, several commenters expressed a preference for using an 80 percent minimum MLR for CHIP, rather than the 85 percent minimum CMS proposed. They stated that at least one state currently uses an 80 percent minimum MLR in CHIP, while several states use an 85 percent minimum MLR in Medicaid. A few commenters suggested that we allow states to ask for an MLR adjustment to the minimum MLR for CHIP.

Response: We appreciate commenters’ support of adopting an MLR calculation and reporting requirement in CHIP and use of MLR reporting and projections as part of the rate setting process. We clarify, however, that this rule does not impose a minimum MLR requirement on CHIP (or Medicaid) managed care plans. Rather, the rule requires that rates be developed in a manner to meet a target MLR; a plan’s failure to meet that target MLR does not result in violation of these regulations. The imposition of any penalty or consequence for failing to meet a specific minimum MLR is a

matter of state law and policy. MLR data reported by plans may also be used by states in establishing rates in subsequent contracts.

We disagree with commenters that we should use a lower MLR as the target MLR used in rate development for CHIP. The 85 percent standard is consistent with both the Medicaid standard in § 438.4(b)(9) and the large group private insurance market standard in 45 CFR 158.210. Some commenters suggested that because CHIP plans tend to have comparable administrative costs to Medicaid, but cover children with, on average, lower medical costs, the resulting medical to overall cost ratio is lower. We disagree that this will significantly affect rate development using a target MLR of 85 percent MLR. We believe that the same standard is an appropriate target MLR for CHIP plans, as most CHIP plans are large enough to distribute fixed administrative costs such that a comparable MLR can be achieved. Smaller plans may take advantage of the credibility adjustment in § 438.8(h), effectively lowering their reported MLR. For similar reasons, we decline to allow states to ask for an MLR adjustment. We note that while 45 CFR 158.301 allows states to request an MLR adjustment, the adjustment is only for plans sold on the private individual insurance market. It is not applicable to either the large group or small group market, which are more comparable to CHIP. As noted, states are not required to take contract or enforcement action against a CHIP managed care plan if the plan reports an MLR which is less than 85 percent; that information can and should be considered in rate-setting for future years, as it may indicate that adjustments in capitation rates are necessary to meet the 85 percent MLR target.

Comment: Several commenters encouraged us to apply additional Medicaid provisions related to the establishment of capitation rates and other payment standards and methodologies for MCOs, PIHPs and PAHPs to CHIP, including all of §§ 438.4, 438.5, 438.6, and 438.7. Commenters stated that, even without a statutory mandate to meet particular actuarial soundness requirements, CHIP rates should be actuarially sound and rates should be calculated according to widely accepted principles of actuarial science.

Response: We agree that states must develop payment rates for MCOs, PIHPs, and PAHPs for CHIP using actuarially sound principles, as required under § 457.1203(a) of the final rule. However, Title XXI does not provide the same specificity about rate development

standards as Title XIX, and while we agree that we have authority under section 2101 of the Act to establish additional standards, we have determined it would not be appropriate to impose all of the Medicaid rate-setting standards on separate CHIPs at this time including those cited by commenters. Per § 457.1201 of the final rule, states are required to include payment rates in their managed care contracts submitted to CMS. As we gain additional experience with rate setting in CHIP, we may consider developing additional standards for CHIP in the future.

Comment: One commenter asked CMS to clarify in § 457.1203 that states have flexibility to implement and test reimbursement methodologies that pay for outcomes.

Response: States have discretion under the regulations to incentivize and retain certain types of providers to participate in the delivery of care to CHIP beneficiaries, including under a managed care arrangement, and including use of outcome or value-based purchasing models. Managed care plans are a key partner in achieving the goals of improved population health and better care at lower cost, and we encourage states to partner with their managed care plans to achieve delivery system and payment reform and performance improvements. We agree with the commenter that the proposed regulation text was unclear and have clarified in § 457.1203(a) that implementing value-based purchasing models for provider reimbursement is one mechanism states can use to enroll efficient and high quality providers.

Comment: One commenter asked us to require in § 457.1205 that states submit a summary description of the MLR reports received from the MCOs, PIHPs and PAHPs along with the actuarial certification.

Response: We agree with the commenter that state submissions to CMS should include some information about the MLR, and that the language in proposed § 457.1205 related to submission of the summary descriptions of the MLR reports was unclear. We intended to propose that states submit a summary description of the MLR reports, just as Medicaid agencies are required to do under § 438.8(k), while acknowledging that the reports would not be submitted with the actuarial certifications described in § 438.7 because such certifications are not required in CHIP. We are revising the language, finalized at § 457.1203(e) of the final rule, to better reflect our intent.

Comment: Many commenters referred us to their comments on proposed

§ 438.4(b)(8) (related to developing rates to meet the minimum MLR and redesignated in this rule at § 438.4(b)(9)) and § 438.74 (related to state oversight of the MLR) or made comments similar to those that were made on those regulations.

Response: We refer commenters to the preamble discussion of § 438.4(b)(9) and § 438.74 above for a more complete discussion of the comments we received on these provisions and our responses, which apply equally to CHIP.

After consideration of the public comments, we are finalizing proposed §§ 457.1203 and 457.1205 with modifications. First, we are moving the substance of the provisions of proposed § 457.1205 to § 457.1203(e) and (f), and renaming this section "Rate development standards and medical loss ratio" to streamline the regulation text. In § 457.1203, we are modifying the text in paragraph (a) to expressly provide that implementing value-based purchasing models for provider reimbursement is permitted. In paragraph (b), we are including the word "or" to clarify that a state may establish higher rates to assure sufficient provider participation or provider access or to enroll certain other providers. We are streamlining the text in paragraph (c). The language proposed in § 457.1205(a) (redesignated to § 457.1203(e)) is revised to clarify that states must submit summary MLR reports but that these reports are not required to be submitted with the actuarial certification required for Medicaid described in § 438.7.

6. Non-Emergency Medical Transportation PAHPs (§ 457.1206)

States may use a PAHP structure to deliver NEMT services in CHIP, as is done in some states in Medicaid. As such, we proposed to adopt the Medicaid approach to regulating NEMT PAHPs, pursuant to which only certain provisions of the regulations would apply. However, under the proposed rule, if a state chooses to use a PAHP to provide NEMT services along with other ambulatory medical services, the PAHP is considered a traditional PAHP, as defined in § 457.10, and all the PAHP provisions throughout subpart L of this part applicable to PAHPs generally would apply.

At § 457.1206, we proposed largely to mirror the terms of § 438.9, which sets out the standards that apply to PAHPs that provide only NEMT services in Medicaid, with two exceptions. First, proposed § 457.1206 did not include standards related to advance directives or LTSS. Second, instead of requiring actuarial soundness, as is required

under § 438.9(b)(2) by reference to § 438.4, we proposed to require that NEMT PAHPs in CHIP follow the standards in § 457.1203 related to rate development.

We received the following comments in response to proposed § 457.1206.

Comment: Commenters noted that we did not propose to apply the advance directive and LTSS provisions in § 438.9(b)(1)(ii)–(iii) (which cross references to § 438.3(j) and § 438.3(o)), and suggested that we reconsider. While they understand that these provisions may have limited applicability to the CHIP population, they believe there are some CHIP beneficiaries for whom these provisions would apply. In particular, they stated that children over age 18 and pregnant women would benefit from the advance directive provision and children with special health care needs would benefit from the LTSS provisions.

Response: We do not agree that these standards should apply to CHIP. We believe that the advance directives provisions described in § 438.3(j) and § 422.128 would create a significant burden on states and MCOs, PIHPs, and PAHPs in the CHIP context, with correspondingly little benefit for beneficiaries, as there are very few adult beneficiaries in CHIP and very few children need an advance directive. As we explained in section II.A.4 of the preamble for the proposed rule, we do not believe the LTSS standards described in § 438.3(o) are appropriate for CHIP. Section 438.3(o) requires that home and community based services authorized for Medicaid beneficiaries under sections 1915(c), 1915(i), or 1915(k) of the Act which are provided by a Medicaid MCO, PIHP, or PAHP be delivered in a setting which satisfies the requirements of § 441.301. There are no comparable statutory provisions relating to provision of home and community based services for children eligible for a separate CHIP.

Comment: Commenters noted that there were several places that proposed § 457.1206 deviated from § 438.9. In particular, commenters noted that:

- § 457.1206(b)(1)(ii) excluded audited financial reports, while there was no similar exclusion in § 438.9 for NEMT PAHPs in Medicaid;
- § 457.1206(b)(7) was not fully aligned with § 438.9(b)(7); and
- § 457.1206 did not contain a reference to confidentiality provisions.

They also noted a technical error in § 457.1206(b)(1), in which they said we inadvertently referred to § 457.1202 rather than § 457.1201.

Response: We intended to align § 457.1206 with all provisions in

§ 438.9, with the exception of the standards related to advance directives and LTSS, discussed above. The confidentiality provisions in existing § 457.1110 apply broadly to any entity that contracts with the state, including NEMT PAHPs, therefore we did not need to explicitly include a cross-reference to § 457.1110 in § 457.1206. In addition to the discrepancies noted by commenters, we note that proposed § 457.1206(b)(9) (related to the prohibition against affiliation with individuals debarred or excluded by federal agencies) was inadvertently broader than proposed § 438.9(b)(9), in that § 457.1206(b)(9) cross referenced to § 457.1285 rather than to § 438.610 (which is cross referenced in § 438.9(b)(9)), and applied to CHIP via the cross reference to all of part 438 subpart H in § 457.1285. In response to comments, we are finalizing the regulation text at § 457.1206 with the following changes:

- In § 457.1206(b)(1), we removed the exclusion for audited financial reports.
- We corrected the cross reference in § 457.1206(b)(7) to § 457.1233(a), (b), and (d);

We also made the following technical corrections:

- In § 457.1206(b)(1), we corrected the cross reference to § 457.1201 and clarified that the standards related to physician incentive plans is located in § 457.1201(h) and the standards related to mental health parity are in § 457.1201(l);
- In § 457.1206(b)(2), we removed the proposed cross reference to the rate development standards in § 457.1203 because a similar cross reference to the Medicaid rate development standards in § 438.5 was not included § 438.9. Our intent was to align § 457.1206 with § 438.9;

• We redesignated the paragraphs following paragraph (b)(2) to account for the change in paragraph (b)(2);

- In § 457.1206(b)(8) we corrected the cross reference to § 438.610, as cross referenced by § 457.1285; and

• In § 457.1206(b)(9), we added text and a cross reference to § 457.1209 (relating to requirements for contacts involving Indians, Indian Health Care Providers, and Indian managed care entities) to maintain alignment with Medicaid regulations, which have added a similar cross reference to § 438.14 in § 438.9 of the final rule.

Comment: Commenters noted that CMS included a cross reference to a new provision against provider discrimination in § 457.1206(b)(4), but that we neglected to include a provision cross referencing to § 438.12 (the Medicaid provision against provider

discrimination) in the regulatory text but cross-referenced § 457.1208, which is about provisions related to Indians, IHCPs and IMCEs. They believed that CMS intended to fully align these provisions, and they recommended that HHS add a new provision to subpart L of part 457 for provider discrimination generally, and apply that new provision for NEMT PAHPs at § 457.1206(b)(4).

Response: Commenters are correct that we intended to incorporate anti-discrimination provisions in § 438.12 into part 457, subpart L, and that the cross reference in § 457.1206(b) to § 457.1208 as relating to provider non-discrimination requirements was an error as proposed § 457.1208 referenced managed care contracts involving Indians, Indian Health Care Providers, and Indian Managed Care Entities. We are finalizing a new § 457.1208 to address the incorporated protections regarding provider non-discrimination and we have redesignated proposed § 457.1208 (relating to requirements for managed care contracts involving Indians, Indian Health Care Providers, and Indian Managed Care Entities) as § 457.1209, and included a cross reference to both § 457.1208 and § 457.1209 in § 457.1206(b) of the final rule as applicable to NEMT PAHPs.

After consideration of the public comments, we are finalizing § 457.1206 substantially as proposed with revisions to paragraph (b) to improve the sentence flow, to correct cross-references, and to add new text to include cross references to apply to NEMT PAHPs both requirements for managed care contracts involving Indians, Indian Health Care Providers, and Indian Managed Care Entities. We are not finalizing the exclusion of the contract requirement for the NEMT PAHP to submit audited financial reports and the requirement that the rates for NEMT PAHP be developed pursuant to § 457.1203.

7. Information Requirements (§ 457.1207)

Section 2103(f)(3) of the Act, as amended by section 403 of CHIPRA, specifies that the provision of information standards at section 1932(a)(5) of the Act apply to CHIP managed care programs. As such, we proposed to align CHIP with Medicaid information standards at § 438.10, which effectuate section 1932(a)(5) of the Act. We proposed adding § 457.1207, which provides that states must require CHIP MCOs, PAHPs, PIHPs, PCCMs, and PCCM entities to provide enrollment notices, informational materials and instructional materials relating to enrollees and potential enrollees in the

same manner and subject to the same standards as provided in § 438.10. Including the cross reference to Medicaid managed care information standards supports CMS' goal to align and maximize coordination between insurance affordability programs. The proposed revisions include a more structured and coherent set of state and managed care plan standards for beneficiary information, and permit the availability of beneficiary information in electronic form.

We received the following comments in response to our proposal to add § 457.1207.

Comment: Commenters supported adopting the Medicaid information requirements in CHIP. They did not have specific comments on the CHIP proposed regulation; they referred us to their comments on the Medicaid proposal.

Response: We appreciate the support of this proposal. Because § 457.1207 cross-references the Medicaid regulation, it by reference incorporates all of the comments received on the Medicaid provision.

After consideration of the public comments, we are finalizing § 457.1207 as proposed with minor wordsmithing revisions.

8. Requirement Related to Indians, Indian Health Care Providers, and Indian Managed Care Entities (§ 457.1209)

Section 2107(e)(1)(M) of the Act, as added by section 5006 of ARRA, specifies that the provisions related to managed care contracts that involve Indians, Indian health care providers (IHCP), and Indian managed care entities (IMCE) at sections 1932(a)(2)(C) and 1932(h) of the Act apply to CHIP. As such, we proposed to align CHIP with Medicaid when MCOs, PIHPs, PAHPs, PCCMs, or PCCM entities enroll Indians and to incorporate the requirements at § 438.14, which effectuate sections 1932(a)(2)(C) and 1932(h) of the Act into the CHIP regulations at § 457.1208.

We received the following comments on proposed § 457.1208, redesignated at § 457.1209 in the final rule.

Comment: Commenters supported adopting the Medicaid information requirements in CHIP. They did not have specific comments on the CHIP proposed regulation; they referred us to their comments on the Medicaid proposal.

Response: We appreciate the support of this proposal and refer readers to the responses to comments received on proposed § 438.14.

After consideration of the public comments, we are finalizing § 457.1208 as proposed but redesignated at § 457.1209 with minor wordsmithing revisions.

9. Managed Care Enrollment (§ 457.1210)

Section 2103(f)(3) of the Act, as amended by section 403 of CHIPRA, specifies that the section 1932(a)(4) of the Act (relating to enrollment and disenrollment protections) applies to CHIP managed care programs. We proposed adding § 457.1210 to implement section 1932(a)(4)(C) and (D) of the Act (related to enrollment protections) for CHIP. We proposed adding § 457.1212 to implement section 1932(a)(4)(A) and (B) (related to disenrollment protections) for CHIP. Further discussion of § 457.1212 is below.

We did not propose to adopt in CHIP the full Medicaid enrollment provision for mandatory managed care enrollment in § 438.54, which as proposed, required states to give potential enrollees a set period to choose a plan and required them to use a default enrollment process when individuals did not actively choose a plan. We did not propose the application of the choice or default enrollment provisions to CHIP because there is no requirement under Title XXI that states offer more than one managed care plan in CHIP. In addition, Title XXI provides states with flexibility in establishing the enrollment start date for CHIP, such that some states do not consider a child enrolled in CHIP until the family has actively selected a managed care plan and paid the applicable premium.

Instead of adopting § 438.54, we proposed standards in § 457.1210 for states that elect to use a default enrollment process. The standards were similar, but not identical, to those proposed for the default enrollment process established for Medicaid in § 438.54(d).

We received the following comments in response to our proposal to add § 457.1210.

Comment: Most commenters supported our approach. Many stated that adopting the Medicaid approach would delay coverage for CHIP beneficiaries by requiring a choice period, particularly in states that use prospective enrollment. However, one commenter suggested adopting the portion of the Medicaid provision that requires a choice period.

Response: We appreciate the comments we received on this proposed provision. As noted above, we have decided to remove the choice period for

Medicaid from the final regulation, and we are not adopting a choice period in CHIP. We agree with commenters that, in states that use prospective enrollment in CHIP, a choice period could result in a delay of coverage.

Comment: One commenter encouraged us to adopt a default enrollment process in CHIP, which does not require a choice of more than one plan. Another commenter thought we proposed to require a default enrollment process, which the commenter opposed. Many others agreed with our proposed approach, indicating that the statute was ambiguous about whether a default enrollment process is required, and noting that such a process would be difficult to implement in CHIP.

Response: We appreciate the comments on this topic. As we noted in the proposed regulation, we do not believe requiring a default enrollment process is appropriate for CHIP. Under this final rule, states would be permitted to use a default enrollment process, but are not required to do so. Some states use prospective enrollment, so children are not enrolled in the program until they have selected a managed care plan and, if applicable, paid a premium. Requiring a default enrollment process would disrupt this practice, which is permitted under the statute for CHIP.

Comment: One commenter encouraged us to adopt the Medicaid provisions at §§ 438.54(c)(3) and 438.54(d)(3), which requires that states provide informational notices to potential enrollees that explain the process for enrolling in an MCO, PIHP, PAHP, PCCM, or PCCM entity.

Response: We appreciate these suggestions. We agree that states should provide thorough informational notices to potential enrollees, because in some cases, this notice will be the last one from the state to the enrollee until their eligibility redetermination or their annual right to change plans. It is critical that this notice be as complete, clear, factual, and easy to understand as possible. Plain language notices that are accessible to individuals with limited English proficiency and individuals living with disabilities is also critical, consistent with our standards for eligibility notices in § 457.340. Therefore, we are adding a new paragraph (c) in § 457.1210 of the final rule to include standards similar to those in § 438.54(c)(3) and (d)(3).

Comment: Several commenters suggested that we collect additional information about CHIP enrollment processes, to understand more fully the range of enrollment processes in the states.

Response: We agree that it would be helpful to have additional information about CHIP enrollment processes and will consider the best way to collect such information and share best practices with states.

Comment: One commenter asked us to make the list of additional criteria that states may consider to conduct default enrollment process, a requirement that states must take into consideration when conducting default enrollment processes in CHIP.

Response: We included these optional criteria because we agree they could add value to a default enrollment processes and encourage states to utilize them as appropriate. However, inasmuch as states are not required to implement a default enrollment process, we believe that states should have the flexibility to determine when the criteria are both appropriate for their population and feasible for the state.

Comment: One commenter noted a technical error in the proposed regulation. In proposed § 457.1210(a)(1), the commenter noted that the text read “To be a qualified, the MCO . . .” when it should have read “To be qualified, the MCO . . .”

Response: We have made this correction.

After consideration of the public comments, we are finalizing § 457.1210 with revisions. We are revising paragraph (a)(1) of this section to make a technical correction, revising the heading of the section, and adding paragraph (c) to clarify the information states should provide to beneficiaries about the enrollment process. We are not finalizing the proposal that states must “seek to preserve existing provider-beneficiary relationships and relationships with providers that have traditionally served CHIP beneficiaries” because a default enrollment process is not a requirement in CHIP, and instead provide states with flexibilities to use a variety of mechanisms, including previous encounter data and contacting enrollees, as a means to maintain provider-enrollee relationships. Additionally, as we are not requiring a default enrollment process in CHIP, we are finalizing an exception to the requirement that the state must evenly distribute beneficiaries equitably among contracted managed care plans. Also, we are simplifying the language at § 457.1210(a)(3) which is finalized at § 457.1210(a)(1)(iii).

10. Disenrollment (§ 457.1212)

Section 2103(f)(3) of the Act, as amended by section 403 of CHIPRA, specifies that the enrollment provision at section 1932(a)(4) of the Act applies

to CHIP managed care programs. We proposed adding § 457.1212, which implements section 1932(a)(4)(A) and (B) of the Act for CHIP. The proposed regulation provided that states must follow, and ensure MCOs, PAHPs, PIHPs, PCCMs, and PCCM entities follow, the Medicaid disenrollment standards provided at § 438.56. Section 403 of CHIPRA did not apply the choice of managed care entity (MCE) standard in section 1932(a)(3) of the Act; therefore, separate CHIPs do not need to offer an alternative plan or delivery system option at the time of enrollment. However, because section 1932(a)(4) of the Act gives individuals the right to disenroll from their MCE while still remaining eligible to receive benefits, the state must contract with at least two MCEs, or contract with one MCE and operate an alternate delivery system, such as FFS, to provide CHIP benefits to those who have disenrolled from the state’s contracted MCE. The state could also contract with some, or all, of the state’s existing Medicaid provider network.

We received the following comments in response to our proposal to add § 457.1212.

Comment: Commenters supported adopting the Medicaid disenrollment standards in CHIP.

Response: We appreciate the support of this proposal.

Comment: One commenter suggested that we adopt additional bases for disenrollment, including when an enrollee’s provider leaves the network.

Response: We believe our regulations at § 457.1212 adequately provides the necessary minimum bases for disenrollment, as we are retaining alignment with Medicaid regulations at § 438.56, which we believe includes the key provisions for permitting disenrollment. States have flexibility to permit disenrollment in other circumstances as they deem appropriate. We refer commenters to section I.B.5.b. of this final rule for additional discussion relating to § 438.56.

Comment: In proposed § 457.1212, we noted that references to fair hearings in § 457.56 should be read to refer to reviews as described in subpart K of part 457. One commenter encouraged us to have a single fair hearings process for both Medicaid and CHIP.

Response: States have the flexibility to use the Medicaid fair hearings process for CHIP. However, since CHIP is not an entitlement program and does not confer the same due process protections as those that attach to Medicaid, we are not requiring states to use the Medicaid fair hearings process.

If a state chooses to use a single process, it would need to comply with the Medicaid fair hearings regulations in part 431, subpart E and part 438, subpart F.

After consideration of the public comments, we are finalizing § 457.1212 substantively as proposed but with minor wordsmithing revisions for clarity.

11. Conflict of Interest Safeguards (§ 457.1214)

Section 2103(f)(3) of the Act, as amended by section 403 of CHIPRA, specifies that the conflict of interest provisions at section 1932(d)(3) of the Act apply to CHIP managed care programs. We proposed adding § 457.1214, which provides that states have safeguards against conflict of interest in accordance with the terms of § 438.58.

We received the following comments in response to our proposal to add § 457.1214.

Comment: Commenters supported adopting the Medicaid conflict of interest safeguards in CHIP. They did not have specific comments on the CHIP proposed regulation; they referred us to their comments on the Medicaid proposal.

Response: We appreciate the support of this proposal and refer readers to the responses to comments received on proposed § 438.58.

After consideration of the public comments, we are finalizing § 457.1214 substantively as proposed but with minor revisions for clarity.

12. Continued Services to Enrollees (§ 457.1216)

Section 2103(f)(3) of the Act, as amended by section 403 of CHIPRA, specifies that the enrollment provision at section 1932(a)(4) of the Act applies to CHIP managed care programs. This provision is described above in the discussion of the Medicaid provision at § 438.62. Related to change in enrollment, we proposed adding § 457.1216, which provides that states must follow the Medicaid standards related to continued services to enrollees at § 438.62.

We received the following comments in response to our proposal to add § 457.1216.

Comment: Commenters did not have specific comments on the CHIP proposed regulation; they referred us to their comments on the Medicaid proposal.

Response: We refer readers to the responses to comments received on proposed § 438.62.

After consideration of the public comments, we are finalizing § 457.1216 substantively as proposed with minor revisions for clarity.

13. Network Adequacy Standards (§ 457.1218)

Section 2103(f)(3) of the Act, as amended by section 403 of CHIPRA, specifies that the provisions at section 1932(a)(5) of the Act, requiring that MCEs assure adequate capacity to serve expected enrollment, apply to CHIP managed care programs. As such, we proposed to align CHIP with Medicaid network adequacy standards at § 438.68, which effectuate section 1932(a)(5) of the Act. We proposed adding § 457.1218, which provides that states have network adequacy standards and ensure that MCOs, PIHPs, and PAHPs meet such standards in accordance with the terms of § 438.68. We solicited comment on whether we should include additional standards for additional types of pediatric providers, for example children's hospitals or child and adolescent behavioral health providers.

We received the following comments in response to our proposal to add § 457.1218.

Comment: Several commenters supported the addition of network adequacy standards for CHIP at § 457.1218 and their alignment with Medicaid at § 438.68. Specifically, commenters applauded the additional pediatric-focused network adequacy requirements that CMS included for Medicaid and CHIP, such as pediatric primary care, specialty care, and dental standards.

One commenter suggested that CMS amend § 457.1218 by deleting the second sentence for additional requirements for pediatric specialists and dentists, as that requirement is already captured in § 438.68. Other commenters asked us to further clarify the second sentence to say that CHIP covers comprehensive services.

Many commenters responded to CMS' request for comments regarding whether states should require network adequacy standards for additional types of pediatric providers. Commenters recommended that CMS include standards for mental health and substance use providers, optometrists, developmental specialists, pediatric hospitals, as well as other pediatric subspecialists. One commenter recommended that networks should include providers that are capable of providing treatment in particular settings. Another commenter suggested that CMS apply standards based on adequate access to specialists rather than provider type. In contrast, some

commenters stated that it was not necessary for CMS to include network adequacy standards for additional types of pediatric providers in CHIP.

Response: We are removing the second sentence in proposed § 457.1218, because we agree with commenters that it is redundant with the Medicaid standards in § 438.68(b) and could create confusion about the types of services states must provide in CHIP. After further consideration of the proposed policy and comments, we decline to list additional provider types and categories as commenters recommended. We are not requiring states to add children's hospitals as a network provider, as there is not a parallel requirement in Medicaid and the limited availability of children's hospitals may affect plan participation. We encourage states and plans to include children's hospitals in their provider networks whenever possible. Furthermore, we believe that the provider types listed in § 438.68 (which includes certain pediatric providers) strikes the appropriate balance of ensuring access to care and state flexibility. However, note that we have added pediatric behavioral health specialists at § 438.68(b) of the final rule as one of the provider types for which states must develop standards for Medicaid managed care plans, which also applies to CHIP managed care plans by cross-reference. In addition, states have the authority to add additional provider types to their network adequacy standards to meet the needs of their CHIP programs and enrollees.

Comment: One commenter requested clarification of what flexibility will be provided to states with workforce shortages in pediatric specialties.

Response: Under § 438.68 of the regulation, applied to CHIP by cross reference at § 457.1218, states have the flexibility to define network adequacy standards. The standards can reflect known workforce shortages, if determined appropriate by the state. We believe that states will be in the best position to determine the appropriateness of incorporating workforce shortages into their network adequacy standards.

Comment: Many commenters referred us to their comments on the proposed regulation at § 438.68 or made comments similar to those that were made on that regulation.

Response: We refer commenters to the preamble discussion of § 438.68 above for a more complete discussion of the comments we received on these provisions.

After consideration of the public comments, we are deleting the second

sentence of proposed § 457.1218, making minor revisions to improve the clarity of the text, but otherwise finalizing as proposed.

14. Enrollee Rights (§ 457.1220)

Section 2103(f)(3) of the Act, as amended by section 403 of CHIPRA, specifies that the enrollee rights provisions at section 1932(a)(5)(B)(ii) of the Act apply to CHIP managed care programs. As such, we proposed to align CHIP with Medicaid enrollee rights provisions at § 438.100, which effectuate section 1932(a)(5)(B)(ii) of the Act. We proposed adding § 457.1220, which provides that states must ensure that MCOs, PAHPs, PIHPs, PCCMs, and PCCM entities follow the enrollee rights standards in accordance with the terms of § 438.100.

We received the following comments in response to our proposal to add § 457.1220.

Comment: We received only one comment on this provision, which supported adopting § 438.100 in CHIP.

Response: We thank the commenter for their support.

After consideration of the public comments, we are finalizing § 457.1220 substantively as proposed, with minor revisions for clarity.

15. Provider-Enrollee Communication (§ 457.1222)

Section 2103(f)(3) of the Act, as amended by section 403 of CHIPRA, specifies that the enrollee rights provisions at section 1932(b)(3) of the Act apply to CHIP managed care programs. As such, we proposed to align CHIP with Medicaid's enrollee rights protections of communications between providers and enrollees at § 438.102, which effectuate section 1932(b)(3) of the Act. We proposed adding § 457.1222, which provides that states must ensure that MCOs, PAHPs, and PIHPs protect communications between providers and enrollees in accordance with the terms of § 438.102.

We received the following comments in response to our proposal to add § 457.1222.

Comment: We received only one comment on this provision, which supported adopting § 438.102 in CHIP.

Response: We thank the commenter for their support.

After consideration of the public comments, we are finalizing § 457.1222 substantively as proposed, with minor revisions for clarity.

16. Marketing Activities (§ 457.1224)

Section 2103(f)(3) of the Act, as amended by section 403 of CHIPRA, specifies that the restrictions on

marketing at section 1932(d)(2) of the Act apply to CHIP managed care programs. As such, we proposed to align CHIP with Medicaid standards related to marketing at § 438.104, which effectuate section 1932(d)(2) of the Act. We proposed adding § 457.1224, which provides that states must ensure that MCOs, PAHPs, PIHPs, PCCMs, and PCCM entities follow the standards of § 438.104. The proposed definition of marketing in § 438.104(a), as adopted by cross-reference in § 457.1224, excludes the communication to a CHIP beneficiary from the issuer of a QHP. Therefore, a QHP issuer that also operates a CHIP managed care plan would not be prohibited from contacting a family with CHIP eligible children about QHP coverage. Indeed, we recognize that there may be benefit to the family from being informed about the availability of coverage through the Marketplace and selecting an issuer who offers both types of products.

We solicited comment on whether our proposed approach was appropriate, or whether we should take an alternate approach, for example by following the QHP marketing regulations at 45 CFR 156.225 or adopting a subset of the Medicaid regulations. We also specifically solicited comment on our proposal to apply to CHIP the standard at § 438.104(c) that, in reviewing marketing materials, the state must consult with the Medical Care Advisory Committee or an advisory committee with similar membership.

We received the following comments in response to our proposal to add § 457.1224.

Comment: Most commenters expressed support for adopting the Medicaid marketing standards in CHIP, although several asked for clarifications or modifications. Several commenters opposed the provision in § 457.1224 that would permit QHP issuers to market QHP plans to families of CHIP-eligible children, and recommend that CMS change this standard. Similarly, some commenters expressed concern that exclusion of QHPs from the definition of private insurance would allow QHPs with Medicaid and CHIP enrollment information to target current enrollees without abiding by the marketing safeguards. In contrast, some commenters supported the proposed marketing rules allowing Medicaid and CHIP MCOs to provide QHP information to beneficiaries.

Response: We specifically excluded communications by QHPs from the definition of marketing because of the high rate of CHIP and Medicaid beneficiaries that move between those programs and the Marketplace, and the

number of parents of CHIP children who are QHP eligible. We believe the exclusion of QHPs from the definition of marketing will facilitate coverage and provide enrollees with information that will enable them to make more informed managed care plan selections.

Comment: One commenter requested that CMS specifically address and permit states to allow licensed agents and brokers to have an active role in marketing CHIP managed care products in § 457.1224.

Response: Section 438.104(a) provides that the terms “MCO, PIHP, PAHP, PCCM or PCCM entity” include any of the entity’s employees, network providers, agents, or contractors. Licensed agents and brokers which are serving as an agent or contractor of a plan can engage in marketing activities on the plan’s behalf, subject to the provisions of § 438.104, incorporated into the CHIP regulations by cross reference at § 457.1224.

Comment: Several commenters opposed CMS’s proposal to apply § 438.104(c) to CHIP and recommended that consultation with the Medical Care Advisory Committee be left to the discretion of the state.

Response: We appreciate commenters’ input on this topic. We agree that CHIP should have flexibility in this area, given that the Medical Care Advisory Committee was created under Title XIX as an advisory committee specific to Medicaid. CHIP does not require a similar advisory body. We are finalizing § 457.1224 with text to exclude the requirement in § 438.104(c) from § 457.1224 in the final regulation, although we encourage states to consult with their Medical Care Advisory Committee in reviewing CHIP plans’ marketing materials, as we believe that this Advisory Committee has expertise which would be valuable for CHIP, as well as Medicaid.

Comment: Many commenters referred us to their comments on the proposed regulation at § 438.104 or made comments similar to those that were made on that regulation.

Response: We refer commenters to the preamble discussion of § 438.104 above for a more complete discussion of the comments we received on these provisions.

After consideration of the public comments, we are finalizing § 457.1224 as proposed, except that we are excluding the standards in § 438.104(c) for CHIP and making minor revisions for clarity.

17. Liability for Payment (§ 457.1226)

Section 2103(f)(3) of the Act, as amended by section 403 of CHIPRA,

specifies that the protections for enrollees against liability for payment at section 1932(b)(6) of the Act apply to CHIP managed care programs. As such, we proposed to align CHIP with Medicaid liability protections at § 438.106, which effectuate section 1932(b)(6) of the Act. We proposed adding § 457.1226, which provides that states must ensure that MCOs, PAHPs, and PIHPs do not hold enrollees liable for services or debts of the MCO, PAHP, and PIHP in accordance with the terms of § 438.106.

We received the following comments in response to our proposal to add § 457.1226.

Comment: We received one comment on this provision, seeking to reconcile § 457.1226 with proposed § 438.420(d).

Response: CHIP regulations do not incorporate § 438.420, so there is no need to reconcile § 457.1226 and § 438.420(d).

After consideration of the public comments, we are finalizing § 457.1226 substantively as proposed but with minor revisions for clarity.

18. Emergency and Poststabilization Services (§ 457.1228)

Section 2103(f)(3) of the Act, as amended by section 403 of CHIPRA, specifies that the requirement that MCEs provide emergency and poststabilization services at section 1932(b)(2) of the Act applies to CHIP managed care programs. As such, we proposed to align CHIP with the Medicaid emergency and poststabilization services standard at § 438.114, which effectuates section 1932(b)(2) of the Act. We proposed adding § 457.1228, which provides that states must ensure that MCOs, PAHPs, and PIHPs make emergency and poststabilization services available, and that the state make emergency and poststabilization services available to enrollees of PCCMs and PCCM entities, in accordance with the terms of § 438.114.

Comment: We received only one comment on this provision, which supported adopting § 438.114 in CHIP.

Response: We thank the commenter for their support.

After consideration of the public comments, we are finalizing § 457.1228 substantively as proposed, but with minor revisions for clarity.

19. Access Standards (§ 457.1230)

Section 2103(f)(3) of the Act, as amended by section 403 of CHIPRA, specifies that the quality assurance standards at section 1932(c) of the Act apply to CHIP managed care programs. Section 1932(c)(1) of the Act requires states that contract with MCOs to

develop and implement a quality assessment and improvement strategy that addresses standards related to access, which we interpret as including standards related to the availability of services, coordination and continuity of care, and coverage and authorization of services. As such, we proposed to align CHIP with Medicaid access standards at §§ 438.206, 438.207, 438.208, and 438.210, which implement section 1932(c)(1) of the Act.

We proposed adding § 457.1230(a), which provides that states must require CHIP MCOs, PAHPs, and PIHPs to ensure that covered services are available and accessible to enrollees in accordance with the terms of § 438.206. At § 457.1230(b), we proposed that states must ensure that CHIP MCOs, PAHPs, and PIHPs have adequate capacity to serve expected enrollees in accordance with the terms of § 438.207. At § 457.1230(c), we proposed that states must ensure that CHIP MCOs, PAHPs, and PIHPs comply with the coordination and continuity of care standards in accordance with the terms of § 438.208.

Finally, at § 457.1230(d), we proposed that states must ensure that CHIP MCOs, PAHPs, and PIHPs comply with some of the coverage and authorization of services standards in accordance with the terms of § 438.210. There are several paragraphs of § 438.210 that we did not propose to apply to CHIP managed care, including the standards related to medically necessary services in § 438.210(a)(5), because CHIP does not need to use the same medical necessity standard as Medicaid, and states are not required to provide EPSDT benefits in CHIP. In addition, we did not propose to adopt the time frames for decisions in § 438.210(d). Instead, we proposed to follow the time frames described in § 457.1160. We also solicited comment on whether we should create an exception for § 438.210(b)(2)(iii) (related to authorizing LTSS based on an enrollee's current needs assessment and consistent with the person-centered service plan), since LTSS is not a required service and few separate CHIP programs provide this service. We made a technical error in § 457.1230(d)(2) of the proposed regulation. We stated that CHIP should follow the notice of adverse benefit determination requirements of § 457.1260, rather than those of § 438.210(c). However, both § 457.1260(c) and § 438.210(c) require that notices of adverse benefit determinations to meet the standards of § 438.404. Therefore, the exception we made in § 457.1230(d)(2) is not necessary, and we have removed it.

We received the following comments in response to our proposal to add § 457.1230.

Comment: Commenters supported adopting the Medicaid availability of services standards in § 438.206 for CHIP. They did not have specific comments on the CHIP proposed regulation; they referred us to their comments on the Medicaid proposal.

Response: We appreciate the support of this proposal and refer readers to the responses to comments received on proposed § 438.206.

Comment: Commenters supported adopting the Medicaid assurances of adequate capacity and services at § 438.207 in CHIP at § 457.1230(b). One commenter suggested that CMS add a stipulation to § 457.1230(b) that entities should be able to document their ability to provide access to pediatric specialty providers.

Response: Sections 438.68, 438.206, and 438.207 of the final rule, which are applied to CHIP via cross-reference per §§ 457.1218, 457.1230(a) and 457.1230(b) require states and MCOs, PIHPs, and PAHPs to demonstrate access to pediatric specialists. Section 438.68, applied to CHIP via cross reference at § 457.1218, requires states to develop network adequacy standards for pediatric specialists, among other types of providers. Section 438.206(a), incorporated by cross-reference at § 457.1230(a) in CHIP, requires states to ensure that each MCO, PIHP, and PAHP has provider networks that meet the standards in § 438.68. Section 438.207(d), incorporated by cross-reference at § 457.1230(b) requires states ensure that each MCO, PIHP, and PAHP meets the state's standard for availability of services in § 438.206. We do not believe that additional regulation text requiring application of access standards to pediatric specialists is necessary.

Comment: Several commenters supported the addition of § 457.1230(c) related to continuity and coordination of care standards. However, one commenter stated that the coordination of care standards at § 438.208 should not apply to CHIP because care coordination is not a covered service in many CHIP plans.

Response: We disagree that the standards in § 438.208 should not apply to CHIP. While states are not required to cover care coordination as a specific benefit under CHIP, facilitating coordination and continuity of care are a fundamental component of a managed care delivery system. If states choose to provide CHIP services through managed care, the standards in § 438.208 will apply.

Comment: Several commenters expressed support for the omission of standards related to medically necessary services at § 438.210(a)(5). However, one commenter suggested that CMS add language to this subsection to give states discretion to use the standard in § 438.210(a)(5) and another commenter recommended that CMS follow the EPSDT federal guidance for medical necessity as a minimum standard.

Response: We are maintaining the exception to § 438.210(a)(5) for CHIP. While medical necessity is essentially an individualized medical determination, we do not require states to use the same medical necessity standard for a separate child health program as the standard adopted either for Medicaid beneficiaries generally, or the medical necessity standard applied for the EPSDT benefit per section 1905(r)(5) of the Act. States have the flexibility to adopt the same standard for both programs, and states have the flexibility under the regulation to apply EPSDT standards to CHIP; specific regulatory authority is not needed.

Comment: Several commenters suggested that we should not create an exemption from the timeliness standards in § 438.210(d) for CHIP. They stated that this would create a significant inconsistency with Medicaid, as CHIP MCOs, PIHPs, and PAHPs would have 90 days to make coverage decisions, while Medicaid decisions must be made within 14 days.

Response: We agree with commenters that the timeframes for coverage decisions made by Medicaid and CHIP managed care plans should align. We now believe our deference to the timeframes in § 457.1160 for CHIP in the proposed rule was misplaced. Section 457.1160 relates to reviews of eligibility and health services matters conducted by the State agency. Section 438.210(d), in contrast, relates to coverage authorization decisions made by managed care plans. We are removing the exception to § 438.210(d) from § 457.1230(d). Under the final rule, MCOs, PIHPs and PAHPs in CHIP will be held to the same timeframes for making coverage decision as are applied to MCOs, PIHPs and PAHPs in Medicaid.

Comment: CMS sought comment regarding whether CHIP should be exempted from the standard in § 438.210(b)(2)(iii) relating to authorizing LTSS. Several commenters recommended that CMS adopt the standard for CHIP to benefit children with chronic conditions and other special health care needs. Other commenters supported creating an

exception because states are not required to cover any LTSS under CHIP.

Response: We agree with the commenters who stated that CHIP § 438.210(b)(2)(iii) should not be applied to CHIP, as states are not required to cover LTSS under CHIP, and many states do not do so. States that choose to cover LTSS will have flexibility to determine the role the MCOs and other entities have in authorizing LTSS.

After consideration of the public comments, we are finalizing § 457.1230 substantially as proposed, except that we are removing § 457.1230(d)(2) and (d)(3) from the exceptions and adding paragraph (b)(2)(iii) to the exceptions, for reasons described in the responses to comments. We are also finalizing minor revisions to the text to improve its clarity.

20. Structure and Operation Standards (§ 457.1233)

Section 2103(f)(3) of the Act, as amended by section 403 of CHIPRA, specifies that section 1932(c)(1) of the Act, relating to developing and implementing a quality and assessment improvement strategy, including access standards, examination of care and service delivery, and monitoring procedures applies to CHIP. Sections 438.214 (related to provider selection), 438.230 (related to subcontractual relationships and delegation), 438.236 (related to practice guidelines), and 438.242 (related to health information systems) effectuate section 1932(c)(1) of the Act. We proposed adding § 457.1233 to align CHIP with Medicaid standards in §§ 438.214, 438.230, 438.236, and 438.242. Section § 438.224 (relating to confidentiality) also implements section 1931(c)(1) of the Act. However, we did not propose that CHIP align with the Medicaid confidentiality provision as set forth in § 438.224 because there is an existing confidentiality requirement at § 457.1110, which is similar to the standard in § 438.224.

Comment: Several commenters expressed support for the alignment of CHIP with Medicaid structure and operation standards as proposed.

Response: We thank commenters for their support.

Comment: One commenter suggested that CMS make several revisions to § 438.230 related to subcontractual relationships and delegation that should also directly to CHIP at § 457.1233.

Response: We address this comment in section I.B.4.b. of this final rule, relating to § 438.230.

Comment: Several commenters supported the reliance on existing CHIP standards at § 457.1110 related to

confidentiality requirements. However, some commenters stated that they did not identify a provision in subpart L of part 457 which would apply this confidentiality provision to managed care.

Response: We agree with commenters that subpart L should include a cross reference to § 457.1110. We have added a cross reference in § 457.1233(e) related to confidentiality requirements.

After consideration of the public comments, we are adding a cross reference to § 457.1110 in a new paragraph (e), and otherwise finalizing § 457.1233 as proposed.

21. Quality Measurement and Improvement (§ 457.1240, § 457.700, § 457.760)

Section 2103(f)(3) of the Act, as amended by section 403 of CHIPRA, specifies that section 1932(c) of the Act applies to CHIP managed care programs. As such, we proposed (with minor exceptions) to align CHIP with Medicaid quality measurement and improvement standards at §§ 438.330, 438.332, 438.334, and 438.340, which implement section 1932(c) of the Act. We proposed adding § 457.1240(a), which describes the scope of the quality measurement and improvement standards. At § 457.1240(b), we proposed that states must ensure that CHIP MCOs, PIHPs and PAHPs have an ongoing comprehensive QAPI program for the services they furnish to enrollees as set forth in § 438.330. At § 457.1240(c), we proposed that states must review and approve the performance of each MCO, PIHP, and PAHP in accordance with the requirements set forth in § 438.332. At § 457.1240(d), we proposed that states must collect data and apply the methodology established under the process described in § 438.330(a)(2) to determine a Managed Care rating or ratings for each CHIP MCO, PIHP, and PAHP in accordance with the standards set forth in § 438.334. At § 457.1240(e), we proposed to adopt the elements of the state comprehensive quality strategy related to managed care set forth in § 438.340. Finally, at § 457.760, we proposed that states must incorporate CHIP into their state comprehensive quality strategy that establishes the minimum standards inclusive of all delivery systems as set forth in § 431 subpart I.

We received the following comments in response to our proposal to add § 457.760 and § 457.1240.

Comment: Several commenters supported including CHIP in the state comprehensive quality strategy. Commenters made suggestions for additions or clarifications to the

comprehensive quality strategy to reflect the CHIP population and children in general.

Response: We appreciate the support for this provision and suggestions to improve it. However, because we are not finalizing the comprehensive quality strategy in subpart I of part 431 (see discussion in section I.B.6.c of this rule), we are not finalizing the CHIP component of the comprehensive quality strategy in § 457.760 or the related changes to the basis, scope, and applicability provision in § 457.700. The parts of proposed subpart I of part 431 (specifically, of proposed § 431.502) which are included in § 438.340 of the final regulation are also included in the final rule for CHIP via the cross reference to § 438.340 in § 457.1240(e).

Comment: Commenters noted that we indicated in the preamble that we were adopting § 438.310 in CHIP, but it was not cross-referenced in the regulatory text. They encouraged us to add the cross-reference in § 457.1240.

Response: We decline to cross-reference to § 438.310 in § 457.1240 because we believe that §§ 438.310(a) and 438.310(b) simply describe the statutory basis and scope of the quality measurement and improvement regulations in detail.

Comment: One commenter suggested that we should not adopt § 438.340 in CHIP, or limit the number of PIPs to the number that would produce the most value.

Response: We are maintaining this provision in the final rule. We believe a robust QAPI program supports managed care plans' efforts to assess and improve the quality of care provided to enrollees, and that the annual review of a plan's QAPI can assist the state in plan oversight and is important component for CHIPs. The performance measures and PIPs conducted under QAPI provide valuable information which is validated and independently evaluated during the annual EQR process. This section is critical for states' ability to assess the quality of care provided by MCOs, PIHPs, and PAHPs, and CMS's ability to oversee states and managed care entities through EQR reports. States are in the best position to determine the number of PIPs appropriate for their managed care plans. Therefore, under §§ 438.330 and 457.1240(b) of the final rule, states have flexibility to identify the appropriate number of PIPs, as long as the PIPs identified include any which may be specified by CMS under § 438.330(a)(2).

Comment: Several commenters expressed concern that states would be required to create separate quality

strategies for Medicaid and CHIP. The commenters suggested that separate quality strategies would be duplicative and burdensome to states, providers, MCOs, and EQROs.

Response: States may create a single, combined quality strategy for Medicaid and CHIP. Because CHIP has adopted most, but not all, of the Medicaid regulations, states using a combined quality strategy would need to comply with all of the Medicaid regulations. If a state opts to create combined quality strategies for Medicaid and CHIP, it will be critical that it choose measures and PIPs that focus on pediatric care.

Comment: One commenter noted that in states where the CHIP benefits differ from Medicaid, the resources required to separately measure and report data on CHIP may be substantial. The commenter recommended that CMS encourage states to account for the additional administrative resources that will be needed to accomplish the regulatory standards in capitation payments.

Response: We agree with the commenter that states should accurately account for the cost of conducting quality activities in the capitation payment to MCOs, PIHPs, and PAHPs.

Comment: Several commenters referred us to their comments on the Medicaid quality measurement and improvement proposals in §§ 438.310 through 438.340.

Response: We refer readers to the responses to comments received on proposed §§ 438.310 through 438.340.

After consideration of the public comments, we are not finalizing the changes to § 457.700, and are not adding § 457.760. We are finalizing § 457.1240, with the following revisions:

- We are clarifying that the standards set forth in paragraphs (b) and (e) apply to risk-bearing PCCM entities by adding a reference to PCCM entities to paragraph (a) and are adding paragraph (f) to describe the subset of PCCM entities to which paragraphs (b) and (e) apply. In the proposed regulation, these requirements were described in § 457.1201(m), which specified the quality measurement and improvement standards that applied to PCCM entities, but they were not included in § 457.1240. In addition, we are revising paragraphs (b) and (e) to specify which paragraphs of § 438.330 and § 438.340 apply to PCCM entities. We are also correcting the cross-reference to § 438.330(d)(4), related to standards for plans that serve dual eligibles.

- We are removing the reference to § 438.330(a)(2) from paragraph (d), to align with changes to § 438.330.

- We are revising paragraph (c) to align with the changes made to § 438.332.

As discussed in section I.B.6.c of the preamble for § 438.334 above, we are not finalizing the proposed option for states to default to the MA Five-Star Rating system for those plans that serve dual eligible beneficiaries only, therefore all of the managed care quality rating system requirements in § 438.334 are incorporated here to apply to CHIP. The regulation text has been updated to reflect this change.

- Updating paragraph (e) to reflect the changes to the quality strategy.

- Finally, we are finalizing a new paragraph (f) to explain how and when these standards apply to PCCM entities in CHIP.

22. External Quality Review (§ 457.1250)

Section 2103(f)(3) of the Act, as amended by section 403 of CHIPRA, specifies that the EQR standards at section 1932(c) of the Act apply to CHIP managed care programs. Section 1932(c)(2) of the Act requires external independent review of managed care activities. As such, we proposed to align CHIP with Medicaid EQR standards at § 438.350, which effectuate section 1932(c)(2) of the Act. At § 457.1250(a), we proposed that each state that contracts with MCOs, PIHPs or PAHPs follow all applicable EQR standards as set forth in §§ 438.350, 438.352, 438.354, 438.356, 438.358, and 438.364. We did not propose to adopt provisions related to plans serving dual eligible populations, because CHIP has a very limited number of dual eligibles. We note that the cost of CHIP quality activities (including EQR) represents an administrative expense, subject to the 10 percent limit on administrative expenditures permitted for non-primary services as set forth in section 2105(a) and (c) of the Act.

Proposed § 457.1250(b), outlined the provisions that do not apply to the CHIP EQR process for states contracting with MCOs, PIHPs or PAHPs, including the nonduplication of mandatory activities at § 438.360 and the exemption from EQR at § 438.362. We also proposed allowing states to amend current EQR contracts for Medicaid to add CHIP.

We received the following comments in response to our proposal to add § 457.1250.

Comment: Several commenters suggested that quality activities should not be subject to the 10 percent administrative limit. They suggested that treating quality activities as a primary expenditure under § 457.618 (which would result in their exemption

from the administrative limit) was consistent with the treatment of quality-related activities under the MLR. In the MLR, quality-related activities are part of the numerator, suggesting that they are more closely linked to claims than to administrative expenses. One commenter requested that if CMS applied the 10 percent limit to quality activities, we allow “look alike” CHIP programs to prorate EQRO activities based on the Medicaid/CHIP population ratio in the state.

Response: Section 2105(a) and (c) limit CHIP expenditures that are not for health benefits to 10 percent of the state’s total computable expenditures on health benefits (referred to as the 10 percent administrative limit). Quality activities do not fall into the definition health benefits, and therefore are subject to this limit. In terms of prorating EQRO activities based on the ratio of Medicaid and CHIP populations in the state, allocation of joint costs appears to be required by cost allocation principles. Thus, we are open to discussing the suggested allocation method, or other reasonable allocation methods with states.

Comment: One commenter requested that CMS allow for the non-duplication of mandatory activities in § 438.360 when CHIP plans also participate in Medicaid and are accredited already by a national accrediting organization.

Response: We agree with the commenter that states should be permitted to use information from private accreditation reviews that support Medicaid EQR activities if the conditions for non-duplication set forth in § 438.360 are met, and we are incorporating this option for CHIP by cross reference at § 457.1250(a). For states to exercise this option under § 438.360, the state is required to identify in its quality strategy the EQR activities for which it has exercised the option, and explain the rationale for the State’s determination that the private accreditation activity is comparable to the EQR activities identified. We are not permitting Medicare accreditation to substitute for EQR activities for CHIP, however, as very few children are covered under Medicare and therefore the findings from a Medicare accreditation would not be relevant for children.

Comment: Several commenters referred us to their comments on the Medicaid EQR proposals in §§ 438.350, 438.352, 438.354, 438.356, 438.358, and 438.364.

Response: We refer readers to the responses to comments received on proposed §§ 438.350, 438.352, 438.354, 438.356, 438.358, and 438.364.

After consideration of the public comments, we are finalizing § 457.1250 with the following revisions

- We are incorporating the option for states to use information from private accreditation reviews in paragraph (a) and adding text to address PCCM entities;

- We are deleting paragraph (b)(1), because we believe it is unnecessary to state which provisions of part 438, subpart E do not apply to CHIP. If they are not listed in paragraph (a), they do not apply.

- We are redesignating paragraph (b)(2) as paragraph (b) and deleting the clause “provided that the existing contract meets the requirements in § 438.356.” This language is unnecessary because all Medicaid contracts must meet the requirements of § 438.356, which is not being changed through this rulemaking.

23. Grievances (§ 457.1260)

Section 2103(f)(3) of the Act, as amended by section 403 of CHIPRA, specifies section 1932(b)(4) of the Act, relating to grievances, applies to CHIP managed care programs. As such, we proposed generally to align CHIP with the Medicaid grievance and appeals sections in subpart F of part 438, which implement section 1932(b)(4) of the Act. We proposed adding § 457.1260, which provides that states must ensure that MCOs, PAHPs, and PIHPs comply with subpart F of part 438, with one exception. Specifically, we did not propose to adopt § 438.420, which requires continuation of benefits pending appeal. Proposed § 457.1260 also provides that references to fair hearings in subpart F of part 438 should be read as references to reviews as described in subpart K of part 457.

We received the following comments in response to our proposal to add § 457.1260.

Comment: Nearly all commenters were supportive of applying the Medicaid appeal and grievance provisions to CHIP. Many commenters suggested that CMS also apply to CHIP the standards in § 438.420, which require MCOs, PIHPs, and PAHP to continue benefits until the resolution of an appeal or state fair hearing. Commenters noted that excluding § 438.420 from CHIP would allow managed care entities to deny provision of medical services to CHIP enrollees pending an appeal. In addition, one commenter stated that a pre-termination hearing is a basic due process right for a government benefit program. In contrast, some commenters recognized that while benefits pending appeal would be valuable to CHIP enrollees,

the nature of the CHIP program merits different treatment.

Response: We agree with the commenters who believe that the standards in § 438.420 should not be applied to CHIP. The right to benefits pending the outcome of a grievance or appeal does not derive from section 1932(b)(4), but from the constitutional due process protections afforded to beneficiaries of an entitlement program, under *Goldberg v. Kelly*, 397 U.S. 254 (1970) and its progeny, including provision of benefits to beneficiaries who are being terminated from or denied coverage pending appeal. Unlike Medicaid, CHIP is not an entitlement program. Therefore, we do not believe that it appropriate to apply this requirement to CHIP.

Comment: One commenter recommended that CMS evaluate whether the managed care plans and ombudsman appeals processes in states with separate CHIP programs sufficiently address the access and quality barriers faced by children and pregnant women.

Response: We appreciate the suggestion and will consider such an evaluation in the future.

Comment: Two commenters asked whether states could continue benefits for Title XXI enrollees in the same manner they do for Title XIX enrollees, at state option.

Response: States currently have, and will continue to have the option to continue benefits pending appeal.

Comment: One commenter encouraged CMS to give CHIP contractors the option to offer grievance and appeals processes consistent with the regulations at 45 CFR 147.136, which applies to Marketplace plans stating that this would benefit families who have children on CHIP and other family members in QHPs.

Response: We believe that maximizing alignment between the CHIP and Medicaid managed care grievances and appeals regulations is most important, and the final CHIP regulations reflect that goal. Wherever possible, we also have sought to align the grievances and appeals procedures across different health coverage, so the Medicaid and CHIP regulations also largely align with regulations for QHPs at 45 CFR 147.136 and Medicare Advantage regulations in 42 CFR part 422, subpart M. When the regulations for Medicaid and/or CHIP do not align with the regulations governing plans participating in other programs or markets, we have made a determination that a different policy is required or appropriate and states must ensure that the CHIP plans with which they

contract comply with the terms of the CHIP regulations.

After consideration of the public comments, we are finalizing § 457.1260 substantively as proposed but with minor revisions for clarity.

24. Sanctions (§ 457.1270)

Section 2103(f)(3) of the Act, as amended by section 403 of CHIPRA, specifies that the sanctions provisions at section 1932(e) of the Act apply to CHIP managed care programs. As such, we proposed to align CHIP with the Medicaid sanctions sections at subpart I of part 438, which effectuate section 1932(e) of the Act. We proposed adding § 457.1270, which provides that states must ensure that MCOs, PAHPs, and PIHPs comply with the Medicaid sanctions in accordance with the terms of subpart I of part 438.

We received the following comment in response to our proposal to add § 457.1270.

Comment: One commenter supported adopting the Medicaid sanctions standards in subpart I of part 438.

Response: We appreciate the support of this proposal.

After consideration of the public comments, we are finalizing § 457.1270 substantively as proposed, with minor revisions for clarity.

25. Program Integrity—Conditions Necessary To Contract as an MCO, PAHP, or PIHP (§§ 457.955, 457.1280, and 457.1285)

Section 2107 of the Act includes several program integrity standards, including sections 2107(b), 2107(e)(1)(D), and 2107(e)(2) of the Act. We proposed to effectuate those standards by adopting many of the Medicaid program integrity standards in CHIP. In addition, we proposed to maintain but relocate the current CHIP regulations related to managed care program integrity.

We proposed to redesignate all of § 457.955 as § 457.1280. Section § 457.955 was located in the general CHIP program integrity subpart I. Because the section specifies conditions necessary for entities to contract as an MCO, PAHP, PIHP, we proposed to move it to the new subpart L. We proposed several minor changes to the regulation text: (1) To update references to MCE to MCO, PAHP, or PIHP; (2) to add at paragraph (b)(1) that MCOs, PAHPs, and PIHPs must comply with applicable state and Federal statutes and regulations, in addition to complying with state and Federal standards; and (3) to add at paragraph (b)(3) that there must be mechanisms for MCOs, PAHPs,

and PIHPs to report providers to the state.

We also proposed to adopt nearly all of the of the Medicaid program integrity standards. In § 457.1285, we proposed to adopt subpart H of part 438, with the exception of § 438.604(a)(2), which does not apply because we did not propose to adopt in CHIP all of the Medicaid actuarial soundness requirements.

We received the following comments in response to our proposal to redesignate § 457.955 as new § 457.1280 and to newly proposed § 457.1285.

Comment: Several commenters expressed support for the alignment of the CHIP managed care program integrity standards at § 457.1280 and § 457.1285.

Response: We appreciate the support.

Comment: Some commenters noted that the instructions for the redesignation of § 457.955 at § 457.1280 and revision of newly designated § 457.1280, erroneously refer to subpart K instead of subpart L.

Response: We agree that references to subpart K should be to subpart L.

Comment: One commenter expressed concern that the proposed provision at § 457.1280(d) related to the ability of States to inspect, evaluate and audit MCOs, PIHPs and PAHPs could limit broader existing contractual arrangements. The commenter noted that some states currently require all subcontracts to include a provision allowing the State and federal governments to audit. Therefore, the commenter suggested that CMS refrain from creating a new “reasonable possibility of fraud” standard related to the right to audit. The commenter recommended that CMS revise the language at § 457.1280(b)(3) to end after “at any time,” eliminating the phrase “as necessary, in instances where the State determines that there is a reasonable possibility of fraudulent and abusive activity.”

Response: We did not propose to modify the current regulations at § 457.955(d) which we proposed to redesignate at § 457.1280(d) and are not revising this paragraph in the final rule. We disagree with the commenter’s view that § 457.1280(d) is too limiting. Both § 457.1201(g) and § 457.1233(b) (incorporating, by cross-reference § 438.208(c)(3)) of the final rule) give states and other oversight bodies a broad right to inspect the records and facilities of MCOs, PAHPs, PIHPs, PCCMs and PCCM entities and their subcontractors. Under proposed § 457.1280(d), states have the latitude to conduct an inspection at any time there is a suspicion of possible fraud or abuse; as such we have revised the regulation text

to read that the State may inspect, evaluate, and audit MCOs, PIHPs, and PAHPs at any time, where the state determines that there is a reasonable possibility of “fraudulent or abusive activity” rather than “fraudulent and abusive activity.” Additionally, States are responsible for exercising general oversight over plans’ compliance with their contracts and adherence to federal and state laws, regulations and policies, not only when fraud or abuse is suspected.

Comment: Several commenters expressed support for the application of subpart H of part 438 to CHIP at § 457.1285. In contrast, some commenters expressed concern about adopting some of the standards in subpart H, particularly § 438.602(b) related to screening and enrolling providers, § 438.602(c) related to state review of ownership and control disclosures submitted by subcontractors, § 438.602(d) related to performance of federal database checks, and § 438.602(e) related to periodic audits of contractors to be conducted not less than every 3 years. The commenter suggested that the NAIC standard of not less than every 5 years was more appropriate for CHIP.

Response: We decline to exempt states from the oversight responsibilities of managed care plans set forth in § 438.602(b) through (e). We note that the standards in § 438.602(b) through (d) already apply to CHIP through § 457.935 and § 457.990. Section 457.935 applies to CHIP part 455, subpart B, which includes the ownership and control disclosures. Section 457.990 applies to CHIP part 455, subpart E, which includes the screen and enroll and federal data base check standards. In addition, because a major goal of this regulation is alignment between Medicaid and CHIP, we decline to adopt the NAIC standard for periodic audits rather than the Medicaid standard.

After consideration of the public comments, we are finalizing § 457.1280 as proposed, except that we are removing the final clause from § 457.1280(d) and specifying that states may inspect, evaluate, and audit MCOs, PIHPs, and PAHPs at any time, when a state determines there is a reasonable possibility of fraudulent “or” abusive activity as discussed in the comments above. We are also finalizing § 457.1285 as proposed.

III. Third Party Liability

A. Background

Medicaid is the payer of last resort. This means that other available resources—known as third party

liability, or TPL—must be used before Medicaid pays for services received by a Medicaid-eligible individual. Title XIX of the Act requires state Medicaid programs to identify and seek payment from liable third parties, before billing Medicaid. Specifically, section 1902(a)(25)(A) of the Act requires that states take all reasonable measures to ascertain legal liability of third parties to pay for care and services available under the plan. That provision further specifies that a third party is any individual, entity, or program that is or may be liable to pay all or part of the expenditures for medical assistance furnished under a state plan.

Examples of liable third parties include private insurance companies through employment-related or privately purchased health insurance; casualty coverage resulting from an accidental injury; payment received directly from an individual who has voluntarily accepted or been assigned legal responsibility for the health care of one or more Medicaid recipients; fraternal groups, unions, or state workers’ compensation commissions; and medical support provided by a parent under a court or administrative order. Section 1902(a)(25)(A)(i) of the Act specifies that the state plan must provide for the collection of sufficient information to enable the state to pursue claims against third parties.

To support identification of TPL, and under the authority of in section 1902(a)(25)(A) of the Act, we issued regulations at § 433.138 in 1987 that established requirements for state Medicaid agencies to obtain information via data matching with the state workers compensation files or state motor vehicle accident reports. Additionally, we required states to identify all paid claims indicative of trauma as identified by diagnosis codes found in ICD–9–CM, 800 through 999, except 994.6.

Section 433.138(e) specifically references the use and application of the ICD–9–CM medical coding system to assist in identifying liable third parties as primary payers before Medicaid. By 1990, however, we realized it had been too prescriptive to require states to review all ICD–9–CM trauma codes, and amended § 433.138 to allow states to submit waiver requests to cease editing codes proven to be unproductive in identifying liable third parties. States have over 25 years of experience identifying trauma codes indicating the likelihood of third party liability, which contributes to payment of Medicaid expenses.

In 1990, the World Health Organization (WHO) approved the International Classification of Diseases,

10th Revision, Clinical Modification (ICD–10–CM) for diagnosis coding, including the Official ICD–10–CM Guidelines for Coding and Reporting, and the International Classification of Diseases, 10th Revision, Procedure Coding System (ICD–10–PCS) for inpatient hospital procedure coding, including the Official ICD–10–PCS Guidelines for Coding and Reporting (collectively, ICD–10). In 2009, the Secretary adopted ICD–10 as the Health Insurance Portability and Accountability Act of 1996 (HIPAA) standard code set to replace ICD–9–CM with an October 1, 2013 compliance date. The compliance date was delayed until October 1, 2014 and again until October 1, 2015 in subsequent rules. All HIPAA covered entities are now required to use ICD–10 to code claims with dates of service on or after the ICD–10 compliance date of October 1, 2015.

B. Summary of Proposed Provisions and Analysis of and Responses to Comments

In the June 1, 2015 proposed rule (80 FR 31175 through 31176), we proposed to address third party liability for trauma codes. Brief summaries of each proposed provision, a summary of the public comments we received (with the exception of specific comments on the paperwork burden or the economic impact analysis), and our responses to the comments are as follows. Comments related to the paperwork burden and the impact analyses are addressed in the “Collection of Information Requirements” and “Regulatory Impact Analysis” sections in this final rule.

Section 433.138(e), requiring the use of ICD–9–CM coding, had to be amended to account for the implementation of ICD–10 coding for health services provided on or after October 1, 2015. We considered ways to best achieve this, keeping in mind that states bear the responsibility for interpreting and applying the increased number of new ICD–10 codes and that state Medicaid programs need greater discretionary authority in developing trauma code edits to best identify liable third parties and achieve the highest TPL return from their efforts. We reviewed previous regulatory amendments, which demonstrated a progression from explicit federally-prescribed requirements to less prescriptive approaches that, while maintaining the federal designation of trauma codes subject to review, allowed states to propose waivers of editing for trauma codes that were not cost-effective to pursue.

This regulation was last amended in 1995 to remove trauma code-specific

waiver authority from § 433.138(e) and add § 433.138(l), establishing the possibility of waiver of non-statutory requirements in §§ 433.138 and 433.139, including § 433.138(e), permitting states to request adjustments to any of several non-statutory requirements, including the code editing requirements, if they determined the activity to not be cost-effective. Section 433.138(l) specified that an activity would not be cost-effective if the cost of the required activity exceeded the TPL recoupment and the required activity accomplishes, at the same or at a higher cost, the same objective as another activity that is being performed by the state.

The background information in the preamble for the regulatory amendment published in the July 10, 1995 **Federal Register** (60 FR 35498 through 35503) affirmed that we had been prescriptive in the initial 1987 regulations for trauma code editing, explaining that TPL was then in its “infancy” and there was concern that states were not identifying instances of traumatic injury for which a liable third party might exist. By 1995, when the last amendment to the trauma code was proposed, we acknowledged that states had other means of identifying potential TPL for trauma cases, including federally-required data matches with state motor vehicle administration accident files and with state worker’s compensation files, and that the majority of states have aggressive and comprehensive TPL programs. It has been almost 20 years since we last amended the regulations for trauma code editing. States’ information technology systems have greatly improved to support refined procedures to identify instances where a Medicaid beneficiary’s traumatic injury may result in a liable third party.

The proposed revision amendment to § 433.138(e), which would remove references to ICD–9–CM, offered an opportunity to make a substantive change to this regulation while affirming the continued responsibility of state Medicaid programs to identify trauma-related claims to determine TPL and ensure that state Medicaid programs remain secondary payers. Therefore, we proposed to replace the reference to a specific coding system with a general description of the types of medical diagnoses indicative of trauma for which states are expected to edit claims. This revision did not propose that any state change its current trauma code editing process with regard to codes that the state has identified as not yielding third party recoveries and that CMS has agreed the state may discontinue editing. In § 433.138(e)(1), we proposed to remove the reference to the ICD–9–

CM code range 800 through 999 that defined the codes that were indicative of traumatic injury. The ICD–9–CM coding system has now been replaced by the ICD–10 coding system, which had an October 1, 2015 compliance date.

We proposed to retain the regulatory references to complete trauma code editing and the state’s ability to request a waiver of these requirements to adjust the trauma code editing process beyond the scope allowed by these changes to § 433.138(e).

We also proposed to remove § 433.138(e)(2), as the regulation specifically refers to exclusion of the ICD–9–CM code for motion sickness for consistency with the proposal to remove all references to ICD–9–CM-specific coding in this section. The deletion of paragraph (e)(2) of § 433.138 would eliminate the necessity to identify the remaining regulatory text as § 433.138(e)(1), so we proposed to delete paragraph (e)(1).

We received the following comments in response to our proposal to revise § 433.138.

Comment: Several commenters supported the removal of a specific diagnostic coding system for trauma code editing to identify TPL. Most commenters agreed that states have expertise in this area and can perform effective and efficient trauma code editing. One commenter added that this change allows for non-regulatory/statutory adjustments to accommodate future changes to new diagnostic coding systems.

Response: We thank commenters for their support.

Comment: A few commenters requested clarification if states would be required to obtain a waiver from CMS to discontinue review of each diagnostic code indicative of trauma.

Response: We are not requiring states to obtain a waiver to discontinue the review of trauma codes that states determine are not cost-effective. We are available to provide technical assistance to states.

Comment: A few commenters requested clarification on the TPL rights of managed care plans, including requiring third parties to treat a managed care plan as if it were the state Medicaid agency with regard to sharing information to identify Medicaid beneficiaries with third party coverage; accepting the state’s assignment to the managed care plan of the right to third party payments, including the right to recover overpayments; and refraining from denying payment of claims for procedural reasons.

Response: The requested clarifications are outside the scope of the trauma code editing regulation, but we note that CMS published guidance in 2012 on [Medicaid.gov](http://www.Medicaid.gov) affirming that a managed care plan should be treated as if it were the state Medicaid program when the state has delegated responsibility and authority to perform TPL functions to the managed care plan. We also note that states have wide latitude in deciding what, if any, required Medicaid coordination of benefits/TPL functions they will delegate to the managed care plans, and third parties may request confirmation from the state of the delegation of authority.

Comment: One commenter requested that the final rule include CMS facilitation of multi-payer collaboration tools to assist coordination of benefits by all payers, including Medicare and TRICARE. The commenter also requested alignment of timely filing limits across Medicare and TRICARE, and more consistency among state claims filing limits.

Response: These requests are outside the scope of the trauma code editing regulation, however we note that federal law requires states to have laws that establish a claims filing period for the state Medicaid program of not less than 3 years. It is up to each state to determine if a longer period is appropriate for its Medicaid program.

Comment: One commenter requested that CMS limit managed care plans' "look-back" period to recoup payments from providers of pharmacy services to no more than 18 months when a beneficiary's third party coverage is identified after the managed care plan has paid for the service. The commenter also requested that CMS approve a new method for managed care plans to obtain third party payment for pharmacy services in this circumstance. The commenter suggested that managed care plans be allowed to use the Medicaid pharmacy subrogation transaction (45 CFR 162.1901) currently used by state Medicaid programs to submit claims.

Response: The requested clarifications are outside the scope of the trauma code editing regulation.

Comment: One commenter requested that CMS require states to implement systems and procedures that protect the confidentiality of a Medicaid beneficiary who has refused to provide information about third party resources to support Medicaid's coordination of benefits with third parties, under the "good-cause exception" to this requirement. The requested protection would extend to use of means such as electronic records and databases to

identify and bill third parties. The commenter also requested that states ensure that managed care plans are informed of the good-cause exception. The commenter noted that federal statute and regulation already exists to require exemption from the required identification of third party resources when there is good cause.

Response: The requested clarifications are outside the scope of the trauma code editing regulation, but we note that federal statute and regulation allow a beneficiary to request an exemption for good cause, as the commenter indicates.

After consideration of the public comments, we are finalizing § 433.138(e) as proposed.

IV. Finding of Good Cause; Waiver of Delay in Effective Date

Under 5 U.S.C. 553(d) of the Administrative Procedure Act (APA), there is a mandatory minimum 30-day delay in effective date after issuance or publication of a rule. This 30-day delay in the effective date can be waived, however, if an agency finds for good cause that the delay is impracticable, unnecessary or contrary to the public interest, and the agency incorporates a statement of the finding and its reasons in the rule issued. Under 5 U.S.C. 801 *et seq.*, the Congressional Review Act also mandates a 60-day delay in effective date of major rules. However, this statute also provides an exception for the mandatory delay when the agency finds good cause. 5 U.S.C. 808(2). The rules finalized here at §§ 433.15(b)(10) and 438.370, regarding the amount of federal financial participation available for the cost of external quality review and related activities performed in connection with managed care plans that are not Medicaid managed care organizations (MCOs), are effective immediately based on a finding that it is contrary to the public interest to delay the effective date of these provisions.

These regulations governing the amount of federal financial participation are based on section 1903(a)(3)(C)(ii) and 1903(a)(7) of the Act. Section 1903(a)(3)(C)(ii) of the Act provides a 75 percent rate for federal financial participation for costs "attributable to the performance of independent external reviews conducted under section 1932(c)(2)" while section 1903(a)(7) of the Act provides a 50 percent rate for federal financial participation for costs of the administration of the state plan. Section 1932(c)(2) of the Act requires external quality review of MCOs and refers specifically both to MCOs and contracts under section 1903(m) of the Act,

which, in turn, authorizes MCO contracts. Neither section 1903(a)(3)(C)(ii) of the Act nor section 1932(c)(2) of the Act mention or require additional review of non-MCO contracts, such as contracts with pre-paid inpatient health plans (PIHPs), pre-paid ambulatory health plans (PAHPs), or primary care case managers (PCCMs or PCCM entities). Therefore, the cost of external quality review of these non-MCO contracts is eligible only for the 50 percent match rate authorized by section 1903(a)(7) of the Act. Payment of an amount in excess of what is authorized under section 1903(a)(7) of the Act is beyond our authority and could constitute an improper payment. Having recognized the limits of section 1903(a)(3)(C)(ii) of the Act and the applicability of section 1903(a)(7) of the Act—and the 50 percent match rate—to the cost of external quality review of non-MCO contracts, we lack authority to continue paying federal financial participation at the higher rate. Continuing to make payment in unauthorized amounts is contrary to the public interest. Therefore, we find that there is good cause to waive the requirement for a delay in the effective date of the rules finalized here at §§ 433.15(b)(10) and 438.370.

V. Collection of Information Requirements

Under the Paperwork Reduction Act of 1995 (PRA), we are required to publish a 60-day notice in the **Federal Register** and solicit public comment before a collection of information requirement is submitted to the Office of Management and Budget (OMB) for review and approval.

To fairly evaluate whether an information collection should be approved by OMB, PRA section 3506(c)(2)(A) requires that we solicit comment on the following issues:

- The need for the information collection and its usefulness in carrying out the proper functions of our agency.
- The accuracy of our burden estimates.
- The quality, utility, and clarity of the information to be collected.
- Our effort to minimize the information collection burden on the affected public, including the use of automated collection techniques.

Our June 1, 2015 proposed rule (80 FR 31098) solicited public comment on each of the section 3506(c)(2)(A)-required issues for the following information collection requirements (ICRs) in this final rule. PRA-related comments were received and are summarized below along with our response. The comments addressed

requirements/burden proposed under part 438.

A. Background

The burden associated with the requirements under part 438 is the time and effort it will take each of the Medicaid programs to comply with this rule's requirements. More specifically, this rule revises the Medicaid managed care regulations to implement statutory provisions, strengthens actuarial soundness and other payment regulations improving accountability of rates paid in the Medicaid managed care program, implements changes supporting alignment with other public and insurance affordability programs, strengthens beneficiary protections, and modernizes the regulations recognizing changes in usage of managed care delivery systems since the release of the part 438 final rule in 2002.

Section 433.138(e)(1) makes a technical correction addressing state Medicaid agencies' review of claims with trauma codes, to identify instances where third party liability (TPL) may exist for expenditures for medical assistance covered under the state plan. The correction will remove references to the International Classification of Disease, 9th edition, Clinical Modification Volume 1 (ICD-9-CM) by replacing the references with a general description of the types of medical diagnoses indicative of trauma. States must use the International Classification of Disease that they are using at the time of claims processing. There is no additional cost to the state related to the changes to § 433.138(e) since the changes do not require any action by the state, if the state wishes to continue editing for the same types of traumatic injuries currently identified with ICD-9-CM codes after the conversion of the

claims processing system to ICD-10 codes. Further, since trauma code editing is based on current MMIS claims processing, revisions to accommodate the coding system change from ICD-9-CM to ICD-10 are already in progress as a required adjustment of each state's MMIS. This final rule allows states to make adjustments to certain TPL activities without preparing a formal waiver request to seek CMS's permission. There is no requirement for a state to make such adjustments.

The June 1, 2015 proposed rule (80 FR 31098) included a proposed part 431 subpart I, which laid out the requirements for the proposed comprehensive quality strategy, which would have applied to all services covered under state Medicaid programs, not just those covered through an MCO or PIHP. The burden associated with proposed §§ 431.502 and 431.504 was captured in ICRs 1 and 2 of the proposed rule. Based upon comments received in response to the proposed rule, we have withdrawn the proposal for a comprehensive quality strategy that applied to Medicaid services delivered by FFS and managed care (see discussion in section I.B.6.b(2)(f)). We are retaining the requirement in § 438.340 of the final rule for a quality strategy that addresses services delivered by MCOs, PIHPs, PAHPs, and PCCM entities described in § 438.310(c)(2) of the final rule. As appropriate, burden estimates from proposed part 431 subpart I are moved to the burden estimate for § 438.340 of the final rule, with revisions based on the application to only managed care.

We have added a new subpart L to part 457, which contains the regulations related to CHIP managed care plans. While most of the requirements in this subpart are new, we have also moved

portions of § 457.950 and all of § 457.955 from subpart I to the new subpart L. This will ensure that all related information is contained in one subpart.

Burden estimates for Part 438 utilized enrollment, managed care plan, and state data for CY 2012 from the MSIS. Enrollment data was trended forward as appropriate for certain estimates utilizing a 3.3 percent annual growth rate as determined by the Office of the Actuary. The enrollment data reflected 31,827,858 enrollees in MCOs, 12,116,645 enrollees in PIHPs, 1,0985,021 enrollees in PAHPs, and 7,775,297 enrollees in PCCMs, for a total of 62,704,821 managed care enrollees. This includes duplicative counts when enrollees are enrolled in multiple managed care plans concurrently. This data also showed 36 states that contract with 335 MCOs, 20 states that contract with 176 PIHPs, 12 states that contract with 41 PAHPs, 18 states that contract with 20 non-emergency transportation PAHPs, 25 states with 25 PCCM and 9 PCCM entities, and 16 states that contract with one or more managed care plan for MLTSS. Many states contract with more than one entity; however, we de-duplicated to determine that 40 states contract with MCOs, PIHPs, and/or PAHPs; and 42 states contract with MCOs, PIHPs, PAHPs, and/or PCCMs.

B. Wage Estimates

To derive average costs, we used data from the U.S. Bureau of Labor Statistics' May 2014 National Occupational Employment and Wage Estimates for all salary estimates (www.bls.gov/oes/current/oes_nat.htm). Table 1 presents the mean hourly wage, the cost of fringe benefits (calculated at 100 percent of salary), and the adjusted hourly wage.

TABLE 1: Occupation Titles and Wage Rates

Occupation Title	Occupation Code	Mean Hourly Wage(\$/hr)*	Fringe Benefit (\$/hr)	Adjusted Hourly Wage(\$/hr)
Accountant	13-2011	33.19	33.19	66.38
Actuary	15-2011	46.22	46.22	92.44
Business Operations Specialist	13-1000	32.23	32.23	64.46
Computer Programmer	15-1131	39.16	39.16	78.32
Customer Service Rep	43-4051	17.93	17.93	35.86
General and Operations Mgr	11-1021	70.40	70.40	140.80
Healthcare Social Worker	21-1022	25.77	25.77	51.54
Mail Clerk	43-9051	15.46	15.46	30.92
Office and Administrative Support Worker	43-9000	18.27	18.27	36.54
Registered Nurse	29-1141	33.46	33.46	66.92

*This final rule sets out revised labor estimates that are based on BLS' 2014 wage data. The proposed rule's estimates were based on 2013 data.

As indicated, we are adjusting our employee hourly wage estimates by a factor of 100 percent. This is necessarily a rough adjustment, both because fringe benefits and overhead costs vary significantly from employer to employer, and because methods of estimating these costs vary widely from study to study. Nonetheless, there is no practical alternative and we believe that doubling the hourly wage to estimate total cost is a reasonably accurate estimation method.

C. Information Collection Requirements (ICRs)

1. ICRs Regarding Standard Contract Requirements (§§ 438.3, 438.10(c)(5), 438.14(b), 438.110(a), 438.210(b)(2)(iii), 438.242(c), 438.402 and 438.608)

The following requirements and burden estimates were set out in the proposed rule and are being adopted without change except for the minor adjustments to hourly rates. No comments were received.

Section 438.3 contains a list of provisions that must be included in MCO, PIHP, PAHP, HIO, and/or PCCM contracts. While the burden associated with the implementation and operation of the contracts is set out when warranted under the appropriate CFR section, the following burden estimate addresses the effort to amend existing contracts. The estimate also includes the burden for additional contract amendments are required under:

- § 438.10(c)(5) requires specific information to be provided to enrollees.
- § 438.14(b) specifies requirements for Indian enrollees and providers.
- § 438.110(a) requires the establishment and maintenance of member advisory committees.
- § 438.210(b)(2)(iii) requires LTSS to be authorized consistent with the enrollee's needs assessment and person centered plan.
- § 438.242(c) requires specific provisions for encounter data.
- § 438.608 requires administrative and management arrangements and

procedures to detect and prevent fraud, waste, and abuse.

We estimate a one-time state burden of 6 hr at \$64.46/hr for a business operations specialist to amend all contracts. In aggregate, we estimate 3,636 hr (335 MCO + 176 PIHP + 61 PAHP + 34 PCCM contracts × 6 hr) and \$234,376.56 (3,636 hr × \$64.46/hr).

We are annualizing the one-time development since we do not anticipate any additional burden after the 3-year approval period expires.

2. ICRs Regarding Rate Standards (§ 438.5)

The following requirements and burden estimates were set out in the proposed rule and are being adopted without change except for the minor adjustments to hourly rates. No comments were received.

Section 438.5 describes the development and documentation of capitation rates paid to risk-based MCOs, PIHPs and PAHPs. Generally, we require: The use of appropriate base data; the application of trends that have

a basis in actual experience; a comprehensive description of the development of the non-benefit component of the rate; descriptions of the adjustments applied to the base data, rate, or trends; actuarial certification of the final contract rates paid to the plans; and a description of budget neutral risk adjustment methodologies.

We believe that the requirements related to the use appropriate base data and the adequate description of rate setting standards, such as trend, the non-benefit component, adjustments, and risk adjustment, are already required as part of actuarial standards of practice and accounted for in § 438.7. We clarified that risk adjustment should be done in a budget neutral manner, but the manner in which risk adjustment is applied should not create additional burden on the state.

In § 438.5(g), the certification of final contract rates places additional burden on the states. We estimate that most states currently certify a range as compared to the actual contract rate paid to the managed care plan. Therefore, out of the total 70 certifications submitted to CMS from 39 states, the process underlying 50 certifications will need to be modified.

We estimate it will take approximately 10 hr at \$92.44/hr for an actuary and 1 hr at \$140.80/hr for a general and operations manager to comply with this requirement. In aggregate, we estimate an annual state burden of 550 hr (50 certifications × 11 hr) and \$53,260 [50 certifications × ((10 hr × \$92.44/hr) + (1 hr × \$140.80/hr))].

3. ICRs Regarding Rate Certification Submission (§ 438.7)

The following requirements and burden estimates were set out in the proposed rule and are being adopted without change except for the minor adjustments to hourly rates. No comments were received.

Section 438.7 describes the submission and documentation requirements for all managed care actuarial rate certifications. The certification will be reviewed and approved by CMS concurrently with the corresponding contract(s). Section 438.7(b) details CMS' expectations for documentation in the rate certifications. We believe these requirements are consistent with actuarial standards of practice and previous Medicaid managed care rules.

While the 2002 final rule (under § 438.6(c)) set out the burden per contract (15,872 hr based on 32 hr per plan), experience has shown that states do not submit certifications per plan.

We believe a better estimation of the burden is associated with the development of the rate certification. In this regard, we estimate it takes 230 hr to develop each certification, consisting of 100 hr (at \$92.44/hr) for an actuary, 10 hr (at \$140.80/hr) for a general and operations manager, 50 hr (at \$78.32/hr) for a computer programmer, 50 hr (at \$64.46/hr) for a business operations specialist, and 20 hr (at \$36.54/hr) for an office and administrative support worker.

The revised burden of 228 hours is based on a total of 16,100 hr (230 hr × 70 certifications) which is an increase of 228 hr (16,100 hr–15,872 hr) for all 70 certifications due to the new regulatory requirements, adjusted to 3.3 hr per certification (228 hr/70 certifications). In aggregate, we estimate an annual state burden of \$18,948.57 [70 certifications × ((1.5 hr × \$92.44/hr) + (0.13 hr × \$140.80/hr) + (0.73 hr × \$78.32/hr) + (0.73 hr × \$64.46/hr) + (0.26 hr × \$36.54/hr))]. (Prorating the time of the actuary, general operations manager, computer programmer, business operations specialist, and office and administrative support worker across the 3.3 hr per certification.)

4. ICRs Regarding Minimum Medical Loss Ratio (§ 438.8)

While one PRA-related public comment was received with regard to our proposed requirements and burden estimates, we have considered the comment and are adopting the proposed provisions/estimates without change. See below for our finalized estimates along with a summary of the comment and our response.

Section 438.8(c) requires that MCOs, PIHPs, and PAHPs report to the state annually their total expenditures on all claims and non-claims related activities, premium revenue, the calculated MLR, and, if applicable, any remittance owed.

We estimate the total number of MLR reports that MCOs, PIHPs, and PAHPs are required to submit to states amount to 572 contracts. While the number of contracts includes 549 credible contracts and 23 non-credible contracts, all MCOs, PIHPs, and PAHPs will need to report the information required under § 438.8 regardless of their credibility status.

We estimate a one-time private sector burden of 168 hr for the initial administration activities. We estimate that 60 percent of the time will be completed by a computer programmer (101 hr at \$78.32/hr), 30 percent will be completed by a business operations specialist (50 hr at \$64.46/hr), and 10 percent will be completed by a general and operations manager (17 hr at

\$140.80/hr). This amounts to \$13,526.92 ((101 hr × \$78.32) + (50 hr × \$64.46) + (17 hr × \$140.80)) per report or \$7,737,398.24 (572 × \$13,526.92) for 572 MCOs, PIHPs, and PAHPs in 2017 (the one-time burden). We are annualizing the one-time development since we do not anticipate any additional burden after the 3-year approval period expires.

In subsequent years, since the programming and processes established in 2017 will continue to be used, the burden will decrease from 168 hr to approximately 53 hr. Using the same proportions of labor allotment, we estimate an annual private sector burden of \$4,241.60 per report and a total of \$2,426,195.20 [572 contracts × \$4,241.60 ((32 hr × \$78.32/hr) + (16 hr × \$64.46/hr) + (5 hr × \$140.80/hr))]. We expect that states will permit MCOs, PIHPs, and PAHPs to submit the report electronically. Since the submission time is included in our reporting estimate, we are not setting out the burden for submitting the report.

We received the following comment:

Comment: We received one comment on the burden estimate for proposed § 438.8: "MCOs report to the state annually their total expenditures on all claims and non-claims related activities, premium revenue, MLR and remittance owed. \$2,185,050.56 [568 contracts × \$3,846.92 ((32 hr × \$73.60/hr) + (16 hr × \$53.32/hr))]. The commenter believed that this number should account for MCO time and expense required to complete financial reporting and encounter data submission and believed the estimate only reflected the financial reporting.

Response: The hours reflected in the estimate are for the calculation and reporting requirements proposed in § 438.8(c). The estimates quoted in the comment are for continuation of reporting in 2017 and beyond. The estimates in the COI for 2016 included 115 additional hours for initial process development and programming. Hours for submitting encounter data are not included as that is a requirement under existing § 438.242 and the COI only reflects changes in hours based on proposed changes. To the extent changes were proposed in § 438.242, hours were appropriately reflected for that section. We decline to revise this estimate.

5. ICRs Regarding Information Requirements (§ 438.10)

The following requirements and burden estimates were set out in the proposed rule and are being adopted without change except for the minor adjustments to hourly rates. No comments were received.

Section 438.10(c)(3) requires states to operate a Web site that provides the information required in § 438.10(f). Since states already have Web sites for their Medicaid programs and most also include information about their managed care program, most states will only have to make minor revisions to their existing Web site.

We estimate 6 hr at \$78.32/hr for a computer programmer to make the initial changes. In aggregate, we estimate a one-time state burden of 252 hr (42 states × 6 hr) and \$19,736.64 (252 hr × \$78.32/hr). We are annualizing the one-time development since we do not anticipate any additional burden after the 3-year approval period expires. We also estimate 3 hr for a computer programmer to periodically add or update documents and links on the site. In subsequent years, we estimate an annual state burden of 126 hr (42 states × 3 hr) and \$9,868.32 (126 hr × \$78.32/hr).

Section 438.10(c)(4)(i) recommends that states develop definitions for commonly used terms to enhance consistency of the information provided to enrollees. We estimate it will take 6 hr at \$64.46/hr for a business operations specialist to develop these definitions. In aggregate, we estimate a one-time state burden of 252 hr (42 states × 6 hr) and \$16,243.92 (252 hr × \$64.46/hr). We are annualizing the one-time development since we do not anticipate any additional burden after the 3-year approval period expires.

Section 438.10(c)(4)(ii) recommends that states create model enrollee handbooks and notices. Since many states already provide model handbooks and notices to their entities, we estimate 20 states may need to take action to comply with this provision. We estimate it will take 20 hr at \$64.46/hr for a business operations specialist to create these documents. We also estimate 2 hr per year for a business operations specialist to revise these documents, if needed. In aggregate, we estimate a one-time state burden of 400 hr (20 states × 20 hr) and \$25,784 (400 hr × \$64.46/hr). We are annualizing the one-time development since we do not anticipate any additional burden after the 3-year approval period expires. In subsequent years we estimate an annual burden of 40 hr (20 states × 2 hr) and \$2,578.40 (40 hr × \$64.46/hr).

Section 438.10(d)(2)(i) requires that states add taglines to all printed materials for potential enrollees explaining the availability of translation and interpreter services as well as the phone number for choice counseling assistance. As the prevalent languages within a state do not change frequently,

we are not estimating the burden for the rare updates that will be needed to update these taglines. We estimate it will take 2 hr at \$64.46/hr for a business operations specialist to create the taglines and another 4 hr to revise all document originals. In aggregate, we estimate a one-time state burden of 252 hr (42 states × 6 hr) and \$16,243.92 (252 hr × \$64.46/hr). We are annualizing the one-time development since we do not anticipate any additional burden after the 3-year approval period expires.

Section 438.10(e)(1) clarifies that states can provide required information in paper or electronic format. As this is an existing requirement, the only burden change we estimate is adding two new pieces of information generated in § 438.68 (network adequacy standards) and § 438.330 (quality and performance indicators). We estimate 1 hr at \$64.46/hr for a business operations specialist to update or revise existing materials and 1 min at \$30.92/hr for a mail clerk to mail the materials to 5 percent of the enrollees that are new (3,135,242). In aggregate, we estimate a one-time state burden of 42 hr (42 states × 1 hr) and \$2,707.32 (42 hr × \$64.46/hr) to update/revise existing materials. We are annualizing the one-time development since we do not anticipate any additional burden after the 3-year approval period expires. The currently approved burden estimates 5 min per mailing for 65,000 total hour. By updating the enrollment count from the current burden estimate to 2,069,259 (62,704,821 total enrollees × .033 growth rate) and reducing the time from 5 min to 1 min (to acknowledge automated mailing processes), we estimate the annual state burden for mailing as – 30,512 hr (34,488 hr – 65,000 hr) and – \$943,431.04 (– 30,512 hr × \$30.92/hr).

Section 438.10(g)(1) requires that MCOs, PIHPs, PAHPs, and PCCMs provide an enrollee handbook. Since § 438.10(g) has always required the provision of this information (although it did not specifically call it a “handbook”), we believe only new managed care entities will need to create this document. Given the requirement in § 438.10(c)(4)(ii) for the state to provide a model template for the handbook, the burden on a new entity will be greatly reduced.

For existing entities that already have a method for distributing the information, we believe that 100 entities will need to modify their handbook to comply with a new model provided by the state. We estimate that 100 entities rely on a business operations specialist to spend 4 hr at \$64.46/hr to update their handbook. Once revised, the handbooks need to be sent to enrollees.

We estimate 1 min by a mail clerk at \$32.23/hr to send handbooks to 10,659,819 enrollees (17 percent of 62,704,821 total enrollment). To update the handbook, we estimate a one-time private sector burden of 400 hr (100 entities × 4 hr) and \$25,784 (400 hr × \$64.46/hr). We are annualizing the one-time development since we do not anticipate any additional burden after the 3-year approval period expires. To send the handbook to existing enrollees in the 100 entities, we estimate a one-time private sector burden of 178,019 hr (10,659,819 enrollees × 1 min) and \$5,504,346.78 (178,019 hr × \$30.92/hr). We are annualizing the one-time development since we do not anticipate any additional burden after the 3-year approval period expires.

With regard to new enrollees, they must receive a handbook within a reasonable time after receiving notice of the beneficiary's enrollment. We assume a 3.3 percent enrollee growth rate thus 2,069,259 enrollees (3.3% percent of 62,704,821) will need to receive a handbook each year. We estimate 1 min by a mail clerk at \$30.92/hr to mail the handbook or 34,557 hr (2,069,259 enrollees × 1 min). The currently approved burden estimates 5 min per mailing for 390,000 enrollees or 32,500 total hour. Updating the enrollment figure and reducing the time from 5 min to 1 min (to acknowledge current automated mailing processes), the annual private sector burden is increased by 2,057 hr (34,557 hr – 32,500 hr) and \$63,602.44 (2,057 hr × \$30.92/hr).

Since all of the 335 MCO + 176 PIHP + 61 PAHP + 9 PCCM entities will need to keep their handbook up to date, we estimate it will take 1 hr at \$64.46/hr for a business operations specialist to update the document. While the updates are necessary when program changes occur, we estimate 1 hr since each change may only take a few minutes to make. In aggregate, we estimate an annual private sector burden of 581 hr (335 MCO + 176 PIHP + 61 PAHP + 9 PCCM entities × 1 hr) and \$37,451.26 (581 hr × \$64.46/hr).

Section 438.10(h) requires that all MCO, PIHP, PAHP, and PCCM entities make a provider directory available in electronic form, and on paper upon request. Producing a provider directory is a longstanding requirement in § 438.10 and in the private health insurance market. Given the time sensitive nature of provider information and the high error rate in printed directories, most provider information is now obtained via the Internet or by calling a customer service representative. In this regard, the only

new burden is the time for a computer programmer to add a few additional fields of data, including the provider Web site addresses, additional disability accommodations, and adding behavioral and long-term services and support providers.

We estimate that it takes approximately 1 hr at \$78.325/hr for a computer programmer to update the existing directory. Updates after the creation of the original program will be put on a production schedule as part of usual business operations and would not generate any additional burden. In aggregate, we estimate a one-time private sector burden of 581 hr (335 MCO + 176 PIHP + 61 PAHP + 9 PCCM entities \times 1 hr) and \$45,503.92 (581 hr \times \$78.32/hr). We are annualizing the one-time development since we do not anticipate any additional burden after the 3-year approval period expires.

6. ICRs Regarding Requirements That Apply to MCO, PIHP, PAHP, and PCCM Contracts Involving Indians, Indian Health Care Providers, and Indian Managed Care Entities (§ 438.14)

The following requirements and burden estimates were set out in the proposed rule and are being adopted without change except for the minor adjustments to hourly rates. No comments were received.

Section 438.14(c) requires states to make supplemental payments to Indian providers if the MCO, PIHP, PAHP, and PCCM entity does not pay at least the amount paid to Indian providers under the FFS program. There are approximately 31 states with 463 managed care entities with Indian providers. This type of payment arrangement typically involves the managed care entity sending a report to the state that then calculates and pays the amount owed to the Indian health care provider.

We estimate it takes 1 hr at \$78.32/hr for a private sector computer programmer to create the claims report and approximately 12 hr at \$64.46/hr for a state business operations specialist to process the payments. We estimate that approximately 25 of the 31 states will need to use this type of arrangement; the remaining six require the managed care plan to pay the full amount due to the IHCP and no supplemental is needed. In aggregate, we estimate a one-time private sector burden of 463 hr (463 entities \times 1 hr) and \$36,262.16 (463 hr \times \$78.32/hr). We are annualizing the one-time development since we do not anticipate any additional burden after the 3-year approval period expires. We also estimate an annual state burden of 300

hr (25 states \times 12 hr) and \$19,338 (300 hr \times \$64.46/hr).

After the MCO, PIHP, PAHP, and PCCM report is created, it will most likely run automatically at designated times and sent electronically to the state as the normal course of business operations; therefore, no additional private sector burden is estimated after the first year. (Note: this process is not necessary when the MCO, PIHP, PAHP, or PCCM entity pays the IHCP at least the full amount owed under this regulation.)

7. ICRs Regarding Managed Care Enrollment (§ 438.54)

The following requirements and burden estimates were set out in the proposed rule and are being adopted with revisions and minor adjustments to hourly rates. No comments were received.

Section 438.54(c)(3) and (d)(3) requires states to notify the potential enrollee of the implications of not making an active choice during the allotted choice period. This information should be included in the notice of eligibility determination (or annual redetermination) required under § 445.912, thus no additional burden is estimated here.

Section 438.54(c)(8) requires states to send a notice to enrollees in voluntary programs that utilize a passive enrollment process confirming their managed care enrollment when the enrollee's initial opportunity to select a delivery system has ended. We assume 15 states will continue using a passive enrollment process, with a total of 22,394,579 enrollees. Assuming that 5 percent of these will be new each year, and of those, approximately 75 percent will not take action within the allotted time and will remain enrolled in the managed care plan passively assigned by the state (22,394,579 \times 0.05 \times 0.75 = 839,797) we estimate 1 min per notification by a mail clerk at \$30.92/hr. In aggregate, we estimate an annual state burden of 9,350 hours (839,797 enrollees \times 1 min) and \$433,640.94 (14,025 hr \times \$30.92/hr).

In § 438.54(c)(2), our proposed rule had set out requirements and burden which would have required states having voluntary programs that use a passive enrollment process to provide a 14 day choice period before enrolling the potential enrollee into a managed care plan. To accommodate the 14 day choice period, we estimated that 15 states would have to alter the programming of their passive enrollment algorithm to delay the enrollment in a managed care plan until the enrollee makes a plan selection or

the 14 day period expires. This burden estimate has been deleted because the 14 day choice period is not being finalized. This is discussed in section I.B.5.a.

8. ICRs Regarding Continued Services to Beneficiaries (§ 438.62)

The following requirements and burden estimates were set out in the proposed rule and are being adopted without change except for the minor adjustments to hourly rates. No comments were received.

Section 438.62(b)(1) requires states to have a transition of care policy for all beneficiaries moving from FFS Medicaid into a MCO, PIHP, PAHP or PCCM, or when an enrollee is moving from one MCO, PIHP, PAHP, or PCCM to another and that enrollee experiences a serious detriment to health or be at risk of hospitalization or institutionalization without continued access to services. As states are currently required to ensure services for enrollees during plan transitions, they have a policy but it may need to be revised to accommodate the requirements and to include transitions from FFS. We estimate it will take 42 states 5 hours at \$64.46/hr for a state business operations specialist to revise their policies and procedures and 4 hr at \$78.32/hr for a computer programmer to create a program to compile and send the data. In aggregate, we estimate a one-time state burden of 378 hr (42 states $-$ 9 hr) and \$26,694.36 (210 hr (42 \times 5) $-$ \$64.46/hr + 168 hr (42 \times 4) \times \$78.32/hr). We are annualizing the one-time development since we do not anticipate any additional burden after the 3-year approval period expires. We are not estimating additional burden for the routine running of these reports since they will be put into a normal production schedule.

Section 438.62(b)(2) requires that MCOs, PIHPs, PAHPs, and PCCMs implement their own transition of care policy that meets the requirements of § 438.62(b)(1). Under current requirements and as part of usual and customary business practice for all managed care plans, the MCOs, PIHPs, PAHPs, or PCCMs already exchange data with each other for this purpose. To revise their existing policies to reflect the standards in (b)(1), we estimate 1 hr at \$64.46 for a business operations specialist. To develop computer programs to receive and store FFS data, we estimate 4 hr at \$78.32/hr for a computer programmer. We are not estimating additional burden for the routine running of these reports since they will likely be put into a production schedule. In aggregate, we estimate a

one-time private sector burden of 586 hr (335 MCOs + 176 PIHPs + 41 PAHPs, and 34 PCCMs × 1 hr) and \$37,773.56 (586 hr × \$64.46/hr) and 2,344 hr (586 × 4 hr) and \$183,582.08 (2,272 hr × \$78.32/hr). We are annualizing the one-time development since we do not anticipate any additional burden after the 3-year approval period expires.

For transitions, we estimate 10 min (per request) at \$66.92/hr for a registered nurse to access the stored data and take appropriate action. We also estimate that approximately 0.05 percent of 6,274,080 new enrollees (313,704) may meet the state defined criteria for serious detriment to health and/or risk of hospitalization or institutionalization. In aggregate, we estimate an annual private sector burden of 52,294 hr (313,704 enrollees × 10 min) and \$3,499,545.05 (52,294 hr × \$66.92/hr).

9. ICRs Regarding State Monitoring Procedures (§ 438.66)

The following requirements and burden estimates were set out in the proposed rule and are being adopted without change except for the minor adjustments to hourly rates. No comments were received.

Section 438.66(a) and (b) requires states with MCO, PIHP, PAHP, or PCCM programs to have a monitoring system including at least the 13 areas specified in paragraph (b). While having a monitoring system is a usual and customary business process for all of the state Medicaid agencies, including all 13 areas will require most states to make at least some revisions to their existing processes and policies. We estimate 8 hr at \$64.46/hr for a business operations specialist to expand or revise existing policies and procedures. In aggregate, we estimate a one-time state burden of 336 hr (42 states × 8 hr) and \$21,658.56 (336 hr × \$64.46/hr). We are annualizing the one-time development since we do not anticipate any additional burden after the 3-year approval period expires.

Section 438.66(c) requires states with MCO, PIHP, PAHP, or PCCM programs to utilize data gathered from its monitoring activities in 12 required areas to improve the program's performance. While all states currently utilize data for program improvement to some degree, incorporating all 12 areas will likely require some revisions to existing policies and procedures. We estimate a one-time state burden of 20 hr at \$64.46/hr for a business operations specialist to revise existing or to create new policies and procedures for utilizing the collected data. In aggregate, we estimate 840 hr (42 states × 20 hr) and \$54,146.40 (840 hr × \$64.46/hr). We

are annualizing the one-time development since we do not anticipate any additional burden after the 3-year approval period expires.

Section 438.66(d)(1) through (3) requires that states include a desk review of documents and an on-site review for all readiness reviews when certain events occur. For preparation and execution of the readiness review, we estimate 5 hr (at \$140.80/hr) for a general and operations manager, 30 hr (at \$64.46/hr) for a business operations specialist, and 5 hr (at \$78.32/hr) for a computer programmer. The time and staff types are estimated for a new program or new entity review and may vary downward when the review is triggered by one of the other events listed in (d)(1). Given the varying likelihood of the 3 events listed in (d)(1), we will use an average estimate of 20 states per year having one of the triggering events. In aggregate, we estimate an annual state burden of 800 hr (20 states × 40 hr) and \$60,588 [20 states × ((5 × \$140.80/hr) + (30 × \$64.46/hr) + (5 × \$78.32/hr))].

For MCO, PIHP, PAHP, or PCCM preparation and execution, we estimate 5 hr (at \$140.80/hr) for a general and operations manager, 30 hr (at \$64.46/hr) for a business operations specialist, and 5 hr (at \$78.32/hr) for a computer programmer. In aggregate, we estimate an annual private sector burden of 800 hr (20 entities × 40 hr) and \$60,588 [20 entities × ((5 × \$140.80/hr) + (30 × \$64.46/hr) + (5 × \$78.32/hr))].

Section 438.66(e)(1) and (2) requires that states submit an annual program assessment report to CMS covering the topics listed in § 438.66(e)(2). The data collected for § 438.66(b) and the utilization of the data in § 438.66(c) will be used to compile this report. We estimate an annual state burden of 6 hr at \$64.46/hr for a business operations specialist to compile and submit this report to CMS. In aggregate, we estimate an annual state burden of 252 hr (42 states × 6 hr) and \$16,243.92 (252 hr × \$64.46/hr).

10. ICRs Regarding Network Adequacy (§ 438.68)

The following requirements and burden estimates were set out in the proposed rule and are being adopted without change except for the minor adjustments to hourly rates. No comments were received.

Section 438.68(a) requires that states set network adequacy standards that each MCO, PIHP and PAHP must follow. Section 438.68(b) and (c) would require that states set standards which must include time and distance standards for specific provider types

and must develop network standards for LTSS if the MCO, PIHP or PAHP has those benefits covered through their contract.

We estimate states will spend 10 hr in the first year developing the network adequacy standards for the specific provider types found in § 438.68(b)(1). While 40 states have contracted with at least one MCO, PIHP or PAHP, we believe that 20 will need to develop the standards and 20 already have a network adequacy standard in place. After the network standards have been established, we estimate that the maintenance of the network standards will occur only periodically as needs dictate; therefore, we do not estimate additional burden for states after the first year.

To develop network standards meeting the specific provider types found in § 438.68(b)(1), we estimate a one-time state burden of 10 hr at \$64.46/hr for a business operations specialist. In aggregate, we estimate 200 hr (20 states × 10 hr) and \$12,892 (200 hr × \$64.46/hr). We are annualizing the one-time development since we do not anticipate any additional burden after the 3-year approval period expires.

To develop LTSS standards, we estimate a one-time state burden of 10 additional hr at \$64.46/hr for a business operations specialist to develop those standards. In aggregate, we estimate 160 hr (16 states with MLTSS programs × 10 hr) and \$10,313.60 (160 hr × \$64.46/hr). We are annualizing the one-time development since we do not anticipate any additional burden after the 3-year approval period expires.

Section 438.68(d) requires that states develop an exceptions process for use by MCOs, PIHPs, and PAHPs unable to meet the network standards established in § 438.68(a). We estimate a one-time state burden of 3 hr at \$64.46/hr for a business operations specialist to design an exceptions process for states to use to evaluate requests from MCOs, PIHP, and PAHPs for exceptions to the network standards. With a total of 40 states contracting with at least one MCO, PIHP or PAHP, we estimate a one-time aggregate state burden of 120 hr (40 states × 3 hr) and \$7,735.20 (120 hr × \$64.46). We are annualizing the one-time development since we do not anticipate any additional burden after the 3-year approval period expires.

The exception process should not be used very often as MCOs, PIHPs, and PAHPs meeting the established standards is critical to enrollee access to care. As such, after the exceptions process is established, we estimate that the occasional use of it will not generate

any measurable burden after the first year.

States' review and reporting on exceptions granted through the process developed in § 438.68(d) is estimated under § 438.66 so we do not estimate any additional burden for this requirement.

11. ICRs Regarding Stakeholder Engagement When LTSS Is Delivered Through a Managed Care Program (§ 438.70)

The following requirements and burden estimates were set out in the proposed rule and are being adopted without change except for the minor adjustments to hourly rates. No comments were received.

Section 438.70(c) requires that states continue to solicit and address public input for oversight purposes. Existing MLTSS programs already meet this requirement and we estimate no more than 14 new programs will be established by states.

We estimate an annual state burden of 4 hr at \$64.46/hr for a business operations specialist to perform this task. In aggregate, we estimate 56 hr (14 states × 4 hr) and \$3,609.76 (152 hr × \$64.46/hr).

12. ICRs Regarding Beneficiary Support System (§ 438.71)

The following requirements and burden estimates were set out in the proposed rule and are being adopted with revision and minor adjustments to hourly rates. Two comments were received.

Section 438.71(a) requires that state develop and implement a system for support to beneficiaries before and after enrollment in a MCO, PIHP, PAHP, or PCCM. This will most likely be accomplished via a call center including staff having email capability—internal to the state or subcontracted—that will assist beneficiaries with questions. As most state Medicaid programs already provide this service, we estimate only 20 states may need to take action to address this requirement.

A state has multiple ways to implement this provision; it could procure a vendor for this function, amend an existing contract (for example, enrollment broker), or add staff or train existing internal call center, outreach, or ombudsman staff. We offer a burden here for procuring a new contractor or establishing a new call center, although we do not believe these are the options that most states will elect. We include a 150 hour burden here as an average for the more costly options available to states—procuring a new vendor or creating a

call center. The one-time state burden would consist of 125 hr (at \$64.46/hr) for a business operations specialist, and 25 hr (at \$140.80/hr) for a general and operations manager. In aggregate, we estimate 3,000 hr (20 states × 150 hr) and \$231,550 [20 states × ((125 hr × \$64.46/hr) + (25 hr × \$140.80/hr))]. We acknowledge that there may be on-going burden associated with this provision; however, given the multiple options for implementing it, we are unable to estimate that burden at this time.

Section 438.71(b) requires that the system include choice counseling for enrollees, outreach for enrollees, and education and problem resolution for services, coverage, and access to LTSS. This system must be accessible in multiple ways including at a minimum, by telephone and email. Some in-person assistance may need to be provided in certain circumstances. Most states will likely use the call center created in § 438.71(a) to handle the majority of these responsibilities and use existing community-based outreach/education and ombudsman staff, whether state employees or contractors, for the occasional in person request. The use of existing staff will add no additional burden as it is part of standard operating costs for operating a Medicaid program.

In § 438.71(d), our proposed rule had set out requirements and burden which would have required that states develop training materials for provider education on MLTSS. That requirement is not being finalized, as discussed in I.B.5.c.

We received the following comments:

Comment: We received a few comments expressing concern that the beneficiary support systems will not be funded adequately to be effective. CMS estimates one-time expenditures of 150 hours to create a call center and 3 hours to create provider education materials, plus one hour annually for those same materials (see 80 FR at 31182). The commenters disagreed that states would use call centers and existing ombudsman program and, therefore, would incur more expense than estimated. Commenters believed that an effective beneficiary support network would require time and resources that far exceed the current estimates.

Response: We are unclear why the commenters believe our estimates are low. Many states already have call centers and/or use enrollment brokers to perform many of the functions proposed in § 438.71. While some states may need to amend their existing contracts or provide additional staff training, we believe that most already have the foundation for the beneficiary support

system between existing state, contractual, and ombudsman resources.

Comment: One commenter believed that CMS vastly underestimated the amount of time it takes to develop training and education materials and to keep those materials updated for the proposed provisions in § 438.71(b)(1)(ii) and (d) in a continuously changing health care environment.

Response: Based on comments received to proposed provisions in § 438.71(b)(1)(ii) and (d), we will not be finalizing those paragraphs. See section I.B.5.c. for additional detail.

13. ICRs Regarding Member Advisory Committee (§ 438.110)

The following requirements and burden estimates were set out in the proposed rule and are being adopted without change except for the minor adjustments to hourly rates. No comments were received.

Section 438.110(a) requires that each MCO, PIHP, and PAHP establish and maintain a member advisory board if the LTSS population is covered under the contract. We estimate an annual private sector burden of 6 hr at \$64.46/hr for a business operations specialist to maintain the operation of the committee (hold meetings, distribute materials to members, and maintain minutes) for up to 14 new programs. Existing programs already meet this requirement and we estimate no more than 14 new programs will be established by states. In aggregate, we estimate 84 hr (14 states × 6 hr) and \$5,414.64 (84hr × \$64.46/hr).

14. ICRs Regarding Assurances of Adequate Capacity and Services (§ 438.207)

The following requirements and burden estimates were set out in the proposed rule and are being adopted without change except for the minor adjustments to hourly rates. No comments were received.

Section 438.207(c) requires that the documentation required in § 438.207(b) be submitted to the state at least annually. As the MCOs, PIHPs, and PAHPs will already run and review these reports periodically to monitor their networks as part of normal network management functions and as part of the provisions of § 438.68, the only additional burden would possibly be (if the state doesn't already require this at least annually) for the MCOs, PIHPs, and PAHPs to revise their policy to reflect an annual submission. We estimate a one-time private sector burden of 1 hr at \$64.46/hr for a business operations specialist to revise the policy, if needed. We are annualizing the one-time development

since we do not anticipate any additional burden after the 3-year approval period expires.

In aggregate, we estimate 552 hr (335 MCOs + 176 PIHPs + 41 PAHPs × 1 hr) and \$35,581.92 (552 hr × \$64.46/hr) for policy revision. We also estimate an annual private sector burden of 2 hr to compile and submit the information necessary to meet the requirements in § 438.207(b) through (d). For compilation and submission, we estimate 1,104 hr (335 MCOs + 176 PIHPs + 41 PAHPs × 2 hr) and \$71,163.84 (1,104 hr × \$64.46/hr).

15. ICRs Regarding Coordination and Continuity of Care (§ 438.208)

While one PRA-related public comment was received with regard to our proposed requirements and burden estimates, we have considered the comment and are adopting the proposed provisions/estimates without change. See below for our finalized provisions/estimates along with a summary of the comment and our response.

Section 438.208(b)(2)(iii) requires that MCOs, PIHPs and PAHPs coordinate service delivery with the services the enrollee receives in the FFS program (carved out services). This involves using data from the state to perform the needed coordination activities. The exchange of data and the reports needed to perform the coordination activity is addressed in the requirements in § 438.62(b)(2). Since only a small percentage of enrollees receive carved out services and need assistance with coordination, we estimate 5 percent of all MCO, PIHP, and PAHP enrollees (2,331,626 of 46,632,522 MCO, PIHP, and PAHP enrollees) will be affected. We estimate an ongoing private sector burden of 10 min (per enrollee) at \$51.54/hr for a healthcare social worker to perform the care coordination activities. In aggregate, we estimate 457,838 hr (2,331,626 enrollees × 10 min) and \$23,596,970.52 (457,746 hr × \$51.54/hr).

Section 438.208(b)(3) requires that a MCO, PIHP or PAHP make its best effort to conduct an initial assessment of each new enrollee's needs within 90 days of the enrollment. We believe that most MCOs and PIHPs already meet this requirement and only 25 percent of the MCOs and PIHPs (84 MCOs + 44 PIHPs) will need to alter their processes; however, we do not believe this to be as common a practice among PAHPs and assume that all 41 non-NEMT PAHPs will need to add this assessment to their initial enrollment functions. We estimate a one-time private sector burden of 3 hr at \$64.46/hr for a business operations specialist to revise

their policies and procedures. In aggregate, we estimate 507 hr [(84 MCOs + 44 PIHPs + 41 PAHPs) × 3 hr] and \$32,681.22 (507 hr × \$64.46/hr). While PRA-related public comments were received with regard to our proposed requirements and burden estimates, we have considered the comments and are adopting the proposed provisions/estimates without change. See below for our finalized provisions/estimates along with a summary of the comments and our response.

We estimate that in a given year, only 5 percent (726,143) of 25 percent of MCO and PIHP (10,703,220) and all (3,819,643 non-NEMT) PAHP enrollees are new to a managed care plan. We estimate an annual private sector burden of 10 min (on average) at \$35.86/hr for a customer service representative to complete the screening. In aggregate, we estimate 121,023 hr (726,143 enrollees × 10 min) and \$4,320,550 (121,023 hr × \$35.86/hr).

Section 438.208(b)(4) requires that MCOs, PIHPs, and PAHPs share with other MCOs, PIHPs, and PAHPs serving the enrollee the results of its identification and assessment of any enrollee with special health care needs so that those activities are not duplicated. The burden associated with this requirement is the time it takes each MCO, PIHP or PAHP to disclose information on new enrollees to the MCO, PIHP or PAHP providing a carved out service. This would most likely be accomplished by developing a report to collect the data and electronically posting the completed report for the other MCO, PIHP, or PAHP to retrieve.

We estimate a one-time burden of 4 hr at \$78.32/hr for a computer programmer to develop the report. In aggregate, we estimate 2,272 hr (335 MCOs + 176 PIHPs + 41 PAHPs × 4 hr) and \$177,943.04 (2,272 hr × \$78.32/hr). However, while the currently approved burden sets out 45 min per enrollee and 464,782 annual hours, to provide more accurate estimates we are adjusting the burden by using one-time per plan estimates and recognizing the use of automated reporting. In aggregate, we estimate a one-time private sector burden of – 462,510 hr (2,272 hr – 464,782 hr) and – \$36,223,783.20 (– 462,510 hr × \$78.32/hr). While a PRA-related public comment was received with regard to our proposed requirements and burden estimates, we have considered the comments and are adopting the proposed provisions/estimates without change. See below for our finalized provisions/estimates along with a summary of the comments and our response. Once put on a production schedule, no additional staff time will

be needed, thus no additional burden is estimated.

Section 438.208(c)(2) and (3) currently require that MCOs, PIHPs and PAHPs complete an assessment and treatment plan for all enrollees that have special health care needs; this rule adds “enrollees who require LTSS” to this section. These assessments and treatment plans should be performed by providers or MCO, PIHP or PAHP staff that meet the qualifications required by the state. We believe the burden associated with this requirement is the time it takes to gather the information during the assessment. (Treatment plans are generally developed while the assessment occurs so we are not estimating any additional time beyond the time of the assessment.) We believe that only enrollees in MCOs and PIHPs will require this level of assessment as most PAHPs provide limited benefit packages that do not typically warrant a separate treatment plan.

While this is an existing requirement, we estimate an additional 1 percent of the total enrollment of 42,812,879 in MCOs and PIHPs (42,812,879 × .01 = 428,128) given the surge in enrollment into managed care of enrollees utilizing LTSS. We estimate an annual private sector burden of 1 hr (on average) at \$66.92/hr for a registered nurse to complete the assessment and treatment planning. In aggregate, we estimate an additional 428,128 hr (428,128 enrollees × 1 hr) and \$28,650,325.76 (428,128 hr × \$66.92/hr).

Section 438.208(c)(3)(v) requires that treatment plans be updated at least annually or upon request. We estimate a one-time private sector burden of 1 hr at \$64.46/hr for a business operations specialist to revise policies and procedures to reflect a compliant time frame. In aggregate, we estimate 552 hr (335 MCOs + 176 PIHPs + 41 PAHPs × 1 hr) and \$35,581.92 (552 hr × \$64.46/hr).

We received the following comment:

Comment: One commenter believed the COI estimate for proposed § 438.208(b)(2) of 10 minutes at a social worker's rate is low and should be 20–30 minutes at a nurse's rate.

Response: We disagree with the commenter that the burden estimate is low. There is great variation in the processes used by states and managed care plans to accommodate transition periods. Many provide a period of time for all new enrollees to maintain existing provider relationships while locating a participating provider. Many also give automatic transition periods based on the enrollee's course of treatment. For example, many managed care plans automatically authorize

pregnant women to remain with their existing provider through their postpartum visit. These types of mechanisms reduce the average amount of time and the type of managed care plan staff needed per enrollee. As such, we believe our estimate is a reasonably representative average. We decline to revise our estimate.

16. ICRs Regarding Coverage and Authorization of Services (§ 438.210)

The following requirements and burden estimates were set out in the proposed rule and are being adopted without change except for the minor adjustments to hourly rates. No comments were received.

Section 438.210(a)(4)(ii)(B) requires that MCOs, PIHPs, and PAHPs authorize services for enrollees with chronic conditions or receiving LTSS in a way that reflects the on-going nature of the service. While we expect this to already be occurring, we also expect that most MCOs, PIHPs, and PAHPs will review their policies and procedures to ensure compliance. We estimate a one-time private sector burden of 20 hr at \$66.92/hr for a registered nurse to review and revise, if necessary, authorization policies and procedures. In aggregate, we estimate 11,440 hr (335 MCOs + 176 PIHPs + 61 PAHPs × 20 hr) and \$765,564.80 (11,440 × \$66.92/hr). We are annualizing the one-time development since we do not anticipate any additional burden after the 3-year approval period expires.

Section 438.210(c) currently requires that each contract provide for the MCO or PIHP to notify the requesting provider of a service authorization request denial, and give the enrollee written notice of any decision by the MCO, PIHP, or PAHP to deny a service authorization request, or to authorize a service in an amount, duration, or scope that is less than requested. In this final rule, PAHPs are added to this requirement.

The burden associated with sending adverse benefit determination notices is included in § 438.404. While we believe PAHPs already provide notification of denials, we expect they may need to be revised to be compliant with § 438.404. We estimate a one-time public sector burden of 1 hr at \$64.46/hr for a business operations specialist to revise the template. In aggregate, we estimate 61 hr (61 PAHPs × 1 hr) and \$3,932.06 (61 hr × \$64.46/hr). We are annualizing the one-time development since we do not anticipate any additional burden after the 3-year approval period expires.

17. ICRs Regarding Subcontractual Relationships and Delegation (§ 438.230)

The following requirements and burden estimates were set out in the proposed rule and are being adopted without change, except for the minor adjustments to hourly rates. No comments were received.

Section 438.230 would require additional provisions in MCO, PIHP, or PAHP subcontracts, other than agreements with network providers. We estimate a one-time private sector burden of 3 hr at \$64.46/hr for a business operations analyst to amend appropriate contracts. In aggregate, we estimate 1,716 hr (335 MCO + 176 PIHPs + 61 PAHPs × 3 hr) and \$110,613.36 (1,716 × \$64.46/hr). We are annualizing the one-time development since we do not anticipate any additional burden after the 3-year approval period expires.

18. ICRs Regarding Health Information Systems (§ 438.242)

While one PRA-related public comment was received with regard to our proposed requirements and burden estimates, we have considered the comment and are adopting the proposed provisions/estimates without change. See below for our finalized provisions/estimates along with a summary of the comment and our response.

Section 438.242(b) and (c) currently requires MCOs and PIHPs to collect and submit to the state enrollee encounter data. This rule adds non-NEMT PAHPs to the requirement. We estimate a one-time private sector burden of 20 hr at \$78.32/hr for a computer programmer to extract this data from a PAHP's system and report it to the state. In aggregate, we estimate 820 hr (41 PAHPs × 20 hr) and \$64,222.40 (820 hr × \$78.32/hr). After creation, these reports would be set to run and sent to the state at on a production schedule. We are annualizing the one-time development since we do not anticipate any additional burden after the 3-year approval period expires.

We received the following comment on this collection of information estimate:

Comment: We received one comment on the COI burden estimate in § 438.242: "MCOs collect and submit to the state enrollee encounter data. 820 hr (41 PAHPs × 20 hr) and \$60,352 (820 hr × \$73.60/hr)." The commenter believed CMS is drastically under valuing the time and expense it takes to build this capability within complex systems.

Response: We disagree that the estimated hours undervalue the time

necessary given that the majority of encounter data is sent to a managed care plan in a standardized format (most often the ASC X12N 837) which is also the format that § 438.242 requires that the managed care plan utilize when submitting the same data to the state. The use of standardized formats was included in § 438.242 to, among other reasons, minimize the amount of programming time and customization needed and permit managed care plans to maximize the efficiencies of submitting encounter data in the same format in which it receives most claim data. Additionally, § 438.242 has required managed care plans to submit encounter data to the state since part 438 was finalized in 2002; we do not believe the changes proposed here will require managed care plans in most states to make an unreasonable amount of programming changes. We decline to revise this estimate.

19. ICRs Regarding Basis, Scope, and Applicability (§ 438.310)

The following requirements and burden estimates were set out in the proposed rule and are being adopted without change except for the minor adjustments to hourly rates. No comments were received.

Section 438.310(c)(2) applies § 438.330(b)(2), (b)(3), (c), and (e), § 438.340(e) and § 438.350 to states whose contracts with PCCM entities include shared savings, incentive payments, or other financial reward for the PCCM entity for improved quality outcomes. This will affect a specific subset of approximately 9 PCCM entities and 5 states.

We estimate a one-time state burden of 2 hr at \$64.46/hr for a business operations specialist to address the performance assessment of PCCM entities described in § 438.310(c)(2) by revising a state's policies and procedures. We are annualizing the one-time development since we do not anticipate any additional burden after the 3-year approval period expires. In aggregate, we estimate 10 hr (5 states × 2 hr) and \$644.60 (10 hr × \$64.46/hr), annualized to 3.3 hr and \$214.87.

20. ICRs Regarding Quality Assessment and Performance Improvement Program (§ 438.330, formerly § 438.240)

While one PRA-related public comment was received with regard to our proposed requirements and burden estimates for this section, we have considered the comment and are adopting the proposed provisions/estimates without change except for the minor adjustments to hourly rates. See below for our finalized provisions/

estimates along with a summary of the comments and our response.

Section 438.330(a)(2) specifies the process CMS will use if it elects to specify a common set of national QAPI performance measures and PIP topics, which will include a public notice and comment process. Assuming that we do use this process to identify QAPI performance measures and PIP topics at least once every 3 years, the burden for states will be altered. Some may experience a decrease in the time spent selecting performance measures and PIP topics while others might experience a slight increase in the form of programming their MMIS systems to account for the specified performance measures and PIP topics.

We estimate a state burden of 10 hr (every 3 years) at \$78.32/hr for a computer programmer to make the MMIS programming changes. In aggregate, we estimate an annualized burden of 133.3 hr [(40 states × 10 hr)/3 years] and \$10,440.06 (133.3 hr × \$78.32/hr). We cannot estimate the amount of possible decrease in burden as we have no way to know the average amount of time a state expended on selecting performance measures or PIP topics and how this might change based on this revision.

Section 438.330(a)(2) also will allow states to apply for an exemption from the CMS-specified QAPI performance measures and PIP topics established under § 438.330(a)(2). While we have no data on how many states will take advantage of this option, given that the performance measures and PIP topics under § 438.330(a)(2) will be identified through a public notice and comment process, we estimate that approximately 11 states will ask for an exemption every 3 years. We estimate a state burden of 1 hr (every 3 years) at \$64.46/hr for a business operations specialist to comply with the exemption process. In aggregate, we estimate an annualized burden of 3.7 hr [(11 states × 1 hr)/3 years] and \$238.50 (3.7 hr × \$64.46/hr).

Proposed § 438.330(a)(2)(ii) would allow states to select performance measures and PIPs in addition to those specified by CMS under § 438.330(a)(2)). Since this requirement exists under § 438.330(c) of the final rule, we are not finalizing proposed § 438.330(a)(2)(ii). This has no impact on the burden as compared to the proposed rule.

Section 438.330(a)(3) identifies the regulatory components of § 438.330 that apply to the QAPI of a PCCM entity described in § 438.310(c)(2). The burden associated with these regulatory components in regards to PCCM entities in §§ 438.330(b)(3), (c), and (e) is described below.

Section 438.330(b)(3) clarifies that MCOs, PIHPs, and PAHPs will have an approach to evaluate and address findings regarding the underutilization and overutilization of services. Because utilization review in managed care has become commonplace in the private, Medicare, and Medicaid settings, we do not believe that this regulatory provision imposes any new burden on MCOs, PIHPs, or PAHPs. However, in accordance with § 438.310(c)(2), PCCM entities (we estimate there are 9 total) will now be subject to this operational component.

We recognize that PCCM entities may not currently have in place mechanisms to assess and address underutilization and overutilization of services in accordance with § 438.330(b)(3). We estimate a one-time private sector burden of 10 hr at \$64.46/hr for a business operations specialist to establish the policies and procedures. We are annualizing the one-time development burden since we do not anticipate any additional development burden after the 3-year approval period expires. In aggregate, we estimate 90 hr (9 PCCM entities × 10 hr) and \$5,801.4 (90 hr × \$64.46/hr), annualized to 30 hr and \$1,933.8, for the establishment of policies and procedures. We also estimate an ongoing annual burden of 10 hr to evaluate and address the findings. In aggregate, we estimate 90 hr (9 PCCM entities × 10 hr) and \$5,801.4 (90 hr × \$64.46/hr) for program maintenance.

Section 438.330(c) addresses QAPI performance measurement. Section 438.330(c)(1) requires that the state identify standard performance measures for their managed care plans, including LTSS measures if appropriate. These must include any performance measures specified by CMS under § 438.330(a)(2). We believe that it is standard practice for states to identify performance measures for their contracted managed care plans; therefore there is no burden associated with this paragraph.

Section 438.330(c)(2) requires each MCO, PIHP, PAHP, and PCCM entity (described in § 438.310(c)(2)) to annually measure its performance using the standard measures specified by the state in § 438.330(c)(1) and to report on its performance to the state. We assume that each of the 335 MCOs and 176 PIHPs will report on three performance measures to the state. The use of performance measures is commonplace in private, Medicare, and Medicaid managed care markets; therefore we believe that MCOs and PIHPs already collect performance measures.

For MCOs (335) and PIHPs (176), we estimate an annual private sector

burden of 0.1 hr at \$64.46/hr for a business operations specialist to report on a single performance measure to the state. In aggregate, we estimate 153.3 hr (511 MCOs and PIHPs × 3 performance measures × 0.1 hr) and \$9,881.72 (153.3 hr × \$64.46/hr).

We recognize that PAHPs and PCCM entities (described in § 438.310(c)(2)) may not currently engage in performance measurement as described in § 438.330(c)(2). We estimate that each PCCM entity and each PAHP will report to the state on 3 performance measures annually. For the 41 PAHPs and 9 PCCM entities, we estimate an annual private sector burden of 4 hr (per measure) at \$64.46/hr for a business operations specialist to collect, calculate, and submit each performance measure to the state. In aggregate, we estimate 600 hr (51 PAHPs and PCCMs × 3 performance measures × 4 hr) and \$38,676 (600 hr × \$64.46/hr).

Section 438.330(c)(2) also requires each MCO, PIHP, PAHP, and PCCM entity (described in § 438.310(c)(2)) providing LTSS to annually measure its performance using the standard measures specified by the state in § 438.330(c)(1)(ii) and to report on its performance to the state. Section 438.330(c)(1)(ii) requires states to identify standard performance measures in two LTSS-specific categories for managed care plans that provide LTSS. Assuming that each of the 179 MLTSS plans will report on at least one measure per category and a burden of 4 hr (per measure) at \$64.46/hr for a business operations specialist to collect, calculate, and submit each LTSS performance measure to the state, we estimate an aggregated annual private sector burden of 1,432 hr (179 MLTSS plans × 2 performance measures × 4 hr) and \$92,306.72 (1,432 hr × \$64.46/hr).

Under § 438.330(d)(1) through (3), states must ensure that each MCO, PIHP, and PAHP has an ongoing program of PIPs, designed to achieve sustainable improvement, which the managed care plan will report on to the state as requested, but at least once per year. We assume that each MCO and PIHP will conduct at least 3 PIPs in any given year. We further expect that states would request the status and results of each entity's PIPs annually. The currently approved burden under this control number estimates that each of the 539 MCOs and PIHPs conducts 3 PIPs, for a burden of 12,936 hr (539 MCOs and PIHPs × 3 PIPs × 8 hr). However, this figure overestimates the number of MCOs and PIHPs. Therefore, we estimate an annual private sector burden of 8 hr at \$64.46/hr for a business operations specialist to report

on each PIP. In aggregate, we estimate 12,264 hr (511 MCOs and PIHPs \times 8 hr \times 3 PIPs) and \$790,537.44 (12,264 hr \times \$64.46/hr).

We assume that each PAHP will conduct at least one PIP each year, and that states will request the status and results of each PAHP's PIP annually. We estimate a one-time private sector burden of 2 hr at \$64.46/hr for a business operations specialist to develop policies and procedures. We are annualizing the one-time development burden since we do not anticipate any additional burden after the 3-year approval period expires. In aggregate, we estimate 82 hr (41 PAHPs \times 2 hr) and \$5,285.72 (82 hr \times \$64.46/hr), annualized to 27.3 hr and \$1,761.91. We also estimate an annual private sector burden of 8 hr to prepare a PIP report. In aggregate, we estimate 328 hr (41 PAHPs \times 1 PIP \times 8 hr) and \$21,142.88 (328 hr \times \$64.46/hr).

Section 438.330(e)(1) requires the state to review the impact and effectiveness of each MCO's, PIHPs, and PAHP's QAPI at least annually. States must also review the QAPI of each PCCM entity (described in § 438.310(c)(2)). We estimate an annual state burden of 15 hr at \$64.46/hr for a business operations specialist to assess the performance of a single PCCM entity (described in § 438.310(c)(2)). In aggregate, we estimate 135 hours (9 PCCM entities \times 15 hr) and \$8702.1 (135 hr \times \$64.46/hr).

Under section 438.330(e)(1)(ii), states will include outcomes and trended results of each MCO, PIHP, and PAHP's PIPs in the state's annual review of QAPI programs. We estimate a one-time state burden of 0.5 hr at \$64.46/hr for a business operations specialist to modify policies and procedures for the 40 states with MCOs, PIHPs and PAHPs. We are annualizing the one-time development since we do not anticipate any additional burden after the 3-year approval period expires. In aggregate, we estimate 20 hr (40 states \times 0.5 hr) and \$1,289.20 (20 hr \times \$64.46/hr), annualized to 6.7 hr and \$429.73. We also estimate an annual state burden of 1 hr to conduct the additional annual review of the outcomes and trended results for each of the 552 MCOs, PIHPs, and PAHPs (335 MCOs, 176 PIHPs, 41 PAHPs). In aggregate, we estimate 552 hr (552 MCOs, PIHPs, and PAHPs \times 1 hr) and \$35,581.92 (552 hr \times \$64.46/hr).

Section 438.330(e)(1)(iii) is a new program component, related to § 438.330(b)(5), which will require a state (in its annual review) to assess the results of any efforts to support state goals to promote community integration of beneficiaries using LTSS in place at

the MCO, PIHP, or PAHP. We estimate that the 16 states with MLTSS plans will need to modify their policies and procedures regarding the annual review of QAPI programs in their managed care entities. We estimate a one-time state burden of 0.5 hr at \$64.46/hr for a business operations specialist to modify the state's policies and procedures. We are annualizing the one-time development burden since we do not anticipate any additional burden after the 3-year approval period expires. In aggregate, we estimate 8 hr (16 states \times 0.5 hr) and \$515.68 (8 hr \times \$64.46/hr), annualized to 2.7 hr and \$171.89. We also estimate an annual burden of 1 hr for the assessment of rebalancing efforts of each of the 179 MLTSS plans. In aggregate, we estimate 179 hr (179 MLTSS plans \times 1 hr) and \$11,538.34 (179 hr \times \$64.46/hr) for the assessment.

We received the following comments regarding the proposed ICRs regarding QAPI program:

Comment: One commenter noted that the proposed changes to QAPI (along with the proposed changes to EQR and the proposed CQS) drove the new burden associated with the proposed quality revisions. The commenter believed that the cost estimates for these changes seemed understated, and that state might not be able to successfully bear this burden without consideration of a temporary enhanced match or other funding.

Response: While the commenter believed that the QAPI estimates were understated, it is not clear to us in what respect that is the case. We developed the estimates for QAPI based off of established estimates for MCOs and PIHPs for this topic. We note that these are estimates, and actual states practices and implementation may cause actual experience to be more, less, or the same as these estimates. Without clearer direction as to where our estimate is lacking, we decline to revise the QAPI burden estimates.

21. ICRs Regarding State Review of the Accreditation Status of MCOs, PIHPs, and PAHPs (§ 438.332)

Under § 438.332 of the proposed rule, titled "State Review and Approval of MCOs, PIHPs, and PAHPs," we proposed that states would review and approve MCO, PIHP, and PAHP performance, at least once every 3 years, in accordance with standards at least as strict as those used by a private accrediting entity that is approved or recognized by CMS under the existing Marketplace and MA programs, as a condition of contracting with the state. We also proposed to grant states the option of allowing MCOs, PIHPs, and

PAHPs to meet this standard by presenting proof of accreditation by a private accrediting entity recognized by CMS. MCOs, PIHPs, and PAHPs would have been required to maintain state approval for the duration of participation in the Medicaid program. State approval of MCOs, PIHPs, and PAHPs would have been renewed every 3 years.

As discussed in section I.B.6.b(2)(e) of this rule, in response to public comments also discussed in that section, we are not finalizing our proposal to require states to review and approve MCO, PIHP, and PAHP performance; instead, we are finalizing § 438.332 with modification to require states to confirm the accreditation status (accredited or not) of each contracted MCO, PIHP, and PAHP annually. As a part of this revision, we are finalizing proposed § 438.332(c), with modification, to require this information to be posted online each year. Therefore we are deleting the burden estimate associated with proposed §§ 438.332(a) and (b) and replacing it with the burden associated with states annually confirming the accreditation status of contract MCOs, PIHPs, and PAHPs and posting this information online.

Under § 438.332(a), states must confirm the accreditation status of contracted MCOs, PIHPs, and PAHPs once a year. We estimate an annual state burden of 0.25 hr at \$64.46/hr for a business operations specialist to review the accreditation status of each of the estimated 552 MCOs, PIHPs, and PAHPs. In aggregate, we estimate an annual burden of 138 hr (0.25 hr \times 552 MCOs, PIHPs, and PAHPs) and \$8,895.48 (138 hr \times \$64.46/hr).

Section 438.332(b) describes the information MCOs, PIHPs, and PAHPs must authorize the private accrediting entity to release to the state regarding the plan's accreditation status. We believe that states will need to amend their MCO, PIHP, and PAHP contracts to reflect this requirement, and estimate a one-time burden of 0.25 hr per contract amendment. We are annualizing the one-time development since we do not anticipate any additional burden after the 3-year approval period expires. In aggregate, we estimate a one-time burden of 138 hr (0.25 hr \times 552 MCOs, PIHPs, and PAHPs) and \$8,895.48 (138 hr \times \$64.46/hr), annualized to 46 hr and \$2,965.16.

Under § 438.332(c), states will document the accreditation status of each contracted MCO, PIHP, and PAHP on the state's Web site, and will update this information at least annually. The burden is included in § 438.10.

22. ICRs Regarding Medicaid Managed Care Quality Rating System (§ 438.334)

We received comments that expressed concern that we had underestimated the burden associated with the proposed MMC QRS. While no specific alternative estimates were provided, we increased the hour estimates associated with this ICR to respond to commenters' concerns. We have also made minor adjustments to hourly rates. Additional detail about this comment and our response may be found at the end of this section.

We received a number of comments on the MMC QRS proposal. In response to these comments, and to improve clarity, we restructured this section. Under the final rule, § 438.334(a) provides the general rule that states must operate a MMC QRS, as did proposed § 438.334(a)(1). Section 438.334(b) of the final rule describes the CMS-developed MMC QRS, which was previously described in proposed § 438.334(a)(2) and (3). Section 438.334(c) of the final rule describes the option for states to operate, contingent on CMS approval, an alternative MMC QRS, which was described in § 438.334(c) of the proposed rule. In the final rule, § 438.334(c) provides additional detail regarding the public engagement process required for an alternative MMC QRS. The requirement for states to collect data from MCOs, PIHPs, and PAHPs each year and to use that data to generate a quality rating for the plan is finalized at § 438.334(d), and was proposed at § 438.334(b). Finally, § 438.334(e) of the final rule, as in the proposed rule, requires states to post the quality ratings online. In response to public comments regarding proposed § 438.334(d), we are not finalizing our proposal to allow states to elect to utilize the MA Five-Star rating for MCOs, PIHPs, or PAHPs and therefore are deleting the burden associated with that proposal. See section I.B.6.b(2)(e) for additional discussion of this restructuring and other revisions made in response to public comments.

Section 438.334(a) requires each state that contracts with an MCO, PIHP or PAHP to adopt a MMC QRS to generate plan ratings annually. States must either adopt the quality rating system developed by CMS in accordance with § 438.334(b) or an alternative MMC QRS in accordance with § 438.334(c). We assume each state will create a single MMC QRS for all of the state's contracted MCOs, PIHPs, and PAHPs. We are aware of 8 states that currently operate a quality rating system or quality report card for the state's Medicaid managed care program; we

assume that these states may want to continue to use their existing system given the investments already made in these systems. We also assume that a couple of states may determine that a state-specific approach is most suitable for them. Therefore, we estimate that of the 40 states that contract with MCOs, PIHPs, and PAHPs, 30 states will elect to adopt the MMC QRS developed by CMS in accordance with § 438.334(b), while the remainder (10 states) will elect to utilize an alternative MMC QRS in accordance with § 438.334(c). We further estimate that 75 percent (414) of MCOs, PIHPs, and PAHPs operate in these 30 states. We assume that, given the robust public engagement process CMS will use to develop the MMC QRS in accordance with § 438.334(b), states electing to adopt the CMS-developed MMC QRS will not need to conduct additional public engagement and will require less time to develop their MMC QRS as compared to states which elect to adopt an alternative MMC QRS consistent with § 438.334(c).

Therefore, for states adopting the CMS-developed MMC QRS under § 438.334(b), we estimate the state burden for the development and implementation of the MMC QRS as 200 hr at \$64.46/hr for a business operations specialist, 100 hr at \$78.32/hr for a computer programmer, and 30 hr at \$140.80/hr for a general and operations manager. We are annualizing the one-time development burden since we do not anticipate any additional burden after the 3-year approval period expires. In aggregate, we estimate a one-time state burden of 9,900 hr (30 states × 330 hr) and \$748,440 [30 states × ((200 hr × \$64.46/hr) + (100 hr × \$78.32/hr) + (30 hr × \$140.80/hr)], annualized to 3,300 hr and \$249,480, for the development of states' MMC QRS consistent with 438.334(b).

The burden is more variable for states seeking CMS approval for the adoption of an alternative MMC QRS per § 438.334(c). A state may submit an existing MMC QRS, may submit a modified version of an existing MMC QRS, or may develop a new MMC QRS. We assume that the burden for each of these options will vary by state and will be lowest for states that submit an existing MMC QRS for CMS approval and highest for states that develop a new MMC QRS. For the purposes of this estimate, we assume a standard burden across all states for the development of an alternative MMC QRS. We believe that the average alternative MMC QRS burden will exceed the burden to adopt the CMS-developed MMC QRS, and will require public engagement by the state. Therefore, we estimate the average state

burden for the development and implementation of an alternative MMC QRS as 800 hr at \$64.46/hr for a business operations specialist, 400 hr at \$78.32/hr for a computer programmer, and 120 hr at \$140.80/hr for a general and operations manager. We estimate an additional 20 hr at \$36.54/hr for an office and administrative support worker for the public engagement process and an additional 50 hr at \$64.46/hr for a business operations specialist to review and incorporate public feedback. We are annualizing the one-time development since we do not anticipate any additional burden after the 3-year approval period expires. In aggregate, we estimate a one-time state burden of 13,900 hr (10 states × 1,390 hr) and \$1,037,458 [10 states × ((800 hr × \$64.46/hr) + (400 hr × \$78.32/hr) + (120 hr × \$140.80/hr) + (20 hr × \$36.54/hr) + (50 hr × \$64.46/hr)], annualized to 4,633.3 hr and \$345,819.33, for the development of states' alternative MMC QRS consistent with § 438.334(c).

To elect the option under § 438.334(c) to use an alternative MMC QRS, a state will submit a request to CMS and must receive written CMS approval. We estimate a one-time state burden of 20 hr at \$64.46/hr for a business operations specialist to seek and receive approval from CMS for the state's Medicaid managed care alternative quality rating system. We are annualizing the one-time development since we do not anticipate any additional burden after the 3-year approval period expires. In aggregate, we estimate 200 hr (10 states × 20 hr) and \$12,892 (200 hr × \$64.46/hr), annualized to 66.7 hr and \$4,297.33.

Section 438.334(c)(3) outlines the process for a state to make changes to an approved alternative MMC QRS. We estimate that it will require 5 hr at \$36.54/hr for an office and administrative support worker and 25 hr at \$64.46/hr for a business operations specialist to complete the public comment process, and an additional 5 hr at \$64.46/hr from a business operations specialist to seek and receive approval from CMS for the change. While we have no data to estimate how frequently a state may elect to alter an approved alternative MMC QRS, we estimate that CMS will revise the MMC QRS under § 438.334(b) on average approximately once every three years. We assume that states will revise their alternative QRS on a similar frequency (once every three years) to ensure that the alternative QRS continues to yield substantially comparable information regarding MCO, PIHP, and PAHP performance, and apply this assumption here. Therefore, we estimate an aggregate annualized burden of 116.7 hr

[(10 states × 35 hr)/3 years] and \$7,055 [(10 states × ((5 hr × \$36.54/hr) + (30 × \$64.46/hr)))/3 years].

Under § 438.334(d), each state will collect information from its MCOs, PIHPs, and PAHPs to calculate and then issue a quality rating each year. We expect that states will rely on information and data already provided to them by their MCOs, PIHPs, and PAHPs; therefore, we do not expect this data collection to pose an additional burden on the private sector. However, each year states will rate each MCO, PIHP, or PAHP with which they contract. We estimate 40 hr at \$64.46/hr for a business operations specialist for a state to rate a MCO, PIHP, or PAHP. We believe this burden will be similar for states regardless of if they adopt the CMS-developed MMC QRS consistent with § 438.334(b) or the alternative MMC QRS consistent with § 438.334(c). In aggregate, we estimate an annual state burden of 22,080 hr (552 MCOs, PIHPs, and PAHPs × 40 hr) and \$1,423,276.80 (22,080 hr × \$64.46/hr).

Section 438.334(e) requires states to prominently display quality rating information for plans on the state Web site described in § 438.10. The burden associated with this process is captured in § 438.10.

We received the following comments regarding the proposed ICRs regarding the MMC QRS:

Comment: One commenter stated that the estimate for the creation of the MMC QRS was not realistic and was extremely understated. This commenter did not believe that the estimate adequately addressed the administrative burden for creating a rating system, and disagreed with the assumption that all of the data required for a MMC QRS is readily available in a useable format. Another commenter noted that a state ratings system will incur costs related to design, development, training, and implementation.

Response: CMS did not have experience on which to base the estimated burden for the MMC QRS. Therefore, we give deference to the commenters' concerns, and we increased the estimated hours associated with each component of the MMC QRS burden in the final rule. We also note that this estimate takes into account the technical assistance available to states from CMS, both in the form of a CMS-developed MMC QRS available for adoption (and guidance, in the case of alternative QRS) and to support the development of alternative MMC QRS.

23. ICRs Regarding Managed Care State Quality Strategy (§ 438.340, formerly § 438.204)

In part 431 subpart I and § 438.340, we proposed that states would maintain a written comprehensive quality strategy that applied to services provided through all delivery systems, including FFS and managed care. Proposed part 431 subpart I described the general rule for the CQS, the CQS elements, the development and revision process, and connected the CQS to the managed care quality strategy elements in proposed § 438.340, which would apply to states contracting with MCOs, PIHPs, PAHPs, and some PCCM entities. Based on public comment, we are not finalizing the requirement for a CQS as described in proposed part 431 subpart I. However, we are continuing to require a managed care quality strategy (which applies to states contracting with MCOs, PIHPs, PAHPs, and PCCM entities described in § 438.310(c)(2)), and are redesignating sections from proposed part 431 subpart I into § 438.340 of the final rule. The general rule for the managed care quality strategy is redesignated at § 438.340(a) and is a revised version of the general rule from proposed § 431.502(a). Section 438.340(b) of the final rule describes the required elements of the managed care quality strategy, and combines the language from proposed §§ 431.502(b) and 438.340. It also contains additional revisions to reflect cross-references from other sections and responses to public comment. This includes the addition of an element focused on the state's plan to identify, evaluate, and reduce health disparities, which incorporates the requirement previously located at § 438.204(b)(2) that states provide certain demographic information to MCOs and PIHPs at the time of enrollment. Proposed § 431.504 is finalized as § 438.340(c) with revisions to reflect the more limited scope (to Medicaid managed care) and for clarity. Proposed § 431.504(d) is finalized as § 438.340(d) with minor revisions. For additional discussion of these revisions, please see section I.B.6(b)(2)(f).

While a PRA-related public comment was received with regard to our proposed requirements and burden estimates, we have considered the comment and are not revising our burden estimates in response to these PRA-related comment. However, our finalized burden estimates for § 438.340 have been revised to reflect the finalized version of this section (which takes into account non-PRA-related comments), and minor adjustments to hourly rates. See below for our finalized provisions/

estimates along with a summary of the comments and our response.

Previous regulations at § 438.204(b)(2) described a quality strategy element, specifically that states contracting with MCOs and/or PIHPs identify the race, ethnicity, and primary language spoken of each Medicaid enrollee, and report this information to MCOs and PIHPs upon enrollment into a plan. While we had inadvertently proposed to delete this quality strategy element, under the final rule we are retaining this element and incorporating it into § 438.340(b)(6), which requires states to include a plan to identify, evaluate, and reduce health disparities in the managed care quality strategy. Therefore, under the final rule there is a burden on states to provide the identified demographic data (age, race, ethnicity, sex, primary language, and disability status) to MCOs, PIHPs, and PAHPs. The burden associated with previous regulations at § 438.204(b)(2) was estimated at 80 hr per state (for 15 states) to complete the programming necessary to collect and report on the race, ethnicity, and primary language spoken, for an aggregate burden of 1,200 hr (15 states × 80 hr) (note that the previous burden did not include an associated hourly wage). We are replacing that burden with a new estimate to account for the additional demographic information which states must provide to MCOs, PIHPs, and PAHPs under § 438.340(b)(6). Assuming that the estimated 40 states that contract with MCOs, PIHPs, and PAHPs provide demographic information electronically to these plans once each year, we estimate a burden for the reporting of these six demographic factors to MCOs, PIHPs, and PAHPs of 130 hr, half at \$64.46/hr for a business operations analyst and half at \$36.54/hr for an office and administrative support worker. In aggregate, we estimate an ongoing annual state burden of 5,200 hr (130 hr × 40 states) and \$262,600 [40 states × ((65 hr × \$64.46/hr) + (65 hr × \$36.54/hr))].

In accordance with § 438.340(c)(2), states will review and revise their quality strategies as needed, but no less frequently than once every 3 years. While the 37 states that contract with MCOs and/or PIHPs currently revise their quality strategies periodically, approximately half of those states (18) revise their quality strategies less frequently than proposed. We estimate a burden for the revision of a quality strategy of, once every 3 years, 25 hr at \$64.46/hr for a business operations analyst to review and revise the comprehensive quality strategy, 2 hr at \$36.54/hr for an office and administrative support worker to

publicize the strategy, 5 hr at \$64.46/hr for a business operations specialist to review and incorporate public comments, and 1 hr at \$36.54/hr for an office and administrative support worker to submit the revised quality strategy to CMS. In aggregate, we estimate an ongoing annualized state burden of 198 hr [(18 states × (33 hr)/3 years)] and \$12,260.52 [(18 states × ((30 hr × \$64.46/hr) + (3 hr × \$36.54/hr)))/3 years].

The revision of a quality strategy will be a new process for the estimated three states with only PAHPs and the estimated two states with only PCCM entities. We estimate that those states need 0.5 hr at \$64.46/hr for a business operations specialist to revise their policies and procedures. We are annualizing the one-time development burden since we do not anticipate any additional development burden after the 3-year approval period expires. In aggregate, we estimate a one-time state burden of 2.5 hr (5 states × 0.5 hr) and \$161.15 (2.5 hr × \$64.46/hr), annualized to 0.8 hr and \$53.72, to update policies and procedures.

We assume that it will be less burdensome to revise an existing quality strategy than to draft an initial strategy. Therefore, we estimate an ongoing burden for the quality strategy revision process for states with only PAHPs and PCCM entities, once every 3 years, of 25 hr at \$64.46/hr for a business operations analyst to review and revise the comprehensive quality strategy, 2 hr at \$36.54/hr for an office and administrative support worker to publicize the strategy, 5 hr at \$64.46/hr for a business operations specialist to review and incorporate public comments, and 1 hr at \$36.54/hr for an office and administrative support worker to submit the revised quality strategy to CMS. In aggregate, we estimate an ongoing annualized state burden of 55 hr [(5 states × (33 hr)/3 years)] and \$3,405.70 [(5 states × ((30 hr × \$64.46/hr) + (3 hr × \$36.54/hr)))/3 years].

Consistent with § 438.340(c)(2), the review of the quality strategy will include an effectiveness evaluation conducted within the previous 3 years. We estimate the burden of this evaluation at 40 hr at \$64.46/hr for a business operations specialist once every 3 years for all 42 states that contract with MCOs, PIHPs, PAHPs, and/or PCCM entities (described in § 438.310(c)(2)). The currently approved burden estimates for creating and submitting an implementation and effectiveness report to CMS for the 37 states with MCOs and/or PIHPs takes 40 hr per state once every 3 years, for an

annualized burden of 493.3 hr [(37 states × 40hr)/3]; therefore, the only new burden is associated with the estimated 3 states with only PAHPs and the estimated 2 states with only PCCM entities. Therefore, we estimate a net ongoing annualized burden of 66.7 hr [(42 states × 40 hr) – (37 states × 40 hr)]/3 years] and \$4,299.48 (66.7 hr × \$64.46/hr) to evaluate the effectiveness of a quality strategy.

Section § 438.340(c)(2)(ii) requires states to post the managed care quality strategy effectiveness evaluation on the state's Medicaid Web site. In the proposed rule we stated that while this standard was subject to the PRA, we believed that the associated burden was exempt from the PRA in accordance with 5 CFR 1320.3(b)(2). We believed that the time, effort, and financial resources necessary to comply with the aforementioned standards would be incurred by persons during the normal course of their activities and, therefore, should be considered a usual and customary business practice. Upon further consideration, however, we determined that states today do not necessarily post the quality strategy effectiveness evaluation online.

Therefore, we estimate that posting the quality strategy effectiveness evaluation online will require 0.25 hr at \$64.46 from a business operations specialist once every 3 years. In aggregate, we estimate an ongoing annualized burden of 3.5 hr [(42 states × 0.25 hr)/3 years] and \$225.61 (3.5 hr × \$64.46/hr).

As described in § 438.340(c)(3), states will submit to CMS a copy of the initial quality strategy and any subsequent revisions. The burden associated with this standard has been incorporated into burden estimates for initial and revised quality strategies. As this will be a new standard for the estimated 3 states with only PAHPs and the estimated 2 states with only PCCM entities, we believe that these states will need to modify their policies and procedures to incorporate this action. We estimate a burden of 0.5 hr at \$64.46/hr for a business operations specialist. We are annualizing the one-time development burden since we do not anticipate any additional development burden after the 3-year approval period expires. In aggregate, we estimate a one-time state burden of 2.5 hr (5 states × 0.5 hr) and \$161.15 (2.5 hr × \$64.46/hr), annualized to 0.8 hr and \$53.72.

Section 438.340(d) requires states to post the final quality strategy to their Medicaid Web sites. In the proposed rule, we stated that while this standard is subject to the PRA, we believed that the associated burden was exempt from the PRA in accordance with 5 CFR

1320.3(b)(2). We believed that the time, effort, and financial resources necessary to comply with the aforementioned standards would be incurred by persons during the normal course of their activities and, therefore, should be considered a usual and customary business practice. Upon further consideration, however, we determined that states today do not necessarily post the final quality strategy online, though some do. Therefore, we estimate that posting the final quality strategy online will require 0.25 hr at \$64.46 from a business operations specialist once every 3 years. In aggregate, we estimate an ongoing annualized burden of 3.5 hr [(42 states × 0.25 hr)/3 years] and \$225.61 (3.5 hr × \$64.46/hr).

We received the following comments regarding the proposed ICRs regarding the managed care State quality strategy:

Comment: One commenter noted that the proposed CQS (along with the proposed changes to QAPI and EQR) drove the new burden associated with the proposed quality revisions. The commenter believed that the costs estimates for this proposal seemed understated, and that state might not be able to successfully bear this burden without consideration of a temporary enhanced match or other funding.

Response: We are withdrawing the proposed Part 431, Subpart I, but retaining the requirement for a managed care quality strategy, described in § 438.340 of the final rule. With this change, we moved the burden associated with the proposed new Part 431, Subpart I to § 438.340, where it largely replaced the burden associated with proposed § 438.340. Given that we will not apply the QS requirements to FFS delivery systems, we do not believe the burden is understated and decline to revise the estimate.

24. ICRs Regarding External Quality Review (§ 438.350)

While the proposed rule expanded EQR to PAHPs (it already applied to MCOs and PIHPs), we did not develop a burden estimate for § 438.350, though we did for other EQR provisions. Upon further consideration, and in light of the clarification in 438.310(c)(2) that certain PCCM entities will be required to undergo an annual EQR, we have determined it necessary to develop a burden for the amendment of EQRO contracts in states with MCOs and PIHPs which we assume will amend existing EQRO contracts to include PAHPs and PCCM entities.

We estimate that there are 12 states that contract with PAHPs (of which 3 states contract with only PAHPs) and 5 states that contract with PCCM entities

which will be required to undergo an annual EQR (of which 2 states contract only with PCCM entities). Therefore, we estimate that there are 17 states that contract with PAHPs or PCCM entities in addition to MCOs and PIHPs which will amend their existing EQRO contracts. We estimate a one-time burden of 1 hr at \$64.46/hr for a business operations specialist to amend the EQRO contract. We are annualizing the one-time development burden since we do not anticipate any additional development burden after the 3-year approval period expires. In aggregate, we estimate a one-time state burden of 17 hr (17 states \times 1 hr) and \$1,095.82 (17 hr \times \$64.46/hr), annualized to 5.7 hr and \$365.27.

25. ICRs Regarding Activities Related to External Quality Review (§ 438.358)

Proposed § 438.3(r) stated that PCCM entities whose contract with the state provides for shared savings, incentive payments or other financial reward for improved quality outcomes would be subject to EQR. However, proposed § 438.350(b) and its associated preamble, inaccurately described EQR as optional for these PCCM entities (see section I.B.6.b(2)(h) for additional discussion). In the final rule, we clarified that EQR of PCCM entities (described in § 438.310(c)(2) of the final rule) are required to undergo an annual EQR. Therefore, we are revising this ICR to include the burden associated with conducting the EQR-related activities on PCCM entities (described in § 438.310(c)(2) of the final rule). Additionally, in response to public comments, we are finalizing an optional EQR-related activity at § 438.358(c)(6) of the final rule which can assist states with the quality rating of MCOs, PIHPs, and PAHPs (for additional discussion, see section I.B.6.b(2)(e)).

While a PRA-related public comment was received with regard to our proposed requirements and burden estimates, we have considered the comment and are not modifying this estimate in response to the comment. However, we are revising this ICR to reflect the changes described above and minor adjustments to hourly rates. See below for our finalized provisions/estimates along with a summary of the comment and our response.

Section 438.358 addresses the EQR-related activities. Per § 438.358(a)(1), the EQR-related activities described in paragraphs (b) and (c) of this section may be conducted by the state, its agent that is not an MCO, PIHP, PAHP, or PCCM entity (described in § 438.310(c)(2)), or an EQRO; we describe the burden assuming that the

state conducts these activities, though we believe the burdens will be similar regardless of who conducts each activity.

The burden associated with the mandatory EQR-related activities described in § 438.358(b)(1) is the time and effort for a state to conduct and document the findings of the four mandatory activities: (1) The annual validation of PIPs conducted by the MCO, PIHP, or PAHP, (2) the annual validation of performance measures calculated by the MCO, PIHP, or PAHP, (3) a review of MCO, PIHP, or PAHP compliance with structural and operational standards, performed once every 3 years; and (4) validation of MCO, PIHP, or PAHP network adequacy during the preceding 12 months. Each of the activities will be conducted on the 552 MCOs, PIHPs, and PAHPs that we estimate provide Medicaid services.

The types of services provided by MCOs, PIHPs, and PAHPs, and the number of PIPs conducted and performance measures calculated will vary. The previously approved burden under control number 0938-0786 (CMS-R-305) for these three activities assumed that each of the then-estimated 458 MCOs and PIHPs validate one PIP by a professional at \$63/hr for 65 hr, validate one performance measure by a professional at \$63/hr for 53 hr, and complete an annual a compliance review by a professional at \$63/hr for 361 hr. The previously approved annual burden was 219,382 hr (479 hr \times 458 MCOs and PIHPs) and \$13,821,066 (219,382 hr \times \$63/hr). However, based on recent experience (for MCOs and PIHPs), we estimate that each MCO or PIHP will conduct 3 PIPs, each PAHP will conduct 1 PIP, and that each MCO, PIHP, or PAHP will calculate 3 performance measures. Furthermore, using the time estimates developed for MCOs and PIHPs for the previously approved burden estimates under control number 0938-0786 (CMS-R-305) (and assuming that the same time estimates will also apply to PAHPs), we estimate it will take an average of 65 hr/PIP validation, 53 hr/performance measure validation, and 361 hr/compliance review (occurs once every 3 years) for a business operations specialist, at \$64.46/hr, to conduct the mandatory EQR activities. For MCOs and PIHPs, we estimate an annual state burden of 242,367.3 hr (511 MCOs and PIHPs \times [(65 hr \times 3 PIPs) + (53 hr \times 3 performance measures) + (361 hr/3 year)]) and \$15,622,996.16 (242,367.3 hr \times \$64.46/hr) for the first three mandatory EQR-related activities. This estimate replaces the previous burden; the net change in annual state burden

for MCOs and PIHPs is 22,985.3 hr (242,367.3 hr – 219,382 hr) and \$1,801,930.16 (\$15,622,996.16 – \$13,821,066).

For PAHPs, we estimate an aggregate annual state burden of 14,116.3 hr (41 PAHPs \times 344.3 hr [(65 hr \times 1 PIPs) + (53 hr \times 3 performance measures) + (361 hr/3 years)]) and \$909,936.70 (14,116.3 hr \times \$64.46/hr) for the first three mandatory EQR-related activities.

The fourth mandatory EQR-related activity described in § 438.358(b)(1)(iv) requires the validation of MCO, PIHP, and PAHP network adequacy during the preceding 12 months. States will conduct this activity for each MCO, PIHP, and PAHP. Given that this is a new activity, we do not have historic data on which to base an hourly burden estimate for the network validation process. We estimate that it will take less time than the validation of a PIP but more time than the validation of a performance measure. Therefore, we estimate an annual state burden of 60 hr at \$64.46/hr for a business operations specialist to support the validation of network adequacy activity. In aggregate, we estimate 33,120 hr (552 MCOs, PIHPs, and PAHPs \times 60 hr) and \$2,134,915.20 (33,120 hr \times \$64.46/hr) for the validation of network adequacy activity.

Section 438.358(b)(2) describes the mandatory EQR-related activities which must be conducted for each PCCM entity (described in § 438.310(c)(2)), specifically the activities described in § 438.358(b)(1)(ii) and (iii). Given that we do not have data to estimate the time required for each of these activities for these PCCM entities, we rely on the time per activity estimates used for MCOs, PIHPs, and PAHPs; we assume the validation of one performance measure per PCCM entity (described in § 438.310(c)(2)). Therefore, we estimate an annual state burden of 1,560 hr (9 PCCM entities \times 173.3 hr [(53 hr \times 1 performance measure) + (361 hr/3 years)]) and \$100,557.60 (1,560 hr \times \$64.46/hr) for the mandatory EQR-related activities for PCCM entities (described in § 438.310(c)(2)).

The burden associated with § 438.358(b)(1) also includes the time for an MCO, PIHP, or PAHP to prepare the information necessary for the state to conduct the mandatory EQR-related activities. We estimate that it will take each MCO, PIHP, or PAHP 200 hr to prepare the documentation for these four activities, half (100 hr) at \$64.46/hr by a business operations specialist and half (100 hr) at \$36.54/hr by an office and administrative support worker. The burden associated with § 438.358(b)(2) also includes the time

for a PCCM entity (described in § 438.310(c)(2)) to prepare the information necessary for the state to conduct the mandatory EQR-related activities. Given the estimate of 200 hr for an MCO, PIHP, or PAHP, and that there are only 2 mandatory EQR-related activities for PCCM entities (described in § 438.310(c)(2)), we estimate it will take 100 hr to prepare the documentation for these 2 activities, half (50 hr) at \$64.46/hr by a business operations specialist and half (50 hr) at \$36.54/hr by an office administrative support worker. In aggregate, we estimate an annual private sector burden of 111,300 hr [(552 MCOs, PIHPs, and PAHPs × 200 hr) + (9 PCCM entities × 100 hr)] and \$5,620,650 [(55,650 hr × \$64.46/hr) + (55,650 hr × \$36.54/hr)]. The previously approved burden under control number 0938–0786 (CMS–R–305) estimated 160 hr per MCO or PIHP to prepare the information for the three existing mandatory EQR-related activities (finalized as § 438.358(b)(1)(i) through (iii)), half by a professional at \$63/hr and half by clerical staff at \$12/hr. The previously approved burden for information preparation is 73,280 hr (438 MCOs and PIHPs × 160 hr) and \$2,748,000 [(36,640 hr × \$63/hr) + (36,640 hr × \$12/hr)]. When comparing the previously approved burden against this final rule's revised burden, we estimate a change in burden of 38,020 hr (111,300 hr – 73,280 hr) and \$2,872,650 (\$5,620,650 – \$2,748,000) for the preparation of information for the mandatory EQR-related activities described in § 438.358(b)(1) and (b)(2). We note that in the proposed rule, Table 2 identified the net burden associated with the time for an MCO, PIHP, or PAHP to prepare the information necessary for the state to conduct the mandatory EQR-related activities in proposed § 438.358(b)(1). In this final rule, Table 2a shows the revised burden for this activity.

Section 438.358(c) describes the six optional EQR-related activities: (1) Validation of client level data (such as claims and encounters); (2) administration or validation of consumer or provider surveys; (3) calculation of performance measures; (4) conduct of PIPs; (5) conduct of focused studies; and (6) assist with the quality rating of MCOs, PIHPs, and PAHPs consistent with § 438.334. As with the mandatory activities described in § 438.358(b), these activities may be conducted by the state, its agent that is not an MCO, PIHP, or PAHP, or an EQRO, but for the purposes of this burden estimate we assume that the state conducts the activities.

We have no data to estimate the hours associated with how long it will take to conduct the optional EQR activities. Without that information, our best guess is that it will take 350 hr to validate client level data and 50 hr to validate consumer or provider surveys. We estimate it will take three times as long to calculate performance measures (159 hr) as it takes on average to validate and three times as long to conduct PIPs and focused studies (195) as it takes on average to validate PIPs. We also estimate that it will take three times as long to administer a consumer or provider survey than it takes to validate a survey (150 hr).

The previously approved burden under control number 0938–0786 (CMS–R–305) uses state-reported data from 2001 to estimate that states will: (1) Validate the encounter data of 69 percent (316) of MCOs and PIHPs; (2) administer or validate consumer or provider surveys of 43 percent (197) of MCOs and PIHPs; (3) calculate performance measures of 29 percent (133) of MCOs and PIHPs; (4) conduct PIPs of 38 percent (174) of MCOs and PIHPs; and (5) conduct focused studies of 76 percent (348) of MCOs and PIHPs. Using the hourly estimates (above) for each task and assuming the work is completed by a professional at \$63/hr (the job title and wage used in the previously approved burden under control number 0938–0786 (CMS–R–305)), CMS–R–305 previously estimated a total burden of 240,759 hr and \$15,167,817. However, based on our review of EQR technical report submissions since the original promulgation of these regulations, we have observed that many states do not conduct the optional EQR-related activities as frequently as assumed in our original estimates. While the exact states and number vary from year to year, we have not observed participation at the level observed in 2001 state-reported data.

Therefore, we revise our estimate and assume that each year 10 percent (51) of MCOs and PIHPs will be subject to each of the optional EQR-related activities. Regarding the administration or validation of consumer or provider surveys, we assume that half of the MCOs and PIHPs (25) will administer surveys while half (26) will validate surveys. We also estimate that a mix of professionals will work on each optional EQR-related activity: 20 Percent by a general and operations manager (\$140.80/hr); 25 percent by a computer programmer (\$78.32/hr); and 55 percent by a business operations specialist (\$64.46/hr). For the purposes of this estimate, we assume that the 10

percent of affected MCOs and PIHPs operate within 10 percent of states that contract with MCOs and PIHPs (4 states). We understand that this estimate may not reflect the number of states that require these optional EQR-related activities, and that there is variation in the number of plans that operate within a given state.

To validate client level data, we estimate 17,850 hr (51 MCOs and PIHPs × 350 hr) and \$1,484,995.05 [(17,850 hr × 20 percent × \$140.80/hr) + (17,850 hr × 25 percent × \$78.32/hr) + (17,850 hr × 55 percent × \$64.46/hr)]. To administer consumer or provider surveys, we estimate 3,750 hr (25 MCOs and PIHPs × 150 hr) and \$311,973.75 [(3,750 hr × 20 percent × \$140.80/hr) + (3,750 hr × 25 percent × \$78.32/hr) + (3,750 hr × 55 percent × \$64.46/hr)]. To validate consumer or provider surveys, we estimate 1,300 hr (26 MCOs and PIHPs × 50 hr) and \$108,150.90 [(1,300 hr × 20 percent × \$140.80/hr) + (1,300 hr × 25 percent × \$78.32/hr) + (1,300 hr × 55 percent × \$64.46/hr)]. To calculate performance measures, we estimate 8,109 hr (51 MCOs and PIHPs × 159 hr) and \$674,612.04 [(8,109 hr × 20 percent × \$140.80/hr) + (8,109 hr × 25 percent × \$78.32/hr) + (8,109 hr × 55 percent × \$64.46/hr)]. To conduct PIPs, we estimate 9,945 hr (51 MCOs and PIHPs × 195 hr) and \$827,354.39 [(9,945 hr × 20 percent × \$140.80/hr) + (9,945 hr × 25 percent × \$78.32/hr) + (9,945 hr × 55 percent × \$64.46/hr)]. To conduct focused studies, we estimate 9,945 hr (51 MCOs and PIHPs × 195 hr) and \$827,354.39 [(9,945 hr × 20 percent × \$140.80/hr) + (9,945 hr × 25 percent × \$78.32/hr) + (9,945 hr × 55 percent × \$64.46/hr)]. In aggregate, the annual state burden for optional EQR-related activities for MCOs and PIHPs is 50,899 hr (17,850 hr + 3,750 hr + 1,300 hr + 8,109 hr + 9,945 hr + 9,945 hr) and \$4,234,440.51 [(50,899 hr × 20 percent × \$140.80/hr) + (50,899 hr × 25 percent × \$78.32/hr) + (50,899 hr × 55 percent × \$64.46/hr)].

The optional EQR-related activities described in § 438.358(c) may also be conducted on PAHPs and PCCM entities (described in § 438.310(c)(2)). Since neither PAHPs or PCCM entities (described in § 438.310(c)(2)) have historically been subject to EQR, we do not have any data on which to base an estimate regarding how states will apply the optional EQR-related activities to these delivery systems. Therefore, we will apply the time, wage, and participation estimates developed for MCOs and PIHPs to PAHPs and PCCM entities (described in § 438.310(c)(2)). To validate client level data, we estimate 2,100 hr (6 PAHPs and PCCM

entities × 350 hr) and \$174,705.30 [(2,100 hr × 20 percent × \$140.80/hr) + (2,100 hr × 25 percent × \$78.32/hr) + (2,100 hr × 55 percent × \$64.46/hr)]. To administer consumer or provider surveys, we estimate 450 hr (3 PAHPs and PCCM entities × 150 hr) and \$21,981 [(450 hr × 20 percent × \$140.80/hr) + (450 hr × 25 percent × \$78.32/hr) + (450 hr × 55 percent × \$64.46/hr)]. To validate consumer or provider surveys, we estimate 150 hr (3 PAHPs and PCCM entities × 50 hr) and \$12,478.95 [(150 hr × 20 percent × \$140.80/hr) + (150 hr × 25 percent × \$78.32/hr) + (150 hr × 55 percent × \$64.46/hr)]. To calculate performance measures, we estimate 954 hr (6 PAHPs and PCCM entities × 159 hr) and \$79,366.12 [(954 hr × 20 percent × \$140.80/hr) + (954 hr × 25 percent × \$78.32/hr) + (954 hr × 55 percent × \$64.46/hr)]. To conduct PIPs, we estimate 1,170 hr (6 PAHPs and PCCM entities × 195 hr) and \$97,335.81 [(1,170 hr × 20 percent × \$140.80/hr) + (1,170 hr × 25 percent × \$78.32/hr) + (1,170 hr × 55 percent × \$64.46/hr)]. To conduct focused studies, we estimate 1,170 hr (6 PAHPs and PCCM entities × 195 hr) and \$97,335.81 [(1,170 hr × 20 percent × \$140.80/hr) + (1,170 hr × 25 percent × \$78.32/hr) + (1,170 hr × 55 percent × \$64.46/hr)]. In aggregate, the total annual state burden for optional EQR-related activities for PAHPs and PCCM entities (described in § 438.310(c)(2)) is 5,994 hr (2,100 hr + 450 hr + 150 hr + 954 hr + 1,170 hr + 1,170 hr) and \$498,658.84 [(5,994 hr × 20 percent × \$140.80/hr) + (5,994 hr × 25 percent × \$78.32/hr) + (5,994 hr × 55 percent × \$64.46/hr)].

Section 438.358(c)(6) allows a state to contract with an EQRO to support the quality rating of MCOs, PIHPs, and PAHPs consistent with § 438.334. We do not believe that the effort required to rate a plan changes based on which entity (state or EQRO) develops the plan rating. Therefore, we believe that any burden associated with this optional EQR-related activity will only offset the burden associated with § 438.334(d).

We received the following comments regarding the proposed ICRs regarding the activities related to EQR:

Comment: One commenter noted that the proposed changes to EQR (along with the proposed changes to QAPI and the proposed CQS) drove the new burden associated with the proposed quality revisions. The commenter believed that the cost estimates for these changes seemed understated, and that state might not be able to successfully bear this burden without consideration of a temporary enhanced match or other funding.

Response: While the commenter believed that the EQR estimates were understated, it is not clear to us in what respect that is the case. We developed the EQR estimates based off of established estimates for MCOs and PIHPs for this topic and our experience via EQR technical report submissions. We note that these are estimates, and actual states practices and implementation may cause actual experience to be more, less or the same as these estimates. Without clearer direction as to where our estimate is lacking, we decline to revise the EQR burden estimates. We also note that there is an enhanced 75 percent match rate available for EQR and EQR-related activities conducted by an EQRO on an MCO (see § 438.370); we lack statutory authority to provide any additional enhanced match rate or other financial support for EQR and EQR-related activities.

26. ICRs Regarding Nonduplication of Mandatory Activities (§ 438.360)

The following requirements and burden estimates were set out in the proposed rule and are being adopted without change except for the minor adjustments to hourly rates. No comments were received.

Section 438.360(a) grants states the option to use the information obtained from a Medicare or private accreditation review of an MCO, PIHP, or PAHP in place of information otherwise generated from the three mandatory activities specified in § 438.358(b)(1)(i) through (iii). Specifically, this section allows states to apply the non-duplication option to all MCOs, PIHPs, and PAHPs and it allows states to apply the non-duplication option to the validation of performance measures, the validation of PIPs, and to the compliance review. Section 438.360(c) requires states to address the use of non-duplication as an element of the quality strategy.

Section 438.360(b) describes when a state may elect to use information from a Medicaid or private accreditation review in place of information that would otherwise be generated by the mandatory EQR-related activities in § 438.358(b)(1)(i) through (iii). The burden associated with non-duplication is the time and effort for an MCO, PIHP, or PAHP to disclose the reports, findings, and other results of the Medicare or private accreditation review to the state agency.

While states could elect to allow all 552 MCOs, PIHPs, and PAHPs to substitute information from a Medicare or private accreditation review for the three mandatory EQR-related activities

specified at § 438.358(b)(1)(i) through (iii), in practice we find that states utilize this option infrequently. Therefore, we estimate that states will apply the non-duplication option to 10 percent (55) of MCOs (33), PIHPs (18), and PAHPs (4). The currently approved burden under control number 0938–0786 (CMS–R–305) estimates that 336 MCOs and/or PIHPs take advantage of the nonduplication provision, requiring 8 hr at \$37.50/hr per MCO or PIHP to disclose the necessary information to the state, for a total currently approved burden of 2,688 hr (336 MCOs and PIHPs × 8 hr) and \$100,800 (2,688 hr × \$37.50/hr). Since this appears to be an overestimate of the burden for MCOs and PIHPs, we estimate a revised annual private sector burden of 2 hr at \$64.46/hr for a business operations specialist and 6 hr at \$36.54/hr for an office and administrative support worker to disclose the necessary documentation to the state each year for a single MCO or PIHP. In aggregate, we estimate a private sector burden of 408 hr (51 MCOs and PIHPs × 8 hr) and \$17,756.16 [(51 MCOs and PIHPs × (2 hr × \$64.46/hr) + (6 hr × \$36.54/hr)]. Under this rule, states may apply the nonduplication provisions to PAHPs. In aggregate, we estimate 32 hr (4 PAHPs × 8 hr) and \$1,392.64 [4 PAHPs × (2 hr × \$64.46/hr) + (6 hr × \$36.54/hr)].

The process in § 438.360(b) includes the provision of all of the reports, findings, and other results of the Medicare or private accreditation review to the appropriate EQRO by the state agency. The currently approved burden under control number 0938–0786 (CMS–R–305) estimates that sharing the reports, findings, and results with EQROs for 336 MCOs and PIHPs will take states 8 hr at \$37.50/hr per plan, for a total burden of 2,688 hr (336 MCOs × 8 hr) and \$100,800 (2,688 hr × \$37.50/hr). However, we estimate it will take, on average, 2 hr at \$36.54/hr for an office and administrative support worker to disclose the necessary documentation to the appropriate EQRO. This represents a decrease in the estimated hourly burden for this task, as we believe that the use of electronic tracking and transmission tools has significantly decreased the hourly burden associated with state staff forwarding the documentation to the EQRO. In aggregate, we estimate an annual state burden of 110 hr (55 MCOs, PIHPs, and PAHPs × 2 hr) and \$4,019.40 (110 hr × \$36.54/hr) to forward non-duplication-related documentation to the EQROs.

Assuming that states will apply the non-duplication provision to 10 percent of MCOs, PIHPs, and PAHPs, we

estimate that this provision will offset the burden associated with § 438.358(b)(1)(i) through (iii) for 51 MCOs and PIHPs, and 4 PAHPs (since these activities will no longer be necessary for these 55 plans). Consistent with the estimates used in § 438.358(b)(1)(i) through (iii), we estimate an aggregated state offset of $-25,566.50$ hr [$(-51$ MCOs and PIHPs $\times 474.3$ hr) $+ (-4$ PAHPs $\times 344.3$ hr)] and $-\$1,648,016.59$ ($-25,566.50$ hr \times $\$64.46$).

Additionally, the MCOs, PIHPs, and PAHPs subject to non-duplication will not have to prepare the documentation necessary for the three mandatory EQR-related activities. Based on the assumption in § 438.358(b)(1) that an MCO, PIHP, or PAHP will need 200 hr to prepare the documentation for the four mandatory activities, we estimate that it will take 150 hr to prepare the documentation for the three activities subject to non-duplication, half (100 hr) at $\$64.46$ /hr by a business operations specialist and half (100 hr) at $\$36.54$ /hr by an office and administrative support worker. In aggregate, we estimate a decrease in annual private sector burden of $-8,250$ hr (-55 MCOs, PIHPs, and PAHPs $\times 150$ hr) and $-\$416,625$ [$(-4,125$ hr \times $\$64.46$ /hr) $+ (-4,125$ \times $\$36.54)$].

27. ICRs Regarding Exemption From External Quality Review (§ 438.362)

The following requirements and burden estimates were set out in the proposed rule and are being adopted without change except for the minor adjustments to hourly rates. No comments were received.

Section 438.362 reflects that PIHPs cannot be exempted from EQR, as they do not qualify as a MA Organization under part C of Title XVII of the Act or under section 1876 of the Act, and they do not qualify as an MCO under section 1903(m) of the Act. This led to a decrease in our estimate of the number of plans that might be exempt from the EQR process.

Under § 438.362, exempted MCOs have to provide (annually) to the state agency the most recent Medicare review findings reported to the MCO by CMS or its agent. Of the approximately 335 MCOs, we estimate that approximately half (168) might provide Medicare services in addition to Medicaid services. Of these 168 MCOs that might potentially provide Medicare services in addition to Medicaid services, we further estimate that state agencies will allow approximately 10 percent (17) of the MCOs to be exempt from the EQR process.

We estimate an annual private sector burden of 8 hr (2 hr at $\$64.46$ /hr for a business operations specialist and 6 hr at $\$36.54$ /hr for an office and administrative support worker) for an MCO to prepare and submit the necessary documentation to the state agency. In aggregate, we estimate 136 hr (17 MCOs $\times 8$ hr) and $\$5,918.72$ (17 MCOs $\times [(2$ hr \times $\$64.46$ /hr) $+ (6$ hr \times $\$36.54$ /hr)]. The previously approved burden under control number 0938–0786 (CMS–R–305) estimated that states would allow 10 percent (20) of the 202 MCOs (which might provide Medicare services in addition to Medicaid services) to be exempt from the EQR process, and that it would take each MCO approximately 8 hr at $\$37.50$ /hr to prepare the necessary materials for a total burden of 160 hr (20 MCOs $\times 8$ hr) and $\$6,000$ (160 hr \times $\$37.50$ /hr). Therefore, we estimate a change in burden of -24 hr (136 hr $-$ 160 hr) and $-\$81.28$ ($\$5,918.72$ $-$ $\$6,000$). We note that in the proposed rule, Table 2 identified the net burden associated with § 438.362; in this final rule, Table 2a shows the revised burden for this section.

28. ICRs Regarding External Quality Review Results (§ 438.364)

The following requirements and burden estimates were set out in the proposed rule and are being adopted without change except for the minor adjustments to hourly rates and to reflect the mandatory application of EQR to PCCM entities described in § 438.310(c)(2), which increases the estimated number of states impact by this section to 42. No comments were received.

Section 438.364(a) describes the information that will be included in the annual detailed technical report that is the product of the EQR. Section 438.364(a)(1)(iii) specifies that the EQR technical report includes baseline and outcomes data regarding PIPs and performance measures. Many states already provide much of this information in their final EQR technical report. The burden of compiling this data for MCOs, PIHPs, PAHPs, and select PCCM entities is captured in § 438.358. Under § 438.364(a)(3), EQR technical reports will include recommendations on how the state can use the goals and objectives of its managed care quality strategy to support improvement in the quality, timeliness, and access to care for beneficiaries. We believe that states will amend their EQRO contracts to address the changes to § 438.364(a). We estimate a one-time state burden of 0.5 hr at $\$64.46$ /hr for a business operations specialist to

amend the EQRO contract in the estimated 37 states with existing EQRO contracts. We are annualizing the one-time development since we do not anticipate any additional burden after the 3-year approval period expires. In aggregate, we estimate 18.5 hr (37 states $\times 0.5$ hr) and $\$1,192.51$ (18.5 hr \times $\$64.46$ /hr), annualized to 6.2 hr and $\$397.50$. We believe that the 5 states that contract only with PAHPs and PCCM entities will incorporate this section into their initial EQRO contracts, and therefore we do not believe there is an EQRO amendment burden associated with the changes to this section for those 5 states.

Section 438.364(b)(1) clarifies that the EQRO will produce and submit to the state an annual EQR technical report, and that states may not substantively revise the report without evidence of error or omission. This is consistent with existing policy and should not pose a burden on the states or the private sector. The April 30th deadline for the finalization and submission of EQR technical reports is consistent with existing subregulatory guidance.

While we do not anticipate that these changes would pose a significant burden on states or the private sector, we estimate that this provision may necessitate a change in a state's EQRO contract for approximately 10 states. In this regard, we estimate a one-time state burden of 0.5 hr at $\$64.46$ /hr for a business operations specialist to modify the EQRO contract. We are annualizing the one-time development since we do not anticipate any additional burden after the 3-year approval period expires. In aggregate, we estimate 5 hr (10 states $\times 0.5$ hr) and $\$322.30$ (5 hr \times $\$64.46$ /hr), annualized to 1.7 hr and $\$107.43$.

Under § 438.364(c)(ii), each state agency will provide copies of technical reports, upon request, to interested parties such as participating health care providers, enrollees and potential enrollees of the MCO, PIHP, or PAHP, beneficiary advocacy groups, and members of the general public. States will also make the most recent EQR technical report publicly available on the state's Web site, the burden for which is included in § 438.10.

We believe that by making these reports available online, states will be able to significantly decrease the burden associated with responding to requests from the public for this information, as it will already be easily accessible. The burden associated with section is the time and effort for a state agency to furnish copies of a given technical report to interested parties. The currently approved burden under control number 0938–0786 (CMS–R–

305) estimates a burden of 91,600 hr and \$1,099,200. This assumed 329 MCOs and 129 PIHPs (for a total of 458), 25 requests per MCO or PIHP, and 8 hr to respond to each request by staff at \$12/hr. In light of recent technological changes described in this section of this final rule, we estimate an annual state burden of 5 min (on average) at \$36.54/hr for an office and administrative support worker to disclose the reports (per request), and that a state will receive five requests per MCO, PIHP, PAHP, or PCCM entity (described in § 438.310(c)(2)) per year. In aggregate, we estimate 233.7 hr [(561 MCOs, PIHPs, PAHPs, and PCCM entities × 5 requests × 5 min)/60 min] and \$8,539.40 (233.7 hr × \$36.54/hr). Overall, we estimate a change in burden of –91,366.3 hr (233.7 hr – 91,600 hr) and –\$1,090,660.6 (\$8,539.40 – \$1,099,200). We note that in the proposed rule, Table 2 identified the net burden associated with proposed § 438.364(b)(2); in this final rule, Table 2a shows the revised burden for § 438.364(c)(ii).

29. ICRs Regarding Federal Financial Participation (§ 438.370)

The following requirements and burden estimates were set out in the proposed rule and are being adopted without change except for the minor adjustments to hourly rates. No comments were received.

Section 438.370(c) will require states to submit their EQRO contracts to CMS for review and approval prior to claiming FFP at the 75 percent rate. Since most states already consult with CMS regarding EQRO contracts, we estimate only 12 states will need to amend their policies and procedures to comply with this process. We estimate a one-time state burden of 0.5 hr at \$64.46/hr for a business operations specialist to amend their state's policies and procedures. We are annualizing the one-time development since we do not anticipate any additional burden after the 3-year approval period expires. In aggregate, we estimate 6 hr (12 states × 0.5 hr) and \$386.76 (6 hr × \$64.46/hr), annualized to 2.0 hr and \$128.92.

The 12 states which do not currently work with CMS on their EQRO contracts will need to submit the EQRO contracts to CMS for review and approval if they plan to claim the enhanced 75 percent federal match. We estimate a one-time state burden of 0.25 hr at \$36.54/hr for an office and administrative support worker to submit the EQRO contract to CMS. We are annualizing the one-time development since we do not anticipate any additional burden after the 3-year approval period expires. In aggregate, we estimate 3 hr (12 states × 0.25 hr)

and \$109.62 (3 hr × \$36.54/hr), annualized to 1.0 hr and \$36.54.

30. ICRs Regarding Statutory Basis and Definitions (§ 438.400)

The following requirements and burden estimates were set out in the proposed rule and are being adopted without change except for the minor adjustments to hourly rates. No comments were received.

Section 438.400(b) replaces “action” with “adverse benefit determination” and revises the definition. It also revises the definitions of “appeal” and “grievance” and add a definition for “grievance system.” In response, states, MCOs and PIHPs need to update any documents where these terms are used. (PAHPs will use these updated definitions when they develop their systems in § 438.402.)

We estimate a one-time private sector burden of 5 hr at \$64.46/hr for a business operations specialist to amend all associated documents to the new nomenclature and definitions. In aggregate, we estimate 2,555 hr (335 MCO + 176 PIHP × 5 hr) and \$164,695.30 (2,555 hr × \$64.46/hr). We also estimate a one-time state burden for states of 200 hr (40 states × 5 hr) and \$12,892 (200 hr × \$64.46/hr) to make similar revisions. We are annualizing the one-time development since we do not anticipate any additional burden after the 3-year approval period expires.

31. ICRs Regarding General Requirements for Grievance System (§ 438.402)

The following requirements and burden estimates were set out in the proposed rule and are being adopted without change except for the minor adjustments to hourly rates. No comments were received.

Section 438.402(a) adds non-NEMT PAHPs to the existing requirement for MCOs and PIHPs to have a grievance system. There are 41 PAHPs that will need to have their contract amended. The burden for revising their contract is included in § 438.3.

To set up a grievance system, we estimate it takes 100 hr (10 hr at \$140.80/hr for a general and operations manager, 75 hr at \$64.46/hr for a business operations specialist, and 15 hr at \$78.32/hr for a computer programmer) for each PAHP. In aggregate, we estimate a one-time private sector burden of 4,100 hr (41 PAHPs × 100 hr) and \$304,109.30 [41 PAHPs × ((10 hr × \$140.80/hr) + (75 hr × \$64.46/hr) + (15 hr × \$78.32/hr))]. We are annualizing the one-time development since we do not anticipate

any additional burden after the 3-year approval period expires.

We further estimate that the average PAHP only receives 10 grievances per month due to their limited benefit package and will only require 3 hr at \$64.46/hr for a business operations specialist to process and handle grievances and adverse benefit determinations. In aggregate, we estimate an annual private sector burden of 14,760 hr (41 PAHPs × 10 grievances × 3 hr × 12 months) and \$951,429.60 (14,760 hr × \$64.46/hr).

Section 438.402(b) limits MCOs, PIHPs, and PAHPs to one level of appeal for enrollees. This will likely eliminate a substantial amount of burden from those that currently have more than one, but we are unable to estimate that amount since we do not know how many levels each managed care plan currently utilizes. We requested comment from managed care plans to help us estimate the savings from this provision. We received no comments and will finalize this section with no estimated cost savings.

32. ICRs Regarding Timely and Adequate Notice of Adverse Benefit Determination (§ 438.404)

The following requirements and burden estimates were set out in the proposed rule and are being adopted without change except for the minor adjustments to hourly rates. No comments were received.

Section 438.404(a) adds PAHPs as an entity that must give the enrollee timely written notice. It also sets forth the requirements of that notice. Consistent with the requirements for MCOs and PIHPs, PAHPs must give the enrollee timely written notice if it intends to: deny, limit, reduce, or terminate a service; deny payment; deny the request of an enrollee in a rural area with one plan to go out of network to obtain a service; or fails to furnish, arrange, provide, or pay for a service in a timely manner.

We estimate an annual private sector burden of 1 min at \$30.92/hr for a mail clerk to send this notification. We also estimate that 2 percent (240,000) of the 12 million PAHP enrollees will receive one notice of adverse benefit determination per year from a PAHP. In aggregate, we estimate an annual state burden of 4,000 hr (240,000 enrollees × 1 min) and \$123,927.36 (4,000 hr × \$30.92/hr).

33. ICRs Regarding Resolution and Notification: Grievances and Appeals (§ 438.408)

The following requirements and burden estimates were set out in the

proposed rule and are being adopted without change except for the minor adjustments to hourly rates. No comments were received.

Section 438.408(b) changes the time frame for appeal resolution from 45 days to 30 days. For MCOs, PIHPs, and PAHPs that have Medicare and/or QHP lines of business, this reflects a reduction in burden as this aligns Medicaid time frames with Medicare and QHP. For MCOs, PIHPs, and PAHPs that do not have Medicare and/or QHP lines of business, and whose state has an existing time frame longer than 30 days, they will need to revise their policies and procedures. Of the 568 MCOs, PIHPs, and PAHP, we assumed at least 50 percent offered either a Medicare or QHP product line. Of that, we then assumed that some plans already had 30 day timeframes. Of those plans remaining, we believed 200 to be a reasonable estimate. Among the 200 MCOs, PIHPs, and PAHPs, we estimate a one-time private sector burden of 1 hr at \$64.46/hr for a business operations specialist. In aggregate, we estimate 200 hr (200 MCOs, PIHPs, and PAHPs \times 1 hr) and \$12,892 (200 hr \times \$64.46). We are annualizing the one-time development since we do not anticipate any additional burden after the 3-year approval period expires.

34. ICRs Regarding Recordkeeping Requirements (§ 438.416)

The following requirements and burden estimates were set out in the proposed rule and are being adopted without change except for the minor adjustments to hourly rates. No comments were received.

This section adds PAHPs to the requirement to maintain records of grievances and appeals. We estimate that approximately 240,000 enrollees (2 percent) of the approximately 12 million PAHP enrollees file a grievance or appeal with their PAHP. As the required elements will be stored and tracked electronically, we estimate 1 min per grievance and appeal at \$36.54/hr for an office and administrative support worker to maintain each grievance and appeals record. In aggregate, we estimate an annual private sector burden of 4,000 hr (240,000 grievances \times 1 min) and \$146,452.32 (4,000 hr \times \$36.54/hr).

Maintaining records for grievances and appeals has always been required for MCOs and PIHPs. However, this rule requires specific data so a few MCOs and PIHPs (10 percent 335 MCOs + 176 PIHPs) may have to revise their policies and systems to record the required information. We estimate 3 hr at \$78.32 for a computer programmer to make

necessary changes. We estimate a one-time private sector burden of 153 hr (51 MCOs and PIHPs \times 3 hr) and \$11,982.96 (153 hr \times \$78.32/hr). We are annualizing the one-time development since we do not anticipate any additional burden after the 3-year approval period expires. As the required elements will be stored and tracked electronically, we estimate 1 min per grievance and appeal at \$36.54/hr for an office and administrative support worker to maintain each grievance and appeals record. In aggregate, we estimate an annual private sector burden of 14,299 hr (856,257 grievances (.02 \times 4,394,450 (.10 \times 43,944,503 MCO and PIHP enrollees) \times 1 min) and \$522,503.43 (14,299 hr \times \$36.54/hr).

35. ICRs Regarding Continuation of Benefits While the MCO, PIHP, or PAHP Appeal and the State Fair Hearing are Pending. (§ 438.420)

The following requirements and burden estimates were set out in the proposed rule and are being adopted without change except for the minor adjustments to hourly rates. No comments were received.

Section 438.420(c)(4) removes the time period or service limit of a previously authorized service has been met as a criteria for defining the duration of continued benefits and adds "PAHP" as a conforming change to § 438.400. This action requires that MCOs and PIHPs revise current policies and procedures to reflect having only 3 criteria instead of 4. PAHPs would incorporate the options in § 438.420(c)(1) through (3) when developing their system under § 438.402 and thus the elimination of § 438.420(c)(4) would have no impact on PAHPs.

For MCOs and PIHPs, we estimate a one-time private sector burden of 4 hr at \$64.46/hr for a business operations specialist to revise current policies and procedures. In aggregate, we estimate 2,044 hr (335 MCOs + 176 PIHPs \times 4 hr) and \$131,756.24 (2,044 hr \times \$64.46/hr).

Section 438.420(d) adds PAHPs to the list of entities that can recover costs if the adverse determination is upheld. PAHPs are required to include the policies and procedures necessary to recover costs when developing their system under § 438.402 and thus will not incur additional burden.

36. ICRs Regarding State Responsibilities (§ 438.602)

The following requirements and burden estimates were set out in the proposed rule and are being adopted without change except for the minor adjustments to hourly rates. No comments were received.

Section 438.602(a) details state responsibilities for monitoring MCO, PIHP, PAHP, PCCM or PCCM's compliance with §§ 438.604, 438.606, 438.608, 438.610, 438.230, and 438.808. As all of these sections are existing requirements, the only new burden is for states to update their policies and procedures, if necessary, to reflect revised regulatory text. We estimate a one-time state burden of 6 hr at \$64.46/hr for a business operations specialist to create and/or revise their policies. In aggregate, we estimate 252 hr (42 states \times 6 hr) and \$16,243.92 (252 hr \times \$64.46/hr). We are annualizing the one-time development since we do not anticipate any additional burden after the 3-year approval period expires.

Section 438.602(b) requires states to screen and enroll MCO, PIHP, PAHP, PCCM and PCCM entity providers in accordance with 42 CFR part 455, subparts B and E. Given that states already comply with these subparts for their FFS programs, the necessary processes and procedures have already been implemented. Additionally, since some states require their managed care plan providers to enroll with FFS, the overlap that occurs in many states due to provider market conditions, and the exemption from this requirement for Medicare approved providers, we believe the pool of managed care providers that will have to be newly screened and enrolled by the states is small. We expect the MCOs, PIHPs, and PAHPs will need to create data files to submit new provider applications to the state for the screening and enrollment processes. As PCCMs and PCCM entities are already FFS providers, there would be no additional burden on them or the state. As such, we estimate a one-time private sector burden of 6 hr at \$78.32/hr for a computer programmer to create the necessary programs to send provider applications/data to the state. We are annualizing the one-time development since we do not anticipate any additional burden after the 3-year approval period expires. In aggregate, we estimate 3,432 hr (335 MCOs + 176 PIHPs + 61 PAHPs \times 6 hr) and \$268,794.24 (3,432 hr \times \$78.32/hr). Once created, the report will likely be put on a production schedule and generate no additional burden.

Section 438.602(e) requires states to conduct or contract for audits of MCO, PIHP, and PAHP encounter and financial data once every 3 years. As validation of encounter data is also required in § 438.818(a), we assume no additional burden. For the financial audits, states could use internal staff or an existing contractual resource, such as their actuarial firm. For internal staff,

we estimate an annual state burden of 20 hr at \$66.38/hr for an accountant. In aggregate, we estimate 3,680 hr (335 MCOs + 176 PIHPs + 41 PAHPs × 20 hr) / 3) and \$244,278.40 (3,680 hr × \$66.38/hr).

Section 438.602(g) requires states to post the MCO's, PIHP's, and PAHP's contracts, data from § 438.604, and audits from § 438.602(e) on their Web site. As most of these activities will only occur no more frequently than annually, we estimate an annual state burden of 1 hr at \$78.32/hr for a computer programmer to post the documents. In aggregate, we estimate 40 hr (40 states × 1 hr) and \$3,132.80 (40 hr × \$78.32/hr).

37. ICRs Regarding Program Integrity Requirements (§ 438.608)

The following requirements and burden estimates were set out in the proposed rule and are being adopted without change except for the minor adjustments to hourly rates. No comments were received.

Section 438.608(a) requires that MCOs, PIHPs, and PAHPs to have administrative and management arrangements or procedures which are designed to guard against fraud and abuse. The arrangements or procedures must include a compliance program as set forth under § 438.608(a)(1), provisions for reporting under § 438.608(a)(2), provisions for notification under § 438.608(a)(3), provisions for verification methods under § 438.608(a)(4), and provisions for written policies under § 438.608(a)(5).

The compliance program under § 438.608(a)(1), must include: Written policies, procedures, and standards of conduct that articulate the organization's commitment to comply with all applicable federal and state standards and requirements under the contract; the designation of a Compliance Officer; the establishment of a Regulatory Compliance Committee on the Board of Directors; effective training and education for the organization's management and its employees; and provisions for internal monitoring and a prompt and effective response to noncompliance with the requirements under the contract.

While § 438.608(a)(1) is an existing regulation, we expect all MCOs, PIHPs, and PAHPs review their policies and procedures to ensure that all of the above listed items are addressed. We estimate a one-time private sector burden of 2 hr at \$64.46/hr for a business operations specialist to review and (if necessary) revise their policies and procedures. In aggregate, we estimate 1,104 hr (335 MCOs + 176

PIHPs + 41 PAHPs × 2 hr) and \$71,163.84 (1,104 hr × \$64.46/hr). We are annualizing the one-time development since we do not anticipate any additional burden after the 3-year approval period expires. Section 438.608(a)(2) and (3) requires the reporting of overpayments and enrollee fraud. As these would be done via an email from the MCO, PIHP, or PAHP to the state and do not occur very often, we estimate an annual private sector burden of 2 hr at \$64.46/hr for a business operations specialist. In aggregate, we estimate 1,104 hr (335 MCOs + 176 PIHPs + 41 PAHPs × 2 hr) and \$71,163.84 (1,104 hr × \$64.46/hr).

Section 438.608(a)(4) requires that the MCO, PIHP, or PAHP use a sampling methodology to verify receipt of services. Given that this is already required of all states in their FFS programs, many states already require their MCOs, PIHPs, and PAHPs to do this. Additionally, many managed care plans perform this as part of usual and customary business practice. Therefore, we estimate only approximately 200 MCOs, PIHPs, or PAHPs may need to implement this as a new procedure. As this typically involves mailing a letter or sending an email to the enrollee, we estimate that 200 MCOs, PIHPs, or PAHPs will mail to 100 enrollees each. We estimate an annual private sector burden of 1 min at \$30.92/hr for a mail clerk to send each letter. In aggregate, we estimate 333 hr (20,000 letters × 1 min/letter) and \$10,327.28 (333 hr × \$30.92/hr). This estimate will be significantly reduced as the use of email increases.

Section 438.608(b) reiterates the requirement in § 438.602(b) whereby the burden is stated in section V.C.36. of this final rule.

Section 438.608(c) and (d) requires that states include in all MCO, PIHP, and PAHP contracts, the process for the disclosure and treatment of certain types of recoveries and reporting of such activity. While the burden to amend the contracts is included in § 438.3, we estimate a one-time private sector burden of 1 hr at \$78.32/hr for a computer programmer to create the report. In aggregate, we estimate 552 hr (335 MCOs + 176 PIHPs + 41 PAHPs × 1 hr) and \$43,232.64 (552 hr × \$78.32/hr). Once developed, the report will be put on a production schedule and add no additional burden.

38. ICRs Regarding Disenrollment During Termination Hearing Process (§ 438.722)

The following requirements and burden estimates were set out in the proposed rule and are being adopted

without change except for the minor adjustments to hourly rates. No comments were received.

After a state has notified an MCO, PIHP, PAHP or PCCM of its intention to terminate its contract, § 438.722(a) provides that the state may give the entity's enrollees written notice of the state's intent to terminate its contract. States already have the authority to terminate contracts according to state law and some have previously already opted to provide written notice to MCO and PCCM enrollees when exercising this authority.

We estimate that no more than 12 states may terminate 1 contract per year. We also estimate an annual state burden of 1 hr at \$64.46/hr for a business operations specialist to prepare the notice. In aggregate, we estimate a one-time state burden of 12 hr (12 states × 1 hr) and \$773.52 (12 hr × \$64.46/hr). We are annualizing the one-time development since we do not anticipate any additional burden after the 3-year approval period expires.

To send the notice, we estimate 1 min (per beneficiary) at \$30.92/hr for a mail clerk. We estimate an aggregate annual state burden of 18,075 hr (12 states × 90,378 enrollees/60 mins per hour) and \$560,015.35 (18,075 hr × \$30.92/hr).

39. ICRs Regarding Enrollee Encounter Data (§ 438.818)

The following requirements and burden estimates were set out in the proposed rule and are being adopted without change except for the minor adjustments to hourly rates. No comments were received.

Section 438.818(a)(2) requires that the encounter data be validated prior to its submission. States can perform this validation activity themselves, contract it to a vendor, or contract it to their EQRO. In this regard, a state already using EQRO to validate its data at an appropriate frequency will incur no additional burden. Since approximately 10 states already use their EQRO to validate their data, only 27 states that use a MCO and/or PIHP may need to take action to meet this requirement. The method selected by the state will determine the amount of burden incurred. We assume an equal distribution of states selecting each method, thus 9 states per method.

A state using EQRO to validate data on less than an appropriate frequency may need to amend their EQRO contract. In this case, we estimate 1 hr at \$64.46/hr for a business operations specialist. In aggregate, we estimate a one-time state burden of 9 hr (9 states × 1 hr) and \$580.14 (9 hr × \$64.46/hr). We are annualizing the one-time

development since we do not anticipate any additional burden after the 3-year approval period expires.

A state electing to perform validation internally needs to develop processes and policies to support implementation. In this case, we estimate 10 hr at \$64.46/hr for a business operations specialist to develop policy and 100 hr at \$78.32/hr for a computer programmer to develop, test, and automate the validation processes. In aggregate, we estimate a one-time state burden of 990 hr (9 states \times 110 hr) and \$76,289.40 [9 states \times ((10 hr \times \$64.46/hr) + (100 hr \times \$78.32/hr))].

For a state electing to procure a vendor, given the wide variance in state procurement processes, our burden is conservatively estimated at 150 hr for writing a proposal request, evaluating proposals, and implementing the selected proposal. We estimate 125 hr at \$64.46/hr for a business operations specialist to participate in the writing, evaluating, and implementing, and 25 hr at \$140.80/hr for a general and operations manager to participate in the writing, evaluating, and implementing. In aggregate, we estimate an annual state burden of 1,350 hr [9 states \times (150 hr)] and \$104,197.50 [9 states \times ((125 hr \times \$64.46/hr) + (25 hr \times \$140.80/hr))].

CHIP Information Collection Requirements (ICRs): We have updated enrollment estimates based on updated information obtained from the Statistical Enrollment Data System (SEDS) from December 2015. Additionally, we revised our estimate that there are 62 plans that states use to contract with CHIP separately from their Medicaid programs as a result of discussions with states since the publication of the NPRM. As of December 2015, there are 25 states with approximately 2.3 million children enrolled in managed care in separate CHIP programs. CMS estimates that there are 62 entities that contract with CHIP separately from their Medicaid contracts, including approximately 55 MCOs and PIHPs, 3 PAHPs, and 4 PCCMs. Wage data has been updated to reflect data from the U.S. Bureau of Labor Statistics' May 2014 National Occupational Employment and Wage Estimates for all salary estimates (www.bls.gov/oes/current/oes_nat.htm).

40. ICRs Regarding Standard Contract Requirements (§§ 457.1201, 457.1205, 457.1207, 457.1208, 457.1210, 457.1212, 457.1218, 457.1220, 457.1222, 457.1224, 457.1226, 457.1228, 457.1230, 457.1233, 457.1240, 457.1250, 457.1260, 457.1270, and 457.1285)

The following requirements and burden estimates were set out in the proposed rule and are being adopted

with the following changes: As stated above, we have updated the projected enrollment of children in managed care in CHIP (to approximately 2.3 million children) with updated enrollment numbers obtained from the SEDS, as well as updated the number of states and plans with managed care upon further information gathering from states (to 62 entities that contract with CHIP separately from their Medicaid contracts, including approximately 55 MCOs and PIHPs, 3 PAHPs, and 4 PCCMs). We have also made minor adjustments to the hourly rates. No comments were received. Section 457.1201 contains a list of standard requirements that must be included in MCO, PIHP, PAHP, and PCCM contracts. The following burden estimate addresses the effort to amend such contracts in addition to the contract amendments associated with §§ 457.1203, 457.1207, 457.1208, 457.1209, 457.1210, 457.1212, 457.1218, 457.1220, 457.1222, 457.1224, 457.1226, 457.1228, 457.1230, 457.1233, 457.1240, 457.1250, 457.1260, 457.1270, and 457.1285. We estimate a one-time state burden of 6 hr at \$64.46/hr for a business operations specialist to amend all contracts associated with the aforementioned requirements. In aggregate, we estimate 372 hr (62 contracts \times 6 hr) and \$23,979.12 (372 hr \times \$64.46/hr). We are annualizing the one-time development since we do not anticipate any additional burden after the 3-year approval period expires.

41. ICRs Regarding Rate Development Standards and Medical Loss Ratio (§ 457.1203 (and Former § 457.1205))

The following requirements and burden estimates were set out in the proposed rule and are being adopted with minor revisions to account for the number of contracts and to provide for minor adjustments to hourly rates. No comments were received.

Section 457.1203 (which has been modified in this final rule to include the requirements proposed at § 457.1205) applies the requirements of § 438.8 to CHIP. Section 438.8(c) requires that MCOs, PIHPs, and PAHPs report to the state annually their total expenditures on all claims and non-claims related activities, premium revenue, the calculated MLR, and, if applicable under other authority, any remittance owed.

We estimate the total number of MLR reports that MCOs, PIHPs, and PAHPs will be required to submit to the state will amount to 58 reports. We estimate a one-time burden of 168 hr for the initial administration activities. In the first year, we estimate that 60 percent of

the time will be completed by a computer programmer (101 hr at \$78.32/hr), 30 percent will be completed by a business operations specialist (50 hr at \$64.46/hr), and 10 percent will be completed by a general and operations manager (17 hr at \$140.80/hr). The first year burden amounts to 168 hr and \$13,526.92 ((101 hr \times \$78.32) + (50 hr \times \$64.46) + (17 hr \times \$140.80)) per report or, in aggregate, 9,744 hr (58 reports \times 168 hr) and \$784,561.36 (58 \times \$13,526.92).

In subsequent years, since the programming and processes established in year 1 will continue to be used, the burden will be decrease from 168 hr to an ongoing burden of approximately 53 hr. Using the same proportions of labor allotment, we estimate 53 hr and \$4,261.73 ((31.8 hr \times \$78.32) + (15.9 hr \times \$64.46) + (5.3 hr \times \$140.80)) per report and a total of 3,074 hr (53 hr \times 58 reports) and \$247,180.34 (58 reports \times \$4,261.73). We expect states to permit MCOs and PIHPs to submit the report electronically. Since the submission time is included in our reporting estimate, we are not setting out the burden for submitting the report.

42. ICRs Regarding Non-emergency Medical Transportation PAHPs (§ 457.1206)

The following requirements and burden estimates were set out in the proposed rule and are being adopted without change except for the minor adjustments to hourly rates. No comments were received.

Section 457.1206 provides a list of standard requirements that must be included in NEMT PAHP contracts. The following burden estimate addresses the effort to amend such contracts in addition to the contract amendments associated with §§ 457.1203, 457.1207, 457.1208, 457.1209, 457.1212, 457.1214, 457.1216, 457.1220, 457.1222, 457.1224, 457.1226, 457.1230, and 457.1233. We estimate a one-time state burden of 4 hr at \$64.46/hr for a business operations specialist to amend all contracts associated with the aforementioned requirements. In aggregate, we estimate 12 hr (3 contracts \times 4 hr) and \$773.52 (12 hr \times \$64.46/hr). We are annualizing the one-time development since we do not anticipate any additional burden after the 3-year approval period expires.

43. ICRs Regarding Information Requirements (§ 457.1207)

The following requirements and burden estimates were set out in the proposed rule and are being adopted with the minor adjustments to hourly rates and a lower estimate as to the number of states affected by this

provision as we have reviewed information from the SEDS since the publication of the proposed rule and reduced the estimate as a result. No comments were received.

Section 457.1207 applies the requirements of § 438.10 to CHIP. Section 438.10(c)(1) requires that states with separate CHIPs with managed care (25) to provide enrollment notices, informational materials, and instructional materials in an easily understood format. We anticipate that most states already do this and will only have to make minor revisions. We estimate an annual burden of 4 hr at \$64.46/hr for a business operations specialist to make these revisions. In aggregate, we estimate 100 hr (25 states × 4 hr) and \$6,446 (100 hr × \$64.46/hr).

Section 438.10(c)(3) requires that states operate a Web site which provides the information set out under § 438.10(f). Since all states already have Web sites for their Medicaid programs and most also include information about their managed care program, most states will probably only have to make minor revisions to their existing Web site. We estimate a one-time state burden of 6 hr at \$78.32/hr for a computer programmer to make the initial changes. In aggregate, we estimate 150 hr (25 states × 6 hr) and \$11,748 (150 hr × \$78.32/hr). We also estimate an annual burden of 3 hr at \$78.32/hr for a computer programmer to periodically add or update documents and links on the Web site. In aggregate, we estimate 75 hr (25 states × 3 hr) and \$5,874 (75 hr × \$78.32/hr).

Section 438.10(c)(4)(i) recommends that states develop definitions for commonly used terms to enhance consistency of the information provided to enrollees. We estimate a one-time state burden of 6 hr at \$64.46/hr for a business operations specialist to develop these definitions. In aggregate, we estimate 150 hr (25 states × 6 hr) and \$9,669 (150 hr × \$64.46/hr). We are annualizing the one-time development since we do not anticipate any additional burden after the 3-year approval period expires.

Section 438.10(c)(4)(ii) recommends that states create model enrollee handbooks and notices. Since many states already provide model handbooks and notices to their entities, we estimate that 15 states may need to take action to comply with this provision. We estimate a one-time state burden of 40 hr at \$64.46/hr for a business operations specialist to create these documents. In aggregate, we estimate 600 hr (15 states × 40 hr) and \$38,676.00 (600 hr × \$64.46/hr). We also estimate an annual state burden of 2 hr at \$64.46/hr for a business operations specialist to

maintain these documents. In aggregate, we estimate 30 hr (15 states × 2 hr) and \$1,933.80 (30 hr × \$64.46/hr).

Section 438.10(d)(1) requires that states identify prevalent non-English languages spoken in each managed care entity's service area. Given that states must already determine the prevalent non-English languages spoken in their entire Medicaid service area based on the policy guidance "Enforcement of Title VI of the Civil Rights Act of 1964—National Origin Discrimination Against Persons With Limited English Proficiency" from the U.S. Department of Justice, we believe that dividing the information by plan service area requires only minimal IT programming. More specifically, we estimate a one-time state burden of 4 hr at \$78.32/hr for a computer programmer to create these reports. We are annualizing the one-time development since we do not anticipate any additional burden after the 3-year approval period expires. In aggregate, we estimate 100 hr (25 states × 4 hr) and \$7,832 (100 hr × \$78.32/hr) to create these reports. We estimate no additional burden for the running of these reports as they will be put into a production schedule, and putting a report into production adds no additional burden.

Section 438.10(d)(2)(i) requires that states add taglines to all printed materials for potential enrollees explaining the availability of translation and interpreter services as well as the phone number for choice counseling assistance. We estimate a one-time state burden of 2 hr at \$64.46/hr for a business operations specialist to create the taglines and another 4 hr to revise all document originals. In aggregate, we estimate 150 hr (25 states × 6 hr) and \$9,669 (150 hr × \$64.46/hr). As the prevalent languages within a state do not change frequently, we are not estimating burden for the rare updates that will be needed to these taglines.

Section 438.10(e)(1) clarifies that states can provide required information in paper or electronic format. As the amount and type of information that can be provided electronically will vary greatly among the states due to enrollee access and knowledge of electronic communication methods, it is not possible to estimate with any accuracy the amount that will be able to be converted from written to electronic format. Therefore, we will use estimates for all written materials knowing that some of this burden will be alleviated as the states are gradually able to convert to electronic communication methods. In this regard, we estimate a one-time state burden of 40 hr at \$64.46/hr for a business operations specialist to create

the materials. We are annualizing the one-time development since we do not anticipate any additional burden after the 3-year approval period expires. Many states already provide similar information to potential enrollees, so we anticipate that only 15 states will need to create these materials. We also estimate 1 min at \$36.54/hr for an office and administrative support worker to mail the materials annually. For existing states, we estimate 1 hr at \$64.46/hr for a business operations specialist to update or revise existing materials and 1 min at \$36.54/hr for an office and administrative support worker to mail the materials to 5 percent of the enrollees that are new (115,000 enrollees). In aggregate, we estimate a one-time state burden of 600 hr (15 states × 40 hr) and \$38,676.00 (600 hr × \$64.46/hr) to create materials. We are annualizing the one-time development since we do not anticipate any additional burden after the 3-year approval period expires. We estimate a one-time state burden of 25 hr (25 states × 1 hr) and \$1,611.50 (25 hr × \$64.46/hr) to update or revise existing materials. We are annualizing the one-time development since we do not anticipate any additional burden after the 3-year approval period expires. The state will also need to mail the materials. We estimate an ongoing burden of 1,916.67 hr (115,000 enrollees × 1 min) and \$59,263.44 (1,916.67 hr × \$36.54/hr) to mail materials.

Although § 438.10(g)(1) and (2) require the provision of an enrollee handbook, Medicaid regulations have always required the provision of this information (although it did not specifically call it a "handbook") so we do not anticipate that all entities will need to create a new handbook. Additionally, given the requirement in § 438.10(c)(4)(ii) (which is adopted in CHIP through § 457.1207) for the state to provide a model template for the handbook, the burden on an entity is greatly reduced. We estimate approximately 5 new managed care entities per year using 10 hr at \$64.46/hr for a business operations specialist to create a handbook using their state's model template. In aggregate, we estimate 50 hr (5 entities × 10 hr) and \$3,223.00 (50 hr × \$64.46/hr). For existing MCOs, PIHPs, PAHPs, and PCCMs that already have a method for distributing the information, we believe that 20 entities will need to modify their existing handbook to comply with a new model provided by the state. We also estimate a one-time private sector burden of 4 hr at \$64.46/hr for a business operations specialist to update

their entity's handbook. Once revised, we estimate 1 min at \$36.54/hr for an office and administrative support worker to send these handbooks to 1,150,000 enrollees (50 percent of total enrollment). In aggregate, we estimate 80 hr (20 entities × 4 hr) and \$5,156.80 (80 hr × \$64.46/hr) to update handbooks. To send the updated handbooks, we estimate 19,166.67 hr (1,150,000 enrollees × 1 min) and \$698,523.12 (19,166.67 hr × \$36.54/hr).

All new enrollees must receive a handbook within a reasonable time after receiving notice of the beneficiary's enrollment. We assume a 5 percent enrollee growth rate thus 115,000 enrollees (5 percent of 2,300,000) will need to receive a handbook each year. (Existing enrollees typically do not receive a new handbook annually unless significant changes have occurred so this estimate is for new beneficiaries only.) We estimate a private sector state burden of 1 min at \$36.54/hr for an office and administrative support worker to mail the handbook. In aggregate, we estimate 1,916.67 hr (115,000 enrollees × 1 min) and \$70,035.12 (1,916.67 hr × \$36.54/hr) to send handbooks to new enrollees.

All entities will need to keep their handbook up to date. In this regard, we estimate an annual private sector burden of 1 hr at \$64.46/hr for a business operations specialist to update the handbook. While the updates need to be made as program changes occur, we estimate 1 hr since each change may only take a few minutes to make. In aggregate, we estimate 62 hr (62 entities × 1 hr) and \$3,996.52 (62 hr × \$64.46/hr).

Section 438.10(h) requires that MCOs, PIHPs, PAHPs, and PCCMs make a provider directory available in paper or electronic form. Producing a provider directory is a longstanding Medicaid requirement in § 438.10, as well in the private health insurance market. Additionally, given the time sensitive nature of provider information and the notorious high error rate in printed directories, most provider information is now obtained via Web site or by calling the customer service unit. Thus, the only new burden estimated is the time for a computer programmer to add a few additional fields of data as appropriate, specifically, provider Web site addresses, additional disability accommodations, and adding behavioral and long-term services and support providers. We estimate a one-time private sector burden of 1 hr at \$78.32/hr for a computer programmer to update the existing directory. In aggregate, we estimate 62 hr (62 entities × 1 hr) and \$4,855.84 (62 hr × \$78.32/hr). Updates

after creation of the original program will be put on a production schedule, which generates no additional burden.

44. ICRs Regarding Requirements That Apply to MCO, PIHP, PAHP, and PCCM Contracts Involving Indians, Indian Health Care Providers, and Indian Managed Care Entities (§ 457.1209)

The following requirements and burden estimates were set out in the proposed rule and are being adopted with revisions to reduce the estimate of states affected, as well as minor revisions to reflect updated wage data. No comments were received.

Section 457.1209 (incorrectly listed as § 457.1208 in the proposed rule) applies the requirements of § 438.14 to CHIP. Section 438.14(c) requires states to make supplemental payments to Indian providers if the managed care entity does not pay at least the amount paid to Indian providers under the FFS program. There are approximately 18 states with separate CHIPs that have federally recognized tribes. We do not know how many managed care entities have Indian providers, but estimate that it is approximately 40 entities. This type of payment arrangement typically involves the managed care entity sending a report to the state, which then calculates and pays the amount owed to the Indian health care provider. We estimate it will take 1 hr at \$78.32/hr for a computer programmer to create the claims report and approximately 12 hr at \$64.46/hr for a state business operations specialist to process the payments. We estimate that approximately 18 states will need to use this type of arrangement. In aggregate, we estimate a one-time private sector burden of 40 hr (40 entities × 1 hr) and \$3,132.80 (40 hr × \$78.32/hr). We are annualizing the one-time development since we do not anticipate any additional burden after the 3-year approval period expires. We also estimate an ongoing state burden of 216 hr (18 states × 12 hr) and \$13,923.36 (216 hr × \$64.46/hr).

After the MCO, PIHP, PAHP, and PCCM report is created, it will most likely run automatically at designated times and sent electronically to the state as the normal course of business operations; therefore, no additional burden is estimated after the first year.

(Note: This process is not necessary when the MCO, PIHP, PAHP, or PCCM entity pays the IHCP at least the full amount owed under this regulation.)

45. ICRs Regarding Managed Care Enrollment (§ 457.1210)

This burden estimate has been revised because of the additions to the

regulation in § 457.1210(c), which are discussed in section II.B.9.

Section 457.1210(a) requires states to establish a process for prioritizing individuals for enrollment into managed care plans. Establishing a default enrollment process requires policy changes and require the state to send notices to enrollees once they have been enrolled in a plan. We estimate that states will need to use the default enrollment process specified in § 457.1210(a) for 5 percent of enrollees (115,000), and that it will take 1 min at \$36.54/hr for an office and administrative support worker to send the notice. In aggregate, we estimate 1,916.67 hr (115,000 beneficiaries × 1 min) and \$70,035.12 (1,916.67 hr × \$36.54/hr) to send the notices.

Section 457.1210(c) requires states to send a notice to potential enrollees. We believe some states already send such notices, so that only 15 states will have to develop new notices. We estimate that it will take 4 hr at \$64.46/hr for a business operations specialist to create the notice. We estimate a one-time burden of 60 hr (4 hr × 15 states) and \$3,867.60 (60 hr × \$64.46) to develop the notice. We are annualizing the one-time development since we do not anticipate any additional burden after the 3-year approval period expires.

In addition, we estimate that states would need to send notices to 5 percent of enrollees (115,000) who would be new to managed care each year. We estimate it would take 1 min/enrollee 1 min at \$36.54/hr for an office and administrative support worker to mail each notice. We estimate a total annual burden of 1,916.67 hr (115,000 beneficiaries × 1 min) and \$70,035.12 (1,916.67 hr × \$36.54/hr) to send the notices.

46. ICRs Regarding Disenrollment (§ 457.1212)

The following requirements and burden estimates were set out in the proposed rule and are being adopted with minor revisions to reflect updated wage data. No comments were received.

Section 457.1212 applies the requirements of § 438.56 to CHIP. To disenroll, § 438.56(d)(1) requires that the beneficiary (or his or her representative) submit an oral or written request to the state agency (or its agent) or to the MCO, PIHP, PAHP, or PCCM, where permitted. We estimate that 5 percent of MCO, PIHP, PAHP, and PCCM enrollees will request that they be disenrolled from an MCO, PIHP, PAHP, or PCCM each year. We also estimate approximately one-fourth of the enrollees will choose a written rather than an oral request.

We estimate an ongoing burden of 10 min for an enrollee to generate a written disenrollment request and 3 min per oral request. In aggregate, we estimate an annual burden (written requests) of 4,791.67 hr (28,750 enrollees × 10 min) and 4,312.5 hr (86,250 enrollees × 3 min) for oral requests.

47. ICRs Regarding Conflict of Interest Safeguards (§ 457.1214)

The following requirements and burden estimates were set out in the proposed rule and are being adopted with minor revisions to reflect updated wage data. No comments were received.

Section 457.1214 applies the requirements of § 438.58 to CHIP. Section 438.58 requires that states have in place safeguards against conflict of interest for employees or agents of the state who have responsibilities relating to the MCO, PIHP, or PAHP. We anticipate that most states already have such safeguards in place, and only 5 states will need to develop new standards to comply with this provision. We estimate a one-time state burden of 10 hr at \$64.46/hr for a business operations specialist to develop those standards. In aggregate, we estimate 50 hr (5 states × 10 hr) and \$3,223.00 (50 hr × \$64.46/hr). We are annualizing the one-time development since we do not anticipate any additional burden after the 3-year approval period expires.

48. ICRs Regarding Continued Services to Beneficiaries (§ 457.1216)

The following requirements and burden estimates were set out in the proposed rule and are being adopted with revisions to reduce the estimate of states affected, as well as minor revisions to reflect updated wage data. No comments were received.

Section 457.1216 applies the requirements of § 438.62 to CHIP. Section 438.62(b)(1) requires that states have a transition of care policy for all beneficiaries moving from FFS CHIP into a MCO, PIHP, PAHP or PCCM, or when an enrollee is moving from one MCO, PIHP, PAHP, or PCCM to another and that enrollee would experience a serious detriment to health or be at risk of hospitalization or institutionalization without continued access to services. We estimate a one-time state burden of 10 hr at \$64.46/hr for a business operations specialist to develop the transition of care policy. In aggregate, we estimate 250 hr (25 states × 10 hr) and \$16,115 (250 hr × \$64.46/hr). We are annualizing the one-time development since we do not anticipate any additional burden after the 3-year approval period expires.

Section 438.62(b)(2) requires that MCOs, PIHPs, PAHPs, or PCCMs implement their own transition of care policy that meets the requirements of § 438.62(b)(1). We estimate it will take 4 hr at \$78.32/hr for a computer programmer to create the program that gathers and sends the FFS data to the MCOs, PIHPs, PAHPs, or PCCMs. We also estimate each MCO, PIHP, PAHP, or PCCM will use 4 hr of a computer programmer time to create programs to receive and store data as well as gather and send data to other plans. We are not estimating additional ongoing burden for the routine running of these reports as they will be put into a production schedule. In aggregate, we estimate a one-time state burden of 100 hr (25 states × 4 hr) and \$7,832 (100 hr × \$78.32/hr) to create the program that gathers and sends the FFS data to the MCOs, PIHPs, PAHPs, or PCCMs. We are annualizing the one-time development since we do not anticipate any additional burden after the 3-year approval period expires. We also estimate a one-time private sector burden of 248 hr (62 MCOs, PIHPs, PAHPs, or PCCMs × 4 hr) and \$19,423.36 (248 hr × \$78.32/hr) to create programs to receive and store data as well as gather and send data to other plans. We are annualizing the one-time development since we do not anticipate any additional burden after the 3-year approval period expires.

Once a MCO, PIHP, PAHP, or PCCM receives a request or identifies a need to arrange for the transition of services, we estimate a registered nurse at the managed care plan may need 10 min, on average, to access the stored information and take appropriate action. We believe that an average of 25,000 beneficiaries will transition into managed care each year from FFS and 5,000 may switch between plans that meet the state defined standards to qualify for the transition of care policy. In aggregate, we estimate an annual for private sector burden of 5,000 hr (30,000 beneficiaries × 10 min) and \$334,600.00 (5,000 hr × \$66.92/hr).

49. ICRs Regarding Network Adequacy Standards (§ 457.1218)

The following requirements and burden estimates were set out in the proposed rule and are being adopted with minor revisions to reflect updated wage data. No comments were received.

Section 457.1218 applies the requirements of § 438.68 to CHIP. Section 438.68(a) requires that states set network adequacy standards that each MCO, PIHP and PAHP must follow. Section 438.68(b) and (c) require that states set standards that must include

time and distance standards for specific provider types and network standards for LTSS (if the MCO, PIHP or PAHP has those benefits covered through their contract).

We believe some states already comply with these requirements and that only 12 states will need to develop the standards. We estimate a one-time first year burden of 15 hr at \$64.46/hr for a business operations specialist to develop network standards meeting the specific provider types found in § 438.68(b)(1). In aggregate, we estimate 180 hr (12 states × 15 hr) and \$11,602.80 (180 hr × \$64.46/hr). We are annualizing the one-time development since we do not anticipate any additional burden after the 3-year approval period expires.

Very few states include LTSS in CHIP, therefore we estimate only 5 states will need to develop related standards. We estimate a one-time burden of 10 additional hr at \$64.46/hr for a business operations specialist to develop those standards. In aggregate, we estimate 50 hr (5 states × 10 hr) and \$3,223.00 (50 hr × \$64.46/hr) for the development of LTSS standards. After network standards are established, we estimate that the maintenance of the network standards will be part of usual and customary business practices and therefore, we do not estimate any burden for states after the first year.

Section 438.68(d) requires that states: (1) Develop an exceptions process for plans unable to meet the state's standards; and (2) review network performance for any MCO, PIHP or PAHP to which the state provides an exception. We estimate a one-time state burden of 3 hr at \$64.46/hr for a business operations specialist to establish an exceptions process. In aggregate, we estimate 75 hr (25 states × 3 hr) and \$4,834.50 (75 hr × \$64.46/hr). We are annualizing the one-time development since we do not anticipate any additional burden after the 3-year approval period expires.

The exception process should not be used very often as MCOs, PIHPs, and PAHPs meeting the established standards is critical to enrollee access to care. As such, after the exceptions process is established, we estimate that the occasional use of it will not generate any measurable burden after the first year.

50. ICRs Regarding Enrollee Rights (§ 457.1220)

The following requirements and burden estimates were set out in the proposed rule and are being adopted with minor revisions to reflect updated wage data. No comments were received.

Section 457.1220 applies the requirements of § 438.100 to CHIP. We do not anticipate a burden associated with implementing this section because the requirements to provide enrollees with treatment options and alternatives, allow enrollees to participate in decisions regarding health care, ensure that enrollees are free from restraint or seclusion, are standard practice in the field. The burden associated with providing information in accordance with 45 CFR 164.524 and 164.526 is accounted for in the collection of information associated with those regulations. The burden associated with modifying contracts to comply with this regulation are accounted for under § 457.1202.

51. ICRs Regarding Provider-Enrollee Communication (§ 457.1222)

The following requirements and burden estimates were set out in the proposed rule and are being adopted with minor revisions to update the wage data. No comments were received.

Section 457.1222 applies the requirements of § 438.102 to CHIP. Section 438.102(a)(2) provides that MCOs, PIHPs, and PAHPs are not required to cover, furnish, or pay for a particular counseling or referral service if the MCO, PIHP, or PAHP objects to the provision of that service on moral or religious grounds and that written information on these policies is available to: (1) Prospective enrollees, before and during enrollment; and (2) current enrollees, within 90 days after adopting the policy for any particular service.

We believe the burden for providing written notice to current enrollees within 90 days of adopting the policy for a specific service, will affect no more than 3 MCOs or PIHPs annually since it will apply only to the services they discontinue providing on moral or religious grounds during the contract period. PAHPs are excluded from this estimate because they generally do not provide services that are affected by this provision.

We estimate that each of the 3 MCOs or PIHPs will have such a policy change only once annually. We estimate that it will take 1 hr at \$64.46/hr for a business operations analyst to update the policies. In aggregate, we estimate 3 hr (3 MCOs/PIHPs × 1 hr) and \$193.38 (3 hr × \$64.46/hr). We further estimate that it will take 4 hr at \$64.46/hr for a business operations specialist to create the notice and 1 min at \$36.54/hr for an office and administrative support worker to mail each notice. With an average MCO/PIHP enrollment of 78,000 enrollees, we estimate a total annual

burden of 12 hr (3 MCOs/PIHPs × 4 hr/notice) and \$773.52 (12 hr × \$64.46/hr) to create the notice. To mail the notice we estimate 3,900 hr (3 MCOs/PIHPs × 78,000 enrollees × 1 min/notice) and \$142,506.00 (3,900 hr × \$36.54/hr).

52. ICRs Regarding Marketing Activities (§ 457.1224)

The following requirements and burden estimates were set out in the proposed rule and are being adopted with minor revisions to update the wage data. No comments were received.

Section 457.1224 applies the requirements of § 438.104 to CHIP. Section 438.104(c) requires that the state review marketing materials submitted by managed care entities. We believe that each entity will revise its materials once every 3 years. We estimate a state burden of 3 hr at \$64.46/hr for a business operations specialist to review an entity's materials. In aggregate, we estimate an annual state burden of 75 hr [3 hr × 25 entities (one third of the total entities)] and \$4,834.50 (75 hr × \$64.46/hr).

We estimate that 5 entities may need to revise and submit updated materials. We estimate a private sector burden of 2 hr at \$64.46/hr for a business operations specialist to update and submit the materials. In aggregate, we estimate a one-time burden of 10 hr (5 entities × 2 hr) and \$644.60 (10 hr × \$64.46).

53. ICRs Regarding Access Standards (§ 457.1230)

The following requirements and burden estimates were set out in the proposed rule and are being adopted with revisions to the wage data and updated estimates on the number of plans. No comments were received.

Section 457.1230 applies the requirements of §§ 438.206, 438.207, 438.208, and 438.210 to CHIP. Section 438.206(c)(3), adopted in CHIP through § 457.1230(a), requires that MCOs, PIHPs, and PAHPs ensure that providers assure access, accommodations, and equipment for enrollees with physical and/or mental disabilities. We believe that MCOs, PIHPs, and PAHPs will need to review and revise (possibly) their policies and procedures for network management to ensure compliance with this requirement.

We estimate a one-time private sector burden of 3 hr at \$64.46/hr for a business operations specialist to review and revise their network management policies and procedures. In aggregate, we estimate 174 hr (58 MCO/PIHP/PAHPs × 3 hr) and \$11,216.04 (174 hr × \$64.46/hr). We are annualizing the one-time development since we do not

anticipate any additional burden after the 3-year approval period expires.

Section 438.207(b), adopted in CHIP through § 457.1230(b) would require that each MCO, PIHP, and PAHP (where applicable) submit documentation to the state, in a format specified by the state, to demonstrate that it: (1) Complies with specified requirements, and (2) has the capacity to serve the expected enrollment in its service area in accordance with the state's standards for access to care. Section 438.207(c) would require that the documentation be submitted to the state at least annually, at the time the MCO, PIHP, or PAHP enters into a contract with the state, and at any time there has been a significant change (as defined both by the state) in the MCO, PIHP, or PAHP's operations that would affect adequate capacity and services.

We estimate an annual private sector burden of 20 hr at \$64.46/hr for a business operations specialist to compile the information necessary to meet this requirement. In aggregate, we estimate 1,160 hr (58 entities × 20 hr) and \$74,773.60 (1,160 hr × \$64.46/hr).

After reviewing the documentation, § 438.207(d), adopted in CHIP through § 457.1230(b), would require that the state certify (to CMS) that the entity has complied with the state's requirements regarding the availability of services, as set forth at § 438.68. We estimate an annual state burden of 1 hr/contract at \$64.46/hr for a business operations specialist to review documentation and submit the certification to CMS. In aggregate, we estimate 58 hr (58 entities × 1 hr) and \$3,738.68 (59 hr × \$64.46/hr).

Section 438.208(b)(2)(iii) through § 457.1230(c), requires that MCOs, PIHPs and PAHPs coordinate service delivery with the services the enrollee receives in the FFS program (carved out services). This would involve using data from the state to perform the needed coordination activities. Since only a small percentage of enrollees receive carved out services and need assistance with coordination, we estimate 2 percent of all MCO, PIHP, and PAHP enrollees (64,000) will be affected.

We estimate an annual private sector burden of 10 min/enrollee at \$51.54/hr for a healthcare social worker. In aggregate, we estimate 10,666 hr (64,000 enrollees × 10 min) and \$589,440 (10,666 hr × \$55.26/hr).

Section 438.208(b)(3), adopted in CHIP through § 457.1230(c), would require that an MCO, PIHP or PAHP make its best effort to conduct an initial assessment of each new enrollee's needs within 90 days of the enrollment. We believe that most MCOs and PIHPs

already meet this requirement and only 25 percent of the MCOs and PIHPs (14) would need to alter their processes; however, we do not believe this to be as common a practice among PAHPs and assume that all 3 PAHPs will be need to add this assessment to their initial enrollment functions. We estimate a one-time private sector burden of 3 hr at \$64.46/hr for a business operations specialist to revise their policies and procedures. In aggregate, we estimate 51 hr [(14 MCOs and PIHPs + 3 PAHPs) × 3 hr] and \$3,287.46 (51 hr × \$64.46/hr). We are annualizing the one-time development since we do not anticipate any additional burden after the 3-year approval period expires.

We estimate that in a given year, approximately 10 percent of all enrollees are new to a managed care plan. Thus, 230,000 enrollees would be considered new and in need of an initial assessment. As PAHPs are typically a single entity within the state, we estimate that only 5 percent of their enrollees (10,000 enrollees) would need an initial assessment. In general, we believe these assessments will take 10 min on average to complete by Call Center staff at \$36.54/hr. In aggregate, we estimate an annual private sector burden of 38,333 hr (230,000 enrollees × 10 min) and \$1,400,700 (38,333 hr × \$36.54/hr).

Section 438.208(b)(4), adopted in CHIP through § 457.1230(c), requires that MCOs, PIHPs, and PAHPs share with other MCOs, PIHPs, and PAHPs serving the enrollee the results of its identification and assessment of any enrollee with special health care needs so that those activities need not be duplicated. The burden associated with this requirement is the time it takes each MCO, PIHP or PAHP to disclose information on enrollees with special health care needs to the MCO, PIHP or PAHP providing a carved out service. This would most likely be accomplished by developing a report to collect the data and sending that report to the other MCO, PIHP, or PAHP.

We estimate a one-time private sector burden of 4 hr at \$78.32/hr for a computer programmer to develop the report. In aggregate, we estimate of 232 hr (58 MCOs, PIHP, and PAHPs × 4 hr) and \$18,170.24 (232 hr × \$78.32/hr). We are annualizing the one-time development since we do not anticipate any additional burden after the 3-year approval period expires. Once put into production on a schedule, no additional staff time would be needed, thus no additional burden is estimated.

Section 438.208(c)(2) and (3), adopted in CHIP through § 457.1230(c), requires that the MCOs, PIHPs and PAHPs

complete a comprehensive assessment and treatment plan for all enrollees that have special health care needs. The assessments and treatment plans should be completed by providers or MCO, PIHP or PAHP staff that meet the qualifications specified by the state. We believe the burden associated with this requirement is the time it takes to gather the information during the assessment. (Treatment plans are generally developed while the assessment occurs so we are not estimating any additional time beyond the time of the assessment.) We believe that only enrollees in MCOs and PIHPs will require this level of assessment as most PAHPs provide limited benefit packages that do not typically warrant a separate treatment plan.

We estimate that 1 percent of the total enrollment of 2,300,000 (23,000) are enrolled in either a MCO, PIHP or both, and would qualify as an individual with special health care needs. The time needed for the assessment and for treatment planning will, on average, take 1 hr at \$66.92/hr for a registered nurse to complete. In aggregate, we estimate an annual private sector burden of 23,000 hr (23,000 enrollees × 1 hr) and \$1,539,160 (23,000 hr × \$66.92/hr). Section 438.210(c), adopted in CHIP through § 457.1230(d), requires that each contract provide that the MCO, PIHP, or PAHP notify the requesting provider, and give the enrollee written notice of any decision by the MCO, PIHP, or PAHP to deny a service authorization request, or to authorize a service in an amount, duration, or scope that is less than requested.

We estimate an annual private sector burden of 30 min at \$66.92/hr for a registered nurse to generate the notice. We estimate that each of 58 MCOs, PIHPs and PAHPs will process 20 denials/service reductions per 1,000 members. This is our best estimate based on the data available in the SEDS, conversations with states and observations of trends in Medicaid and the commercial market. With average enrollment of 78,000, each entity is estimated to process a total of 1,560 denials and service reductions annually. In aggregate, we estimate 45,240 hr (58 entities × 1,560 denials or service reductions/entity × 30 min) and \$3,027,460.80 (45,240 hr × \$66.92/hr).

54. ICRs Regarding Structure and Operation Standards (§ 457.1233)

The following requirements and burden estimates were set out in the proposed rule and are being adopted with revisions to update the wage data and amend the estimates on the number

of plans affected. No comments were received. Although we added paragraph § 457.1233(d) in response to comments (as discussed in section II.B.20), it references an existing CHIP requirement, and will not create additional burden.

Section 457.1233 applies the requirements of §§ 438.214, 438.230, 438.236, and 438.242 to CHIP. Section 438.214 requires that MCOs, PIHPs, and PAHPs have policies for the selection and retention of providers. As described in section V.C.54. of this final rule, we believe that the requirements in § 438.214 are part of the usual course of business and will not add additional burden onto entities because the entities will have policies for selecting and retaining providers even in the absence of these regulations.

Section 438.230, adopted in CHIP through § 457.1233(b), requires that MCOs, PIHPs, and PAHPs oversee subcontractors and specifies the subcontracted activities. We estimate 3 hr at \$64.46/hr for a business operations analyst to amend appropriate contracts. We estimate a one-time private sector burden of 174 hr (58 MCOs, PIHPs, and PAHPs × 3 hr) and \$11,216.04 (174 hr × \$64.46). We are annualizing the one-time development since we do not anticipate any additional burden after the 3-year approval period expires.

Section 438.236(c), adopted in CHIP through § 457.1233(c), requires that each MCO, PIHP, and PAHP disseminate guidelines to its affected providers and, upon request, to enrollees and potential enrollees. The burden associated with this requirement is the time required to disseminate the guidelines, usually by posting on their Web site. This is typically done annually. We estimate an annual private sector burden of 2 hr at \$64.46/hr for a business operations specialist. In aggregate, we estimate 116 hr (58 entities × 2 hr) and \$7,477.36 (116 hr × \$64.46/hr). In § 438.242(b)(2), adopted in CHIP through § 457.1233(b), the state is required to stipulate that each MCO and PIHP collect data on enrollee and provider characteristics (as specified by the state) and on services furnished to enrollees (through an encounter data system or other such methods as may be specified by the state). We estimate a one-time private sector burden of 20 hr at \$78.32/hr for a computer programmer to extract this data from an entity's system and report to the state. In aggregate, we estimate 1,100 hr (55 entities × 20 hr) and \$86,152 (1,100 hr × \$78.32/hr). We are annualizing the one-time development since we do not anticipate any additional burden after the 3-year approval period expires. After the initial

creation, the reports will be set to run and sent to the state at specified times as part of a production schedule.

55. ICRs Regarding Quality Measurement and Improvement (§ 457.1240)

No comments were received on the burden estimates in the proposed rule. However, we are revising the burden estimates in response to the changes to the regulation discussed in II.B.21.

Section 457.1240 applies the requirements of §§ 438.330, 438.332, 438.334, and 438.340 to CHIP. Section 438.330(a)(2), adopted in CHIP through § 457.1240(b), specifies the process CMS will use if it elects to specify national QAPI and PIP topics, which will include a public notice and comment process. Assuming that we do use this process to identify performance measures and PIP topics at least once every 3 years, the burden for states will be altered. Some may experience a decrease in the time spent selecting performance measures and PIP topics while others might experience a slight increase in the form of programming their MMIS systems to account for the specified performance measures and PIP topics.

We estimate that MMIS programming changes requires 10 hr (every 3 years) at \$78.32/hr for a computer programmer. In aggregate, we estimate an ongoing annualized state burden of 83 hr [(25 states × 10 hr)/3 years] and \$6,500.56 (83 hr × 78.32/hr). We cannot estimate the amount of possible decrease in burden as we have no way to know the average amount of time a state expended on selecting performance measures or PIP topics and how this might change based on this revision. Section 438.330(a)(2)(i) allows states to apply for an exemption from the CMS-required performance measure and PIP topic requirements established under § 438.330(a)(2). While we have no data on how many states would take advantage of this option, given that the performance measures and PIP topics under § 438.330(a)(2) would be identified through a public notice and comment process, we estimate that 2 states would ask for an exemption every 3 years. We estimate that the exemption process would require 1 hr at \$64.46/hr for a business operations specialist. In aggregate, we estimate an ongoing annualized state burden of 0.67 hr [(2 states × 1 hr)/3 years] and \$42.54 (0.67 hr × \$64.46/hr).

Section 438.330(a)(2)(ii), adopted in CHIP through § 457.1240(b), allows states to select performance measures and PIPs in addition to those specified by CMS under § 438.330(a)(2). Since

this language continues the flexibility available to states today, we do not believe this creates any change in burden for states or the private sector.

Section 438.330(b)(3) clarifies that MCOs, PIHPs, and PAHPs must have an approach to evaluate and address findings regarding the underutilization and overutilization of services. Because utilization review in managed care has become commonplace in the private, Medicare, and Medicaid settings, we do not believe that this regulatory provision imposes any new burden on MCOs, PIHPs, or PAHPs.

In accordance with § 438.310(c)(2), some PCCM entities (we estimate 3) will now be subject to the requirements of § 438.330(b)(3). We estimate a one-time private sector burden of 10 hr at \$64.46/hr for a business operations specialist to establish the policies and procedures. In aggregate, we estimate 30 hr (3 PCCMs × 10 hr) and \$1,933.80 (30 hr × \$64.46/hr). We are annualizing the one-time development since we do not anticipate any additional burden after the 3-year approval period expires. We also estimate an ongoing burden of 10 hr to evaluate and address the findings. In aggregate, we estimate an annual burden of 30 hr (3 PCCMs × 10 hr) and \$1,933.80 (30 hr × \$64.46/hr) for program maintenance.

Section 438.330(c) addresses QAPI performance measurement. Section 438.330(c)(1), adopted in CHIP through § 457.1240(b), requires the state to identify standard performance measures for their managed care plans, including LTSS measures if appropriate. We believe that it is standard practice for states to identify performance measures for their contracted managed care plans; therefore there is no burden associated with this paragraph.

Section 438.310(c)(2), adopted in CHIP through § 457.1240(b), requires each MCO, PIHP, PAHP, and PCCM entity (described in § 438.310(c)(2)) to annually measure its performance using the standard measures specified by the state in paragraph (c)(1) and to report on its performance to the state. We assume that each of the MCOs and PIHPs would report on three performance measures to the state. The use of performance measures is commonplace in private, Medicare, and Medicaid managed care markets; therefore we believe that MCOs and PIHPs already collect performance measures.

We recognize that PAHPs and PCCM entities (described in § 438.310(c)(2)) may not currently engage in performance measurement as described in § 438.330(c)(2), and estimate that 7 entities might be impacted. We estimate that, in any given year, each PCCM

entity and each PAHP would report to the state on 3 performance measures. We estimate an annual private sector burden of 4 hr per measure at \$64.46/hr for a business operations specialist to prepare a report for each performance measure. In aggregate, we estimate 84 hr [(3 PAHPs + 4 PCCMs) × 3 performance measures × 4 hr] and \$5,414.64 (84 hr × \$64.46/hr).

Section 438.330(c)(1)(ii) requires states to identify standard performance measures in two LTSS-specific categories for managed care plans that provide LTSS. We do not know of any states that have an LTSS plan in CHIP, so there is no burden associated with the proposed provision.

In § 438.330(d), adopted in CHIP through § 457.1240(b), states must ensure that each MCO, PIHP and PAHP have an ongoing program of PIPs, designed to achieve sustainable improvement, which the managed care plan will report on to the state as requested, but at least once per year. We assume that each MCO and PIHP will conduct at least 3 PIPs and each of the 3 PAHPs would conduct at least 1 PIP. We further expect that states will request the status and results of each entity's PIPs annually. Given that PAHPs may not currently conduct PIPs, we estimate a one-time private sector burden of 2 hr at \$64.46/hr for a business operations specialist to develop policies and procedures, for an aggregate burden of 6 hr (3 PAHPs × 2 hr) and \$386.76 (6 hr × 64.46/hr). We are annualizing the one-time development since we do not anticipate any additional burden after the 3-year approval period expires. We estimate an annual burden of 8 hr to prepare a report on each PIP. In aggregate, we estimate 1,344hr [(55 MCOs and PIHPs × 3 PIPs) + (3 PAHPs × 1 PIP)] × 8 hr] and \$86,634.24 (1,344hr × \$64.46/hr) to prepare the report.

Per § 438.310(c)(2), PCCM entities specified are also subject to the requirements in § 438.330(e) through § 457.1240(b). We estimate an annual state burden of 15 hr at \$64.46/hr for a business operations specialist to assess the performance of a single § 438.3(r) PCCM entity. In aggregate, we estimate 45 hours (3 PCCM entities × 15 hr) and \$2,900.70 (45 hr × \$64.46/hr).

Section 438.330(e)(1)(ii), adopted in CHIP through § 457.1240(b), requires that states include outcomes and trended results of each MCO, PIHP, and PAHP's PIPs in the state's annual review of QAPI programs. We estimate a one-time state burden of 0.5 hr at \$64.46/hr for a business operations specialist to modify the state's policies and procedures. We are annualizing the one-

time development since we do not anticipate any additional burden after the 3-year approval period expires. In aggregate, we estimate 12.5 hr (25 states \times 0.5 hr) and \$805.75 (12.5 hr \times 64.46/hr). We also estimate an annual burden of 1 hr for the additional review. In aggregate, we estimate 25 hr (25 states \times 1 hr) and \$1,611.5 (25 hr \times \$64.46/hr).

Section 438.330(e)(1)(iii) sets out a new requirement, related to § 438.330(b)(5), requiring that the state must assess the rebalancing effort results for LTSS in its annual review. We do not know of any states that have an LTSS plan in CHIP, so there is no burden associated with the proposed provision.

Under § 438.332(a), adopted in CHIP through § 457.1240(c), states must confirm the accreditation status of contracted MCOs, PIHPs, and PAHPs once a year. We estimate an annual state burden of 0.25 hr at \$64.46/hr for a business operations specialist to review the accreditation status of each of the estimated 58 MCOs, PIHPs, and PAHPs. In aggregate, we estimate an annual burden of 14.5 hr (0.25 hr \times 58 MCOs, PIHPs, and PAHPs) and \$934.67 (14.5 hr \times \$64.46/hr).

Section 438.332(b), adopted in CHIP through § 457.1240(c), describes the information MCOs, PIHPs, and PAHPs must authorize the private accrediting entity to release to the state regarding the plan's accreditation status. We believe that states will need to amend their MCO, PIHP, and PAHP contracts to reflect this requirement, and estimate a one-time burden of 0.25 hr per contract amendment. In aggregate, we estimate a one-time burden of 15.5 hr (0.25 hr \times 58 MCOs, PIHPs, and PAHPs) and \$934.67 (14.5 hr \times 64.46/hr). We are annualizing the one-time development since we do not anticipate any additional burden after the 3-year approval period expires.

Under § 438.332(c), adopted in CHIP through § 457.1240(c), states will document the accreditation status of each contracted MCO, PIHP, and PAHP on the state's Web site, and will update this information at least annually. The burden is included in § 457.1207.

Section 438.334, adopted in CHIP through § 457.1240(d), requires each state that contracts with an MCO, PIHP, or PAHP to adopt a quality ratings system to generate plan ratings annually. States must either adopt the quality rating system developed by CMS in accordance with § 438.334(b) or an alternative quality rating system in accordance with § 438.334(c).

We assume that states will utilize the same system and processes developed for CHIP managed care plans as was developed for Medicaid managed care

plans. Using the assumptions developed for § 438.332, we estimate that 17 states (with 46 MCOs, PIHPs, and PAHPs) will elect to adopt the quality rating system developed by CMS in accordance with § 438.334(b), while the remainder (8 states with 16 MCOs, PIHPs, and PAHPs) will elect to use an alternative quality rating system in accordance with § 438.334(c). We assume that, given the robust public engagement process CMS will use to develop the QRS in accordance with § 438.334(b), states electing to adopt the CMS-developed QRS will not need to conduct additional public engagement and will require less time to develop their QRS as compared to states which elect to adopt an alternative QRS consistent with § 438.334(c).

Therefore, for states adopting the CMS-developed QRS under § 438.334(b), we estimate the state burden for the development and implementation of the QRS as 200 hr at \$64.46/hr for a business operations specialist, 100 hr at \$78.32/hr for a computer programmer, and 30 hr at \$140.80/hr for a general and operations manager. In aggregate, we estimate a one-time state burden of 5,610 hr (17 states \times 330 hr) and \$424,116 [17 states \times ((200 hr \times \$64.46/hr) + (100 hr \times \$78.32/hr) + (30 hr \times \$140.80/hr))] for the development of a state's quality rating system consistent with 438.334(b). We are annualizing the one-time development since we do not anticipate any additional burden after the 3-year approval period expires.

The burden is more variable for states seeking CMS approval for the adoption of an alternative QRS per § 438.334(c). A state may submit an existing QRS, may submit a modified version of an existing QRS, or may develop a new QRS. We assume that the burden for each of these options would vary by state; therefore, we estimate an average burden for the development of an alternative QRS. We believe that the average alternative QRS burden will exceed the burden to adopt the CMS-developed QRS, and will require public engagement by the state. Therefore, we estimate the average state burden for the development and implementation of an alternative QRS as 800 hr at \$64.46/hr for a business operations specialist, 400 hr at \$78.32/hr for a computer programmer, and 120 hr at \$140.80/hr for a general and operations manager. We estimate an additional 20 hr at \$36.54/hr for an office and administrative support worker for the public engagement process and an additional 50 hr at \$64.46/hr for a business operations specialist to review and incorporate public feedback. In

aggregate, we estimate a one-time state burden of 11,120 hr (8 states \times 1,390 hr) and \$829,966.40 [8 states \times ((800 hr \times \$64.46/hr) + (400 hr \times \$78.32/hr) + (120 hr \times \$140.80/hr) + (20 hr \times \$36.54/hr) + (50 hr \times \$64.46/hr))] for the development of a state's alternative quality rating system consistent with § 438.334(c). We are annualizing the one-time development since we do not anticipate any additional burden after the 3-year approval period expires.

To elect the option under § 438.334(c) to use an alternative QRS, a state will submit a request to CMS and must receive written CMS approval. We estimate a one-time state burden of 20 hr at \$64.46/hr for a business operations specialist to seek and receive approval from CMS for the state's alternative quality rating system. In aggregate, we estimate 160 hr (8 states \times 20 hr) and \$10,313.60 (160 hr \times \$64.46/hr). We are annualizing the one-time development since we do not anticipate any additional burden after the 3-year approval period expires.

Section 438.334(c)(3) outlines the process for a state to make changes to an approved alternative QRS. We estimate that it will require 5 hr at \$36.54/hr for an office and administrative support worker and 25 hr at \$64.46/hr for a business operations specialist to complete the public comment process, and an additional 5 hr at \$64.46/hr from a business operations specialist to seek and receive approval from CMS for the change. While we have no data to estimate how frequently a state may elect to alter an approved alternative QRS, we estimate that CMS will revise the QRS under § 438.334(b) on average approximately once every 3 years. We assume that states will revise their alternative QRS on a similar frequency to ensure that the alternative QRS continues to yield substantially comparable information regarding MCO, PIHP, and PAHP performance, and apply this assumption here. Therefore, we estimate an aggregate annualized burden of 93 hr [(8 states \times 35 hr)/3 years] and \$5,644 [(8 states \times (5 hr \times \$36.54/hr) + (30 \times \$64.46/hr))/3 years]. Under § 438.334(d), each state will collect information from its MCOs, PIHPs, and PAHPs to calculate and then issue a quality rating each year. We expect that states will rely on information and data already provided to them by their MCOs, PIHPs, and PAHPs; therefore, we do not expect this data collection to pose an additional burden on the private sector. However, each year states will rate each MCO, PIHP, or PAHP with which they contract. We estimate 40 hr at \$64.46/hr for a business operations specialist

for a state to rate a MCO, PIHP, or PAHP. We believe this burden will be similar for states regardless of if they adopt the CMS-developed QRS consistent with § 438.334(b) or the alternative QRS consistent with § 438.334(c). In aggregate, we estimate an annual state burden of 2,320 hr (58 MCOs, PIHPs, and PAHPs × 40 hr) and \$149,547.20 (2,320 hr × \$64.46/hr).

Section 438.340, adopted in CHIP through § 457.1240(e), requires states to have a quality strategy for managed care. In accordance with § 438.340(c)(2), states will review and revise their quality strategies as needed, but no less frequently than once every 3 years. While the 25 states that contract with MCOs and/or PIHPs currently revise their quality strategies periodically, approximately half of those states (13) revise their quality strategies less frequently than proposed. We estimate a burden for the revision of a quality strategy of, once every 3 years, 25 hr at \$64.46/hr for a business operations analyst to review and revise the comprehensive quality strategy, 2 hr at \$36.54/hr for an office and administrative support worker to publicize the strategy, 5 hr at \$64.46/hr for a business operations specialist to review and incorporate public comments, and 1 hr at \$36.54/hr for an office and administrative support worker to submit the revised quality strategy to CMS. In aggregate, we estimate an ongoing annualized state burden of 143 hr [(13 states × 33 hr)/3 years] and \$8,854.82 [(13 states × (30 hr × \$64.46/hr) + (3 hr × \$36.54/hr))/3 years].

The revision of a quality strategy will be a new process for the estimated three states with only PAHPs and the estimated two states with only PCCM entities. We estimate that those states need 0.5 hr at \$64.46/hr for a business operations specialist to revise their policies and procedures. In aggregate, we estimate a one-time state burden of 2.5 hr (5 states × 0.5 hr) and \$161.15 (2.5 hr × \$64.46/hr) to update policies and procedures. We are annualizing the one-time development since we do not anticipate any additional burden after the 3-year approval period expires.

We assume that it will be less burdensome to revise an existing quality strategy than to draft an initial strategy. Therefore, we estimate a burden for the quality strategy revision process, once every 3 years, of 25 hr at \$64.46/hr for a business operations analyst to review and revise the comprehensive quality strategy, 2 hr at \$36.54/hr for an office and administrative support worker to publicize the strategy, 5 hr at \$64.46/hr for a business operations specialist to

review and incorporate public comments, and 1 hr at \$36.54/hr for an office and administrative support worker to submit the revised quality strategy to CMS. In aggregate, we estimate an ongoing annualized state burden of 55 hr [(5 states × (33 hr)/3 years] and \$3,405.70 [(5 states × ((30 hr × \$64.46/hr) + (3 hr × \$36.54/hr))/3 years].

Consistent with § 438.340(c)(2), the review of the quality strategy will include an effectiveness evaluation conducted within the previous 3 years. We estimate the burden of this evaluation at 40 hr at \$64.46/hr for a business operations specialist once every 3 years for all 25 states that contract with MCOs, PIHPs, PAHPs, and/or PCCM entities (described in § 438.310(c)(2)). We estimate an annualized burden of 333 hr [(25 states × 40 hr)/3 years] and \$21,486.67 (333 hr × \$64.46/hr) to evaluate the effectiveness of a quality strategy.

States will post the effectiveness evaluation on the state's Medicaid Web site under § 438.340(c)(2)(iii). In the proposed rule we states that while this standard was subject to the PRA, we believed that the associated burden is exempt from the PRA in accordance with 5 CFR 1320.3(b)(2). We believed that the time, effort, and financial resources necessary to comply with the aforementioned standards will be incurred by persons during the normal course of their activities and, therefore, should be considered a usual and customary business practice. Upon further consideration, however, we determined that states today do not necessarily post the quality strategy effectiveness evaluation online. Therefore, we estimate that posting the quality strategy effectiveness evaluation online will require 0.25 hr at \$64.46 from a business operations specialist once every 3 years. In aggregate, we estimate an ongoing annualized burden of 3.5 hr [(42 states × 0.25 hr)/3 years] and \$225.61 (3.5 hr × \$64.46/hr).

As described in § 438.340(c)(3), states will submit to CMS a copy of the initial quality strategy and any subsequent revisions. The burden associated with this standard has been incorporated into burden estimates for initial and revised quality strategies. As this will be a new standard for the estimated 3 states with only PAHPs and the estimated 2 states with only PCCM entities, we believe that these states will need to modify their policies and procedures to incorporate this action. We estimate a burden of 0.5 hr \$64.46/hr for a business operations specialist. In aggregate, we estimate a one-time state burden of 2.5 hr (5 states × 0.5 hr) and \$161.15 (2.5

hr × \$64.46/hr). We are annualizing the one-time development since we do not anticipate any additional burden after the 3-year approval period expires.

Finally, § 438.340(d) requires states to post the final quality strategy to their Medicaid Web sites. In the proposed rule, we stated that while this standard was subject to the PRA, we believed that the associated burden is exempt from the PRA in accordance with 5 CFR 1320.3(b)(2). We believed that the time, effort, and financial resources necessary to comply with the aforementioned standards will be incurred by persons during the normal course of their activities and, therefore, should be considered a usual and customary business practice. Upon further consideration, however, we determined that states today do not necessarily post the final quality strategy online, though some do. Therefore, we estimate that posting the final quality strategy online will require 0.25 hr at \$64.46 from a business operations specialist once every 3 years. In aggregate, we estimate an ongoing annualized burden of 3.5 hr [(42 states × 0.25 hr)/3 years] and \$225.61 (3.5 hr × \$64.46/hr).

56. ICRs Regarding External Quality Review (§ 457.1250)

No comments were received on the burden estimates in the proposed rule. However, we are revising the burden estimates in response to the changes to the regulation discussed in II.B.22.

Section 457.1250 applies the requirements of §§ 438.350, 438.352, 438.354, 438.356, 438.358, and 438.364 to CHIP. Section 438.350, adopted in CHIP through § 457.1250(a), requires that states include CHIP in their EQR. We anticipate that most states includes CHIP in their Medicaid contract with the EQRO and that the burden for adding CHIP will be included in the burden for adding PAHPs to the EQRO contract. We anticipate that 5 states may contract separately for CHIP EQR services and that this requires states to procure a new vendor.

Section 438.358, adopted in CHIP through § 457.1250(a), addresses the EQR-related activities. Per § 438.358(a)(1) of this section, the EQR-related activities described in paragraphs (b) and (c) of this section may be conducted by the state, its agent that is not an MCO, PIHP, PAHP, or PCCM entity (described in § 438.310(c)(2)), or an EQRO; we describe the burden assuming that the state conducts these activities, though we believe the burdens will be similar regardless of who conducts each activity.

The burden associated with the mandatory EQR-related activities described in § 438.358(b)(1) of this section is the time for a state to conduct and document the findings of the four mandatory activities: (1) The annual validation of PIPs conducted by the MCO/PIHP/PAHP; (2) the annual validation of performance measures calculated by the MCO/PIHP/PAHP; (3) once every 3 years, a review of MCO/PIHP/PAHP compliance with structural and operational standards; and (4) validation of MCO, PIHP, and PAHP network adequacy. Each of these activities will be conducted on the 5 MCOs/PIHPs/PAHPs that are currently providing CHIP services separately from Medicaid.

The types of services provided by these managed care entities, the number of PIPs conducted, and the performance measures calculated will vary. We assume that each MCO/PIHP will conduct at least 3 PIPs, each PAHP will conduct at least 1 PIP, and that each MCO/PIHP/PAHP will calculate at least 3 performance measures.

For a business operations specialist to conduct the mandatory EQR activities at \$64.46/hr, we estimate an annual state burden of 65 hr (PIP validation), 53 hr (performance measure validation), 361 hr (compliance review; occurs once every 3 years), and 60 hr (validation of network adequacy activity). In aggregate, we estimate 2,671.67hr ($5 \times [(65 \text{ hr} \times 3 \text{ PIPs}) + (53 \text{ hr} \times 3 \text{ performance measures}) + (361 \text{ hr}/3) + 60 \text{ hr}]$) and \$142,453.27 ($2,372 \text{ hr} \times \$64.46/\text{hr}$).

In § 438.358(b), the burden will include the time for an MCO/PIHP/PAHP to prepare the information necessary for the state to conduct the three mandatory activities. We estimate that it will take each MCO/PIHP/PAHP 160 hr to prepare the documentation for these activities. We estimate that one-half of the time will be for preparing the information which will be performed by a business operations specialist at \$64.46/hr while the other half will be performed by office and administrative support worker at \$36.54/hr. In aggregate, we estimate a private sector burden of 800 hr ($5 \text{ states} \times 160 \text{ hr}$) and \$40,400.00 [$(5 \text{ states} \times 80 \text{ hr} \times \$64.46/\text{hr}) + (5 \text{ states} \times 80 \text{ hr} \times \$36.54/\text{hr})$].

The fourth mandatory EQR-related activity described in § 438.358(b)(1)(iv) requires the validation of MCO, PIHP, and PAHP network adequacy during the preceding 12 months. States will conduct this activity for each MCO, PIHP, and PAHP. Given that this is a new activity, we do not have historic data on which to base an hourly burden estimate for the network validation

process. We estimate that it will take less time than the validation of a PIP but more time than the validation of a performance measure. Therefore, we estimate an annual state burden of 60 hr at \$64.46/hr for a business operations specialist to support the validation of network adequacy activity. In aggregate, we estimate 3,480hr (58 MCOs, PIHPs, and PAHPs \times 60 hr) and \$224,320.80 ($3,480 \text{ hr} \times \$64.46/\text{hr}$) for the validation of network adequacy activity.

Section 438.358(b)(2) describes the mandatory EQR-related activities which must be conducted for each PCCM entity (described in § 438.310(c)(2)), specifically the activities described in paragraphs (b)(1)(ii) and (b)(1)(iii) of this section. Given that we do not have data to estimate the time required for each of these activities for these PCCM entities, we rely on the time per activity estimates used for MCOs, PIHPs, and PAHPs; we assume the validation of one performance measure per PCCM entity (described in § 438.310(c)(2)). Therefore, we estimate an annual state burden of 693.2 hr ($4 \text{ PCCM entities} \times 173.3 \text{ hr} [(53 \text{ hr} \times 1 \text{ performance measure}) + (361 \text{ hr}/3 \text{ years})]$) and \$33,512.75 ($693.2 \text{ hr} \times \$64.46/\text{hr}$) for the mandatory EQR-related activities for PCCM entities (described in § 438.310(c)(2)). The burden associated with § 438.358(b)(1) also includes the time for an MCO, PIHP, or PAHP to prepare the information necessary for the state to conduct the mandatory EQR-related activities. We estimate that it will take each MCO, PIHP, or PAHP 200 hr to prepare the documentation for these four activities, half (100 hr) at \$64.46/hr by a business operations specialist and half (100 hr) at \$36.54/hr by an office and administrative support worker. The burden associated with § 438.358(b)(2) also includes the time for a PCCM entity (described in § 438.310(c)(2)) to prepare the information necessary for the state to conduct the mandatory EQR-related activities. Given the estimate of 200 hr for an MCO, PIHP, or PAHP, and that there are only 2 mandatory EQR-related activities for PCCM entities (described in § 438.310(c)(2)), we estimate it will take 100 hr to prepare the documentation for these 2 activities, half (50 hr) at \$64.46/hr by a business operations specialist and half (50 hr) at \$36.54/hr by an office and administrative support worker. In aggregate, we estimate an annual private sector burden of 12,000 hr [$(58 \text{ MCOs, PIHPs, and PAHPs} \times 200 \text{ hr}) + (3 \text{ PCCM entities} \times 100 \text{ hr})$] and \$641,350 [$(6,000 \text{ hr} \times \$64.46/\text{hr}) + (6,000 \text{ hr} \times \$36.54/\text{hr})$].

Section 438.358(c), adopted in CHIP through § 457.1250(a), describes

optional EQR-related activities. The number of MCOs/PIHPs engaged in optional EQR-related activities will vary. We estimate 48 MCOs/PIHPs will be engaged in validation of client encounter data through a state contract with an EQR; 30 MCOs/PIHPs will be engaged in validation of consumer or provider surveys through a state contract with an EQR; 26 MCOs/PIHPs will be engaged in performance improvement projects (PIPs) conducted by an EQR; 20 MCO/PIHPs will be engaged in calculating performance measures through a state contract with an EQR; and 52 MCOs/PIHPs will be engaged in conducting focused studies. For the optional EQR activities, we have no data to estimate how long it will take to conduct these activities. We, therefore, estimate that it will take 350 hr to validate client level data and 50 hr to validate consumer or provider surveys. We estimate it will take three times as long to calculate performance measures as it takes on average to validate (159 hr) and three times as long to conduct PIPs and focused studies as it takes on average to validate PIPs (195 hr) (see discussion at IV.C.25). We also estimate that it will take three times as long to administer a consumer or provider survey than it takes to validate a survey (60 hr).

For a business operations specialist \$64.46/hr, we estimate: (1) 16,800 hr ($350 \text{ hr} \times 48 \text{ MCOs/PIHPs}$) and \$1,082,928.00 ($16,800 \text{ hr} \times \$64.46/\text{hr}$) to validate client level data; (2) 1500 hr ($50 \text{ hr} \times 30 \text{ MCOs/PIHPs}$) and \$96,690.00 ($1500 \text{ hr} \times 64.46/\text{hr}$) to validate consumer or provider surveys; (3) 3,180 hr ($159 \text{ hr} \times 20 \text{ MCOs/PIHPs}$) and \$204,982.80 ($3,180 \text{ hr} \times \$64.46/\text{hr}$) to calculate performance measures; (4) 5,070 hr ($195 \text{ hr} \times 26 \text{ MCOs/PIHPs}$) and \$326,812.20 ($5,070 \text{ hr} \times \$64.46/\text{hr}$) to conduct PIPs; and (5) 8,268 hr ($159 \text{ hr} \times 52 \text{ MCOs/PIHPs}$) and \$532,955.28 ($8,268 \text{ hr} \times \$64.46/\text{hr}$) to conduct focused studies. In aggregate, we estimate 34,818 hr and \$1,856,495.76 for the optional EQR-related activities.

The optional EQR-related activities described in § 438.358(c) may also be conducted on PAHPs and PCCM entities (described in § 438.310(c)(2)). Since neither PAHPs or PCCM entities (described in § 438.310(c)(2)) have historically been subject to EQR, we do not have any data on which to base an estimate regarding how states will apply the optional EQR-related activities to these delivery systems. Section 438.358(c)(6) allows a state to contract with an EQRO to support the quality rating of MCOs, PIHPs, and PAHPs consistent with § 438.334. We do not believe that the effort required to rate a

plan changes based on which entity (state or EQRO) develops the plan rating. Therefore, we believe that any burden associated with this optional EQR-related activity will only offset the burden associated with § 438.334(d).

Section 438.364(a), adopted in CHIP through § 457.1250(a), describes the information that will be included in the annual detailed technical report that is the product of the EQR. Section 438.364(a)(1)(iii) specifies that the EQR technical report includes baseline and outcomes data regarding PIPs and performance measures. Many states already provide much of this information in their final EQR technical report. The burden of compiling this data for MCOs, PIHPs, and PAHPs is captured in § 438.358. Under § 438.364(a)(3), EQR technical reports will include recommendations on how the state can use the goals and objectives of its comprehensive quality strategy to support improvement in the quality, timeliness, and access to care for beneficiaries. We believe that states will amend their EQRO contracts to address the changes to § 438.364(a). We estimate a one-time state burden of 0.5 hr at \$64.46/hr for a business operations specialist to amend the EQRO contract. In aggregate, we estimate 12.5 hr (25 states × 0.5 hr) and \$805.75 (12.5 hr × \$64.46/hr). We are annualizing the one-time development since we do not anticipate any additional burden after the 3-year approval period expires.

Section 438.364(c)(1), adopted in CHIP through § 457.1250(a), clarifies that the EQRO will produce and finalize the annual EQR-technical report and that states may not substantively revise the report without evidence of error or omission. The April 30th deadline for the finalization and submission of EQR technical reports is consistent with existing Medicaid sub-regulatory guidance.

While we do not anticipate that these changes will pose a significant burden on states or the private sector, we estimate that this provision may necessitate a change in a state's EQRO contract for approximately 5 states. In this regard, we estimate a one-time state burden of 0.5 hr at \$64.46/hr for a business operations specialist to modify the EQRO contract. In aggregate, we estimate 2.5 hr (5 states × 0.5 hr) and \$161.15 (2.5 hr × \$64.46/hr). We are annualizing the one-time development since we do not anticipate any additional burden after the 3-year approval period expires.

Section 438.364(c)(2)(ii), adopted in CHIP through § 457.1250(a), requires that each state agency provide copies of technical reports, upon request, to

interested parties such as participating health care providers, enrollees and potential enrollees of the MCO/PIHP/PAHP, beneficiary advocacy groups, and members of the general public. States will also be required to make the most recent EQR technical report publicly available in a manner specified by CMS. This will likely be accomplished by posting to the state's Web site, the burden for which is included in § 457.1206.

We believe that by making these reports available online, states will be able to significantly decrease the burden associated with responding to requests from the public for this information, as it will already be easily accessible. The burden associated with this requirement is the time for a state agency to disclose copies of a given technical report to interested parties.

We estimate an annual state burden of 5 min at \$36.54/hr for office and administrative support worker to disclose the required information per request. We also estimate that each state will receive 5 requests per MCO/PIHP/PAHP per year. In aggregate, we estimate 24.1 hr (58 MCOs/PIHPs/PAHPs × 5 requests × 5 min) and \$880.61 (24.1 hr × \$36.54/hr).

57. ICRs Regarding Grievances (§ 457.1260)

The following requirements and burden estimates were set out in the proposed rule and are being adopted with minor revisions to update the wage estimates and to reduce the number of states affected based on updated information obtained from SEDS. No comments were received.

Section 457.1260 applies subpart F of part 438 to CHIP. We anticipate that most states currently follow the Medicaid grievance procedures, so we adopt the burden associated with the proposed changes to the Medicaid regulation.

Section 438.400(b), adopted in CHIP through § 457.1260, updates the definition of "Action" to "Adverse benefit determination," clarify "appeal" and "grievance," and add the definition of "grievance system." We estimate a one-time state burden of 5 hr at \$64.46/hr for a business operations specialist to amend all relevant documents to the new nomenclature and definitions. In aggregate, we estimate 165 hr (5 hr × 25 states) and \$8,057.50 (125 hr × \$64.46/hr). We are annualizing the one-time development since we do not anticipate any additional burden after the 3-year approval period expires.

Aligning the definition of "adverse benefit determination" to include medical necessity, appropriateness,

health care setting, or effectiveness requires that plans provide additional hearing resources to actions previously not included. We estimate 3 hr at \$64.46/hr for a business operations specialist and expect that each plan will provide 3 additional hearings per month (36 per year). In aggregate, we estimate an annual private sector burden of 6,264 hr (58 MCOs, PIHPs, and PAHPs × 36 hearings × 3 hr) and \$403,777.44 (6,264 hr × \$64.46/hr). Section 438.402, adopted in CHIP through § 457.1260, specifies the general requirements associated with the grievance system. More specifically, § 438.402: (1) Requires MCOs, PIHPs, and PAHPs to have a grievance system; (2) sets out general requirements for the system; (3) establishes filing requirements; and (4) provides that grievances and appeals may be filed either orally or in writing. The proposed provisions apply to 58 entities. The burden for revising the contracts for these entities is included in § 457.1201.

With regard to setting up a grievance system, we estimate it will take 100 hr (10 hr at \$140.80/hr for a general and operations manager, 75 hr at \$64.46/hr for a business operations specialist, and 15 hr at \$78.32/hr for a computer programmer) for each entity. We estimate that the entities will receive 400 grievances per month. We estimate it will take a business operations specialist 30 min to process and handle each grievance and adverse benefit determinations.

We estimate a one-time private sector burden of 5,800 hr and \$430,203.40 [58 MCOs, PIHPs, and PAHPs × ((10 × \$140.80/hr) + (75 × \$64.46/hr) + (15 × \$78.32/hr))]. We are annualizing the one-time development since we do not anticipate any additional burden after the 3-year approval period expires. We also estimate an ongoing annual burden of 139,200 hr [58 MCOs, PIHPs, and PAHPs × 400 grievances/month × 12 months × 0.5 hr/grievance] and \$8,972,832.00 (139,200 hr × \$64.46/hr) for processing each grievance and adverse benefit determination.

Section 438.404(a), adopted in CHIP through § 457.1260, adds PAHPs as an entity that must give the enrollee timely written notice and sets forth the requirements of that notice. More specifically, the enrollee must be provided timely written notice if an MCO, PIHP, or PAHP intends to: (1) Deny, limit, reduce, or terminate a service; (2) deny payment; (3) deny the request of an enrollee in a rural area with one plan to go out of network to obtain a service; or (4) fails to furnish, arrange, provide, or pay for a service in a timely manner.

We estimate an annual private sector burden of 1 min at \$36.54/hr for an office and administrative support worker to provide written notice of the MCO, PIHP, or PAHP's intended action. We estimate that 5 percent (115,000) of the approximately 2.3 million MCO, PIHP, or PAHP enrollees will receive one notice of intended action per year from their MCO, PIHP, or PAHP. In aggregate, we estimate 1,916.67 hr (115,000 × 1 min) and \$70,035 (1,916.67 hr × \$36.54/hr).

In § 438.416, adopted in CHIP through § 457.1260, the state must require that MCOs, PIHPs and PAHPs maintain records of grievances and appeals. We estimate that approximately 23,000 enrollees (1 percent) of the approximately 2.3 million MCO and PIHP enrollees file a grievance or appeal with their MCO or PIHP. We estimate an annual private sector burden of 1 min (per request) at \$36.54/hr for an office and administrative support worker to record and track grievances. In aggregate, we estimate 383 hr (23,000 grievances × 1 min) and \$14,007 (383 hr × \$36.54/hr).

58. ICRs Regarding Sanctions (§ 457.1270)

The following requirements and burden estimates were set out in the proposed rule and are being adopted with minor revisions to update the wage data. No comments were received.

Section 457.1270 applies subpart I of part 438 to CHIP. In § 438.722(a) adopted in CHIP through § 457.1270, states are provided the option to give MCO, PIHP, PAHP, or PCCM enrollees written notice of the state's intent to terminate its MCO, PIHP, PAHP, or PCCM contract. Notice may be provided after the state has notified the entity of its intention to terminate their contract.

States already have the authority to terminate MCO, PIHP, PAHP or PCCM contracts according to state law and have been providing written notice to the MCO, PIHP, PAHP or PCCM enrollees. While it is not possible to gather an exact figure, we estimate that 8 states may terminate 1 contract per year.

We estimate an annual state burden of 1 hr at \$64.46/hr for a business operations specialist to prepare the notice to enrollees. In aggregate, we estimate 8 hr (1 hr × 8 states × 1 contract/yr.) and \$426.56 (8 hr × \$64.46/hr). We also estimate 1 hr at \$64.46/hr for a business operations specialist to prepare the notice. In aggregate, we estimate an annual state burden of 8 hr (8 states × 1 hr) and \$515.68 (8 hr × \$64.46/hr). To send the notice, we estimate an average enrollment of

30,000 beneficiaries and 1 min (per beneficiary) at \$30.92/hr for a mail clerk. In aggregate we estimate 500 hr (30,000 beneficiaries × 1 min) and \$15,840.00 (500 hr × \$30.92/hr).

Section 438.724, adopted in CHIP through § 457.1270, requires that the state give the CMS Regional Office written notice whenever it imposes or lifts a sanction. The notice must specify the affected MCO, PIHP, PAHP, or PCCM, the kind of sanction, and the reason for the state's decision to impose or lift a sanction.

We anticipate that no more than 15 states will impose or lift a sanction each year and that it will take 30 min at \$64.46/hr for a business operations specialist to give the regional office notice. In aggregate, we estimate an annual burden of 7.5 hr (15 states × 30 min) and \$483.45 (7.5 hr × \$64.46/hr).

59. ICRs Regarding Conditions Necessary To Contract as an MCO, PIHP, or PAHP (§ 457.1280)

The following requirements and burden estimates were set out in the proposed rule and are being adopted without change. No comments were received. The requirements in this section have not changed, rather they have been redesignated from another section of part 457, so we do not estimate any additional burden.

60. ICRs Regarding Program Integrity Safeguards (§ 457.1285)

The following requirements and burden estimates were set out in the proposed rule and are being adopted with minor revisions to update the wage data and to revise the number of states affected based on updated information from the SEDS. No comments were received.

Section 457.1285 applies most of subpart H of part 438 to CHIP. Section 438.602(a), adopted in CHIP through § 457.1285, details state responsibilities for monitoring MCO, PIHP, PAHP, PCCM or PCCM's compliance with other sections of part 438, screening and enrollment of providers, reviewing ownership and control information, performing periodic audits, investigating based on whistleblower information, and imposing sanctions as appropriate. States will need to revise their policies and implement these activities, as needed.

We estimate 50 hr at \$64.46/hr for a business operations specialist to create and/or revise their policies for the activities set out under § 438.602(a). In aggregate, we estimate a one-time state burden of 1,250 hr (25 states × 50 hr) and \$80,575.00 (1,250 hr × \$64.46/hr). We are annualizing the one-time

development since we do not anticipate any additional burden after the 3-year approval period expires.

Section 438.602(b), adopted in CHIP through § 457.1285, requires states to screen and enrollee MCO, PIHP, PAHP, PCCM and PCCM entity providers in accordance with 42 CFR part 455, subparts B and E. States are already required to screen and enroll providers in both FFS and managed care in their CHIP programs through § 457.990, so there is no additional burden associated with this requirement.

Section 438.602(e), adopted in CHIP through § 457.1285, requires states to conduct or contract for audits of MCO, PIHP, and PAHP encounter and financial data once every 3 years. Some states already use their EQRO to validate data. If they conduct this task at an appropriate frequency, it will incur no additional burden. We estimate 12 states already use their EQRO to validate their data, so only 21 states may need to take action to meet this requirement. The method selected by the state will determine the amount of burden incurred. We assume an equal distribution of states selecting each method, thus 7 states per method.

A state using EQRO to validate data on less than an appropriate frequency may need to amend their EQRO contract. In this case, we estimate 1 hr at \$64.46/hr for a business operations specialist. In aggregate, we estimate a one-time state burden of 7 hr (7 states × 1 hr) and \$451.22 (7 hr × \$64.46/hr). We are annualizing the one-time development since we do not anticipate any additional burden after the 3-year approval period expires.

A state electing to perform validation internally must develop processes and policies to support implementation. In this case, we estimate 10 hr at \$64.46/hr for a business operations specialist to develop policy and 100 hr at \$78.32/hr for a computer programmer to develop, test, and automate the validation processes. In aggregate, we estimate a one-time state burden of 770 hr (7 states × 110 hr) and \$59,336.20 [7 states × ((10 hr × \$64.46/hr) + (100 hr × \$78.32/hr))]. We are annualizing the one-time development since we do not anticipate any additional burden after the 3-year approval period expires.

For a state electing to procure a vendor, given the wide variance in state procurement processes, our burden is conservatively estimated at 150 hr for writing a proposal request, evaluating proposals, and implementing the selected proposal. We estimate 125 hr at \$64.46/hr for a business operations specialist to participate in the writing, evaluating, and implementing, and 25

hr at \$140.80/hr for a general and operations manager to participate in the writing, evaluating, and implementing. In aggregate, we estimate an annual state burden of 1,050 hr [7 states × (150 hr)] and \$81,042.50 [7 states × ((125 hr × \$64.46/hr) + (25 hr × \$140.80/hr))].

Section 438.602(g), adopted in CHIP through § 457.1285, requires states to post the MCO's, PIHP's, and PAHP's contracts, data from § 438.604, and audits from § 438.602(e) on their Web site. As most of these activities will only occur no more frequently than annually, we estimate an annual state burden of 1 hr at \$78.32/hr for a computer programmer to post the documents. In aggregate, we estimate 25 hr (25 states × 1 hr) and \$1,958 (25 hr × \$78.32/hr).

Section 438.608(a), adopted in CHIP through § 457.1285, requires that MCOs, PIHPs, and PAHPs have administrative and management arrangements or procedures that are designed to guard against fraud and abuse. The arrangements or procedures must include a compliance program as set forth under § 438.608(a)(1), provisions for reporting under § 438.608(a)(2), provisions for notification under § 438.608(a)(3), provisions for verification methods under § 438.608(a)(4), and provisions for written policies under § 438.608(a)(5).

The compliance program must include: Written policies, procedures, and standards of conduct that articulate the organization's commitment to comply with all applicable federal and state standards and requirements under the contract; the designation of a Compliance Officer; the establishment of a Regulatory Compliance Committee on the Board of Directors; effective training and education for the organization's management and its employees; and provisions for internal monitoring and a prompt and effective response to noncompliance with the requirements under the contract.

We estimate that reviewing their policies and procedures to ensure that all of the above listed items are addressed. We estimate this will require 5 hr at \$64.46/hr for a business operations specialist to review and (if necessary) revise their policies and procedures. In aggregate, we estimate a one-time private sector burden of 290 hr (58 MCOs, PIHPs, and PAHPs × 5 hr) and \$18,693.40 (290 hr × \$64.46/hr). We are annualizing the one-time development since we do not anticipate any additional burden after the 3-year approval period expires. Section 438.608(a)(2) and (3), adopted in CHIP through § 457.1285, require reporting of

overpayments and enrollee fraud. As these will be done via an email from the MCO, PIHP, or PAHP to the state and do not occur very often, we estimate only 2 hr per year by a business operations specialist at \$64.46/hr. We estimate an annual burden of 116 hr (58 MCOs, PIHPs, and PAHPs × 2 hr) and \$7, 77.36 (116 hr × \$64.46/hr).

Section 438.608(a)(4), adopted in CHIP through § 457.1285, requires the MCO, PIHP, or PAHP to use a sampling methodology to verify receipt of services. This typically involves mailing a letter or sending an email to the enrollee, we estimate 25 states mail to 100 enrollees each (25 × 100 = 2,500 mailings) taking 1 min at \$30.92/hr for a mail clerk. We estimate a total annual aggregate burden for private sector of 42 hr (2,500 mailings × 1 min) and \$1,298.64 (42 hr × \$30.92/hr). This burden will be significantly reduced as the use of email increases.

Section 438.608(c) and (d), adopted in CHIP through § 457.1285, requires states to include in all MCO, PIHP, and PAHP contracts, the process for the disclosure and treatment of certain types of recoveries and reporting of such activity. The burden to amend the contracts is included in § 457.1201. We estimate the burden to comply with the reporting to include 1 hr at \$78.32/hr for a computer programmer to create the report. In aggregate, we estimate a one-time private sector burden of 58 hr (58 MCOs, PIHPs, and PAHPs × 1 hr) and \$4,542.56 (58 hr × \$78.32/hr). We are annualizing the one-time development since we do not anticipate any additional burden after the 3-year approval period expires. Once developed, the report will be put on a production schedule and add no additional burden.

D. Summary of Requirements and Burden Estimates

Tables 2a, 2b, and 2c set out our annual burden estimates. While the annual burden estimates (under Frequency) are unchanged, the one-time estimates have been annualized by dividing the one-time hour and cost figures by 3 to account for OMB's 3-year approval period.

The burden associated with this final rule is divided amongst four Paperwork Reduction Act (PRA) packages. We are finalizing the four proposed PRA packages, with some modification. Under our proposal, CMS-10108 would continue to contain all of part 438, except for those provisions related to EQR (§§ 438.350, 438.352, 438.354, 438.356, 438.358, 438.360, 438.362,

438.364, and 438.370), which would remain in the separate CMS-R-305. With this final rule, OMB Control #0938-0920, CMS-10108 will contain all of part 438 except for subpart E, which will be contained in OMB Control #0938-0786, CMS-R-305 and OMB Control #0938-New, CMS-10553. Since our original final rule in 2003, the provisions related to EQR (§§ 438.350, 438.352, 438.354, 438.356, 438.358, 438.360, 438.362, 438.364, and 438.370) have been contained in a separate PRA package (CMS-R-305). We believe this continues to be appropriate, given the EQR protocols, which are also associated with CMS-R-305, are modified on a different schedule from other pieces of this rule. Therefore we will finalize EQR (§§ 438.350, 438.352, 438.354, 438.356, 438.358, 438.360, 438.362, 438.364, and 438.370) in OMB Control #0938-0786, CMS-R-305 as proposed.

We believe that pulling the non-EQR quality provisions (§§ 438.310, 438.320, 438.330, 438.332, 438.334, and 438.340) out of CMS-10108 will make the impact of any future burden revisions and associated subregulatory guidance on these provisions easier to describe and present to the public for consideration. As described in this rulemaking, some non-EQR provisions of subpart E will have associated subregulatory guidance, specifically the Medicaid and CHIP QRS (§ 438.334) and potentially QAPI (§ 438.330; if CMS elects to identify a common set of national QAPI performance measures and PIP topics). Given this, and based on our experience with a standalone PRA package for EQR, we believe that placing the provisions in a separate package will allow any burden changes associated with future guidance to more clearly be presented to the public. We previously proposed that the burden for proposed part 431 subpart I would be contained in a new PRA package (OMB Control# 0938-New, CMS-10553); as we are withdrawing proposed part 431 subpart I, CMS-10553 will instead contain the non-EQR subpart E provisions (§§ 438.310, 438.320, 438.330, 438.332, 438.334, and 438.340). We do not believe this revision will have any negative impacts on the public, as it should serve only to make it easier to assess the impact of future subregulatory guidance.

We proposed that the CHIP managed care regulation burden be in a new PRA package, CMS-10554; we are finalizing the CHIP burden in this package as proposed.

TABLE 2a: Summary of Annual PRA-related Requirements and Burden under 42 CFR Part 438
OMB Control Number 0938-0920 (CMS-10108)

CFR Section	# Respondents	# responses	Burden per response (hours)	Total Annual Hours	Labor Rate (\$/hr)	Cost (\$) per Response	Total cost (\$)	Frequency	Annualized hours*	Annualized costs (\$)
438.3 Contracts	42	606	6	3,636	64.46	386.76	234,376.56	once	1,212	78,125.52
438.5 Rate Standards	39	50	10	500	92.44	924.40	46,220.00	annual	500	46,220.00
438.5 Rate Standards	39	50	1	50	140.80	140.80	7,040.00	annual	50	7,040.00
438.7 Rate Certifications	39	70	1.5	105	92.44	138.66	9,706.20	annual	105	9,706.20
438.7 Rate Certifications	39	70	0.13	9	140.80	18.30	1,281.28	annual	9	1,281.28
438.7 Rate Certifications	39	70	0.73	51	78.32	57.17	4,002.15	annual	51	4002.15
438.7 Rate Certifications	39	70	0.73	51	64.46	47.06	3,293.91	annual	51	3,293.91
438.7 Rate Certifications	39	70	0.26	18	36.54	9.50	665.03	annual	18	665.03
438.8(c) MLR	572	572	101	57,772	78.32	7,910.32	4,524,703.04	once	19,123	1,508,234.35
438.8(c) MLR	572	572	50	28,600	64.46	3,223.00	1,843,556.00	once	9,533	614,518.67
438.8(c) MLR	572	572	17	9,724	140.80	2,393.60	1,369,139.20	once	3,241	456,379.73
438.8(c) MLR	572	572	32	18,304	78.32	2,506.24	1,433,569.28	annual	18,176	1,433,569.28
438.8(c) MLR	572	572	16	9,152	64.46	1,031.36	589,937.92	annual	9,088	589,937.92
438.8(c) MLR	572	572	5	2,860	140.80	704.00	402,688.00	annual	2,840	402,688.00
438.10(c)(3) Information Requirements	42	42	6	252	78.32	469.92	19,736.64	once	84	6,578.88
438.10(c)(3) Information Requirements	42	42	3	126	78.32	234.96	9,868.32	annual	126	9,868.32
438.10(c)(4)(i) Information Requirements	42	42	6	252	64.46	386.76	16,243.92	once	84	5,414.64
438.10(c)(4)(ii) Information Requirements	20	20	20	400	64.46	1,289.20	25,784.00	once	133	8,594.67
438.10(c)(4)(ii) Information Requirements	20	20	2	40	64.46	128.92	2,578.40	annual	40	2,578.40
438.10(d)(2)(i) Information Requirements	42	42	6	252	64.46	386.76	16,243.92	once	84	5,414.64

CFR Section	# Respondents	# responses	Burden per response (hours)	Total Annual Hours	Labor Rate (\$/hr)	Cost (\$) per Response	Total cost (\$)	Frequency	Annualized hours*	Annualized costs (\$)
438.10(e)(1) Information Requirements	42	42	1	42	64.46	64.46	2,707.32	once	14	902.44
438.10(e)(1) Information Requirements	42	2,069,259	0.0167	-30,512	30.92	0.52	-943,431.04	annual	-30,512	-943,431.04
438.10(g) Information Requirements	100	100	4	400	64.46	257.84	25,784.00	once	133	8,594.67
438.10(g) Information Requirements	100	10,659,819	0.0167	178,019	30.92	0.52	5,504,346.78	once	59,340	1,834,782.26
438.10(g) Information Requirements	100	2,069,259	0.0167	2,057	30.92	0.52	63,602.44	annual	34,557	63,602.44
438.10(g) Information Requirements	581	581	1	581	64.46	64.46	37,451.26	annual	577	37,451.26
438.10(h) Information Requirements	581	581	1	581	78.32	78.32	45,503.92	once	192	15,167.97
438.14(c) Contracts	463	463	1	463	78.32	78.32	36,262.16	once	154	12,087.39
438.14(c) Contracts	25	25	12	300	64.46	773.52	19,338.00	annual	300	19,338.00
438.54(c)(8) Enrollment	42	839,797	0.0167	14,025	30.92	0.52	433,640.94	annual	4,665	433,640.94
438.62(b)(1) Transition of Care	42	42	5	210	64.46	322.30	13,536.60	once	70	4,512.20
438.62(b)(1) Transition of Care	42	42	4	168	78.32	313.28	13,157.76	once	56	4,385.92
438.62(b)(2) Transition of Care	586	586	4	2,344	78.32	313.28	183,582.08	once	757	61,194.03
438.62(b)(2) Transition of Care	586	586	1	586	64.46	64.46	37,773.56	once	189	12,591.19
438.62(b)(2) Transition of Care	586	313,704	0.1667	52,294	66.92	11.16	3,499,545.05	annual	52,294	3,499,545.05
438.66(a)-(b) State Monitoring	42	42	8	336	64.46	515.68	21,658.56	once	112	7,219.52
438.66(c) State Monitoring	42	42	20	840	64.46	1,289.20	54,146.40	once	280	18,048.80
438.66(d)(3) State Monitoring	20	20	5	100	140.80	704.00	14,080.00	annual	100	14,080.00
438.66(d)(3) State Monitoring	20	20	30	600	64.46	1,933.80	38,676.00	annual	600	38,676.00
438.66(d)(3) State	20	20	5	100	78.32	391.60	7,832.00	annual	100	7,832.00

CFR Section	# Respondents	# responses	Burden per response (hours)	Total Annual Hours	Labor Rate (\$/hr)	Cost (\$) per Response	Total cost (\$)	Frequency	Annualized hours*	Annualized costs (\$)
Monitoring										
438.66(d)(3) State Monitoring	20	20	5	100	140.80	704.00	14,080.00	annual	100	14,080.00
438.66(d)(3) State Monitoring	20	20	30	600	64.46	1,933.80	38,676.00	annual	600	38,676.00
438.66(d)(3) State Monitoring	20	20	5	100	78.32	391.60	7,832.00	annual	100	7,832.00
438.66(e)(1-2) State Monitoring	42	42	6	252	64.46	386.76	16,243.92	annual	252	16,243.92
438.68(a)-(c) Network Adequacy	20	20	10	200	64.46	644.60	12,892.00	once	67	4,297.33
438.68(a)-(c) Network Adequacy	16	16	10	160	64.46	644.60	10,313.60	once	53	3,437.87
438.68(d) Network Adequacy	40	40	3	120	64.46	193.38	7,735.20	once	40	2,578.40
438.70 MLTSS Engagement	14	14	4	56	64.46	257.84	3,609.76	annual	56	3,609.76
438.71(a) Beneficiary Support System	20	20	125	2,500	64.46	8,057.50	161,150.00	once	833	53,716.67
438.71(a) Beneficiary Support System	20	20	25	500	140.80	3,520.00	70,400.00	once	167	23,466.67
438.110(a) Member Advisory Committee	14	14	6	84	64.46	386.76	5,414.64	annual	84	5,414.64
438.207(b)-(d) Adequate Capacity	552	552	1	552	64.46	64.46	35,581.92	once	189	11,860.64
438.207(b)-(d) Adequate Capacity	552	552	2	1,104	64.46	128.92	71,163.84	annual	1,136	71,163.84
438.208(b)(2)(iii) Care Coordination	552	2,746,476	0.1667	457,838	55.26	9.21	26,195,043.96	annual	457,746	26,195,043.96
438.208(b)(3) Care Coordination	169	169	3	507	64.46	193.38	32,681.22	once	168	10,893.74
438.208(b)(3) Care Coordination	168	726,143	0.1667	121,048	35.68	5.95	4,320,550	annual	121,048	4,320,550
438.208(b)(4) Care Coordination	552	552	4	-462,510	78.32	294.40	36,223,783.20	once	-154,170	12,074,594.40
438.208(c)(2)-(3)	511	428,128	1	428,128	66.92	66.92	28,650,325.76	annual	428,128	28,650,325.76

CFR Section	# Respondents	# responses	Burden per response (hours)	Total Annual Hours	Labor Rate (\$/hr)	Cost (\$) per Response	Total cost (\$)	Frequency	Annualized hours*	Annualized costs (\$)
Care Coordination										
438.208(c)(3)(v) Care Coordination	552	552	1	552	64.46	64.46	35,581.92	once	189	11,860.64
438.210(a)(4)(ii)(B) Authorization of Services	572	572	20	11,440	66.92	1,338.40	765,564.80	once	3,787	255,188.27
438.210(c) Authorization of Services	61	61	1	61	64.46	64.46	3,932.06	once	20	1,310.69
438.230 Subcontracts	572	572	3	1,716	64.46	193.38	110,613.36	once	568	36,871.12
438.242(b)(2) Health Information	41	41	20	820	78.32	1,566.40	64,222.40	once	273	21,407.47
438.310(c)(2) State PCCM Assessment	5	5	2	10.0	64.46	128.92	644.60	once	3.3	214.87
438.330(a)(2) State QAPI Programming	40	40	10	400.0	78.32	783.20	31,328.00	annual	133.3	10,440.06
438.330(a)(2) State QAPI Exemption	11	11	1	11.0	64.46	64.46	709.06	annual	3.7	238.50
438.330(b)(3) Create PCCM Utilization Review Policies	9	9	10	90.0	64.46	644.60	5,801.40	once	30.0	1,933.80
438.330(b)(3) Operate PCCM Utilization Review Policies	9	9	10	90.0	64.46	644.60	5,801.40	annual	90.0	5,801.10
438.330(c)(2) MCO/PIHP Performance Measures	511	1,533	0.1	153.3	64.46	6.45	9,881.72	annual	153.3	9,881.72
438.330(c)(2) PAHP/PCCM Performance Measures	50	150	4	600.0	64.46	257.84	38,676.0	annual	600.0	38,676.0
438.330(c)(2) MLTSS Performance Measures	179	358	4	1,432.0	64.46	257.84	92,306.72	annual	1,432.0	92,306.72
438.330(d)(1)-(3) MCO/PIHP PIPs	511	1,533	8	12,264.0	64.46	515.68	790,537.44	annual	12,264.0	790,537.44
438.330(d)(1)-(3) Create PAHP PIP Policies	41	41	2	82.0	64.46	128.92	5,285.72	once	27.3	1,761.91
438.330(d)(1)-(3)	41	41	8	328.0	64.46	515.68	21,142.88	annual	328.0	21,142.88

CFR Section	# Respon- dents	# responses	Burden per response (hours)	Total Annual Hours	Labor Rate (\$/hr)	Cost (\$) per Response	Total cost (\$)	Fre- quency	Annualized hours*	Annualized costs (\$)
PAHP PIPs										
438.330(e) Assess PCCMs	9	9	15	135.0	64.46	966.90	8,702.10	annual	135.0	8,702.10
438.330(e)(1)(ii) Update State Policies	40	40	0.5	20.0	64.46	32.23	1,289.20	once	6.7	429.73
438.330(e)(1)(ii) State Review of Outcomes	40	552	1	552.0	64.46	64.46	35,581.92	annual	552.0	35,581.92
438.330(e)(1)(iii) Update State Policies	16	16	0.5	8.0	64.46	32.23	515.68	once	2.7	171.89
438.330(e)(1)(iii) State Assess LTSS	16	179	1	179.0	64.46	64.46	11,538.34	annual	179.0	11,538.34
438.332(a) Confirmation of Accreditation Status	40	552	0.25	138.0	64.46	16.12	8,895.48	annual	138.0	8,895.48
438.332(b) Amend MCO, PIHP, PAHP Contracts	40	552	0.25	138.0	64.46	16.12	8,895.48	once	46.0	2,965.16
438.334(b) State Adopts CMS QRS	30	30	200	6,000.0	64.46	12,892.00	386,760.00	once	2,000.0	128,920.00
438.334(b) State Adopts CMS QRS	30	30	100	3,000.0	78.32	7,832.00	234,960.00	once	1,000.0	78,320.00
438.334(b) State Adopts CMS QRS	30	30	30	900.0	140.8 0	4,224.00	126,720.00	once	300.0	42,240.00
438.334(c) State Adopts Alternative QRS	10	10	800	8,000.0	64.46	51,568.00	515,680.00	once	2,666.7	171,893.33
438.334(c) State Adopts Alternative QRS	10	10	400	4,000.0	78.32	31,328.00	313,280.00	once	1,333.3	104,426.67
438.334(c) State Adopts Alternative QRS	10	10	120	1,200.0	140.8 0	16,896.00	168,960.00	once	400.0	56,320.00
438.334(c)(2) Alternative QRS Public Engagement	10	10	20	200.0	36.54	730.80	7,308.00	once	66.7	2,436.00
438.334(c)(2) Alternative QRS Public Engagement	10	10	50	500.0	64.46	3,223.00	32,230.00	once	166.7	10,743.33
438.334(c) Obtain CMS Approval for Alternative QRS	10	10	20	200.0	64.46	1,289.20	12,892.00	once	66.7	4,297.33
438.334(c)(3) Amend	10	10	5	50.0	36.54	182.70	1,827.00	annual	16.7	609.00

CFR Section	# Respondents	# responses	Burden per response (hours)	Total Annual Hours	Labor Rate (\$/hr)	Cost (\$) per Response	Total cost (\$)	Frequency	Annualized hours*	Annualized costs (\$)
Alternative QRS										
438.334(c)(3) Amend Alternative QRS	10	10	25	250.0	64.46	1,611.50	16,115.00	annual	83.3	5,371.67
438.334(c)(3) Amend Alternative QRS	10	10	5	50.0	64.46	322.30	3,223.00	annual	16.7	1,074.33
438.334(d) Calculate and Issue Ratings	40	552	40	22,080.0	64.46	2,578.40	1,423,276.80	annual	22,080.0	1,423,276.80
438.340(b)(6) Report demographic data	40	40	65	2,600.0	64.46	4,189.90	167,596.00	annual	2,600.0	167,596.00
438.340(b)(6) Report demographic data	40	40	65	2,600.0	36.54	2,375.10	95,004.00	Annual	2,600.0	95,004.00
438.340(c)(2) Revise QS MCO/PIHP States	18	18	25	450.0	64.46	1,611.50	29,007.00	annual	150.0	9,669.00
438.340(c)(2) Revise QS MCO/PIHP States	18	18	2	36.0	36.54	73.08	1,315.44	annual	12.0	438.48
438.340(c)(2) Revise QS MCO/PIHP States	18	18	5	90.0	64.46	322.30	5,801.40	annual	30.0	1,933.80
438.340(c)(2) Revise QS MCO/PIHP States	18	18	1	18.0	36.54	36.54	657.72	annual	6.0	219.24
438.340(c)(2) Update Policies PAHP/PCCM States	5	5	0.5	2.5	64.46	32.23	161.15	once	0.8	53.72
438.340(c)(2) Revise QS PAHP/PCCM States	5	5	25	125.0	64.46	1,611.50	8,057.50	annual	41.7	2,685.83
438.340(c)(2) Revise QS PAHP/PCCM States	5	5	2	10.0	36.54	73.08	365.40	annual	3.3	121.80
438.340(c)(2) Revise QS PAHP/PCCM States	5	5	5	25.0	64.46	322.30	1,611.50	annual	8.3	537.17
438.340(c)(2) Revise QS PAHP/PCCM States	5	5	1	5.0	36.54	36.54	182.70	annual	1.7	60.90

CFR Section	# Respondents	# responses	Burden per response (hours)	Total Annual Hours	Labor Rate (\$/hr)	Cost (\$) per Response	Total cost (\$)	Frequency	Annualized hours*	Annualized costs (\$)
438.340(c)(2) QS Effectiveness Evaluation	42	42	40	200.0	64.46	2,578.40	108,292.80	annual	66.7	4,299.48
438.340(c)(2)(ii) Post QS Effectiveness Evaluation Online	42	42	0.25	10.5	64.46	16.12	676.83	annual	3.5	225.61
438.340(c)(3) Revise Policies PAHP/PCCM States	5	5	0.5	2.5	64.46	32.23	161.15	once	0.8	53.72
438.340(d) Post Final QS Online	42	42	0.25	10.5	64.46	16.12	676.83	annual	3.5	225.61
438.350 Amend EQRO Contract	17	17	1	17.0	64.46	64.46	1,095.82	once	5.7	365.27
438.358(b)(1)(i)-(iii) MCO Mandatory EQR-Related Activities	37	335	474.3	158,890.5	64.46	30,573.38	10,242,081.63	annual	158,890.5	10,242,081.63
438.358(b)(1)(i)-(iii) PIHP Mandatory EQR-Related Activities	20	176	474.3	83,476.8	64.46	30,573.38	5,380,914.53	annual	83,476.8	5,380,914.53
438.358(b)(1)(i)-(iii) PAHP Mandatory EQR-Related Activities	12	41	344.3	14,116.3	64.46	22,193.58	909,936.70	annual	14,116.3	909,936.70
438.358(b)(1)(iv) MCO Mandatory EQR-Related Activity	37	335	60	20,100.0	64.46	3,867.60	1,295,646.00	annual	20,100.0	1,295,646.00
438.358(b)(1)(iv) PIHP Mandatory EQR-Related Activity	20	176	60	10,560.0	64.46	3,867.60	680,697.60	annual	10,560.0	680,697.60
438.358(b)(1)(iv) PAHP Mandatory EQR-Related Activity	12	41	60	2,460.0	64.46	3,867.60	158,571.60	annual	2,460.0	158,571.60
438.358(b)(2) PCCM entity Mandatory EQR-Related Activities	5	9	173.3	1,560.0	64.46	11,170.92	100,577.60	annual	1,560.0	100,577.60

CFR Section	# Respondents	# responses	Burden per response (hours)	Total Annual Hours	Labor Rate (\$/hr)	Cost (\$) per Response	Total cost (\$)	Frequency	Annualized hours*	Annualized costs (\$)
438.358(b)(1) Plan Information for Mandatory EQR-Related Activities MCOs/PIHPs/ PAHPs	552	552	100	55,200.0	64.46	6,446.00	3,558,192.00	annual	55,200.0	3,558,192.00
438.358(b)(1) Plan Information for Mandatory EQR-Related Activities MCOs/PIHPs/ PAHPs	552	552	100	55,200.0	36.54	3,654.00	2,017,008.00	annual	55,200.0	2,017,008.00
438.358(b)(2) Plan Information for Mandatory EQR-Related Activities PCCM	9	9	50	450.0	64.46	3,223.00	29,007.00	annual	450.0	29,007.00
438.358(b)(2) Plan Information for Mandatory EQR-Related Activities PCCM	9	9	50	450.0	36.54	1,827.00	16,443.00	annual	450.0	16,443.00
438.358(c)(1) MCO Optional EQR-Related Activities	4	34	70	2,380.0	140.8 0	9,856.00	335,104.00	annual	2,380.0	335,104.00
438.358(c)(1) PIHP Optional EQR-Related Activities	4	17	70	1,190.0	140.8 0	9,856.00	167,552.00	annual	1,190.0	167,552.00
438.358(c)(1) MCO Optional EQR-Related Activities	4	34	87.5	2,975.0	78.32	6,853.00	233,002.00	annual	2,975.0	233,002.00
438.358(c)(1) PIHP Optional EQR-Related Activities	4	17	87.5	1,487.5	78.32	6,853.00	116,501.00	annual	1,487.5	116,501.00
438.358(c)(1) MCO Optional EQR-Related Activities	4	34	192.5	6,545.0	64.46	12,408.55	421,890.70	annual	6,545.0	421,890.70
438.358(c)(1) PIHP Optional EQR-Related Activities	4	17	192.5	3,272.5	64.46	12,408.55	210,945.35	annual	3,272.5	210,945.35
438.358(c)(2) MCO Optional EQR-Related	4	17	30	510.0	140.8 0	4,224.00	71,808.00	annual	510.0	71,808.00

CFR Section	# Respon- dents	# responses	Burden per response (hours)	Total Annual Hours	Labor Rate (\$/hr)	Cost (\$) per Response	Total cost (\$)	Fre- quency	Annualized hours*	Annualized costs (\$)
Activities										
438.358(c)(2) PIHP Optional EQR-Related Activities	4	8	30	240.0	140.8 0	4,224.00	33,792.00	annual	240.0	33,792.00
438.358(c)(2) MCO Optional EQR-Related Activities	4	17	37.5	637.5	78.32	2,937.00	49,929.00	annual	637.5	49,929.00
438.358(c)(2) PIHP Optional EQR-Related Activities	4	8	37.5	300.0	78.32	2,937.00	23,496.00	annual	300.0	23,496.00
438.358(c)(2) MCO Optional EQR-Related Activities	4	17	82.5	1,402.5	64.46	5,317.95	90,405.15	annual	1,402.5	90,405.15
438.358(c)(2) PIHP Optional EQR-Related Activities	4	8	82.5	660.0	64.46	5,317.95	42,543.60	annual	660.0	42,543.60
438.358(c)(2) MCO Optional EQR-Related Activities	4	17	10	170.0	140.8 0	1,408.00	23,936.00	annual	170.0	23,936.00
438.358(c)(2) PIHP Optional EQR-Related Activities	4	9	10	90.0	140.8 0	1,408.00	12,672.00	annual	90.0	12,672.00
438.358(c)(2) MCO Optional EQR-Related Activities	4	17	12.5	212.5	78.32	979.00	16,643.00	annual	212.5	16,643.00
438.358(c)(2) PIHP Optional EQR-Related Activities	4	9	12.5	112.5	78.32	979.00	8,811.00	annual	112.5	8,811.00
438.358(c)(2) MCO Optional EQR-Related Activities	4	17	27.5	467.5	64.46	1,772.65	30,135.05	annual	467.5	30,135.05
438.358(c)(2) PIHP Optional EQR-Related Activities	4	9	27.5	247.5	64.46	1,772.65	15,953.85	annual	247.5	15,953.85
438.358(c)(3) MCO Optional EQR-Related Activities	4	34	31.8	1,081.2	140.8 0	4,477.44	152,232.96	annual	1,081.2	152,232.96
438.358(c)(3) PIHP Optional EQR-Related Activities	4	17	31.8	540.6	140.8 0	4,477.44	76,116.48	annual	540.6	76,116.48
438.358(c)(3) MCO Optional	4	34	39.75	1,351.5	78.32	3,113.22	105,849.48	annual	1,351.5	105,849.48

CFR Section	# Respon- dents	# responses	Burden per response (hours)	Total Annual Hours	Labor Rate (\$/hr)	Cost (\$) per Response	Total cost (\$)	Fre- quency	Annualized hours*	Annualized costs (\$)
EQR-Related Activities										
438.358(c)(3) PIHP Optional EQR-Related Activities	4	17	39.75	675.8	78.32	3,113.22	52,924.74	annual	675.8	52,924.74
438.358(c)(3) MCO Optional EQR-Related Activities	4	34	87.45	2,973.3	64.46	5,637.03	191,658.92	annual	2,973.3	191,658.92
438.358(c)(3) PIHP Optional EQR-Related Activities	4	17	87.45	1,486.7	64.46	5,637.03	95,829.46	annual	1,486.7	95,829.46
438.358(c)(4) MCO Optional EQR-Related Activities	4	34	39	1,326.0	140.8 0	5,491.20	186,700.80	annual	1,326.0	186,700.80
438.358(c)(4) PIHP Optional EQR-Related Activities	4	17	39	663.0	140.8 0	5,491.20	93,350.40	annual	663.0	93,350.40
438.358(c)(4) MCO Optional EQR-Related Activities	4	34	48.75	1,657.5	78.32	3,818.10	129,815.40	annual	1,657.5	129,815.40
438.358(c)(4) PIHP Optional EQR-Related Activities	4	17	48.75	828.8	78.32	3,818.10	64,907.70	annual	828.8	64,907.70
438.358(c)(4) MCO Optional EQR-Related Activities	4	34	107.25	3,646.5	64.46	6,913.34	235,053.39	annual	3,646.5	235,053.39
438.358(c)(4) PIHP Optional EQR-Related Activities	4	17	107.25	1,823.3	64.46	6,913.34	117,526.70	annual	1,823.3	117,526.70
438.358(c)(5) MCO Optional EQR-Related Activities	4	34	39	1,326.0	140.8 0	5,491.20	186,700.80	annual	1,326.0	186,700.80
438.358(c)(5) PIHP Optional EQR-Related Activities	4	17	39	663.0	140.8 0	5,491.20	93,350.40	annual	663.0	93,350.40
438.358(c)(5) MCO Optional EQR-Related Activities	4	34	48.75	1,657.5	78.32	3,818.10	129,815.40	annual	1,657.5	129,815.40
438.358(c)(5) PIHP Optional EQR-Related Activities	4	17	48.75	828.8	78.32	3,818.10	64,907.70	annual	828.8	64,907.70
438.358(c)(5) MCO Optional	4	34	107.25	3,646.5	64.46	6,913.34	235,053.39	annual	3,646.5	235,053.39

CFR Section	# Respon- dents	# responses	Burden per response (hours)	Total Annual Hours	Labor Rate (\$/hr)	Cost (\$) per Response	Total cost (\$)	Fre- quency	Annualized hours*	Annualized costs (\$)
EQR-Related Activities										
438.358(c)(5) PIHP Optional EQR-Related Activities	4	17	107.25	1,823.3	64.46	6,913.34	117,526.70	annual	1,823.3	117,526.70
438.358(c)(1) PAHP Optional EQR-Related Activities	12	4	70	280.0	140.8 0	9,856.00	39,424.00	annual	280.0	39,424.00
438.358(c)(1) PCCM Optional EQR-Related Activities	10	2	70	140.0	140.8 0	9,856.00	19,712.00	annual	140.0	19,712.00
438.358(c)(1) PAHP Optional EQR-Related Activities	12	4	87.5	350.0	78.32	6,853.00	27,412.00	annual	350.0	27,412.00
438.358(c)(1) PCCM Optional EQR-Related Activities	10	2	87.5	175.0	78.32	6,853.00	13,706.00	annual	175.0	13,706.00
438.358(c)(1) PAHP Optional EQR-Related Activities	12	4	192.5	770.0	64.46	12,408.55	49,634.20	annual	770.0	49,634.20
438.358(c)(1) PCCM Optional EQR-Related Activities	10	2	192.5	385.0	64.46	12,408.55	24,817.10	annual	385.0	24,817.10
438.358(c)(2) PAHP Optional EQR-Related Activities	12	2	30	60.0	140.8 0	4,224.00	8,448.00	annual	60.0	8,448.00
438.358(c)(2) PCCM Optional EQR-Related Activities	10	1	30	30.0	140.8 0	4,224.00	4,224.00	annual	30.0	4,224.00
438.358(c)(2) PAHP Optional EQR-Related Activities	12	2	37.5	75.0	78.32	2,937.00	5,874.00	annual	75.0	5,874.00
438.358(c)(2) PCCM Optional EQR-Related Activities	10	1	37.5	37.5	78.32	2,937.00	2,937.00	annual	37.5	2,937.00
438.358(c)(2) PAHP Optional EQR-Related Activities	12	2	82.5	165.0	64.46	5,317.95	10,635.90	annual	165.0	10,635.90
438.358(c)(2) PCCM Optional EQR-Related Activities	10	1	82.5	82.5	64.46	5,317.95	5,317.95	annual	82.5	5,317.95
438.358(c)(2) PAHP Optional	12	2	10	20.0	140.8 0	1,408.00	2,816.00	annual	20.0	2,816.00

CFR Section	# Respon- dents	# responses	Burden per response (hours)	Total Annual Hours	Labor Rate (\$/hr)	Cost (\$) per Response	Total cost (\$)	Fre- quency	Annualized hours*	Annualized costs (\$)
EQR-Related Activities										
438.358(c)(2) PCCM Optional EQR-Related Activities	10	1	10	10.0	140.8 0	1,408.00	1,408.00	annual	10.0	1,408.00
438.358(c)(2) PAHP Optional EQR-Related Activities	12	2	12.5	25.0	78.32	979.00	1,958.00	annual	25.0	1,958.00
438.358(c)(2) PCCM Optional EQR-Related Activities	10	1	12.5	12.5	78.32	979.00	979.00	annual	12.5	979.00
438.358(c)(2) PAHP Optional EQR-Related Activities	12	2	27.5	55.0	64.46	1,772.65	3,545.30	annual	55.0	3,545.30
438.358(c)(2) PCCM Optional EQR-Related Activities	10	1	27.5	27.5	64.46	1,772.65	1,772.65	annual	27.5	1,772.65
438.358(c)(3) PAHP Optional EQR-Related Activities	12	4	31.8	127.2	140.8 0	4,477.44	17,909.76	annual	127.2	17,909.76
438.358(c)(3) PCCM Optional EQR-Related Activities	10	2	31.8	63.6	140.8 0	4,477.44	8,954.88	annual	63.6	8,954.88
438.358(c)(3) PAHP Optional EQR-Related Activities	12	4	39.75	159.0	78.32	3,113.22	12,452.88	annual	159.0	12,452.88
438.358(c)(3) PCCM Optional EQR-Related Activities	10	2	39.75	79.5	78.32	3,113.22	6,226.44	annual	79.5	6,226.44
438.358(c)(3) PAHP Optional EQR-Related Activities	12	4	87.45	349.8	64.46	5,637.03	22,548.11	annual	349.8	22,548.11
438.358(c)(3) PCCM Optional EQR-Related Activities	10	2	87.45	174.9	64.46	5,637.03	11,274.05	annual	174.9	11,274.05
438.358(c)(4) PAHP Optional EQR-Related Activities	12	4	39	156.0	140.8 0	5,491.20	21,964.80	annual	156.0	21,964.80
438.358(c)(4) PCCM Optional EQR-Related Activities	10	2	39	78.0	140.8 0	5,491.20	10,982.40	annual	78.0	10,982.40
438.358(c)(4) PAHP Optional	12	4	48.75	195.0	78.32	3,818.10	15,272.40	annual	195.0	15,272.40

CFR Section	# Respondents	# responses	Burden per response (hours)	Total Annual Hours	Labor Rate (\$/hr)	Cost (\$) per Response	Total cost (\$)	Frequency	Annualized hours*	Annualized costs (\$)
EQR-Related Activities										
438.358(c)(4) PCCM Optional EQR-Related Activities	10	2	48.75	97.5	78.32	3,818.10	7,636.20	annual	97.5	7,636.20
438.358(c)(4) PAHP Optional EQR-Related Activities	12	4	107.25	429.0	64.46	6,913.34	27,653.34	annual	429.0	27,653.34
438.358(c)(4) PCCM Optional EQR-Related Activities	10	2	107.25	214.5	64.46	6,913.34	13,826.67	annual	214.5	13,826.67
438.358(c)(5) PAHP Optional EQR-Related Activities	12	4	39	156.0	140.8 0	5,491.20	21,964.80	annual	156.0	21,964.80
438.358(c)(5) PCCM Optional EQR-Related Activities	10	2	39	78.0	140.8 0	5,491.20	10,982.40	annual	78.0	10,982.40
438.358(c)(5) PAHP Optional EQR-Related Activities	12	4	48.75	195.0	78.32	3,818.10	15,272.40	annual	195.0	15,272.40
438.358(c)(5) PCCM Optional EQR-Related Activities	10	2	48.75	97.5	78.32	3,818.10	7,636.20	annual	97.5	7,636.20
438.358(c)(5) PAHP Optional EQR-Related Activities	12	4	107.25	429.0	64.46	6,913.34	27,653.34	annual	429.0	27,653.34
438.358(c)(5) PCCM Optional EQR-Related Activities	10	2	107.25	214.5	64.46	6,913.34	13,826.67	annual	214.5	13,826.67
438.360(b) MCO/PIHP Nonduplication Disclosure	51	51	2	102.0	64.46	128.92	6,574.92	annual	102.0	6,574.92
438.360(b) MCO/PIHP Nonduplication Disclosure	51	51	6	306.0	36.54	219.24	11,181.24	annual	306.0	11,181.24
438.360(b) PAHP Nonduplication Disclosure	4	4	2	8.0	64.46	128.92	515.68	annual	8.0	515.68
438.360(b) PAHP Nonduplication Disclosure	4	4	6	24.0	36.54	219.24	876.96	annual	24.0	876.96
438.360(b) Nonduplication	40	55	2	110.0	36.54	73.08	4,019.40	annual	110.0	4,019.40

CFR Section	# Respondents	# responses	Burden per response (hours)	Total Annual Hours	Labor Rate (\$/hr)	Cost (\$) per Response	Total cost (\$)	Frequency	Annualized hours*	Annualized costs (\$)
Materials to EQRO										
438.360(b) State Nonduplication Offset - MCO/PIHP	40	-51	474.3	-24,189.3	64.46	30,573.38	-1,559,242.28	annual	-24,189.3	-1,559,242.28
438.360(b) State Nonduplication Offset - PAHP	40	-4	344.3	-1,377.2	64.46	22,193.58	-88,774.31	annual	-1,377.2	-88,774.31
438.360(b) MCO/PIHP/PAHP Nonduplication Offset	55	-55	75	-4,125.0	64.46	4,834.50	-265,897.50	annual	-4,125.0	-265,897.50
438.360(b) MCO/PIHP/PAHP Nonduplication Offset	55	-55	75	-4,125.0	36.54	2,740.50	-150,727.50	annual	-4,125.0	-150,727.50
438.362 Exemption – MCO Information Preparation	40	17	2	34.0	64.46	128.92	2,191.64	annual	34	2,191.64
438.362 Exemption - MCO Information Preparation	40	17	6	102.0	36.54	219.24	3,727.08	annual	102.0	3,727.08
438.364(a) Amend EQRO Contract	37	37	0.5	18.5	64.46	32.23	1,192.51	once	6.2	397.50
438.364(b)(1) Amend EQRO Contract	10	10	0.5	5.0	64.46	32.23	322.30	once	1.7	107.43
438.364(b)(2) Provide EQR Reports	42	2,805	0.0833	233.7	36.54	3.01	8,539.40	annual	233.7	8,539.40
438.370(c) Update State Policies	12	12	0.5	6.0	64.46	32.23	386.76	once	2.0	128.92
438.370(c) Submit EQRO Contract	12	12	0.25	3.0	36.54	9.14	109.62	once	1.0	36.54
438.400(b) Definitions	511	511	5	2,555	64.46	322.30	164,695.30	once	845	54,898.43
438.400(b) Definitions	40	40	5	200	64.46	322.30	12,892.00	once	67	4,297.33
438.402(a) Grievance System	41	41	10	410	140.80	1,408.00	57,728.00	once	137	19,242.67
438.402(a) Grievance System	41	41	75	3,075	64.46	4,834.50	198,214.50	once	1,025	66,071.50

CFR Section	# Respon- dents	# responses	Burden per response (hours)	Total Annual Hours	Labor Rate (\$/hr)	Cost (\$) per Response	Total cost (\$)	Fre- quency	Annualized hours*	Annualized costs (\$)
438.402(a) Grievance System	41	41	15	615	78.32	1,174.80	48,166.80	once	205	16,055.60
438.402(a) Grievance System	41	410	36	14,760	64.46	2,320.56	951,429.60	annual	14,760	951,429.60
438.404(a) Notices	41	240,000	0.0167	4,008	30.92	0.52	123,927.36	annual	4,008	123,927.36
438.408(b) Appeals	200	200	1	200	64.46	64.46	12,892.00	once	67	4,297.33
438.416 Reporting	51	240,000	0.0167	4,008	36.54	0.61	146,452.32	annual	4,008	146,452.32
438.416 Reporting	51	51	3	168	78.32	234.96	11,982.96	once	56	3,994.32
438.416 Reporting	51	856,257	0.0167	14,299	36.54	0.61	522,503.43	annual	14,271	522,503.43
438.420(c)(4) Continuation of Benefits	511	511	4	2,044	64.46	257.84	131,756.24	once	676	43,918.75
438.602(a) Program Integrity	42	42	6	252	64.46	386.76	16,243.92	once	84	5,414.64
438.602(b) Program Integrity	572	572	6	3,432	78.32	469.92	268,794.24	once	1,136	89,598.08
438.602(e) Program Integrity	42	572	6.6667	3,680	66.38	442.54	244,278.40	annual	3,787	244,278.40
438.602(g) Program Integrity	40	40	1	40	78.32	78.32	3,132.80	annual	40	3,132.80
438.608(a)(1) Program Integrity	552	552	2	1,104	64.46	128.92	71,163.84	once	379	23,721.28
438.608(a)(2)- (3) Program Integrity	552	552	2	1,104	64.46	128.92	71,163.84	annual	1,136	71,163.84
438.608(a)(4) Program Integrity	200	20,000	0.0167	334	30.92	0.52	10,327.28	annual	334	10,327.28
438.608(c)-(d) Program Integrity	552	552	1	552	78.32	78.32	43,232.64	once	189	14,410.88
438.722 Disenrollment Notices	12	12	1	12	64.46	64.46	773.52	annual	12	773.52
438.722 Disenrollment Notices	12	1,084,536	0.0167	18,112	30.92	0.52	560,015.35	annual	18,075	560,015.35
438.818(a)(2) Encounter Data	9	9	1	9	64.46	64.46	580.14	once	3	193.38
438.818(a)(2) Encounter Data	9	9	10	90	64.46	644.60	5,801.40	once	30	1,933.80
438.818(a)(2) Encounter Data	9	9	100	900	78.32	7,832.00	70,488.00	once	300	23,496.00

CFR Section	# Respondents	# responses	Burden per response (hours)	Total Annual Hours	Labor Rate (\$/hr)	Cost (\$) per Response	Total cost (\$)	Frequency	Annualized hours*	Annualized costs (\$)
438.818(a)(2) Encounter Data	9	9	125	1,125	64.46	8,057.50	72,517.50	annual	375	72,517.50
438.818(a)(2) Encounter Data	9	9	25	225	140.80	3,520.00	31,680.00	annual	75	31,680.00
Total	606	22,322,607	varies	1,494,684	varies	varies	79,771,085	varies	1,594,366	91,689,781

TABLE 2b: Summary of Annual PRA-related Requirements and Burden under 42 CFR Part 457
OMB Control Number 0938-New (CMS-10554)

CFR section	# Respondents	# responses	Burden per response (hours)	Total Annual Hours	Labor Rate (\$/hr)	Cost (\$) per Response	Total cost (\$)	Frequency	Annualized hours*	Annualized Costs (\$)
457.1201 Contracts	62	62	6	372.0	64.46	386.76	23,979.12	once	124	7,993.04
457.1203 MLR	58	58	101	5858.0	78.32	7,910.32	458,798.56	once	1,952.7	152,932.85
457.1203 MLR	58	58	50	2,900.0	64.46	3,223.00	186,934.00	once	966.7	62,311.33
457.1203 MLR	58	58	17	986.0	140.8	2,393.60	138,828.80	once	328.7	46,276.27
457.1203 MLR	58	58	31.8	1,844.4	78.32	2,490.58	144,453.41	annual	1,844.4	144,453.41
457.1203 MLR	58	58	15.9	922.2	64.46	1,024.91	59,445.01	annual	922	59,445.01
457.1203 MLR	58	58	5.3	307.4	140.8	746.24	44,028.16	annual	307	44,028.16
457.1206 Contracts	3	3	4	12.0	64.46	257.84	773.52	once	4	257.84
457.1207 Information Requirements	25	25	4	100.0	64.46	257.84	6,446.00	annual	100	6,446.00
457.1207 Information Requirements	25	25	6	150.0	78.32	469.92	11,748.00	once	50	3,916.00
457.1207 Information Requirements	25	25	3	75.0	78.32	234.96	5,874.00	annual	75	5,874.00
457.1207 Information Requirements	25	25	6	150.0	64.46	386.76	9,669.00	once	50	3,223.00
457.1207 Information Requirements	15	15	40	600.0	64.46	2,578.40	38,676.00	once	200	12,892.00
457.1207 Information Requirements	15	15	2	30.0	64.46	128.92	1,933.80	annual	30	1,933.80
457.1207 Information Requirements	25	25	4	100.0	78.32	313.28	7,832.00	once	33	2,610.67
457.1207 Information Requirements	25	25	6	150.0	64.46	386.76	9,669.00	once	50	3,223.00
457.1207 Information Requirements	15	15	40	600.0	64.46	2,578.40	38,676.00	once	200	12,892.00
457.1207 Information Requirements	25	25	1	25.0	64.46	64.46	1,611.50	once	8.3	537.17
457.1207 Information Requirements	25	115,000	0.016667	1,916.7	36.54	0.61	70,035.00	once	638.9	23,345.00

CFR section	# Respondents	# responses	Burden per response (hours)	Total Annual Hours	Labor Rate (\$/hr)	Cost (\$) per Response	Total cost (\$)	Frequency	Annualized hours*	Annualized Costs (\$)
457.1207 Information Requirements	5	5	10	50.0	64.46	644.60	3,223.00	once	17	1,074.33
457.1207 Information Requirements	20	20	4	80.0	64.46	257.84	5,156.80	once	27	1,718.93
457.1207 Information Requirements	62	1,150,000	0.016667	19,166.7	36.54	0.61	700,350.00	once	6,388.90	233,450.00
457.1207 Information Requirements	62	115,000	0.01666667	1,916.7	36.54	0.61	70,035	annual	1,916.7	70,035.00
457.1207 Information Requirements	62	62	1	62	64.46	64.46	3,996.52	once	21	1,332.17
457.1207 Information Requirements	62	62	1	62	78.32	78.32	4,855.84	once	21	1,618.61
457.1209 Contracts	40	40	1	40.0	78.32	78.32	3,132.80	once	13	1,044.27
457.1209 Contracts	18	18	12	216.0	64.46	773.52	13,923.36	annual	216	13,923.36
457.1210(a) Enrollment	25	115,000	0.016667	1,916.7	36.54	0.61	70,035.01	annual	1,916.70	70,035.01
457.1210(c) Enrollment	15	15	4	60.0	64.46	257.84	3,867.60	once	20	1,289.20
457.1210(c) Enrollment	25	115,000	0.016667	1,916.7	36.54	0.61	70,035.01	once	639	23,345.00
457.1214 Conflict	5	5	10	50.0	64.46	644.60	3,223.00	once	17	1,074.33
457.1216 Continued Services	25	25	10	250.0	64.46	644.60	16,115.00	once	83	5,371.67
457.1216 Continued Services	25	25	4	100.0	78.32	313.28	7,832.00	once	33	2,610.67
457.1216 Continued Services	62	62	4	248.0	78.32	313.28	19,423.36	once	83	6,474.45
457.1216 Continued Services	30,000	30,000	0.16666667	5,000.0	66.92	11.15	334,600.00	annual	5000	334,600.00
457.1218 Network	12	12	15	180.0	64.46	966.90	11,602.80	once	60	3,867.60
457.1218 Network	5	5	10	50.0	64.46	644.60	3,223.00	once	17	1,074.33
457.1218 Network	25	25	3	75.0	64.46	193.38	4,834.50	once	25	1,611.50
457.1222 Communication	3	3	1	3.0	64.46	64.46	193.38	annual	3	193.38
457.1222 Communication	3	3	4	12.0	64.46	257.84	773.52	annual	12	773.52

CFR section	# Respondents	# responses	Burden per response (hours)	Total Annual Hours	Labor Rate (\$/hr)	Cost (\$) per Response	Total cost (\$)	Frequency	Annualized hours*	Annualized Costs (\$)
457.1222 Communication	3	234,000	0.016667	3,900.0	36.54	0.61	142,506.29	annual	3900	142,506.29
457.1224 Marketing	25	25	3	75.0	64.46	193.38	4,834.50	annual	75	4,834.50
457.1224 Marketing	5	5	2	10.0	64.46	128.92	644.60	once	3	214.87
457.1230(a) Access Stds	58	58	3	174.0	64.46	193.38	11,216.04	once	58	3,738.68
457.1230(b) Access Stds	58	58	20	1,160.0	64.46	1,289.20	74,773.60	annual	1160	74,773.60
457.1230(b) Access Stds	58	58	1	58.0	64.46	64.46	3,738.68	annual	58	3,738.68
457.1230(c) Access Stds	64,000	64,000	0.166667	10,666.7	55.26	9.21	589,440.00	annual	10,666.70	589,440.00
457.1230(c) Access Stds	17	17	3	51.0	64.46	193.38	3,287.46	once	17	1,095.82
457.1230(c) Access Stds	230,000	230,000	0.166667	38,333.0	36.54	6.09	1,400,700.00	annual	38,333.00	1,400,700.00
457.1230(c) Access Stds	58	58	4	232.2	78.32	313.28	18,170.24	once	77.4	6,161.17
457.1230(c) Access Stds	23,000	23,000	1	23,000.0	66.92	66.92	1,539,160.00	annual	23,000	1,539,160.00
457.1230(d) Access Stds	58	90,480	0.5	45,240	66.92	33.46	3,027,460.8	annual	45,240	3,027,460.8
457.1233(b) Structure and Operations	58	58	3	174.0	64.46	193.38	11,216.04	once	58	3,738.68
457.1233(c) Structure and Operations	58	58	2	116.0	64.46	128.92	7,477.36	annual	116	7,747.36
457.1233(d) Structure and Operations	55	55	20	1,100.0	78.32	1,566.40	86,152.00	once	367	28,717.33
457.1240(b) Quality	25	25	3.333333	83.0	78.32	261.07	6,500.56	annual	83	6,500.56
457.1240(b) Quality	2	2	0.33	0.7	64.46	21.27	42.54	annual	0.66	42.54
457.1240(b) Quality	3	3	10	30.0	64.46	644.60	1,933.80	once	10	644.6
457.1240(b) Quality	3	3	10	30.0	64.46	644.60	1,933.80	annual	30	1,933.80
457.1240(b) Quality	7	21	4	84.0	64.46	257.84	5,414.64	annual	84	5,414.64
457.1240(b) Quality	3	3	2	6.0	64.46	128.92	386.76	once	3	128.92
457.1240(b) Quality	55	168	6	1,344.0	64.46	386.76	86,634.24	annual	1344	86,634
457.1240(b) Quality	3	3	6	18.0	64.46	386.76	1,160.28	annual	32	1,160.28
457.1240(b) Quality	3	3	15	45.0	64.46	966.90	2,900.70	annual	45	2,900.70

CFR section	# Respondents	# responses	Burden per response (hours)	Total Annual Hours	Labor Rate (\$/hr)	Cost (\$) per Response	Total cost (\$)	Frequency	Annualized hours*	Annualized Costs (\$)
457.1240(b) Quality	25	25	0.5	12.5	64.46	32.23	805.75	once	4	268.58
457.1240(b) Quality	25	25	1	25.0	64.46	64.46	1,611.50	annual	25	1,611.50
457.1240(c) Quality	58	58	0.25	14.5	64.46	16.12	841	annual	14.5	841
457.1240(c) Quality	58	58	0.25	14.5	64.46	16.12	841	once	4.83	280.33
457.1240(d) Quality	25	25	200	5,000.0	64.46	12,892.00	322,300.00	once	1,666.67	107,433.33
457.1240(d) Quality	17	17	100	1,700.0	78.32	7,832.00	133,144.00	once	566.67	44,381.33
457.1240(d) Quality	17	17	30	510.0	140.80	4,224.00	71,808.00	once	170.00	23,936.00
457.1240(d) Quality	8	8	800	6,400.0	64.46	51,568.00	412,544.00	once	2,133.33	137,514.67
457.1240(d) Quality	8	8	400	3,200.0	78.32	31,328.00	250,624.00	once	1,066.67	83,541.33
457.1240(d) Quality	8	8	120	960.0	140.80	16,896.00	135,168.00	once	320.00	45,056.00
457.1240(d) Quality	8	8	120	960.0	140.80	16,896.00	135,168.00	once	320.00	45,056.00
457.1240(d) Quality	8	8	50	400.0	64.46	3,223.00	25,784.00	once	133.33	8,594.67
457.1240(d) Quality	8	8	20	160.0	64.46	1,289.20	9,024.40	once	53	3,437.87
457.1240(d) Quality	8	8	5	35.0	36.54	182.70	1,278.90	annual	11.67	487.20
457.1240(d) Quality	8	8	25	175.0	64.46	1,611.50	11,280.50	annual	58.33	4,297.33
457.1240(d) Quality	58	58	40	2320	64.46	2,578.40	149,547.20	annual	2,320	149,547.20
457.1240(e) Quality	13	13	25	325.0	64.46	1,611.50	20,949.50	annual	108.33	6,983.17
457.1240(e) Quality	13	13	2	26.0	36.54	73.08	950.04	annual	8.67	316.68
457.1240(e) Quality	13	13	5	65	64.46	322.30	4,189.90	annual	21.67	1,396.63
457.1240(e) Quality	13	13	1	13	36.54	36.54	475.02	annual	4.33	158.34
457.1240(e) Quality	5	5	0.5	2.5	64.46	32.23	161.15	annual	0.83	53.72
457.1240(e) Quality	5	5	25	125.0	64.46	1,611.50	8,057.50	annual	41.67	2,685.83
457.1240(e) Quality	5	5	2	10.0	36.54	73.08	365.40	annual	3.33	121.80
457.1240(e) Quality	5	5	5	25.0	64.46	322.30	1,611.50	annual	8.33	537.17
457.1240(e) Quality	5	5	1	5.0	36.54	36.54	182.70	annual	1.67	60.90
457.1240(e) Quality	25	25	40	1,000.0	64.46	2,578.40	64,460.00	annual	333.33	21,486.67

CFR section	# Respondents	# responses	Burden per response (hours)	Total Annual Hours	Labor Rate (\$/hr)	Cost (\$) per Response	Total cost (\$)	Frequency	Annualized hours*	Annualized Costs (\$)
457.1240(e) Quality	5	5	0.5	2.5	64.46	32.23	161.15	once	0.83	53.72
457.1250(a) EQR	5	5	125	625.0	64.46	8,057.50	40,287.50	once	208	13,429.17
457.1250(a) EQR	5	5	50	250.0	78.32	3,916.00	19,580.00	once	83	6,526.67
457.1250(a) EQR	5	5	10	50.0	140.8	1,408.00	7,040.00	once	17	2,346.67
457.1250(a) EQR	5	5	2	10.0	64.46	128.92	644.60	once	3	214.87
457.1250(a) EQR	5	15	65	975.0	64.46	4,189.90	62,848.50	annual	975	62,848.50
457.1250(a) EQR	5	15	53	795.0	64.46	3,416.38	51,245.70	annual	795	51,245.70
457.1250(a) EQR	5	5	120.3333	602.0	64.46	7,756.69	38,783.43	annual	602	38,783.43
457.1250(a) EQR	5	5	80	400.0	64.46	5,156.80	25,784.00	annual	400	25,784.00
457.1250(a) EQR	5	5	80	400.0	36.54	2,923.20	14,616.00	annual	400	14,616.00
457.1250(a) EQR	58	58	60	3480	64.46	3,867.60	224,320.80	annual	3480	224,320.80
457.1250(a) EQR	4	4	173.3	693.2	64.46	11,170.92	44,683.67	annual	693.2	44,683.67
457.1250(a) EQR	58	58	100	6,000	64.46	6,446.00	386,760	annual	6000	386,786
457.1250(a) EQR	58	58	100	6,000	36.54	3,654.00	219,240.00	annual	6000	219,240.00
457.1250(a) EQR	4	4	50	200.0	64.46	3,223.00	12,892.00	annual	50	12,892.00
457.1250(a) EQR	4	4	50	200	36.54	1,827.00	7,308	annual	50	7,308
457.1250(a) EQR	48	48	350	16,800.0	64.46	22,561.00	1,082,928.00	annual	16800	1,082,928.00
457.1250(a) EQR	30	30	50	1,500.0	64.46	3,223.00	96,690.00	annual	1500	96,690.00
457.1250(a) EQR	20	20	159	3,180.0	64.46	10,249.14	204,982.80	annual	3180	204,982.80
457.1250(a) EQR	26	26	195	5,070.0	64.46	12,569.70	326,812.20	annual	5070	326,812.20
457.1250(a) EQR	52	52	159	8,268.0	64.46	10,249.14	532,955.28	annual	8268	532,955.28
457.1250(a) EQR	25	25	0.5	12.5	64.46	32.23	805.75	annual	12.5	805.75
457.1250(a) EQR	5	5	0.5	2.5	64.46	32.23	161.15	annual	2.5	161.15
457.1250(a) EQR	58	290	0.083333	24.1	36.54	3.05	880.61	annual	24.1	880.61
457.1260 Grievances	25	25	5	125.0	64.46	322.30	8,057.50	annual	125	8,057.50
457.1260 Grievances	58	2088	3	6,264.0	64.46	193.38	403,777.44	annual	6264	403,777.44
457.1260 Grievances	58	58	10	580.0	140.8	1,408.00	81,664.00	once	193	27,221.33

CFR section	# Respondents	# responses	Burden per response (hours)	Total Annual Hours	Labor Rate (\$/hr)	Cost (\$) per Response	Total cost (\$)	Frequency	Annualized hours*	Annualized Costs (\$)
457.1260 Grievances	58	58	75	4,350.0	64.46	4,834.50	280,401.00	once	1450	93,467.00
457.1260 Grievances	58	58	15	870.0	78.32	1,174.80	68,138.40	once	290	22,712.80
457.1260 Grievances	58	278,400	0.5	139,200.0	64.46	32.23	8,972,832.00	annual	139,200.0	8,972,832.00
457.1260 Grievances	115,000	115,000	0.016667	1,916.7	36.54	0.61	70,035.00	annual	1,916.7	70,035.00
457.1260 Grievances	23,000	23,000	0.016667	383.0	36.54	0.61	14,007.00	annual	383	14,007.00
457.1270 Sanctions	8	8	1	8.0	64.46	64.46	515.68	annual	8	515.68
457.1270 Sanctions	30000	30000	0.02	500.0	26.4	0.53	15,840.00	annual	500	15,840
457.1270 Sanctions	15	15	0.5	8.0	64.46	32.23	483.45	annual	8	483.45
457.1285 Program Integrity	25	25	50	1,250.0	64.46	3,223.00	80,575.00	once	416	26,858.33
457.1285 Program Integrity	7	7	1	7.0	64.46	64.46	451.22	once	2	150.41
457.1285 Program Integrity	7	7	10	70.0	64.46	644.60	4,512.20	once	23	1,504.07
457.1285 Program Integrity	7	7	100	700.0	78.32	7,832.00	54,824.00	once	233	18,274.67
457.1285 Program Integrity	7	7	125	875.0	64.46	8,057.50	56,402.50	annual	875	56,402.50
457.1285 Program Integrity	7	7	25	175.0	140.8	3,520.00	24,640.00	annual	175	24,640.00
457.1285 Program Integrity	25	25	1	25.0	78.32	78.32	1,958.00	annual	25	1,958.00
457.1285 Program Integrity	58	58	5	290.0	64.46	322.30	18,693.40	once	96.7	6,231
457.1285 Program Integrity	58	58	2	116	64.46	128.92	7,477.36	annual	116	7,477.36
457.1285 Program Integrity	25	2,500	0.016667	41.7	30.92	0.52	1,288.33	annual	41.7	1,288.33
457.1285 Program Integrity	58	58	1	58.0	78.32	78.32	4,542.56	once	19.3	1,514.19
total	99	2,793,851	varies	411,319.30	varies	varies	24,974,227	varies	365,550	22,123,306.80

TABLE 2c: Summary of Total Annual PRA-related Requirements and Burden under 42 CFR Parts 438 and 457

CFR Section	# Respondents	# responses	Burden per response (hours)	Total Annual Hours	Labor Rate (\$/hr)	Cost (\$) per Response	Total cost (\$)	Frequency	Annualized hours*	Annualized costs (\$)
Part 438 (438.1-.242;.400-.818) OMB # 0938-0920 (CMS-10108)	606	22,309,920	varies	998,929	varies	varies	47,932,486	varies	1,116,040	61,239,313
Part 438 (438.310-340) OMB #0938-NEW (CMS-10553)	606	6,670	varies	69,245	varies	varies	4,740,332.36	varies	51,849.40	3,354,272.44
Part 438 (438.350-370) OMB #0938-0786 (CMS-R-305)	606	6,017	varies	426,509	varies	varies	27,098,266.76	varies	426,476.70	27,096,195.41
Part 457	99	2,793,851	varies	411,319	varies	varies	24,974,227	varies	365,550	22,123,306.80
TOTAL	705	25,116,458	varies	1,906,003	varies	varies	104,745,312	varies	1,959,916	113,813,088

E. Exempt ICRs

No comments were received on these burden estimates.

1. Administrative Actions

While the requirements under §§ 431.220(a)(5) and (6), 431.220(b), 438.710(b)(2), 438.730(b), and 457.1270(a), (b), and (c) are subject to the PRA, since the information collection requirements are associated with an administrative action (5 CFR 1320.4(a)(2) and (c)), they are exempt from the requirements of the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*)

Section 431.220(a)(5) and (6) would add PAHP enrollees as eligible for a state fair hearing as permitted in subpart B of 42 CFR part 438. Section 431.220(b) prescribes procedures for an opportunity for a hearing if the state agency or non-emergency transportation PAHP takes action to suspend, terminate, or reduce services, or an MCO, PIHP or PAHP takes action under subpart.

Before imposing any of the sanctions specified in subpart I, § 438.710(a) would require that the state give the affected MCO, PIHP, PAHP or PCCM written notice that explains the basis and nature of the sanction. Section 438.710(b)(2) states that before terminating an MCO's, PIHP's, PAHP's or PCCM's contract, the state would be required to: (1) Give the MCO or PCCM written notice of its intent to terminate, the reason for termination, the time and place of the hearing; (2) give the entity written notice (after the hearing) of the decision affirming or reversing the

proposed termination of the contract and, for an affirming decision, the effective date of termination; and (3) give enrollees of the MCO or PCCM notice (for an affirming decision) of the termination and information, consistent with § 438.10, on their options for receiving Medicaid services following the effective date of termination.

Section 438.730(b) would require that if CMS accepts a state agency's recommendation for a sanction, the state agency would be required to give the MCO written notice of the proposed sanction. Section 438.730(c) would require that if the MCO submits a timely response to the notice of sanction, the state agency must give the MCO a concise written decision setting forth the factual and legal basis for the decision. If CMS reverses the state's decision, the state must send a copy to the MCO.

Section 457.1270 would apply subpart I (Sanctions) of part 438 to CHIP. Within subpart I, § 438.710(a) would require that the state provide the affected entity with timely written notice of the basis of the sanction. Section 438.710(b) would require that the state provide an entity a pre-termination hearing. If CMS accepts a state agency's recommendation for a sanction, § 438.730(b) would require that the agency provide the MCO, PIHP or PAHP written notice of the proposed sanction. If the MCO submits a timely response to the notice of sanction, § 438.730(c) would require that the state agency provide the MCO, PIHP or PAHP with a concise written decision setting forth the factual and legal basis for the

decision. If we reverse the state's decision, the state must send a copy to the affected MCO, PIHP or PAHP.

2. Fewer Than 10 Respondents

While the requirements under §§ 438.8(m), 438.70(a), 438.102(a)(2), 438.340(a), 438.350, 438.360(c), 438.724, and 438.818(d) are subject to the PRA, in each instance we estimate fewer than 10 respondents. Consequently, the information collection requirements are exempt (5 CFR 1320.3(c)) from the requirements of the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*)

Section 438.8(m) would require the MCO, PIHP, or PAHP to recalculate its MLR for any year in which a retroactive capitation change is made. In our experience working with states on rate setting, retroactive adjustments are not a common practice; therefore, we estimate that no more than three plans per year may have to recalculate their MLR.

Section 438.70(a) would require that states have a process to solicit and address viewpoints from beneficiaries, providers, and other stakeholders as part of the design, implementation, and oversight of the managed LTSS program. Based on our experience approving MLTSS programs and the number of states that have not yet implemented, we estimate no more than 3 states per year would elect to move to a managed LTSS program.

Section 438.102(a)(2) specifies that MCOs, PIHPs, and PAHPs are not required to cover, furnish, or pay for a particular counseling or referral service if the MCO, PIHP, or PAHP objects to the provision of that service on moral or

religious grounds; and that written information on these policies is made available to: Prospective enrollees, before and during enrollment; and current enrollees, within 90 days after adopting the policy for an any particular service. Based on our experience reviewing and approving plan contracts, we believe the burden associated with this requirement affects no more than 3 MCOs or PIHPs annually since it applies only to the services they discontinue providing on moral or religious grounds during the contract period, which varies in length and can be as short as one year. PAHPs are excluded from this estimate because they generally do not provide services that would be affected by this provision.

Section 438.340(a) requires each state that contracts with an MCO, PIHP, PAHP, or PCCM entity (described in § 438.310(c)(2)) to write and implement a quality strategy. We estimate that there are three states that contract only with PAHPs and two states that contract only with PCCM entities (described in § 438.310(c)(2)), and thus do not already have a quality strategy (the other states with PAHPs and PCCM entities (described in § 438.310(c)(2)) also contract with MCOs and/or PIHPs, and thus, already have an initial quality strategy). We estimate that these five states will draft an initial quality strategy.

Section 438.350 adds PAHPs and PCCM entities (described in § 438.310(c)(2)) to the EQR process. We estimate that there are three states with PAHPs and two states with PCCM entities (described in § 438.310(c)(2)) that do not currently have an EQRO contract and will need to enter into a contract with an EQRO.

Section 438.360(c) requires states to document, in the quality strategy required at § 438.340, which mandatory EQR-related activities it will apply the non-duplication provisions to, and why it believes these activities are duplicative. Given that this is already standard practice for the 37 states that currently contract with MCOs and/or PIHPs, only the three states that contract only with PAHPs and the two states that contract only with PCCM entities (described in § 438.310(c)(2)) will have to revise their policies and procedures to include this in their quality strategy.

Section 438.724 would require that the state provide written notice to their CMS Regional Office whenever it imposes or lifts a sanction on a PCCM or PCCM entity. Given the limited scope of benefits provided by a PCCM or PCCM entity and the Regional offices' experience, we anticipate that no more than 3 states may impose or lift a

sanction on a PCCM or PCCM entity in any year.

Section 438.818(d) would have required states new to managed care and not previously submitting encounter data to MSIS to submit an Implementation plan. There are currently only 8 states that do not use MCOs thus these would be the only states that may have to submit an Implementation plan should they adopt managed care in the future. This estimate is no longer needed as this provision is not being finalized.

3. Usual and Customary Business Practices

Section 433.138(e)(1) would make a technical correction addressing state Medicaid agencies' review of claims with trauma codes, to identify instances where third party liability (TPL) may exist for expenditures for medical assistance covered under the state plan. The correction would remove references to the International Classification of Disease, 9th edition, Clinical Modification Volume 1 (ICD-9-CM) by replacing the references with a general description of the types of medical diagnoses indicative of trauma. States would use the International Classification of Disease that they are using at the time of claims processing. There is no additional cost to the state related to the proposed changes to § 433.138(e) because the proposed changes do not require any action by the state, if the state wishes to retain their usual and customary editing for the same types of traumatic injuries currently identified with ICD-9-CM.

While the requirements under §§ 438.10(c)(7), 438.208(b)(2), 438.208(b)(5), 438.210(b), 438.214, 438.360(c), 438.406(b)(5), 438.408(b)(2) and (3), 438.408(f)(1) and (2), and 438.416(b) and (c) are subject to the PRA, we believe the associated burden is exempt from the PRA in accordance with 5 CFR 1320.3(b)(2). We believe that the time, effort, and financial resources necessary to comply with the aforementioned requirements would be incurred by persons during the normal course of their activities and, therefore, should be considered usual and customary business practices.

Section 438.10(c)(7) would add PAHPs and PCCMs to the managed care entities that must have mechanisms in place to help enrollees and potential enrollees understand the requirements and benefits of managed care. These practices are customarily performed to maintain and improve market share.

Section 438.208(b)(2) would require that MCOs, PIHPs and PAHPs coordinate an enrollee's care between

settings or with services received through a different MCO, PIHP, PAHP and FFS. Section 438.208(b)(2)(i) would require discharge planning which has been a long standing industry practice since managed care plans consistently require authorization for all inpatient and facility care. Coordination of care, including discharge planning, is fundamental to managed care and is not unique to Medicaid. It is customarily performed by all managed care insurers, particularly for high-risk or high-cost populations.

Section 438.208(b)(5) would require providers to maintain a record according to medical industry accepted professional standards. Record maintenance is customarily performed as a condition of licensure.

Section 438.210(b) would require contracts with MCOs, PIHPs, or PAHPs and its subcontractors to have written policies and procedures for the processing of requests for initial and continuing authorizations of services. The burden associated with this requirement is the time required to develop the policies and procedures which is standard industry practice for managed care plans. Building and maintaining a network is fundamental to managed care and is not unique to Medicaid. It is customarily performed by all managed care insurers.

In § 438.214, each state must ensure, through its contracts, that each MCO, PIHP, or PAHP implements written policies and procedures for the selection and retention of providers. Since all managed care programs utilize provider networks, this is industry standard practice.

Section 438.406(b)(5) would modify the language for evidence standards for appeals to mirror the private market evidence standards. This aligns the text with private market requirements but does not alter the meaning. Based on our experience approving managed care plan contracts, most insurers offer more than one line of business, and therefore we believe this will make Medicaid consistent with usual and customary business practices.

Section 438.408(b)(2) would change the timeframe an entity has to reach a determination from 45 days to 30 days to align with Medicare. Most insurers offer more than one line of business, and therefore we believe this timeframe will allow MCOs, PIHPs, and PAHPs to be consistent with their usual and customary business practices and reduce their burden. Section 438.408(b)(3) would change the timeframe an entity has to reach a determination in an expedited appeal from 3 days to 72 hr to align with

Medicare and the private market. Based on our experience approving plan contracts, most insurers offer more than one line of business, and therefore we believe this timeframe will make Medicaid consistent with usual and customary business practices.

Section 438.408(f)(1) and (2) would require that an enrollee exhaust the appeals process before proceeding to the state fair hearing process, and change the timeframe in which a beneficiary must request a state fair hearing to 120 days. MCOs, PIHPs, and PAHPs would no longer have to maintain an appeal and a fair hearing simultaneously which will decrease administrative burdens. The changing of the timeframe to request a state fair hearing from “not less than 20 or in excess of 90 days” to 120 days aligns with the private market. Based on our experience approving plan contracts, most insurers offer more than one line of business, and therefore we believe aligning these timeframes will make Medicaid consistent with their usual and customary business practices.

Section 438.416(b) and (c) would set forth a standard for the minimum types of information an entity must record during the appeals process and how that information must be stored. This standard aligns with the standards in the private market. Based on our experience approving plan contracts, most insurers offer more than one line of business, and therefore, we believe aligning record keeping standards will make Medicaid consistent with usual and customary business practices.

Comment: We received one comment on the COI burden estimate in § 438.818(a)(2): “Encounter data be validated prior to its submission. 1,350 hr [9 states × (150 hr)] and \$88,722 [9 states × ((125 hr × \$53.32/hr) + (25 hr × \$127.72/hr)] The commenter believed CMS drastically undervalued the maintenance, reconciliation, modification, and monitoring it takes to accurately submit this data, besides ongoing license fees.

Response: This estimate was one of three addressed in the COI as possible implementation options for § 438.818(a)(2) and offers an estimate for procuring a non-EQRO vendor for the data validation. We disagree that the estimate under values the effort required given the wide variation in state procurement processes. Additionally, we believe most states electing to utilize an outside vendor for this activity will opt to use their EQRO vendor as those expenses receive 75 percent FFP. Additionally, all states contracting with managed care plans should currently be collecting and validating encounter data. Depending on how robust those

validation methods are currently, some states may not need to alter their processes based on proposed § 438.818(a)(2). We decline to revise this estimate.

VI. Regulatory Impact Analysis

A. Statement of Need

This final rule modernizes the Medicaid managed care regulations recognizing changes in the usage of managed care delivery systems since the release of the final rule in 2002. As Medicaid managed care programs have developed and matured in the intervening years, states have taken various approaches to implementing part 438. This has resulted in inconsistencies and, in some cases, less than optimal results. To improve consistency and adopt policies and practices from states that have proven the most successful, we are finalizing revisions to strengthen beneficiary protections, support alignment with rules governing managed care in other public and private sector programs, strengthen actuarial soundness and the accountability of rates paid in the Medicaid managed care program, and implement statutory provisions issued since 2002.

According to the 2014 Actuarial Report on the Financial Outlook for Medicaid, total Medicaid outlays in federal FY 2013 exceeded \$457 billion; \$265 billion, or 58 percent represented federal spending, and \$192 billion, or 42 percent represented state spending.¹⁴ States have continued to expand the use of managed care in the past decade, not only to new geographic areas but to more complex populations, including seniors, persons with disabilities, and those who need LTSS. Today, the predominant form of managed care in Medicaid is capitated risk-based arrangements—similar in structure to some arrangements in the private insurance market. Coordination and alignment with the private insurance market will improve operational efficiencies for states and managed care plans and improve the experience of care for individuals moving between insurance coverage options. Total Medicaid managed care spending (federal and state) exceeded \$132 billion in 2013,¹⁵ with expenditures rising annually as new beneficiaries and programs move into a managed care delivery system. It is CMS’

responsibility to ensure that these dollars are spent wisely, and that there is adequate funding to support the delivery of required services to beneficiaries and to avoid wasting state and federal tax dollars.

Additionally, the prevalence of MLTSS being delivered through a risk-based capitated system has increased from fewer than 8 programs in 2004 to 20 programs in 2014. Beneficiaries using MLTSS are among the most vulnerable and often require enhanced protections to assure health and welfare. This regulation codifies these necessary beneficiary protections in MLTSS. The changes finalized for rate setting, MLR, encounter data, and reporting, will support and reflect the increased efforts of states and managed care plans to provide more comprehensive, coordinated, and effective care while achieving better health outcomes.

The Congress established CHIP in 1997 through the passage of the Balanced Budget Act (BBA) and reauthorized it in 2009 with the passage of the CHIPRA. Since CHIP was established, participation has grown steadily, and the rate of uninsured children has been reduced by half. The most recent data indicate that more than 87 percent of eligible children are enrolled in CHIP or Medicaid. Managed care has always been a large part of CHIP, because the program was established in an era of increased use of managed care in all health care sectors and the flexibility granted to states in administering the program. Many states enroll all or nearly all of their CHIP population in managed care plans. At the same time, CHIP has historically had few regulations related to the use of managed care.

When the Congress reauthorized CHIP in 2009 in section 403 of CHIPRA, it applied a number of the Medicaid managed care provisions in section 1932 of the Act to CHIP. In response, we released two State Health Official (SHO) letters 09–008 and 09–013, issued on August 31, 2009 and October 21, 2009, respectively, which provided initial guidance on the implementation of section 403 of CHIPRA. (SHO #09–008 is available at <http://downloads.cms.gov/cmsgov/archived-downloads/SMDL/downloads/SHO083109a.pdf>. SHO #09–013 is available at <http://www.medicaid.gov/Federal-Policy-Guidance/downloads/SHO102109.pdf>.) This final rule builds on that guidance. Where practical, the rule aligns CHIP managed care standards with those of the Marketplace and Medicaid, ensuring consistency across programs. Consistency has the benefit of creating efficiencies for both

¹⁴ <http://www.medicaid.gov/medicaid-chip-program-information/by-topics/financing-and-reimbursement/downloads/medicaid-actuarial-report-2014.pdf>.

¹⁵ CMS, Financial Management Report—Base Payments, 2013.

plans and beneficiaries, including operational efficiencies for plans from using similar rules and smoother transitions between programs for beneficiaries.

The BBA established quality standards for Medicaid managed care programs: A quality assessment and improvement strategy; and an external, independent review. While these standards initially applied only to MCOs, the application of several of them has spread to PIHPs (via the regulations at part 438, subparts D (Quality Assessment and Performance Improvement, effective on August 13, 2002 (67 FR 40989)) and E (External Quality Review, effective on March 25, 2003 (68 FR 3586)) and to CHIP managed care programs (per the CHIPRA).

Under this final rule, we restructure the quality provisions of part 438 into a single subpart, subpart E, and apply these provisions to states contracting with MCOs, PIHPs, PAHPs, and PCCM entities (described in § 438.310(c)(2)). States that utilize one or more of these four managed care delivery systems will require their plans to operate a QAPI program, will themselves operate a managed care quality strategy, and will contract with a qualified EQR organization to conduct an annual EQR. States will report publicly on the accreditation status of their contract MCOs, PIHPs, and PAHPs; states will also issue an annual quality rating for each of these plans using the state's Medicaid managed care quality rating system. The changes finalized in this rule-making will further align Medicaid with other healthcare programs, specifically Medicare and the Marketplace. The improvements to Medicaid and CHIP managed care quality finalized in this rule give states additional tools to evaluate and improve the care received by beneficiaries.

For all of these reasons, the current regulatory framework is no longer the most appropriate or efficient to achieve program goals. We believe that it is necessary to modernize the Medicaid and CHIP managed care regulations to support health care delivery system reform, improve population health outcomes, and improve the beneficiary experience in a cost effective and consistent manner in all states.

B. Overall Impact

We have examined the impacts of this rule as required by Executive Order 12866 on Regulatory Planning and Review (September 30, 1993), Executive Order 13563 on Improving Regulation and Regulatory Review (January 18, 2011), the Regulatory Flexibility Act

(RFA) (September 19, 1980, Pub. L. 96–354), section 1102(b) of the Act, section 202 of the Unfunded Mandates Reform Act of 1995 (March 22, 1995; Pub. L. 104–4), Executive Order 13132 on Federalism (August 4, 1999) and the Congressional Review Act (5 U.S.C. 804(2)).

Executive Orders 12866 and 13563 direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). Section 3(f) of Executive Order 12866 defines a “significant regulatory action” as an action that is likely to result in a rule: (1) Having an annual effect on the economy of \$100 million or more in any 1 year, or adversely and materially affecting a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or state, local or tribal governments or communities (also referred to as “economically significant”); (2) creating a serious inconsistency or otherwise interfering with an action taken or planned by another agency; (3) materially altering the budgetary impacts of entitlement grants, user fees, or loan programs or the rights and obligations of recipients thereof; or (4) raising novel legal or policy issues arising out of legal mandates, the President's priorities, or the principles set forth in the Executive Order.

A regulatory impact analysis (RIA) must be prepared for major rules with economically significant effects (\$100 million or more in any 1 year). We estimate that this rule is “economically significant” as measured by the \$100 million threshold, and hence also a major rule under the Congressional Review Act. Accordingly, we have prepared a RIA that to the best of our ability presents the costs and benefits of this rule. The numbers presented in this RIA are rounded depending on the level of precision in the data used to generate them. Specifically, all COI costs are rounded to \$0.1 million while transfers are rounded to the nearest \$100 million. This difference also allows us to display the smaller numbers in the COI costs, which would reflect zero if rounded to the nearest \$100 million.

All burden estimates in this final rule utilized 2012 data submitted by states to the MSIS. That data reflected almost 63,000,000 beneficiaries enrolled in 606 MCOs, PIHPs, PAHPs, or PCCMs in 42 states (335 MCOs, 176 PIHPs, 41 PAHPs, 20 NEMT PAHPs, 25 PCCMs, and 9

PCCM entities). For CHIP, burden estimates utilized 2015 data submitted by states to the SEDS. We estimate that there are 62 plans that states use to contract with CHIP separately from their Medicaid programs as a result of discussions with states since the publication of the proposed rule. Utilizing SEDS data available as of December 2015, there are 25 states with approximately 2.3 million children enrolled in managed care in separate CHIP programs.

Tables 3 and 4 show the overall estimates of the financial impact of this final rule. These tables and analyses use administrative burden estimates from the Paperwork Reduction Act documentation as well as any other quantifiable and qualitative benefits and costs when available. Table 3 divides the overall cost estimates into federal costs, state costs, and private sector costs with high and low estimates as appropriate. Table 4 divides the overall transfer estimates into federal and state transfers with high and low estimates as appropriate. Utilizing burden estimates from section V of this final rule (COI) and estimated transfers, federal, state, and private sector costs and transfers were derived by applying the appropriate FMAP to the corresponding burdens in section V of this final rule. For the revisions in part 438, we apply a weighted FMAP of 58.44 percent (weighted for enrollment) to estimate the federal share of private sector costs. This is done to account for private sector costs that are passed to the federal government through the managed care capitation rates. For part 457, we apply an enhanced FMAP of 93.9 for 2016 through 2019 and an enhanced FMAP of 71.5 for 2020 for both state and private sector costs. These represent the average CHIP FMAP in the respective years under current law. Federal CHIP funding is capped and is currently appropriated through 2017; therefore, federal CHIP expenditures will not exceed the total allotments described in section 2104(a) of the Act.

Table 3 separates the overall costs by part 438, which represents Medicaid managed care and part 457, which represents CHIP. As shown in Table 3, the total projected cost associated with this final rule is a cumulative \$91.7 million in the first year for revisions to part 438, and a cumulative \$22.1 million in the first year for revisions to part 457, for a total cost of a cumulative \$113.8 million for all revisions in the first year. Table 4 represents the overall transfer estimates for part 438 only, as part 457 has no estimated transfers. As shown in Table 4, the total estimated

transfers associated with this final rule are \$0 in the first year.

The COI costs estimated for some of the provisions are based on the number of enrollees. As such, as enrollment grows each year, the cost for these provisions will grow accordingly. For this analysis, we used the projected average enrollment growth rate for Medicaid of 3.3 percent¹⁶ for Medicaid managed care enrollment to trend cost burdens. Recognizing the success that

states have had enrolling eligible children in CHIP (more than 87 percent of eligible children enrolled in CHIP or Medicaid)¹⁷ and the current prevalence of managed care in the program, we used a 3 percent growth rate for CHIP managed care enrollment. The burdens estimated for the quality components (part 438 subpart E) are not associated with enrollment, and therefore, do not display any variable costs.

This RIA includes the administrative costs (wage and labor) related to implementing and operating a Medicaid managed care delivery system, as well as non-administrative benefit and cost estimates when available. The burden estimates presented in section V of this final rule provide the detail supporting the summary COI burden estimates presented in this RIA.

TABLE 3: Overall Federal, State, and Private Costs for Parts 438 and 457 (in millions of dollars)

Part 438												
	2016 ²		2017		2018		2019		2020		2016-2020	
	Low	High	Low	High	Low	High	Low	High	Low	High	Low	High
Federal¹	\$54.6	\$54.6	\$58.4	\$58.4	\$68.2	\$68.2	\$68.8	\$68.8	\$70.6	\$70.6	\$320.6	\$320.6
State	\$6.9	\$6.9	\$8	\$8	\$14.1	\$14.1	\$14.7	\$14.7	\$14.9	\$14.9	\$58.6	\$58.6
Private	\$30.2	\$30.2	\$30.4	\$30.4	\$30.9	\$30.9	\$29.5	\$29.5	\$30	\$30	\$151	\$151
Total Part 438	\$91.7	\$91.7	\$96.8	\$96.8	\$113.2	\$113.2	\$113	\$113	\$115.5	\$115.5	\$530.2	\$530.2
Part 457												
	2016		2017		2018		2019		2020		2016-2020	
	Low	High	Low	High	Low	High	Low	High	Low	High	Low	High
Federal³	\$20.8	\$20.8	\$20.9	\$20.9	\$21	\$21	\$19.4	\$19.4	\$14.9	\$14.9	\$97	\$97
State	\$0.2	\$0.2	\$0.2	\$0.2	\$0.2	\$0.2	\$0.2	\$0.2	\$9	\$9	\$1.7	\$1.7
Private	\$1.1	\$1.1	\$1.1	\$1.1	\$1.1	\$1.1	\$1.1	\$1.1	\$5	\$5	\$9.4	\$9.4
Total Part 457	\$22.1	\$22.1	\$22.2	\$22.2	\$22.3	\$22.3	\$20.7	\$20.7	\$20.8	\$20.8	\$108.1	\$108.1
Total Costs for Parts 438 and 457												
	2016		2017		2018		2019		2020		2016-2020	
	Low	High	Low	High	Low	High	Low	High	Low	High	Low	High
Total Part 438	\$91.7	\$91.7	\$96.8	\$96.8	\$113.2	\$113.2	\$113	\$113	\$115.5	\$115.5	\$530.2	\$530.2
Total Part 457	\$22.1	\$22.1	\$22.2	\$22.2	\$22.3	\$22.3	\$20.7	\$20.7	\$20.8	\$20.8	\$108.1	\$108.1
Grand Total	113.8	113.8	119	119	135.5	135.5	133.7	133.7	136.3	136.3	638.3	638.3

¹Includes federal costs based on a weighted FMAP of 58.44 percent.

²Estimates based on 2012 data.

³Includes federal costs based on an average FMAP of 93.9 for 2016-2019 and an average FMAP of 71.5 for 2020.

¹⁶ <http://www.medicaid.gov/medicaid-chip-program-information/by-topics/financing-and-reimbursement/downloads/medicaid-actuarial-report-2013.pdf>.

¹⁷ Genevieve M. Kenney, Nathaniel Anderson, Victoria Lynch. Medicaid/CHIP Participation Rates Among Children: An Update. September 2013. Available at <http://www.urban.org/sites/default/>

<files/alfresco/publication-pdfs/412901-Medicaid-CHIP-Participation-Rates-Among-Children-An-Update.pdf>.

TABLE 4: Overall Federal and State Transfers for Part 438 (in millions of dollars)

*Part 457 does not have transfers

Part 438												
	2016		2017		2018		2019		2020		2016-2020	
	Low	High	Low	High	Low	High	Low	High	Low	High	Low	High
Federal	\$0	\$0	-	\$100	-	\$600	-	\$800	-	\$800	-\$6,900	\$2,300
			\$200		\$1,600		\$2,400		\$2,700			
State	\$0	\$0	-	\$0	-\$900	\$400	-	\$500	-	\$500	-\$3,800	\$1,400
			\$100				\$1,200		\$1,600			
Total Part 438	\$0	\$0	-	\$100	-	\$1,000	-	\$1,300	-	\$1,300	-	\$3,700
			\$300		\$2,500		\$3,600		\$4,300		\$10,700	

All state Medicaid programs receive a federal matching rate of at least 50 percent for administrative expenses and 50 to 73 percent (determined individually by state) for covered service expenses, with exceptions for certain services and eligibility groups. State CHIP programs receive a higher federal funding rate, ranging from 88 to 100 percent for 2016 through 2019 and ranging from 65 to 82 percent for 2020; states receive the same federal funding rate for administrative expenses, but they are capped at 10 percent of a state's total CHIP expenditures. The Medicaid

managed care plans are paid actuarially sound capitation rates to cover the costs of fulfilling their obligations under their contract. These rates are included in the expenditures by the state and subsequently submitted to CMS for federal matching payments at the state's assigned rate. This is reflected in Table 3 in the "Private Sector" row. State expenditures for EQR and EQR-related activities performed by EQROs for MCOs with contracts under section 1903(m) of the Act are eligible for a federal matching rate of 75 percent; EQR on other types of managed care entities

or EQR-related activities conducted by non-EQROs are eligible for a 50 percent federal matching rate. CHIP EQR activities are considered administrative activities, which receive the CHIP federal funding rate, and count towards the administrative cap.

Table 5 shows the estimate of the impact for the COI costs of this final rule, divided into fixed and variable costs. Fixed costs are those which do not change with the number of enrollees while variable costs change with the number of enrollees.

TABLE 5: Overall Fixed and Variable Costs for Parts 438 and 457 (in millions of dollars)

	Part 438				
	2016 ²	2017	2018	2019	2020
Fixed costs	\$30.8	\$28.3	\$28.3	\$22.6	\$22.6
Variable costs¹	\$60.9	\$65.5	\$66.9	\$68.4	\$69.9
Part 438 Subtotal	\$91.7	\$93.8	\$95.2	\$91	\$92.5
	Part 457				
	2016 ²	2017	2018	2019	2020
Fixed costs	\$18	\$18	\$18	\$16.6	\$16.6
Variable costs³	\$4.1	\$4.2	\$4.3	\$4.1	\$4.2
Part 457 Subtotal	\$22.1	\$22.2	\$22.3	\$20.7	\$20.8
Total for Parts 438, and 457	113.8	116	117.5	111.7	113.3

¹Utilizes the average enrollment growth rate as established in the 2013 Actuarial Report on the Financial Outlook for Medicaid: <http://medicaid.gov/Medicaid-CHIP-Program-Information/By-Topics/Financing-and-Reimbursement/Downloads/medicaid-actuarial-report-2013.pdf>.

²Estimates based on 2012 data.

³Utilizes a 3 percent growth rate.

1. Cost Estimates by Guiding Principles

The principles discussed below guided the policy development and changes made in the final rule. These guiding principles and finalized regulatory changes support the coordination and integration of health care, promote effective forms of information sharing, and require transparency on cost and quality information to support greater overall accountability in the Medicaid and CHIP programs. Detailed COI burden estimates can be found in section V of this final rule. This section details the significant COI costs and transfers related to benefits and costs associated with this final rule.

2. Setting Actuarially Sound Rates and Other Payment and Accountability Improvements

This guiding principle seeks to provide more data, analytical rigor, documentation, and transparency in the managed care rate setting process and includes setting actuarially sound capitation rates and program integrity. The estimated first-year COI costs associated with the provisions under this guiding principle account for a cumulative \$1 million of the total estimated first-year burden for the revisions to part 438 and part 457 (detailed burden estimates can be found in the COI section of this final rule at sections IV.C.2 and IV.C.3 for rates and IV.C.36 and IV.C.37 for program integrity).

The final rule also contains requirements related to setting actuarially sound capitation rates in sections § 438.4 through § 438.7. Many of these requirements will codify current policy on developing capitation rates for Medicaid managed care plans. Other requirements set standards for actuaries developing the capitation rates, specify requirements for data and information that must be included in the actuarial certification of the rates, and describe the CMS process for reviewing and approving the rates. As such, we believe that many of these provisions are unlikely to have a direct effect on the actual capitation rates or future Medicaid expenditures. To the extent that these new standards or requirements do have an effect on capitation rates or Medicaid expenditures, we believe this could lead to increases in some cases and decreases in other cases in the capitation payment rates and Medicaid expenditures.

We believe that the combination of the new finalized requirements related to actuarial soundness and to no longer allow states to certify rate ranges and to

require states to certify specific capitation rates may have some financial impact. Currently, 40 states and the District of Columbia have at least one managed care program as part of their Medicaid program. Of these, 26 states and the District of Columbia currently certify rate ranges instead of rates for at least one managed care program in the state (Arkansas; California; Colorado; Delaware; District of Columbia; Georgia; Idaho; Indiana; Iowa; Kansas; Kentucky; Louisiana; Maryland; Massachusetts; Minnesota; Missouri; Nebraska; New Mexico; New York; North Carolina; North Dakota; Oregon; Pennsylvania; Tennessee; Utah; Virginia; and West Virginia). The certified rate ranges in many cases can be large. Based on our review of the most recent actuarial certifications in states that use rate ranges, the width of the rate range is 10 percent or smaller in 14 states (that is, the low end and the high end of the range are within 5 percent of the midpoint of the range), but in some states the ranges may be as wide as 30 percent (that is, the low end and the high end are within 15 percent of the midpoint of the range). In addition, most states tend to set the contracted capitation payment rates toward the lower end of the rate range.

For states that currently use relatively narrower rate ranges (which we would generally define as 10 percent or less), we believe that the states will be able to meet the requirements and reasonably set rates that will be equivalent to those at the low end of the rate ranges (if the states were still able to certify a rate range). For states with relatively wider rate ranges (those that are greater than 10 percent), we believe that these states may not be able to set rates equivalent to the current low end of the rate range. In general, our opinion is that in cases where the rates would be more than 5 percent below the midpoint of the rate ranges it will be more difficult for a state to certify that rate as actuarially sound (and at the same time meet all of the other actuarial soundness requirements).

To estimate the high end of the range of the potential financial impact, we assumed that in states that had rate ranges wider than 10 percent and set rates at the low end of the rate range, that future Medicaid MCO, PIHP, and PAHP premiums would increase 2.5 percent (that is, roughly the average across all states of how much the low end of the rate range would need to increase to bring the width of the rate range to about 10 percent). We also included states for which the rate certification provided no information about the actual contracted capitation

payment rates. For states with wide rate ranges but that paid rates at different points within the rate ranges, we assumed that the rates would increase by 1.25 percent (that is, half of the increase in rates for states that paid at the low end of the rate range). We assumed no impact on states with relatively narrower rate ranges (10 percent or less).

The newly finalized requirements related to actuarial soundness and to no longer allow states to certify rate ranges and to require states to certify specific capitation rates are estimated to increase projected Medicaid managed care expenditures by \$3.7 billion from 2016 to 2020, or about 0.3 percent overall of about \$1.4 trillion in projected Medicaid expenditures on MCOs, PIHPs, and PAHPs over the 5-year period. These estimates will be an increase of about 1.5 percent in costs in states assumed to be affected by this change. We believe that these estimates are a reasonable upper bound on the projected effect of the final rule.

In addition, we believe that there may be cases where these changes would reduce capitation rates and Medicaid expenditures. In particular, there are some states that make significant retroactive changes to the contracted rates at or after the end of the rating period. We do not believe that these changes are made to reflect changes in the underlying assumptions used to develop the rates (for example, the utilization of services, the prices of services, or the health status of the enrollee), but rather believe that they are used to provide additional reimbursements to the plans or to some providers. We believe that the requirements for actuarial soundness and certifying the specific capitation rates would limit these types of changes and may result in some reduction in Medicaid expenditures.

To estimate the high end of the range of the potential financial impact, we assumed that in states that we are aware of that make these types of changes to the capitation rates, an amount equal to 50 percent of the difference between paying MCOs, PIHPs, and PAHPs at the low end and the high end of the rate ranges would not be paid to the plans. Limiting these changes by states decreased projected Medicaid managed care expenditures by \$8.7 billion from 2016 to 2020, or about 0.6 percent of about \$1.4 trillion in projected expenditures on MCOs, PIHPs, and PAHPs over those 5 years. We believe that these estimates are a reasonable upper bound on the projected effect of the final requirements.

Thus, we believe that the effects of these finalized Medicaid managed care actuarial soundness requirements and the requirement to certify the capitation rates could increase expenditures as much as \$3.7 billion from 2016 to 2020

and could decrease expenditures as much as \$8.7 billion from 2016 to 2020. We believe that these estimates reflect reasonable upper and lower bounds on the potential effect of these changes in the final regulation. Assuming that these

changes in the regulation go into effect mid-way through 2016, we estimate that the changes related to actuarial soundness requirements and certifying the capitation rates would have the following effects shown in Table 6.

TABLE 6: Projected Financial Effects (Transfers) of Actuarial Soundness Requirements, FY 2016-2020 (in millions of dollars)

Payer	2016	2017	2018	2019	2020	2016-2020
Low estimate						
Federal	\$0	-\$200	-\$1,500	-\$1,900	-\$2,000	-\$5,600
State	\$0	-\$100	-\$800	-\$1,000	-\$1,200	-\$3,100
Total	\$0	-\$300	-\$2,300	-\$2,900	-\$3,200	-\$8,700
High estimate						
Federal	\$0	\$100	\$600	\$800	\$800	\$2,300
State	\$0	\$0	\$400	\$500	\$500	\$1,400
Total	\$0	\$100	\$1,000	\$1,300	\$1,300	\$3,700

It is possible that the impacts could be more or less than estimated here. More or fewer states may need to adjust capitation rates than we have assumed here. In particular, it is possible that states with relatively narrower ranges may decide that the capitation rates would still need to be higher than what would have been the low end of the rate range previously. States that use rate ranges as wide as 10 percent may still be affected by these changes. In addition, states may adjust their capitation rates to a greater or lesser extent than we have assumed here. While we believe that the final changes related to rate setting may be more likely to affect states that currently use relatively wide rate ranges, it is also possible that this may affect other states, including those that do not use rate ranges at all.

In addition, for states that historically have made significant changes to capitation rates within the rate ranges at the end or after the end of the rating period, those states may adjust their rate setting approaches as well. The payments might be closer to or farther from the final payments than we have estimated. Finally, these projections rely on the data, assumptions, and methodology used to develop the President's FY 2017 Budget projections for Medicaid. Changes in enrollment,

health care costs, and the use of managed care plans within Medicaid may differ from these projections and may lead to greater or lesser Medicaid MCO, PIHP, and PAHP expenditures.

We received the following comment on the RIA.

Comment: We received one comment on Table 6. The commenter believed that codifying the current policy on developing capitation rates for Medicaid managed care plans and requiring states to certify individual rates will be a significant overall burden to both states and MCOs. The commenter encouraged CMS to simplify its approach and eliminate any duplication of review and requirements and believed the burden will increase the time for review by the state and the state's consulting actuaries each year. The commenter also believed this proposal may increase the data requirements. The commenter stated it was difficult to estimate the burden without the details of what this change will impact.

Response: The projected financial effects estimated in Table 6 were based on information gathered from existing state contracts and rate documentation submitted in the previous 2 years. We agree that the effects of the final rule will vary by state depending on the state's current processes but we believe the estimates accurately reflect the most

current information available. We decline to revise this estimate.

3. Program Integrity

Another aspect of this rule that we evaluated under this principle was enhancements to program integrity. We believe that many of these program integrity activities are currently being performed by states and MCOs, PIHPs, and PAHPs. For program integrity activities that would be new or expanded under the final rule, there is very limited information on the effect that program integrity activities in general have on Medicaid expenditures. The total estimated burden on states and managed care plans to implement the finalized provisions is \$471,691.30 (detailed in the Collection of Information). The lack of information is especially true for specific program integrity activities. While we believe these new activities may lead to some additional recoveries from plans, providers, or other individuals and may also deter entities from committing fraud or violating program requirements, it is difficult to determine the financial impacts of these activities and we believe that any financial impact is unknown. Therefore, we are not estimating the financial impact on future Medicaid expenditures.

4. Alignment With Other Insurers

This guiding principle seeks to align Medicaid and CHIP managed care requirements with the Marketplace or MA to better streamline the beneficiary

experience and to reduce operational burdens on health plans across publicly-funded programs and the private market. This guiding principle covers the regulatory topics of marketing, appeals and grievances, MLR, and

standard contract provisions. As shown in Table 7, the COI costs associated with the provisions under this principle account for a cumulative \$6.9 million in the first year for the revisions to part 438.

TABLE 7: Costs of Alignment with Insurers for Part 438 (in millions of dollars)

	2016	2017	2018	2019	2020
Medical Loss Ratio Standards¹					
Federal	2.9	2.9	2.9	1.4	1.4
State	0.0	0.0	0.0	0.0	0.0
Private	2.1	2.1	2.1	1.0	1.0
Appeals and Grievances²					
Federal	1.1	1.1	1.1	1.0	1.1
State	0.0	0.0	0.0	0.0	0.0
Private	0.8	0.8	0.8	0.8	0.8
Total					
Federal	4.0	4.0	4.0	2.4	2.5
State	0.0	0.0	0.0	0.0	0.0
Private	2.9	2.9	2.9	1.8	1.8
Grand Total	\$6.9	\$6.9	\$6.9	\$4.2	\$4.3

¹§438.8.

²§§438.400-438.416.

Similarly, as shown in Table 8, the COI costs associated with implementing

the provisions under this principle account for a cumulative \$10.1 million

in the first year for the revisions to part 457.

TABLE 8: Costs of Alignment with Insurers for Part 457 (in millions of dollars)

	2016	2017	2018	2019	2020
Medical Loss Ratio Standards¹					
Federal	\$0.5	\$0.5	\$0.5	\$0.2	\$0.2
State	\$0	\$0	\$0	\$0	\$0
Private	\$0	\$0	\$0	\$0	\$0.1
Appeals and Grievances²					
Federal	\$9	\$9	\$9	\$8.9	\$6.8
State	\$0	\$0	\$0	\$0	\$0
Private	\$0.6	\$0.6	\$0.6	\$0.6	\$2.7
Total					
Federal	\$9.5	\$9.5	\$9.5	\$9.1	\$7
State	\$0	\$0	\$0	\$0	\$0
Private	\$0.6	\$0.6	\$0.6	\$0.6	\$2.8
Grand Total	\$10.1	\$10.1	\$10.1	\$9.7	\$9.8

¹\$457.1203.²\$457.1260.

5. Medical Loss Ratio

As an increasing and more diverse set of Medicaid services are being delivered through managed care, good measurement systems are increasingly important to ensure that Medicaid funding is used prudently and that capitation rates are sufficiently based on the expenses associated with services. The implementation of MLR-related requirements are an integral part of the overall financial accountability aspects of the proposal and would align Medicaid and CHIP with the private health insurance market, as well as with MA. MLR reporting is a valuable tool to ensure that capitation rates for MCOs, PIHPs, and PAHPs are actuarially sound and adequately based on reasonable expenditures for covered services. Acknowledging that basis for an MLR requirement, there are four benefits to having a common national standard for the calculation, reporting and use of MLR: (1) It will provide greater transparency for the use of Medicaid funding; (2) it will allow comparisons

across states and facilitate better rate setting; (3) it will facilitate better comparisons to MLRs in MA and the private health market; and (4) it will reduce the administrative burden on managed care plans by providing a consistent approach to ensuring financial accountability for plans with multiple product lines and/or operating in multiple states. The final provisions in §§ 438.4, 438.5, 438.8, 457.1203 and 457.1205 require MCOs, PIHPs, and PAHPs to calculate, report, and use a MLR in the development of capitation rates. The estimated first-year COI cost for the provisions in part 438 is a cumulative \$5 million (detailed burden estimates can be found in the COI section of this final rule at section V.C.4 for MLR). The total estimated first-year COI cost associated with implementing the final MLR provisions of part 457 is a cumulative \$0.5 million.

We finalized standards that require the states to calculate and report the MLRs for Medicaid MCOs, PIHPs, and PAHPs in § 438.4 and § 438.5, and to

add new § 438.8 and § 438.74, as well as incorporate an MLR assumption in the rate setting process. These changes, however, do not require that states assess any financial penalties on MCOs, PIHPs, and PAHPs that do not meet a minimum MLR. We encourage states to adopt minimum MLRs (of at least 85 percent) or to develop similar financial arrangements to incentivize better plan performance; however, as states are already permitted to implement a minimum MLR or similar standards and some choose not to do so, we believe that this rule is unlikely to encourage more states to do so and therefore is unlikely to have any direct financial impact on Medicaid expenditures for MCOs, PIHPs, and PAHPs. Despite this, we believe that there is the potential for some financial impact when considering the MLR requirements and the actuarial soundness standards requirements.

We do not collect data or information on the MLRs of Medicaid MCOs, PIHPs, and PAHPs, nor do we collect the data or information necessary to calculate the

loss ratios. Milliman has published a series of annual research papers that review Medicaid MCO performance, including data on MLRs. We have reviewed the most recent research papers covering 2011, 2012, and 2013 for the potential impact of the final regulation on managed care plans' MLRs ("Medicaid Risk-Based Managed Care: Analysis of Financial Results for 2011," Palmer and Pettit, July 2012; "Medicaid Risk-Based Managed Care: Analysis of Financial Results for 2012," Palmer and Pettit, June 2013; "Medicaid Risk-Based Managed Care: Analysis of Financial Results for 2013," Palmer and Pettit, June 2014; and "Medicaid Risk-Based Managed Care: Analysis of Financial Results for 2014," Pettit and Palmer, June 2015). These studies provide an analysis of Medicaid managed care plans, including loss ratios, covering 35 states and territories, including the District of Columbia and Puerto Rico, and up to 182 managed care plans.

From 2011 to 2014, the mean MLR varied between 85.5 percent and 87.9 percent, with an average of 86.7 percent over the 4-year period (weighted by the number of plans reporting each year). A significant percentage of plans experienced loss ratios below the 85-percent target noted in this final rule. In each year, 10 percent of plans experienced loss ratios below 77.4 percent to 79.4 percent, and 25 percent of plans experienced loss ratios below 81.8 percent to 83.6 percent. Thus, we would expect a substantial number of plans would likely not meet a minimum loss ratio of 85 percent each year.

We fit a normal distribution to the MLRs based on the average loss ratios at each percentile shown in the Milliman reports (10th, 25th, 50th, 75th, and 90th) for 2011, 2012, 2013, and 2014. This suggested that between 37 percent and 39 percent of plans would have loss ratios equal to or less than 85 percent over this period. Assuming that the distribution of loss ratios is not affected by the size of the MCO or the MCO's total revenue (in general, the Milliman reports did not suggest any apparent correlation), we calculate that if all states enforced a minimum MLR of 85 percent and if MCOs with smaller loss ratios had to return revenue such that the effective loss ratio would be equal to 85 percent, then managed care plans would, on average, return 1.5 percent to 1.9 percent of total revenue. To the extent that smaller MCOs, PIHPs, and PAHPs would receive a credibility adjustment, which would effectively lower the minimum MLR standard for those plans; we estimated that the impact of the credibility adjustment would be less than 0.1 percent, and

have not made adjustments to the estimates to account for the relatively smaller impact of the credibility adjustment.

In 2013, the sum of MCO, PIHP, and PAHP payments was \$132 billion (CMS, Financial Management Report—Base Payments);¹⁸ therefore, we estimate that if a minimum MLR had been enforced for each MCO, PIHP or PAHP in all states in 2013, between \$2.0 billion and \$2.5 billion would have been returned by MCOs, PIHPs, and PAHPs to the federal government and the states in that year.

As of 2013, we found, based on an internal review, that of the 12 states that had minimum MLR requirements, 6 states did not enforce any financial penalties, and 2 of the 6 states that did enforce penalties had minimum MLRs of less than 85 percent. The 6 states that did enforce financial penalties accounted for about 13 percent of Medicaid MCO, PIHP, and PAHP expenditures in 2014.

There is significant variation in the standards currently in place, as states may have different methods of calculating MLRs (for example, which medical expenses and losses are included, and whether they make certain adjustments to plans' revenues) and different minimum MLRs (although all such minimums are between 80 percent and 88 percent). In addition, many states that implemented the eligibility expansion under the Affordable Care Act to all adults up to age 65 with household incomes of 138 percent or less included a minimum MLR requirement or a similar risk-sharing arrangement in its contracts with MCOs, PIHPs, and PAHPs for 2014. These current requirements and standards may have some effect on the potential impact of the final changes.

For the purpose of illustrating the potential impact of these changes in the regulation, we have developed estimates assuming that all states would require a minimum MLR. If all states implemented the 85 percent minimum MLR requirement that is required by the final rule, we estimate that the federal government would collect about \$7 billion to \$9 billion between 2018 and 2020 and the states would collect about \$4 billion to \$5 billion over the 3-year period. This calculation also accounts for states that already have a minimum loss ratio requirement in place by excluding any effect on states that

currently enforce remittances for plans with MLRs below 85 percent and including only a partial impact from states that currently enforce remittances on plans with MLRs at lower minimum MLR. These estimated amounts would account for about 1.3 percent to 1.7 percent of projected MCO, PIHP, and PAHP expenditures.

We assume that this rule would not lead more states to implement an enforceable, minimum MLR; we therefore conclude that there would be no direct significant financial impact of the MLR provisions of the final rule on MCOs, PIHPs, and PAHPs. For the 2 states that currently enforce penalties at a lower minimum MLR, the estimated effect would be less than 0.1 percent of total MCO, PIHP, and PAHP payments if they increased the minimum MLR to 85 percent. (It is also possible those states may choose to eliminate any MLR penalty, in which case total payments may slightly increase instead.)

Considering the final MLR requirements and changes to the requirements for actuarial soundness in § 438.4(b)(9) that require rates to be developed in such a way that the MCO, PIHP, or PAHP would reasonably achieve an MLR of at least 85 percent for the rate year, we believe it is possible that collecting and reporting MLRs for each MCO, PIHP, or PAHP and additional oversight of the rate setting process may lead states in the future to make adjustments to how they set capitation rates. For example, if this additional information led a state to realize that the loss ratios for the MCOs, PIHPs, or PAHPs were consistently higher or lower than expected, the state may adjust future rates lower or higher. We believe that there may be cases that lead to rate increases and other cases that lead to rate decreases relative to what the rates otherwise would have been.

As the states have the discretion to determine whether or not to require a remittance if plans do not meet the minimum MLR, it is possible that actual savings due to the MLR provisions of the regulation would be less than the estimated savings if remittances were required from all plans. Requiring reporting of the MLR and the actuary to consider those results in developing rates is expected to have some impact, which are described in the following section of this analysis.

Using a similar methodology as described previously to estimate the potential impact if all states were to require a minimum MLR of 85 percent, we have estimated what the effects of reporting the MLR and the other actuarial soundness requirements would

¹⁸ CMS, CMS-64 (Financial Management Report)—Base Payments, 2013. <https://www.medicaid.gov/medicaid-chip-program-information/by-topics/financing-and-reimbursement/expenditure-reports-mbes-cbes.html>.

be on Medicaid payments for MCOs, PIHPs, and PAHPs. Instead of calculating the amount of payments that would be returned if a minimum MLR of 85 percent was required, we have measured the amount of payments that would be returned for plans with MLRs below 82 percent (allowing for a 3 percent random variation from the 85 percent MLR target), and assumed that the indirect effects of these changes would be equal to 50 percent of that amount. We have assumed for plans with MLRs somewhat below 85 percent (which we defined here to be between 82 and 85 percent) that the states may not need to make significant adjustments to rate setting. For plans with MLRs further below 85 percent (82 percent or less), we assumed that these changes would likely lead to decreases in future rates and payments below what would have otherwise occurred; however, we also assumed that the rates and payments would still have been adjusted by the states, as they would have a financial incentive to control managed care plan costs. The percentage of all MCO, PIHP, and PAHP payments that would be paid from the

plans to the federal government and the states for plans under these assumptions is estimated to be between 0.35 and 0.6 percent; or about \$6 billion to \$11 billion of 2014 Medicaid managed care plan payments.

Similarly, we calculated the amount of additional payments that would need to be made for plans with high MLRs, which we assumed to be 95 percent or greater. In these cases, we believe that the plans may have a higher likelihood of experiencing a loss. A report on Medicaid managed care administrative costs found that 10 percent of plans had administrative cost ratios (net of taxes) of 6.1 percent or less (“Medicaid Risk-Based Managed Care: Analysis of Administrative Costs for 2014,” Palmer, Pettit, and McCulla, June 2015.) Thus, for the vast majority of plans, an MLR of 95 percent or more would likely imply a loss in that year for the managed care plan. The Milliman reports found that between 2011 and 2014, 25 percent of all managed care plans had MLRs above 90.0 to 91.9 percent and 10 percent of plans had MLRs above 96.4 to 97.3 percent. We believe that in these cases, the states

may adjust future capitation rates and payments to be higher than they otherwise would have been and further assumed that these adjustments would equal 50 percent of the difference between a MLR of 95 percent and the actual MLR. We estimated that the percentage of all MCO, PIHP, and PAHP payments would be increased by between 0.1 and 0.2 percent due to these changes or about \$2 billion to \$4 billion of 2014 Medicaid managed care plan payments.

The net effect of these changes is estimated to be a decrease in MCO, PIHP, and PAHP payments of about 0.2 to 0.3 percent. Between 2018 and 2020, a 0.3 percent decrease in MCO, PIHP, and PAHP expenditures is projected to be a reduction of \$1.3 billion in federal expenditures and of \$0.7 billion in state expenditures. We believe that this is a reasonable lower bound of the effect of the final changes. We believe that a reasonable upper bound of these estimates would be \$0, assuming that the changes resulted in no financial impact. These estimates are shown in Table 9.

TABLE 9: Projected Financial Effects (Transfers) of Medical Loss Ratio and Actuarial Soundness Requirements, FY 2016-2020 (in millions of dollars)

Payer	2016	2017	2018	2019	2020	2016-2020
Low estimate						
Federal	\$0	\$0	-\$100	-\$500	-\$700	-\$1,300
State	\$0	\$0	-\$100	-\$200	-\$400	-\$700
Total	\$0	\$0	-\$200	-\$700	-\$1,100	-\$2,000
High estimate						
Federal	\$0	\$0	\$0	\$0	\$0	\$0
State	\$0	\$0	\$0	\$0	\$0	\$0
Total	\$0	\$0	\$0	\$0	\$0	\$0

There is a significant amount of uncertainty in these estimates beyond whether or not states would elect to implement an enforceable minimum MLR requirement. States and managed care plans may also adjust their behavior as a result of the minimum MLR requirements; for example, states may set capitation payment rates differently to target certain loss ratios, and managed care plans may make

changes to the way they manage health care costs and utilization for their enrollees. These changes may lead to differences in future expenditures for MCO, PIHP, and PAHP expenditures, and thus, the actual experience may differ from our estimates.

In addition, it is not clear that the reports we relied on measure the MLR the same way as is finalized in the regulation. To the extent that there are

differences, the actual range and distribution of MLRs among MCOs, PIHPs, and PAHPs that would be measured under the final rule may be different than as shown in the studies (for example, if there are expenditures that would be considered medical losses that would be considered medical losses under the final regulation but were not considered medical losses in the Milliman studies). This could lead to the actual effects of the MLR and

actuarial soundness requirements being different than estimated here. In addition, it is possible that the effects of the final actuarial soundness and certification requirements may capture some of the same effects as estimated here; however, we have not made any adjustments to reflect any potential interaction between the two sets of changes.

Moreover, the extent and effectiveness of CMS' and states' efforts to adjust future capitation rates to target certain MLRs are difficult to predict. How CMS and the states respond to these changes would likely have a large bearing on the effect that these sections of the regulation have on future Medicaid expenditures. Finally, these projections rely on the data, assumptions, and methodology used to develop the President's FY 2017 Budget projections for Medicaid. Changes in enrollment, health care costs, and the use of managed care plans within Medicaid may differ from these projections and may lead to greater or lesser Medicaid MCO, PIHP, and PAHP expenditures.

6. Appeals and Grievances

Final changes to the appeals and grievances provisions in §§ 438.400 through 438.416 and § 457.1260 focus on creating state and health plan processes that are consistent across product lines (that is, MA, Medicaid, CHIP, and QHPs). Medicaid currently differs from MA organizations and QHPs in several key ways and these differences hinder a streamlined grievance and appeals process across the public and private managed care sectors, and creates unnecessary administrative complexity for health issuers participating across product lines. Our finalized revisions will allow enrollees to better understand the grievance and appeals processes and receive a resolution of their grievances and appeals more quickly. We believe this will be a tremendous benefit to families that have some family members eligible for Medicaid and other family members eligible for marketplace coverage; enrollees that change between Medicaid and the QHPs due to life changes that affect eligibility; and enrollees that are dually eligible for Medicaid and Medicare. We believe consistency and quicker resolution of issues will not only make the enrollee more comfortable using the grievance and appeal systems, but also more

confident that there is benefit in utilizing them when needed. Health issuers have indicated that alignment of these provisions would reduce operational burden for those that operate across product lines and in different states as it would enable them to create and implement one set of uniform processes and procedures. A significant portion of the burden associated with this principle is the result of the final rule that Medicaid non-NEMT PAHPs comply with the same standards as MCOs and PIHPs. This will require non-NEMT PAHPs to develop compliant grievance and appeals systems, which will generate some one-time burdens, but we believe it is important for enrollees to have an avenue within these entities to raise and receive resolution to their grievances and appeals. The total estimated first-year COI costs for requiring Medicaid non-NEMT PAHPs to meet the same standards as MCOs and PIHPs and provide due process to beneficiaries through provisions in part 438 is a cumulative \$1.9 million (detailed burden estimates can be found in the COI section of this final rule at sections IV.C.30 through IV.C.35 for appeals and grievances). We finalized most of the Medicaid grievance regulations to CHIP MCOs, PIHPs, and PAHPs. The total estimated first-year COI costs associated with implementing the grievance provisions of part 457 under this principle is a cumulative \$9.6 million.

7. Allowing Payment for Institution of Mental Disease for Inpatient Psychiatric Services as an In Lieu of Service

To develop estimates of the impact of the change in policy regarding institutions of mental disease (IMDs), OACT reviewed 2010 data from the Medicaid Analytic eXtract (MAX). Fee-for-service and managed care encounter data were reviewed where the place of service was an inpatient psychiatric facility, which is expected to reflect IMD claims and encounters. Data was reviewed by state and by age of the enrollee.

Using the FFS data for persons ages 22–64,¹⁹ OACT calculated the average inpatient psychiatric facility cost per enrollee, the average cost per claim, and the average cost per unit for each state. These three averages were then multiplied by the number of enrollees in managed care with an inpatient psychiatric facility encounter, the

number of encounters in managed care, and the number of units in managed care, respectively, to impute the costs of these services in managed care.

OACT compared the number of enrollees ages 22–64 with an inpatient psychiatric facility encounter to the total number of enrollees ages 22–64. States in which 0.1 percent or more of the Medicaid enrollees had an inpatient psychiatric facility encounter in managed care were considered likely to be using IMDs as an in lieu of service provider; there were 17 states that met this criteria in 2010. (There were another 9 states that reported a smaller percentage of enrollees with these encounters that could potentially be using IMDs as an in lieu of service provider.) This accounted for an estimated \$6.0 million in expenditures in 2010.

For these 17 states, the ratio of estimated managed care costs for inpatient psychiatric facility services to total expenditures for enrollees ages 22–64 was calculated for each state and an overall average. The average ratio was 0.009 percent (with the highest ratio among these 17 states being 0.029 percent). This represents the average percentage of Medicaid expenditures for enrollees that are for inpatient psychiatric facility services through managed care. OACT assumed that this represents the extent to which IMD services are used in managed care in states that do use IMDs as an in lieu of service provider.

To calculate the impact of the policy, OACT multiplied this ratio (0.009 percent) by the total amount of expenditures for adult enrollees and enrollees with disabilities (which includes adults ages 22–64). This total represented the amount of expenditures if all states used this option to the same extent that states currently using it have done. In 2010, this would have increased expenditures for inpatient psychiatric facility services for adults ages 22–64 through managed care from \$6.0 million to \$17.9 million, or an increase of \$11.9 million.

These amounts were then projected forward using historical data from 2010 through 2014 and the projections of enrollment and expenditures in the President's FY 2017 Budget, with the assumption that this change would be effective for contracts starting July 1, 2017 or later.

¹⁹ Data was used for individuals aged 22–64 to remove utilization for individuals that were age 20

when services began, and therefore, would not be

subject to the statutory prohibition of FFP for patients in an IMD aged 21–64.

TABLE 10: Impact of Allowing IMDs as In Lieu Of Service Provider in Managed Care
(in millions of dollars)

Payer	2016	2017	2018	2019	2020	2016-2020
Federal	\$0	\$2	\$11	\$14	\$15	\$42
State	\$0	\$1	\$7	\$8	\$8	\$24
Total	\$0	\$3	\$18	\$22	\$23	\$66

This estimate is subject to significant uncertainty, and more so than other estimates given the limitations with the data. While we believe that this represents a reasonable estimate of potential impacts, given the lack of clarity about how states allow IMD services to be used as in lieu of services currently makes it more difficult to assess the impact of this section of the regulation. As these are services not allowed for adults under Medicaid, it is not clear how accurate the data is (under FFS or managed care), which contributes to the uncertainty regarding these estimates. Some of the expenditures in the data may be for non-IMD providers; similarly, expenditures for IMDs could be reported elsewhere in the data (for example, as other types of facilities). In addition, it is not clear how many current IMD stays exceed 15 days; we have assumed that none of the IMD stays in the data exceed 15 days. More or fewer states may be using IMDs

as an in lieu of service provider than in 2010, or states may be using this to a greater or lesser extent than in 2010. This estimate assumes that states do not use IMDs more widely than in the past; however, it is possible that they may use IMDs more widely than we are aware of. This estimate also does not account for reductions in other expenditures (either directly, with IMD services replacing inpatient hospital services, or indirectly, with the use of IMD services potentially preventing other utilization in the future).

8. Beneficiary Protections

This guiding principle seeks to protect beneficiaries from harm and encompasses regulatory provisions related to enrollment and disenrollment; beneficiary support system; continuation of benefits pending appeal; authorization of services; continued services and coordination of care; managed LTSS; and stakeholder

engagement. As the use of managed care to deliver Medicaid benefits has grown, so has the inclusion of more vulnerable populations into managed care. These new populations include persons with disabilities, individuals with behavioral health needs, and beneficiaries needing LTSS. The unique needs and vulnerability of these newer populations heightens the need for added beneficiary protections and thus, contributed to the final revisions to the regulations. These protections are expected to benefit all Medicaid beneficiaries.

As shown in Table 11, the COI costs associated with the provisions under this principle account for a cumulative \$50.4 million in the first year for the revisions to part 438 (detailed burden estimates can be found in the COI section of this final rule at sections IV.C.8 and IV.C.15 for coordination/continuity of care and IV.C.16 for authorization of services).

TABLE 11: Costs of Beneficiary Protections for Part 438 (in millions of dollars)

	2016	2017	2018	2019	2020
Coordination/Continuity of Care¹					
Federal	\$29	\$30	\$30	\$31	\$32
State	\$1	\$1	\$1	\$1.1	\$1.1
Private	\$19.8	\$20.3	\$20.9	\$21.3	\$21.9
Authorization of Services²					
Federal	\$0.1	\$0.1	\$0.1	\$0	\$0
State	\$0	\$0	\$0	\$0	\$0
Private	\$0.1	\$0.1	\$0.1	\$0	\$0
Other³					
Federal	\$0.2	\$0.3	\$0.3	\$0.3	\$0.3
State	\$0.2	\$0.3	\$0.3	\$0.2	\$0.2
Private	\$0	\$0	\$0	\$0	\$0
Total					
Federal	\$29.3	\$30.4	\$30.4	\$31.4	\$32.3
State	\$1.2	\$1.3	\$1.3	\$1.2	\$1.3
Private	\$19.9	\$20.4	\$21	\$20.8	\$21.9
Grand Total	\$50.4	\$52.1	\$52.7	\$53.4	\$55.5

¹§438.62, §438.208.

²§438.210.

³§§438.54, 438.70, 438.71, 438.110.

Similarly, as shown in Table 12, the COI costs associated with implementing the provisions under this principle account for a cumulative \$7 million in the first year for the revisions to part 457.

TABLE 12: Costs of Beneficiary Protections for Part 457 (in millions of dollars)

	2016	2017	2018	2019	2020
Continued services to enrollees¹					
Federal	\$0.3	\$0.3	\$0.3	\$0.3	\$0.2
State	\$0	\$0	\$0	\$0	\$0
Private	\$0	\$0	\$0	\$0	\$0.1
Coordination/Continuity of Care²					
Federal	\$3.4	\$3.5	\$3.6	\$3.5	\$2.6
State	\$0	\$0	\$0	\$0	\$0
Private	\$0.2	\$0.2	\$0.2	\$0.2	\$1.1
Authorization of Services³					
Federal	\$2.8	\$2.8	\$2.8	\$2.8	\$2.2
State	\$0	\$0	\$0	\$0	\$0
Private	\$0.2	\$0.2	\$0.2	\$0.2	\$0.9
Enrollment⁴					
Federal	\$0.1	\$0.1	\$0.1	\$0.1	\$0.1
State	\$0	\$0	\$0	\$0	\$0
Private	\$0	\$0	\$0	\$0	\$0
Total					
Federal	\$6.6	\$6.7	\$6.8	\$6.7	\$5.1
State	\$0	\$0	\$0	\$0	\$0
Private	\$0.4	\$0.4	\$0.4	\$0.4	\$2.1
Grand Total	\$7	\$7.1	\$7.2	\$7.1	\$7.2

¹§457.1216.²§457.1230(c).³§457.1230(d).⁴§457.1210

9. Coordination and Continuity of Care

The provisions for coordination and continuity of care are in § 438.62 and § 438.208. Under current regulations, these sections focus only on primary and acute medical care, which may not be appropriate or consistent with the needs of people with disabilities, frail elders, and other LTSS populations. These populations rely heavily on less traditional services, such as support services for work, community activity

access, and assistance with activities of daily living. For example, people with dementia may prefer and be able to live in the community with personal care assistance, memory aids, and alerting systems, but may not be able to identify and notify a care coordinator in situations of neglect or abuse. A young adult with an intellectual disability may be able to work with supports in place, but be at risk of harm if transportation falls through or a support worker does not show up for a scheduled time. These

populations often require heightened levels of monitoring and oversight by the care coordinator to ensure that they are able to fully access the services and supports needed to thrive in the community and to be sure that risks of harm or abuse are mitigated. Additionally, some providers of LTSS are unaccustomed to working with managed care plans and care coordinators can be the bridge to establishing and building a productive

relationship with these providers to best meet enrollees' needs.

The final regulations address these enhanced care coordination needs by finalizing provisions to strengthen the role of care coordinators who help beneficiaries transition from providers and services available through their current delivery system to providers and services available through a managed care plan. Care coordinators can help enrollees with finding specialty providers, understanding how the managed care program works, setting appointments, verifying delivery of services, and reminding enrollees of their appointments. The final regulations have been strengthened to ensure that individuals with LTSS needs complete an accurate and timely person-centered assessment and service planning process with more frequent monitoring to assist beneficiaries in fully utilizing services. The changes to these provisions are designed to enable people with disabilities and LTSS enrollees to live, work, and participate in the setting of their choice more safely, effectively, and with fewer lapses in care. Additionally, we enhanced existing requirements for coordination and continuity of care when enrollees move between managed care plans or programs. While this has always been a requirement in part 438, we are aware of gaps in some states' and managed care plans' implementation for the LTSS population.

Behavioral health, substance use disorders, and institutional services are the most common services that managed care enrollees receive through FFS; coordinating these services with the managed care services is crucial to comprehensive care management. Enrollees receiving behavioral health or substance use treatment on a frequent, sometimes daily, basis are at high risk for emergency department visits or setbacks to their recovery if they experience a disruption in their services. The added protections provided by the finalized changes will ensure that enrollees, particularly those with complex health needs, experience smoother transitions, have fewer incidents of abuse or neglect, are able to retain the ability to live in their communities, and have fewer emergency department visits or admissions. For enrollees receiving ongoing care and LTSS, lapses in care can trigger acute events and even be life threatening. Putting additional protections in place to prevent such occurrences is critical to enrollees' health outcomes. Care coordinators can help enrollees in these situations with finding appropriate providers,

understanding how the managed care program works, setting appointments, and ensuring that appropriate authorizations are in the system to facilitate claims payment.

While we believe that the benefits of care coordination have a significant positive impact on the quality of life, consumer experience, and health outcomes for enrollees, we acknowledge that the activities that would bring about these positive impacts will likely generate costs. From an administrative perspective, the provisions in §§ 438.62 and 438.208 have an estimated first-year COI cost of \$49.8 million (detailed burden estimates can be found in the COI section of this final rule at sections IV.C.8 and IV.C.15, respectively). In general, we expect that most of the activities that would be required under the regulation are already being provided in some form by the state Medicaid program or by their MCOs, PIHPs, and PAHPs. We anticipate little to no new impacts in practice or in expenditures on activities already occurring with existing populations and benefits. However, we believe there is a greater likelihood that the finalized changes in the regulation specific to MLTSS could lead to new or additional care coordination expenditures. There are currently 20 states that use MLTSS. Unfortunately, there is very limited data available to determine the potential impact of this section of the final regulation. We do not collect consistent or validated cost data on Medicaid managed care encounters or administrative costs and, therefore, it is not possible to determine the amount of new expenditures for MCOs, PIHPs, and PAHPs to provide particular services or to serve particular enrollees. In any managed care program, we would generally expect care coordination expenditures to be a notable portion of MCO, PIHP, and PAHP administrative costs. Milliman has published studies²⁰ on the financial performance of Medicaid managed care plans that contains data on administrative costs for plans. These studies provide an analysis of Medicaid managed care plans covering 35 states and territories, including the District of Columbia and Puerto Rico, and up to 167 managed care plans. According to these studies, the average ratio of administrative

²⁰ "Medicaid Risk-Based Managed Care: Analysis of Financial Results for 2011," Palmer and Pettit, July 2012; "Medicaid Risk-Based Managed Care: Analysis of Financial Results for 2012," Palmer and Pettit, June 2013; "Medicaid Risk-Based Managed Care: Analysis of Financial Results for 2013," Palmer and Pettit, June 2014; and "Medicaid Risk-Based Managed Care: Analysis of Financial Results for 2014," Palmer, Pettit, and McCulla.

expenditures to plan revenues ranged from 11.4 percent to 12.3 percent between 2011 and 2014, or about \$20.0 billion to \$21.6 billion of 2014 Medicaid managed care plan payments. We believe that care coordination costs would likely be some fraction of that percentage, but are not able to determine the specific proportion. Given that administrative costs may cover a range of activities including adjudicating and paying claims, developing and maintaining provider networks, assisting consumers, and other general business operations, we believe that it is most likely that care coordination costs are between 1 and 3 percent of plan revenue.

Unfortunately, there is also little data or research available on the amount of care coordination expenditures provided by MCOs, PIHPs, or PAHPs and the effectiveness of care coordination. Some studies have found that care coordination may lead to reductions in preventable inpatient readmissions and costs related to screening, testing, and evaluation. Studies²¹ of transitional care models have found that they may reduce hospital readmissions while other demonstrations have found that care coordination has had some success in reducing hospitalizations and specialist visits).²² There are other studies²³ that have shown that care coordination may not have a significant effect on health care expenditures; for example, a study of one Medicare demonstration²⁴ showed that most care coordination programs did not have a significant effect on the costs or the quality of care, and even successful programs were not able to achieve savings large enough to offset care coordination costs.

It should be noted that these studies, and most other studies available, have examined the effects of care coordination on hospitalizations and

²¹ ("Estimated Federal Savings Associated with Care Coordination Models for Medicare-Medicaid Dual Eligibles," Thorpe 2011.

²² ("Effects of Primary Care Coordination on Public Hospital Patients," Schillinger, Bibbins-Domingo, Vranizan, Bacchetti, Luce, and Bindman, *Journal of General Internal Medicine*, December 2001.

²³ ("Effects of Care Coordination on Hospitalization, Quality of Care, and Health Care Expenditures Among Medicare Beneficiaries," Peikes, Chen, Schore, and Brown, *The Journal of the American Medical Association*, February 2009; "Six Features of Medicare Coordinated Care Demonstration Programs That Cut Hospital Readmissions of High-Risk Patients," Brown, Peikes, Peterson, Schore, and Razafindrakoto, *Health Affairs*, June 2012.

²⁴ ("Effects of Care Coordination on Hospitalization, Quality of Care, and Health Care Expenditures Among Medicare Beneficiaries," Peikes, Chen, Schore, and Brown, *The Journal of the American Medical Association*, February 2009.

utilization of physician services on general Medicaid and/or Medicare populations; we are not aware of any studies or research that focuses specifically on the impact of care coordination on beneficiaries who are using LTSS. Many Medicaid enrollees receiving LTSS are also enrolled in Medicare, and for those enrollees Medicare is typically the primary payer for hospital and physician services. Thus, to the extent care coordination for Medicaid enrollees receiving long-term care services is effective, it is possible that there may be financial impacts to Medicare (and in some cases these impacts may be greater for Medicare than Medicaid).

While we do not collect the amount of managed care capitation payments or expenditures in such a way that the amount paid for managed long-term care services can be determined, we estimate about 38 percent of total Medicaid managed care expenditures were provided for aged and disabled enrollees in 2013 (\$50 billion of \$132 billion), and we expect a significant amount of those expenditures covered acute care services. Thus, the potential amount of expenditures on LTSS under Medicaid managed care programs is expected to be relatively small compared to the rest of the program. We

believe that enrollees will benefit from increased care coordination activity; however, at this time, we believe a reasonable estimate of the financial impact of the changes to care coordination requirements under the regulation is that there would be a net impact of \$0. We believe that the expected increase in care coordination costs is likely to be small and that the effect of those activities on overall health benefit expenditures would be limited. The effect on overall expenditures would vary significantly depending on how successfully the managed care plans implement and/or enhance their current coordination efforts. We expect that provisions finalized in this rule related to setting actuarially sound rates, performance reporting, and encounter data reporting would enable more robust analysis of the effects of care coordination and transition efforts on expenditures in the future.

We finalized some of the Medicaid beneficiary protections to CHIP, specifically the requirements in § 438.62, § 438.208, and § 438.210. We believe these protections will ensure that enrollees, particularly those with complex health needs, experience smoother transitions, and have fewer emergency department visits or

admissions. The final provisions in §§ 438.62, 438.208, and 438.210 associated with implementing the beneficiary protection provisions of part 457 have an estimated first-year COI cost of a cumulative \$7 million.

10. Modernizing Regulatory Requirements

This guiding principle seeks to incorporate the numerous advancements in state activities, managed care plan practices, and federal oversight interests since part 438 was finalized in 2002, with the exception of subpart E which was finalized in 2003. This guiding principle covers the regulatory topics of network adequacy and accessibility of services; quality measurement and improvement; state monitoring standards; information standards; primary care case management; choice of managed care plans; non-emergency transportation; and state plan standards. As shown in Table 13, the COI costs associated with the provisions under this principle account for a cumulative \$31.4 million in the first year for the revisions to part 438 (detailed burden estimates can be found in the COI section of this final rule at section V.C.5 for information standards and sections IV.C.19 through IV.C.29 for quality framework).

TABLE 13: Costs of Modernizing Regulatory Requirements for Part 438 (in millions of dollars)

	2016	2017	2018	2019	2020
Information Standards¹					
Federal	\$0.6	\$2.4	\$2.4	\$1.4	\$1.4
State	\$0	\$0	\$0	\$0	\$0
Private	\$0	\$1.7	\$1.8	\$1	\$1
Quality Measurement and Improvement²					
Federal	\$19.4	\$19.4	\$19.4	\$19.1	\$19.1
State	\$8.6	\$8.6	\$8.6	\$8.3	\$8.3
Private	\$2.6	\$2.6	\$2.6	\$2.6	\$2.6
Other³					
Federal	\$0.1	\$0.1	\$0.1	\$0.1	\$0.1
State	\$0.1	\$0.1	\$0.1	\$0.1	\$0.1
Private	\$0	\$0	\$0	\$0	\$0
Total					
Federal	\$20.1	\$21.9	\$21.9	\$20.6	\$20.6
State	\$8.7	\$8.7	\$8.7	\$8.4	\$8.4
Private	\$2.6	\$4.3	\$4.4	\$3.6	\$3.6
Grand Total	\$31.4	\$34.9	\$35	\$32.6	\$32.6

¹§438.10.

²Subpart E, Quality Framework and External Quality Review.

³§438.66, §438.68, §438.207.

Similarly, as shown in Table 14, the COI costs associated with implementing the provisions under this principle account for a cumulative \$4.6 million in the first year for the revisions to part 457.

TABLE 14: Costs of Modernizing Regulatory Requirements for Part 457
(in millions of dollars)

	2016	2017	2018	2019	2020
Information Standards¹					
Federal	\$0.3	\$0.3	\$0.3	\$0.1	\$0.1
State	\$0	\$0	\$0	\$0	\$0
Private	\$0	\$0	\$0	\$0	\$0
Quality Measurement and Improvement²					
Federal	\$3.9	\$3.9	\$3.9	\$3.4	\$2.6
State	\$0.2	\$0.2	\$0.2	\$0.2	\$0.8
Private	\$0.1	\$0.1	\$0.1	\$0	\$0.2
Other³					
Federal	\$0.1	\$0.1	\$0.1	\$0.1	\$0.1
State	\$0	\$0	\$0	\$0	\$0
Private	\$0	\$0	\$0	\$0	\$0
Total					
Federal	\$4.3	\$4.3	\$4.3	\$3.6	\$2.8
State	\$0.2	\$0.2	\$0.2	\$0.2	\$0.8
Private	\$0.1	\$0.1	\$0.1	\$0	\$0.2
Grand Total	\$4.6	\$4.6	\$4.6	\$3.8	\$3.8

¹§457.1207.²§457.1240, §457.1250.³§457.1218, §457.1230(b).

The provision of information to potential enrollees by the state and to enrollees by the managed care plans has always been a requirement in § 438.10. However, we have finalized changes to this section to better organize and clarify the standards for states and managed care plans. These changes are necessary, and important, since the information provided to potential and current enrollees is critical in aiding them to make informed decisions when selecting a managed care plan and to sufficiently understand the managed care program to maximize the benefits

and rights available to them. For example, without information presented in an easily understood way, an enrollee may choose a managed care plan that does not have their existing providers in the network, which may force the enrollee to change their providers. This is particularly challenging for enrollees with disabilities or receiving LTSS, because these individuals often receive services that assist with activities of daily living in their home. Disruption in services from their usual providers can cause numerous problems and may

prevent them from living safely and effectively in their chosen setting.

We finalized changes to the content and delivery methods for notices, handbooks, formularies, and provider directories to facilitate the dissemination of timely and complete information that potential enrollees and enrollees need. Current § 438.10 pertaining to information requirements do not reflect current technology advances that enable states and managed care plans to provide access to information more quickly, accurately, and less expensively. As more

consumers understand and rely on electronic information, not revising this section and continuing to mandate that all information be provided by mailing paper would be unrealistic, unnecessarily costly, and not in the beneficiaries' or managed care plans' best interest. Many states and managed care plans have been providing required information in both electronic and paper form for several years; the final rule will eliminate this duplication. Since the transition to electronic communication will be gradual and at varying rates, we expect the burden for providing the information required in § 438.10 to diminish over time. The provisions in § 438.10 have an estimated first-year COI cost of a cumulative \$0.6 million (detailed burden estimates can be found in the COI section of this final rule at section V.C.5 for information standards). As required by section 2103(f)(3) of the Act, added by section 403 of CHIPRA, and consistent with the requirements of section 2101(a) to provide coverage in an effective and efficient manner, we also propose to apply the standards of § 438.10 to CHIP in § 457.1207. The total estimated first-year COI costs associated with implementing the information requirements in part 457 is a cumulative \$0.3 million.

11. Quality Measurement and Improvement

There are several items that drive the new burden associated with the finalized quality provisions. Given that some PAHPs may provide clinical services, such as dental or behavioral health services, we will apply the quality standards in part 438 subpart E to PAHPs. This will ensure that they are subject to the same approach to measuring and improving quality as are MCOs and PIHPs, which will allow for better oversight and accountability. We will also apply select provisions of part 438 subpart E (specifically, § 438.330(b)(2), (b)(3), (c), and (e), § 438.340, and § 438.350) to PCCM entities whose contracts with the state provide for shared savings, incentive payments or other financial reward for the PCCM entity for improved quality outcomes. This will ensure appropriate oversight of PCCM entities whose compensation is tied to quality improvement. The QAPI program provisions at § 438.330 reflect the expansion of managed care to LTSS. By specifically addressing LTSS within their QAPI program, MCOs, PIHPs, and PAHPs will have tools that can be used to provide accountability for the care provided to this vulnerable population. The new mandatory EQR-related

activity (validation of network adequacy) and the state review of the accreditation status of MCOs, PIHPs, and PAHPs will also support state oversight of managed care plans, and help to ensure that consumers have access to high-quality plans. Similarly, state-based MMC QRSs for MCOs, PIHPs, and PAHPs will assist consumers in identifying the plan that best meets their needs. States contracting with MCOs or PIHPs currently maintain a written strategy for assessing and improving the quality of managed care services offered by all MCOs and PIHPs. Under the final rule, we have expanded the requirement in § 438.340 for a quality strategy to states contracting with PAHPs and PCCM entities described in § 438.310(c)(2). The total estimated first-year COI costs associated with the finalized modifications to the managed care quality components of the regulations is a cumulative \$30.6 million (detailed burden estimates can be found in the COI section of this final rule at section V.C.19 through V.C.29 for quality framework).

As required by section 2101(f)(3) of the Act, added by section 403 of CHIPRA, and consistent with the requirements of section 2101(a) of the Act to provide coverage in an effective and efficient manner, we also propose to apply the quality standards of 438 subpart E and 431 subpart I to CHIP in §§ 457.760, 457.1240, and 457.1250. The total estimated first-year COI costs associated with implementing the quality standards in part 457 is a cumulative \$4.2 million.

The final regulation makes a number of changes related to Medicaid quality of care, primarily for Medicaid managed care programs, including requirements for state managed care quality strategies, QAPI programs, MMC QRSs, state review of the accreditation status of contracted Medicaid managed care plans, and EQRs. While these changes are expected to lead to improvements in the quality of care delivered by states and Medicaid managed care plans, it is difficult to determine whether or not these changes would have any financial impacts on Medicaid expenditures. We would expect some activities would be unlikely to have a financial impact (such as the posting online of the accreditation status of Medicaid managed care plans per § 438.332), while other activities may lead to some small increases or decreases in expenditures. For example, some activities may require managed care plans to increase expenditures to improve the quality of care and meet certain quality standards associated with some of the changes in the

regulation, while other activities may improve the quality of care and lead to a net decrease in benefit expenditures. We believe that it is not possible to estimate the potential financial impacts of these changes and believe that any impacts on net Medicaid expenditures would be negligible. While we invited comment on possible ways to quantify the costs and/or benefits associated with these proposed provisions, no comments were received on this topic.

12. Network Adequacy

We finalized § 438.68 to establish minimum standards in the area of network adequacy. This section aims to maintain state flexibility while modernizing the current regulatory framework to reflect the maturity and prevalence of Medicaid managed care delivery systems, promote processes for ensuring access to care, and align, where feasible, with other private and public health care coverage programs. Therefore, we finalized standards to ensure ongoing state assessment and certification of MCO, PIHP, and PAHP networks, set threshold standards for the establishment of network adequacy measures for a specified set of providers, establish criteria for developing network adequacy standards for MLTSS programs, and ensure the transparency of network adequacy standards. As many states currently have some network standards in place, we estimate only a small administrative burden to states to implement these provisions.

In general, we would expect strengthening network adequacy standards could increase expenditures, as some plans may need to add more providers to in their networks and, in doing so, may need to increase provider reimbursement rates. In addition, adding more providers to plan networks could potentially lead to more use of health care services among the providers added, whether primary care physicians, specialists, or other providers. However, the changes in the regulation are limited and only include requirements about setting and reporting network adequacy standards. The final regulation does not establish network adequacy standards. Thus, while a state may need to adapt its network adequacy standards to include criteria specified in the regulation or to provide additional reports and information about those standards, we do not assume that these changes would necessitate significant changes to the standards currently in place in states.

13. Implementing Statutory Provisions

This guiding principle seeks to implement the statutory provisions impacting Medicaid and CHIP managed care that have passed since the Balanced Budget Act of 1997 (BBA). This principle covers the regulatory topics of incorporating provisions for encounter data and health information systems requirements established in the Affordable Care Act and requirements for contracts involving Indians established in the American Recovery and Reinvestment Act (ARRA). The total estimated first-year COI costs associated to the provisions under this principle account for a cumulative \$0.1 million (provisions in §§ 438.14, 438.242, and 438.818) (detailed COI burden estimates can be found in the COI section of this final rule at sections IV.C.18 and IV.C.39 for encounter data and health information systems and IV.C.6 for contracts involving Indians). No additional quantifiable benefits or costs were identified for these provisions.

14. Other Provisions

Changes in Subpart F of part 438 that include references to part 431 require minor changes to § 431.220 and § 431.244. Without these changes, the sections would be inconsistent with the changes in part 438. There is no burden associated with this change as it is a technical correction and any related burden is included in § 438.408(f).

In § 433.138, technical corrections remove an obsolete reference to “ICD–9” and replace it with text that does not alter the meaning or need to be updated as newer versions of the International Classification of Diseases are published in the future. There is no burden associated with this change as states are not mandated to make any changes to their policies or procedures as a result of this revised text.

C. Anticipated Effects

The RFA requires agencies to analyze options for regulatory relief of small entities, if a rule has a significant impact on a substantial number of small entities. For purposes of the RFA, we estimate that some PAHPs, PCCMs, and PCCM entities are likely to be small entities as that term is used in the RFA. For purposes of the RFA, we estimate that most MCOs and PIHPs are not small entities as that term is used in the RFA. For purposes of the RFA and according to the Small Business Administration (SBA) and the Table of Small Business Size Standards,²⁵ small entities include

small businesses in the health care sector that are direct health and medical insurance issuers with average annual receipts of less than \$38.5 million and offices of physicians or health practitioners with average annual receipts of less than \$11 million. For purposes of the RFA, individuals and state governments are not included in the definition of a small entity.

As of 2012, there are 335 MCOs, 176 PIHPs, 41 PAHPs, 20 NEMT PAHPs, 25 PCCMs, and 9 PCCM entities participating in the Medicaid managed care program. We estimate that there are an additional 62 entities that serve only CHIPs, including approximately 55 MCOs and PIHPs, 3 PAHPs, and 4 PCCMs. We believe that only a few of these entities qualify as small entities. Research on publicly available records for the entities allowed us to determine the approximate counts presented. Specifically, for the managed care entities participating in Medicaid managed care programs, we believe that 10 to 20 PAHPs, 8 to 15 PCCMs, and 2 to 5 PCCM entities are likely to be small entities. For the managed care entities that serve only CHIP, we believe that 2 to 4 PCCMs and PAHPs are likely to be small entities. We believe that the remaining MCOs and PIHPs have average annual receipts from Medicaid and CHIP contracts and other business interests in excess of \$38.5 million. In analyzing the scope of the impact of these regulations on small entities, we examined the United States Census Bureau’s Statistics of U.S. Businesses for 2012. According to the 2012 data, there are 4,506 direct health and medical insurance issuers with less than 20 employees and 156,408 offices of physicians or health practitioners with less than 20 employees. For purposes of the RFA, we believe that we are impacting less than 1 percent of the small entities that we have identified.

The primary impact on small entities will be through the standards placed on PAHPs, PCCMs, and PCCM entities through the following requirements: (1) Adding PCCMs and PCCM entities, where appropriate, to the information standards in §§ 438.10 and 457.1207 regarding enrollee handbooks, provider directories, and formularies; (2) adding PAHPs, PCCMs, and PCCM entities in § 438.62 to implement their own transition of care policies and PAHPs in § 438.208 to perform initial assessments and care coordination activities and applying these standards to CHIP in §§ 457.1216 and 457.1230(c); (3) adding PAHPs in § 438.242 to collect data on

enrollee and provider characteristics and on services furnished to enrollees through an encounter data system or other such methods and applying these standards to CHIP in § 457.1230(d); (4) adding PCCM entities to the QAPI program standards in § 438.330 and applying these standards to CHIP in § 457.1240; (5) adding PAHPs in § 438.350 to the list of affected entities regarding the EQR process and applying these standards to CHIP in § 457.1250; and (6) adding PAHPs to the types of entities subject to the standards of subpart F to establish a grievances and appeals system and process and applying these standards to CHIP in § 457.1260. We do not believe that the remaining impacts or burdens of the provisions of this final rule are great on the small entities that we have identified.

For purposes of the RFA, all cost estimates were derived from the Collection of Information calculations in section V. of this final rule. The estimated costs associated with the impacts on small entities listed above are primarily attributable to the transition of care policies for PAHPs, PCCMs, and PCCM entities, initial assessments and care coordination activities for PAHPs, and the establishment of a grievances and appeals system and process for PAHPs. Due to the small number of small entities participating in CHIP managed care which we believe will be affected, the Secretary has determined that the regulations in part 457 of this rulemaking will not have a significant economic impact on a substantial number of small entities. With respect to Medicaid, the transition of care policies, initial assessments, and care coordination activities for PAHPs account for approximately \$2.4 million of the cumulative \$4.5 million annual impact on the 41 PAHPs (detailed burden estimates can be found in the COI section of this final rule at sections IV.C.8 and IV.C.15 for coordination/continuity of care). The establishment of a grievances and appeals system and process accounts for approximately \$1.1 million of the cumulative \$4.5 million annual impact on the 41 PAHPs (detailed burden estimates can be found in the COI section of this final rule at sections IV.C.30 through IV.C.35 for grievances and appeals). The total estimated annual burden per PAHP is less than \$0.1 million, or less than 1 percent of the \$38.5 million threshold. The transition of care policies for PCCMs and PCCM entities account for approximately \$0.4 million of the cumulative \$0.6 million annual impact

²⁵ Small Business Administration (SBA), <https://www.sba.gov/contracting/getting-started-contractor/>

[make-sure-you-meet-sba-size-standards/summary-size-standards-industry-sector](https://www.sba.gov/contracting/getting-started-contractor/make-sure-you-meet-sba-size-standards/summary-size-standards-industry-sector).

on the 34 PCCMs and PCCM entities (detailed burden estimates can be found in the COI section of this final rule at sections IV.C.8 and IV.C.15 for coordination/continuity of care). The total estimated annual burden per PCCM or PCCM entity is less than \$0.1 million, or less than 1 percent of the \$11 million threshold.

These small entities must meet certain standards as identified in the provisions of this final rule; however, we believe these are consistent with the nature of their business in contracting with state governments for the provision of services to Medicaid and CHIP managed care enrollees. Therefore, based on the estimates in the COI (section V of this final rule), we have determined, and the Secretary certifies, that this final rule will not have a significant economic impact on a substantial number of small entities. In the proposed rule, we invited comment on our proposed analysis of the impact on small entities and on possible alternatives to provisions of the proposed rule that would reduce burden on small entities. We received no comments and are finalizing our analysis as proposed in this final rule.

In addition, section 1102(b) of the Act requires us to prepare a regulatory impact analysis for any rule that may have a significant impact on the operations of a substantial number of small rural hospitals. This analysis must conform to the provisions of section 604 of the RFA. For purposes of section 1102(b) of the Act, we define a small rural hospital as a hospital that is located outside a Metropolitan Statistical Area and has fewer than 100 beds.

We do not anticipate that the provisions in this final rule will have a substantial economic impact on most hospitals, including small rural hospitals. Provisions include some new standards for State governments, MCOs, PIHPs, PAHPs, PCCMs, and PCCM entities but no direct requirements on individual hospitals. The impact on individual hospitals will vary according to each hospital's current and future contractual relationships with MCOs, PIHPs, PAHPs, PCCMs, and PCCM entities, but any additional burden on small rural hospitals should be negligible. In the proposed rule, we invited comment on our proposed analysis of the impact on small rural hospitals regarding the provisions of the proposed rule. We received no comments.

We are not preparing analysis for either the RFA or section 1102(b) of the Act because we have determined, and the Secretary certifies, that this final

rule will not have a significant economic impact on a substantial number of small entities or a significant impact on the operations of a substantial number of small rural hospitals in comparison to total revenues of these entities.

Section 202 of the Unfunded Mandates Reform Act of 1995 (UMRA) also requires that agencies assess anticipated costs and benefits before issuing any rule whose mandates require spending in any 1 year of \$100 million in 1995 dollars, updated annually for inflation. In 2015, that is approximately \$144 million. This final rule does not contain any federal mandate costs resulting from (A) imposing enforceable duties on state, local, or tribal governments, or on the private sector, or (B) increasing the stringency of conditions in, or decreasing the funding of, State, local, or tribal governments under entitlement programs. We have determined that this final rule does not impose any mandates on state, local, or tribal governments, or the private sector that will result in an annual expenditure of \$144 million or more.

We received the following comment on section 202 of the UMRA:

Comment: One commenter stated that the proposed rule was potentially a significant unfunded mandate and recommended that CMS withdraw the rule.

Response: The commenter did not provide any data or evidence to further this claim or demonstrate the applicability of UMRA; therefore, we retain our position that this final rule does not impose any mandates on state, local, or tribal governments, or the private sector that will result in an annual expenditure of \$144 million or more.

Executive Order 13132 establishes certain requirements that an agency must meet when it issues a final rule that imposes substantial direct requirement costs on state and local governments, preempts state law, or otherwise has Federalism implications. We believe this final regulation gives states appropriate flexibility regarding managed care standards (for example, setting network adequacy standards, setting credentialing standards, EQR activities), while also aligning Medicaid and CHIP managed care standards with those for plans in the Marketplace and MA to better streamline the beneficiary experience and to reduce administrative and operational burdens on states and health plans across publicly-funded programs and the private market. We have determined that this final rule

would not significantly affect states' rights, roles, and responsibilities.

1. Effects on Other Providers

The providers directly affected by the provisions of this rule are the MCOs, PIHPs, PAHPs, PCCMs, and PCCM entities under contract to a state Medicaid or CHIP agency. As detailed in the sections above, the effect of the final rule varies by entity type and amount of burden. Setting actuarially sound rates and MLR are the areas with the largest impact on the managed care plans. We believe that many of the final rate setting provisions are unlikely to have a direct effect on the actual capitation rates or future Medicaid expenditures. To the extent that these new standards or requirements do have an effect on capitation rates or Medicaid expenditures, we believe that generally it is likely that this could lead to increases in some cases and decreases in other cases in the capitation payment rates and Medicaid expenditures. The sum of the estimated financial impacts of these changes could increase expenditures as much as \$3.7 billion from 2016 to 2020, and could decrease expenditures as much as \$8.7 billion from 2016 to 2020.

The regulation finalizes new requirements that would require the states to calculate and report the MLRs for Medicaid MCOs, PIHPs, and PAHPs in § 438.4 and § 438.5, and to add new § 438.8 and § 438.74. These changes, however, do not require that states assess any financial penalties on MCOs, PIHPs, and PAHPs that do not meet a minimum MLR. The net effect of these changes is estimated to range from zero impact to a decrease in MCO, PIHP, and PAHP payments of about 0.2 to 0.3 percent. Between 2018 and 2020, a 0.3-percent decrease in MCO, PIHP, and PAHP expenditures is projected to be a reduction of \$1.3 billion in federal expenditures and of \$0.7 billion in state expenditures.

Many other changes in this final rule will have small COI costs for MCOs, PIHPs, and PAHPs; however, they are negligible. All COI costs are described in section V. of this final rule.

2. Effects on the Medicare and Medicaid Programs

This final rule may have some positive effect on Medicare, but that effect is not quantifiable. Sections 438.62 and 438.208 finalize enhanced care planning, transition, and coordination activities. Many of these activities will affect dually eligible enrollees. If, as expected, those efforts generate savings from more efficient and appropriate use of services, then

Medicare as the primary payer may recognize some benefit.

The provisions of final part 438 will apply to all states using a managed care delivery system for the Medicaid program. Federal matching rates are discussed more fully in section VI.B, Overall Impact. This final rule will help states fulfill the goals and mission of the Medicaid program through better oversight and accountability of their programs and will enable them to detect deficiencies and implement corrective action more quickly and consistently.

D. Alternatives Considered

One alternative considered was leaving part 438 as it is today. While it has been the guiding regulation for Medicaid managed care since its finalization in 2002, many questions and issues have arisen in the intervening 13 years due to the current version's lack of clarity or detail in some areas. The final revisions to the topics of rate setting and enrollment are good examples of this. With no guidance in these areas, states have created various standards, leading to inconsistency and, in some cases, less than optimal program performance. Additionally, many issues have arisen from the evolution of managed care in the last 12 years that have rendered parts of parts 438 nearly obsolete. For example, the existing version gives little acknowledgement to the use of electronic means of communication and no recognition to the recently created health care coverage options offered through the federal and state marketplaces. This creates gaps that leave states and managed care plans with unclear, non-existent, or confusing guidance and standards for program operation. We believe that with consistent standards and clearly defined flexibilities for states, programs can develop in ways that not only transform the healthcare delivery system and fulfill the mission of the Medicaid program, but can improve the health and wellness of Medicaid enrollees. For these reasons, we believe that leaving part 438 as it is now is not a viable option.

Another option was to align completely with standards applicable to plans in Medicare and/or the Marketplace. Given the high rate of cross program participation among the managed care plans in some states, we believe it is important to allow managed care plans to take advantage of operational efficiencies by aligning part 438 with Medicare and the private insurance market wherever possible by creating and implementing uniform

policies and procedures. Alignment also adds consistency and ease of understanding for enrollees as they move between healthcare coverage programs as their life circumstances change. For each regulatory area where a comparable Medicare or Marketplace practice or policy existed, staff evaluated the information against existing Medicaid regulations. When differences were identified, they were evaluated to determine the benefits and drawbacks to adopting and the degree of impact the change would have on the Medicaid population, which is often significantly different from Medicare and the Marketplace populations. Additionally, as Medicaid is a federal-state partnership, we wanted to preserve the flexibility historically provided to states in the design and administration of their programs. As such, complete alignment was only an option in some provisions, while partial alignment was selected in others to recognize and accommodate the unique aspects of the Medicaid program.

We received no public comments on the alternatives considered above.

Regarding quality measurement and improvement (part 438 subpart E), two alternatives were considered: (1) Leaving the language as it exists today; and (2) expanding the application of the quality strategy from Medicaid and CHIP managed care to include services provided FFS. While our regulatory language has remained unchanged since 2002, there have been significant improvements regarding quality measurement and improvement for Medicaid. Under the authority of CHIPRA and the Affordable Care Act, we have developed and issued a set of performance measures to assess the quality of care received by adults and children in the Medicaid and CHIP programs. The National Quality Strategy and CMS Quality Strategy now offer national guidance regarding how we move forward as a nation to offer better health care, improved affordability, and support healthy people and healthy communities. At a state level, Medicaid managed care programs have undergone shifts both in terms of populations and benefits since 2002. Given these changes, we believe that it is necessary and appropriate to revise our regulatory language to address needs of the Medicaid programs both today and into the future.

While the role of managed care in both Medicaid has grown since 2002, we cannot forget that many individuals still receive care through a FFS delivery model, and that certain services are still provided FFS to individuals otherwise

enrolled in managed care programs. We believe that, regardless of delivery system, it is important for states to measure performance to develop a plan to strengthen and improve the quality of care. This led us to propose the expansion of the quality strategy to include services delivered FFS. However, the comments received highlighted the potential challenges and burden associated with this proposal. While we continue to encourage states to measure and improve quality for services provided FFS, we understand that mandating a comprehensive quality strategy may not be the most appropriate approach at this time. Therefore, we determined that the most appropriate course of action would be to revise the Medicaid and CHIP managed care quality regulations to apply to states contracting with MCOs, PIHPs, PAHPs, and select PCCM entities.

For CHIP, we considered two alternatives: (1) Not regulating; or (2) adopting additional Medicaid requirements. CHIPRA applied several of the Medicaid managed care standards to CHIP. In response, we released two SHOs conveying those requirements to states, but have not provided additional guidance. As a result, states do not have clear understanding of the expectations of the federal requirements for CHIP managed care, and CMS does not have needed information about state oversight of managed care plans. Therefore, we determined that regulations were appropriate. When deciding whether to adopt all of the Medicaid regulations, or only the subset finalized in this regulation, we have worked to balance the need for information about state oversight of CHIP managed care plans against the administrative burden of complying with the final regulations. To that end, we only apply the rules that are most important for aligning CHIP managed care with Marketplace and Medicaid managed care rules. The scope of the CHIP regulations is narrower than the revisions and amendments to the Medicaid managed care regulations as discussed throughout section II of this final rule.

E. Accounting Statement and Table

The estimates that appear in the Transfers section of Table 15 combine both cost savings and transfers between members of society. To the extent that the final rule changes provision of medical care, the impacts represent cost savings. Otherwise, the rule's impacts represent transfers to the federal and state governments from MCOs, PIHPs and PAHPs.

TABLE 15: Economic Data: Costs and Benefits Statement

Category	Primary Estimate	Low Estimate	High Estimate	Units			Notes
				Year Dollars	Discount Rate	Period Covered	
Benefits							
Non-Quantified	Improved health outcomes; reduced unnecessary services; improved beneficiary experience; improved access; and improved program transparency which facilitates better decision making.						
Costs							
Annualized Monetized \$ millions/year	126.8			2014	7 percent	2016-2020	
	127.3			2014	3 percent	2016-2020	
Non-Quantified	Costs of activities (other than information collection as defined in the Paperwork Reduction Act) that would be necessary for generating benefits listed above.						
Transfers							
Federal Annualized Monetized \$ millions/year		-428.7	1277.2	2016	7 percent	2016-2020	
		-446.4	1335.1	2016	3 percent	2016-2020	
From/To	From: MCOs, PIHPS & PAHPs			To: Federal Government			
Other Annualized Monetized \$ millions/year		-259.6	701.9	2016	7 percent	2016-2020	
		-271.1	734.6	2016	3 percent	2016-2020	
From/To	From: MCOs, PIHPS & PAHPs			To: State Governments			

List of Subjects

42 CFR Part 431

Grant programs-health, Health facilities, Medicaid, Privacy, Reporting and recordkeeping requirements.

42 CFR Part 433

Administrative practice and procedure, Child support, Claims, Grant programs-health, Medicaid, Reporting and recordkeeping requirements.

42 CFR Part 438

Grant programs-health, Medicaid, Reporting and recordkeeping requirements.

42 CFR Part 440

Grant programs-health, Medicaid.

42 CFR Part 457

Administrative practice and procedure, Grant programs-health, Health insurance, Reporting and recordkeeping requirements.

42 CFR Part 495

Administrative practice and procedure, Electronic health records, Health facilities, Health professions, Health maintenance organizations (HMO), Medicaid, Medicare, Penalties, Privacy, Reporting and recordkeeping requirements.

For the reasons set forth in the preamble, the Centers for Medicare & Medicaid Services amends 42 CFR chapter IV as set forth below:

PART 431—STATE ORGANIZATION AND GENERAL ADMINISTRATION

■ 1. The authority citation for part 431 continues to read as follows:

Authority: Sec. 1102 of the Social Security Act, (42 U.S.C. 1302).

■ 2. Section 431.200 is amended by revising paragraph (b) to read as follows:

§ 431.200 Basis and scope.

* * * * *

(b) Prescribes procedures for an opportunity for a hearing if the State agency or non-emergency transportation PAHP (as defined in § 438.9(a) of this chapter) takes action, as stated in this subpart, to suspend, terminate, or reduce services, or of an adverse benefit determination by an MCO, PIHP or

PAHP under subpart F of part 438 of this chapter; and

* * * * *

■ 3. Section 431.220 is amended by revising paragraphs (a)(5) and (6) to read as follows:

§ 431.220 When a hearing is required.

(a) * * *

(5) Any MCO, PIHP, or PAHP enrollee who is entitled to a hearing under subpart F of part 438 of this chapter.

(6) Any enrollee in a non-emergency medical transportation PAHP (as that term is defined in § 438.9 of this chapter) who has an action as stated in this subpart.

* * * * *

■ 4. Section 431.244 is amended by—

■ a. Revising paragraphs (f)(1) and (f)(2) introductory text.

■ b. Removing paragraph (f)(3).

The revisions read as follows:

§ 431.244 Hearing decisions.

* * * * *

(f) * * *

(1) Ordinarily, within 90 days from the date the enrollee filed an MCO, PIHP, or PAHP appeal, not including the number of days the enrollee took to subsequently file for a State fair hearing.

(2) As expeditiously as the enrollee's health condition requires, but no later than 3 working days after the agency receives, from the MCO, PIHP, or PAHP, the case file and information for any appeal of a denial of a service that, as indicated by the MCO, PIHP, or PAHP—

* * * * *

PART 433—STATE FISCAL ADMINISTRATION

■ 5. The authority citation for part 433 continues to read as follows:

Authority: Sec. 1102 of the Social Security Act, (42 U.S.C. 1302).

■ 6. Effective May 6, 2016, § 433.15 is amended by revising paragraph (b)(10) to read as follows:

§ 433.15 Rates of FFP for administration.

* * * * *

(b) * * *

(10) Funds expended for the performance of external quality review or the related activities described in § 438.358 of this chapter consistent with § 438.370(a) of this chapter: 75 percent; consistent with § 438.370(b): 50 percent.

■ 7. Section 433.138 is amended by revising paragraph (e) to read as follows:

§ 433.138 Identifying liable third parties.

* * * * *

(e) *Diagnosis and trauma code edits.* Except as specified under paragraph (l)

of this section, the agency must take action to identify those paid claims for Medicaid beneficiaries that contain diagnosis codes that are indicative of trauma, or injury, poisoning, and other consequences of external causes, for the purpose of determining the legal liability of third parties so that the agency may process claims under the third party liability payment procedures specified in § 433.139(b) through (f).

* * * * *

PART 438—MANAGED CARE

■ 8. The authority citation for part 438 continues to read as follows:

Authority: Sec. 1102 of the Social Security Act (42 U.S.C. 1302).

■ 9. Effective May 6, 2016, § 438.370 is revised to read as follows:

§ 438.370 Federal financial participation (FFP).

(a) FFP at the 75 percent rate is available in expenditures for EQR (including the production of EQR results) and the EQR-related activities set forth in § 438.358 performed on MCOs and conducted by EQROs and their subcontractors.

(b) FFP at the 50 percent rate is available in expenditures for EQR-related activities conducted by any entity that does not qualify as an EQRO, and for EQR (including the production of EQR results) and EQR-related activities performed by an EQRO on entities other than MCOs.

(c) Prior to claiming FFP at the 75 percent rate in accordance with paragraph (a) of this section, the State must submit each EQRO contract to CMS for review and approval.

■ 10. Effective July 5, 2016, subparts A through J are revised to read as follows:

Subpart A—General Provisions

Sec.

- 438.1 Basis and scope.
- 438.2 Definitions.
- 438.3 Standard contract requirements.
- 438.4 Actuarial soundness.
- 438.5 Rate development standards.
- 438.6 Special contract provisions related to payment.
- 438.7 Rate certification submission.
- 438.8 Medical loss ratio (MLR) standards.
- 438.9 Provisions that apply to non-emergency medical transportation PAHPs.
- 438.10 Information requirements.
- 438.12 Provider discrimination prohibited.
- 438.14 Requirements that apply to MCO, PIHP, PAHP, PCCM, and PCCM entity contracts involving Indians, Indian health care providers (IHCPs), and Indian managed care entities (IMCEs).

Subpart B—State Responsibilities

- 438.50 State Plan requirements.

- 438.52 Choice of MCOs, PIHPs, PAHPs, PCCMs, and PCCM entities.
- 438.54 Managed care enrollment.
- 438.56 Disenrollment: Requirements and limitations.
- 438.58 Conflict of interest safeguards.
- 438.60 Prohibition of additional payments for services covered under MCO, PIHP or PAHP contracts.
- 438.62 Continued services to enrollees.
- 438.66 State monitoring requirements.
- 438.68 Network adequacy standards.
- 438.70 Stakeholder engagement when LTSS is delivered through a managed care program.
- 438.71 Beneficiary support system.
- 438.74 State oversight of the minimum MLR requirement.

Subpart C—Enrollee Rights and Protections

- 438.100 Enrollee rights.
- 438.102 Provider-enrollee communications.
- 438.104 Marketing activities.
- 438.106 Liability for payment.
- 438.108 Cost sharing.
- 438.110 Member advisory committee.
- 438.114 Emergency and poststabilization services.
- 438.116 Solvency standards.

Subpart D—MCO, PIHP and PAHP standards

- 438.206 Availability of services.
- 438.207 Assurance of adequate capacity and services.
- 438.208 Coordination and continuity of care.
- 438.210 Coverage and authorization of services.
- 438.214 Provider selection.
- 438.224 Confidentiality.
- 438.228 Grievance and appeal systems.
- 438.230 Subcontractual relationships and delegation.
- 438.236 Practice guidelines.
- 438.242 Health information systems.

Subpart E—Quality Measurement and Improvement; External Quality Review

- 438.310 Basis, scope, and applicability.
- 438.320 Definitions.
- 438.330 Quality assessment and performance improvement program.
- 438.332 State review of the accreditation status of MCOs, PIHPs and PAHPs.
- 438.334 Medicaid managed care quality rating system.
- 438.340 Managed care State quality strategy.
- 438.350 External quality review.
- 438.352 External quality review protocols.
- 438.354 Qualifications of external quality review organizations.
- 438.356 State contract options for external quality review.
- 438.358 Activities related to external quality review.
- 438.360 Nonduplication of mandatory activities with Medicare or accreditation review.
- 438.362 Exemption from external quality review.
- 438.364 External quality review results.
- 438.370 Federal financial participation (FFP).

Subpart F—Grievance and Appeal System

- 438.400 Statutory basis, definitions, and applicability.
- 438.402 General requirements.
- 438.404 Timely and adequate notice of adverse benefit determination.
- 438.406 Handling of grievances and appeals.
- 438.408 Resolution and notification: Grievances and appeals.
- 438.410 Expedited resolution of appeals.
- 438.414 Information about the grievance and appeal system to providers and subcontractors.
- 438.416 Recordkeeping requirements.
- 438.420 Continuation of benefits while the MCO, PIHP, or PAHP appeal and the State fair hearing are pending.
- 438.424 Effectuation of reversed appeal resolutions.

Subpart G—[Reserved]**Subpart H—Additional Program Integrity Safeguards**

- 438.600 Statutory basis, basic rule, and applicability.
- 438.602 State responsibilities.
- 438.604 Data, information, and documentation that must be submitted.
- 438.606 Source, content, and timing of certification.
- 438.608 Program integrity requirements under the contract.
- 438.610 Prohibited affiliations.

Subpart I—Sanctions

- 438.700 Basis for imposition of sanctions.
- 438.702 Types of intermediate sanctions.
- 438.704 Amounts of civil money penalties.
- 438.706 Special rules for temporary management.
- 438.708 Termination of an MCO, PCCM, or PCCM entity contract.
- 438.710 Notice of sanction and pre-termination hearing.
- 438.722 Disenrollment during termination hearing process.
- 438.724 Notice to CMS.
- 438.726 State plan requirement.
- 438.730 Sanction by CMS: Special rules for MCOs.

Subpart J—Conditions for Federal Financial Participation (FFP)

- 438.802 Basic requirements.
- 438.806 Prior approval.
- 438.808 Exclusion of entities.
- 438.810 Expenditures for enrollment broker services.
- 438.812 Costs under risk and nonrisk contracts.
- 438.816 Expenditures for the beneficiary support system for enrollees using LTSS.
- 438.818 Enrollee encounter data.

Subpart A—General Provisions**§ 438.1 Basis and scope.**

(a) *Statutory basis.* This part is based on the following statutory sections:

(1) Section 1902(a)(4) of the Act requires that States provide for methods of administration that the Secretary finds necessary for proper and efficient operation of the State plan. The

application of the requirements of this part to PIHPs and PAHPs that do not meet the statutory definition of an MCO or a PCCM is under the authority in section 1902(a)(4) of the Act.

(2) Section 1903(i)(25) of the Act prohibits payment to a State unless a State provides enrollee encounter data required by CMS.

(3) Section 1903(m) of the Act contains requirements that apply to comprehensive risk contracts.

(4) Section 1903(m)(2)(H) of the Act provides that an enrollee who loses Medicaid eligibility for not more than 2 months may be enrolled in the succeeding month in the same MCO or PCCM if that MCO or PCCM still has a contract with the State.

(5) Section 1905(t) of the Act contains requirements that apply to PCCMs.

(6) Section 1932 of the Act—

(i) Provides that, with specified exceptions, a State may require Medicaid beneficiaries to enroll in MCOs or PCCMs.

(ii) Establishes the rules that MCOs, PCCMs, the State, and the contracts between the State and those entities must meet, including compliance with requirements in sections 1903(m) and 1905(t) of the Act that are implemented in this part.

(iii) Establishes protections for enrollees of MCOs and PCCMs.

(iv) Requires States to develop a quality assessment and performance improvement strategy.

(v) Specifies certain prohibitions aimed at the prevention of fraud and abuse.

(vi) Provides that a State may not enter into contracts with MCOs unless it has established intermediate sanctions that it may impose on an MCO that fails to comply with specified requirements.

(vii) Specifies rules for Indian enrollees, Indian health care providers, and Indian managed care entities.

(viii) Makes other minor changes in the Medicaid program.

(b) *Scope.* This part sets forth requirements, prohibitions, and procedures for the provision of Medicaid services through MCOs, PIHPs, PAHPs, PCCMs and PCCM entities. Requirements vary depending on the type of entity and on the authority under which the State contracts with the entity. Provisions that apply only when the contract is under a mandatory managed care program authorized by section 1932(a)(1)(A) of the Act are identified as such.

§ 438.2 Definitions.

As used in this part—

Abuse means as the term is defined in § 455.2 of this chapter.

Actuary means an individual who meets the qualification standards established by the American Academy of Actuaries for an actuary and follows the practice standards established by the Actuarial Standards Board. In this part, Actuary refers to an individual who is acting on behalf of the State when used in reference to the development and certification of capitation rates.

Capitation payment means a payment the State makes periodically to a contractor on behalf of each beneficiary enrolled under a contract and based on the actuarially sound capitation rate for the provision of services under the State plan. The State makes the payment regardless of whether the particular beneficiary receives services during the period covered by the payment.

Choice counseling means the provision of information and services designed to assist beneficiaries in making enrollment decisions; it includes answering questions and identifying factors to consider when choosing among managed care plans and primary care providers. Choice counseling does not include making recommendations for or against enrollment into a specific MCO, PIHP, or PAHP.

Comprehensive risk contract means a risk contract between the State and an MCO that covers comprehensive services, that is, inpatient hospital services and any of the following services, or any three or more of the following services:

- (1) Outpatient hospital services.
- (2) Rural health clinic services.
- (3) Federally Qualified Health Center (FQHC) services.
- (4) Other laboratory and X-ray services.
- (5) Nursing facility (NF) services.
- (6) Early and periodic screening, diagnostic, and treatment (EPSDT) services.

- (7) Family planning services.
- (8) Physician services.
- (9) Home health services.

Enrollee means a Medicaid beneficiary who is currently enrolled in an MCO, PIHP, PAHP, PCCM, or PCCM entity in a given managed care program.

Enrollee encounter data means the information relating to the receipt of any item(s) or service(s) by an enrollee under a contract between a State and a MCO, PIHP, or PAHP that is subject to the requirements of §§ 438.242 and 438.818.

Federally qualified HMO means an HMO that CMS has determined is a qualified HMO under section 1310(d) of the PHS Act.

Fraud means as the term is defined in § 455.2 of this chapter.

Health insuring organization (HIO) means a county operated entity, that in exchange for capitation payments, covers services for beneficiaries—

- (1) Through payments to, or arrangements with, providers;
- (2) Under a comprehensive risk contract with the State; and
- (3) Meets the following criteria—
 - (i) First became operational prior to January 1, 1986; or
 - (ii) Is described in section 9517(c)(3) of the Omnibus Budget Reconciliation Act of 1985 (as amended by section 4734 of the Omnibus Budget Reconciliation Act of 1990 and section 205 of the Medicare Improvements for Patients and Providers Act of 2008).

Long-term services and supports (LTSS) means services and supports provided to beneficiaries of all ages who have functional limitations and/or chronic illnesses that have the primary purpose of supporting the ability of the beneficiary to live or work in the setting of their choice, which may include the individual's home, a worksite, a provider-owned or controlled residential setting, a nursing facility, or other institutional setting.

Managed care organization (MCO) means an entity that has, or is seeking to qualify for, a comprehensive risk contract under this part, and that is—

- (1) A Federally qualified HMO that meets the advance directives requirements of subpart I of part 489 of this chapter; or
- (2) Any public or private entity that meets the advance directives requirements and is determined by the Secretary to also meet the following conditions:

- (i) Makes the services it provides to its Medicaid enrollees as accessible (in terms of timeliness, amount, duration, and scope) as those services are to other Medicaid beneficiaries within the area served by the entity.

- (ii) Meets the solvency standards of § 438.116.

Managed care program means a managed care delivery system operated by a State as authorized under sections 1915(a), 1915(b), 1932(a), or 1115(a) of the Act.

Material adjustment means an adjustment that, using reasonable actuarial judgment, has a significant impact on the development of the capitation payment such that its omission or misstatement could impact a determination whether the development of the capitation rate is consistent with generally accepted actuarial principles and practices.

Network provider means any provider, group of providers, or entity that has a network provider agreement

with a MCO, PIHP, or PAHP, or a subcontractor, and receives Medicaid funding directly or indirectly to order, refer or render covered services as a result of the state's contract with an MCO, PIHP, or PAHP. A network provider is not a subcontractor by virtue of the network provider agreement.

Nonrisk contract means a contract between the State and a PIHP or PAHP under which the contractor—

- (1) Is not at financial risk for changes in utilization or for costs incurred under the contract that do not exceed the upper payment limits specified in § 447.362 of this chapter; and

- (2) May be reimbursed by the State at the end of the contract period on the basis of the incurred costs, subject to the specified limits.

Overpayment means any payment made to a network provider by a MCO, PIHP, or PAHP to which the network provider is not entitled to under Title XIX of the Act or any payment to a MCO, PIHP, or PAHP by a State to which the MCO, PIHP, or PAHP is not entitled to under Title XIX of the Act.

Potential enrollee means a Medicaid beneficiary who is subject to mandatory enrollment or may voluntarily elect to enroll in a given MCO, PIHP, PAHP, PCCM or PCCM entity, but is not yet an enrollee of a specific MCO, PIHP, PAHP, PCCM, or PCCM entity.

Prepaid ambulatory health plan (PAHP) means an entity that—

- (1) Provides services to enrollees under contract with the State, and on the basis of capitation payments, or other payment arrangements that do not use State plan payment rates.

- (2) Does not provide or arrange for, and is not otherwise responsible for the provision of any inpatient hospital or institutional services for its enrollees; and

- (3) Does not have a comprehensive risk contract.

Prepaid inpatient health plan (PIHP) means an entity that—

- (1) Provides services to enrollees under contract with the State, and on the basis of capitation payments, or other payment arrangements that do not use State plan payment rates.

- (2) Provides, arranges for, or otherwise has responsibility for the provision of any inpatient hospital or institutional services for its enrollees; and

- (3) Does not have a comprehensive risk contract.

Primary care means all health care services and laboratory services customarily furnished by or through a general practitioner, family physician, internal medicine physician, obstetrician/gynecologist, pediatrician,

or other licensed practitioner as authorized by the State Medicaid program, to the extent the furnishing of those services is legally authorized in the State in which the practitioner furnishes them.

Primary care case management means a system under which:

- (1) A primary care case manager (PCCM) contracts with the State to furnish case management services (which include the location, coordination and monitoring of primary health care services) to Medicaid beneficiaries; or

- (2) A PCCM entity contracts with the State to provide a defined set of functions.

Primary care case management entity (PCCM entity) means an organization that provides any of the following functions, in addition to primary care case management services, for the State:

- (1) Provision of intensive telephonic or face-to-face case management, including operation of a nurse triage advice line.

- (2) Development of enrollee care plans.

- (3) Execution of contracts with and/or oversight responsibilities for the activities of FFS providers in the FFS program.

- (4) Provision of payments to FFS providers on behalf of the State.

- (5) Provision of enrollee outreach and education activities.

- (6) Operation of a customer service call center.

- (7) Review of provider claims, utilization and practice patterns to conduct provider profiling and/or practice improvement.

- (8) Implementation of quality improvement activities including administering enrollee satisfaction surveys or collecting data necessary for performance measurement of providers.

- (9) Coordination with behavioral health systems/providers.

- (10) Coordination with long-term services and supports systems/providers.

Primary care case manager (PCCM) means a physician, a physician group practice or, at State option, any of the following:

- (1) A physician assistant.

- (2) A nurse practitioner.

- (3) A certified nurse-midwife.

Provider means any individual or entity that is engaged in the delivery of services, or ordering or referring for those services, and is legally authorized to do so by the State in which it delivers the services.

Rate cell means a set of mutually exclusive categories of enrollees that is defined by one or more characteristics

for the purpose of determining the capitation rate and making a capitation payment; such characteristics may include age, gender, eligibility category, and region or geographic area. Each enrollee should be categorized in one of the rate cells for each unique set of mutually exclusive benefits under the contract.

Rating period means a period of 12 months selected by the State for which the actuarially sound capitation rates are developed and documented in the rate certification submitted to CMS as required by § 438.7(a).

Risk contract means a contract between the State an MCO, PIHP or PAHP under which the contractor—

- (1) Assumes risk for the cost of the services covered under the contract; and
- (2) Incurs loss if the cost of furnishing the services exceeds the payments under the contract.

Subcontractor means an individual or entity that has a contract with an MCO, PIHP, PAHP, or PCCM entity that relates directly or indirectly to the performance of the MCO's, PIHP's, PAHP's, or PCCM entity's obligations under its contract with the State. A network provider is not a subcontractor by virtue of the network provider agreement with the MCO, PIHP, or PAHP.

State means the Single State agency as specified in § 431.10 of this chapter.

§ 438.3 Standard contract requirements.

(a) *CMS review.* The CMS must review and approve all MCO, PIHP, and PAHP contracts, including those risk and nonrisk contracts that, on the basis of their value, are not subject to the prior approval requirement in § 438.806. Proposed final contracts must be submitted in the form and manner established by CMS. For States seeking approval of contracts prior to a specific effective date, proposed final contracts must be submitted to CMS for review no later than 90 days prior to the effective date of the contract.

(b) *Entities eligible for comprehensive risk contracts.* A State may enter into a comprehensive risk contract only with the following:

- (1) An MCO.
- (2) The entities identified in section 1903(m)(2)(B)(i), (ii), and (iii) of the Act.
- (3) Community, Migrant, and Appalachian Health Centers identified in section 1903(m)(2)(G) of the Act. Unless they qualify for a total exemption under section 1903(m)(2)(B) of the Act, these entities are subject to the regulations governing MCOs under this part.

(4) An HIO that arranges for services and became operational before January 1986.

(5) An HIO described in section 9517(c)(3) of the Omnibus Budget Reconciliation Act of 1985 (as amended by section 4734(2) of the Omnibus Budget Reconciliation Act of 1990).

(c) *Payment.* The following requirements apply to the final capitation rate and the receipt of capitation payments under the contract:

(1) The final capitation rate for each MCO, PIHP or PAHP must be:

(i) Specifically identified in the applicable contract submitted for CMS review and approval.

(ii) The final capitation rates must be based only upon services covered under the State plan and additional services deemed by the State to be necessary to comply with the requirements of subpart K of this part (applying parity standards from the Mental Health Parity and Addiction Equity Act), and represent a payment amount that is adequate to allow the MCO, PIHP or PAHP to efficiently deliver covered services to Medicaid-eligible individuals in a manner compliant with contractual requirements.

(2) Capitation payments may only be made by the State and retained by the MCO, PIHP or PAHP for Medicaid-eligible enrollees.

(d) *Enrollment discrimination prohibited.* Contracts with MCOs, PIHPs, PAHPs, PCCMs and PCCM entities must provide as follows:

(1) The MCO, PIHP, PAHP, PCCM or PCCM entity accepts individuals eligible for enrollment in the order in which they apply without restriction (unless authorized by CMS), up to the limits set under the contract.

(2) Enrollment is voluntary, except in the case of mandatory enrollment programs that meet the conditions set forth in § 438.50(a).

(3) The MCO, PIHP, PAHP, PCCM or PCCM entity will not, on the basis of health status or need for health care services, discriminate against individuals eligible to enroll.

(4) The MCO, PIHP, PAHP, PCCM or PCCM entity will not discriminate against individuals eligible to enroll on the basis of race, color, national origin, sex, sexual orientation, gender identity, or disability and will not use any policy or practice that has the effect of discriminating on the basis of race, color, or national origin, sex, sexual orientation, gender identity, or disability.

(e) *Services that may be covered by an MCO, PIHP, or PAHP.* (1) An MCO, PIHP, or PAHP may cover, for enrollees, services that are in addition to those covered under the State plan as follows:

(i) Any services that the MCO, PIHP or PAHP voluntarily agree to provide,

although the cost of these services cannot be included when determining the payment rates under paragraph (c) of this section.

(ii) Any services necessary for compliance by the MCO, PIHP, or PAHP with the requirements of subpart K of this part and only to the extent such services are necessary for the MCO, PIHP, or PAHP to comply with § 438.910.

(2) An MCO, PIHP, or PAHP may cover, for enrollees, services or settings that are in lieu of services or settings covered under the State plan as follows:

(i) The State determines that the alternative service or setting is a medically appropriate and cost effective substitute for the covered service or setting under the State plan;

(ii) The enrollee is not required by the MCO, PIHP, or PAHP to use the alternative service or setting;

(iii) The approved in lieu of services are authorized and identified in the MCO, PIHP, or PAHP contract, and will be offered to enrollees at the option of the MCO, PIHP, or PAHP; and

(iv) The utilization and actual cost of in lieu of services is taken into account in developing the component of the capitation rates that represents the covered State plan services, unless a statute or regulation explicitly requires otherwise.

(f) *Compliance with applicable laws and conflict of interest safeguards.* All contracts with MCOs, PIHPs, PAHPs, PCCMs and PCCM entities must:

(1) Comply with all applicable Federal and State laws and regulations including Title VI of the Civil Rights Act of 1964; Title IX of the Education Amendments of 1972 (regarding education programs and activities); the Age Discrimination Act of 1975; the Rehabilitation Act of 1973; the Americans with Disabilities Act of 1990 as amended; and section 1557 of the Patient Protection and Affordable Care Act.

(2) Comply with the conflict of interest safeguards described in § 438.58 and with the prohibitions described in section 1902(a)(4)(C) of the Act applicable to contracting officers, employees, or independent contractors.

(g) *Provider-preventable condition requirements.* All contracts with MCOs, PIHPs and PAHPs must comply with the requirements mandating provider identification of provider-preventable conditions as a condition of payment, as well as the prohibition against payment for provider-preventable conditions as set forth in § 434.6(a)(12) and § 447.26 of this chapter. MCOs, PIHPs, and PAHPs, must report all identified provider-

preventable conditions in a form and frequency as specified by the State.

(h) *Inspection and audit of records and access to facilities.* All contracts must provide that the State, CMS, the Office of the Inspector General, the Comptroller General, and their designees may, at any time, inspect and audit any records or documents of the MCO, PIHP, PAHP, PCCM or PCCM entity, or its subcontractors, and may, at any time, inspect the premises, physical facilities, and equipment where Medicaid-related activities or work is conducted. The right to audit under this section exists for 10 years from the final date of the contract period or from the date of completion of any audit, whichever is later.

(i) *Physician incentive plans.* (1) MCO, PIHP, and PAHP contracts must provide for compliance with the requirements set forth in §§ 422.208 and 422.210 of this chapter.

(2) In applying the provisions of §§ 422.208 and 422.210 of this chapter, references to “MA organization,” “CMS,” and “Medicare beneficiaries” must be read as references to “MCO, PIHP, or PAHP,” “State,” and “Medicaid beneficiaries,” respectively.

(j) *Advance directives.* (1) All MCO and PIHP contracts must provide for compliance with the requirements of § 422.128 of this chapter for maintaining written policies and procedures for advance directives, as if such regulation applied directly to MCOs and PIHPs.

(2) All PAHP contracts must provide for compliance with the requirements of § 422.128 of this chapter for maintaining written policies and procedures for advance directives as if such regulation applied directly to PAHPs if the PAHP includes, in its network, any of those providers listed in § 489.102(a) of this chapter.

(3) The MCO, PIHP, or PAHP subject to the requirements of this paragraph (j) must provide adult enrollees with written information on advance directives policies, and include a description of applicable State law.

(4) The information must reflect changes in State law as soon as possible, but no later than 90 days after the effective date of the change.

(k) *Subcontracts.* All subcontracts must fulfill the requirements of this part for the service or activity delegated under the subcontract in accordance with § 438.230.

(l) *Choice of network provider.* The contract must allow each enrollee to choose his or her network provider to the extent possible and appropriate.

(m) *Audited financial reports.* The contract must require MCOs, PIHPs, and PAHPs to submit audited financial

reports specific to the Medicaid contract on an annual basis. The audit must be conducted in accordance with generally accepted accounting principles and generally accepted auditing standards.

(n) *Parity in mental health and substance use disorder benefits.* (1) All MCO contracts, and any PIHP and PAHP contracts providing services to MCO enrollees, must provide for services to be delivered in compliance with the requirements of subpart K of this part insofar as those requirements are applicable.

(2) Any State providing any services to MCO enrollees using a delivery system other than the MCO delivery system must provide documentation of how the requirements of subpart K of this part are met with the submission of the MCO contract for review and approval under paragraph (a) of this section.

(o) *LTSS contract requirements.* Any contract with an MCO, PIHP or PAHP that includes LTSS as a covered benefit must require that any services covered under the contract that could be authorized through a waiver under section 1915(c) of the Act or a State plan amendment authorized through sections 1915(i) or 1915(k) of the Act be delivered in settings consistent with § 441.301(c)(4) of this chapter.

(p) *Special rules for certain HIOs.* Contracts with HIOs that began operating on or after January 1, 1986, and that the statute does not explicitly exempt from requirements in section 1903(m) of the Act, are subject to all the requirements of this part that apply to MCOs and contracts with MCOs. These HIOs may enter into comprehensive risk contracts only if they meet the criteria of paragraph (b) of this section.

(q) *Additional rules for contracts with PCCMs.* A PCCM contract must meet the following requirements:

(1) Provide for reasonable and adequate hours of operation, including 24-hour availability of information, referral, and treatment for emergency medical conditions.

(2) Restrict enrollment to beneficiaries who reside sufficiently near one of the PCCM’s delivery sites to reach that site within a reasonable time using available and affordable modes of transportation.

(3) Provide for arrangements with, or referrals to, sufficient numbers of physicians and other practitioners to ensure that services under the contract can be furnished to enrollees promptly and without compromise to quality of care.

(4) Prohibit discrimination in enrollment, disenrollment, and re-enrollment, based on the beneficiary’s

health status or need for health care services.

(5) Provide that enrollees have the right to disenroll in accordance with § 438.56(c).

(r) *Additional rules for contracts with PCCM entities.* In addition to the requirements in paragraph (q) of this section, States must submit PCCM entity contracts to CMS for review and approval to ensure compliance with the provisions of this paragraph (r); § 438.10; and § 438.310(c)(2).

(s) *Requirements for MCOs, PIHPs, or PAHPs that provide covered outpatient drugs.* Contracts that obligate MCOs, PIHPs or PAHPs to provide coverage of covered outpatient drugs must include the following requirements:

(1) The MCO, PIHP or PAHP provides coverage of covered outpatient drugs as defined in section 1927(k)(2) of the Act, that meets the standards for such coverage imposed by section 1927 of the Act as if such standards applied directly to the MCO, PIHP, or PAHP.

(2) The MCO, PIHP, or PAHP reports drug utilization data that is necessary for States to bill manufacturers for rebates in accordance with section 1927(b)(1)(A) of the Act no later than 45 calendar days after the end of each quarterly rebate period. Such utilization information must include, at a minimum, information on the total number of units of each dosage form, strength, and package size by National Drug Code of each covered outpatient drug dispensed or covered by the MCO, PIHP, or PAHP.

(3) The MCO, PIHP or PAHP establishes procedures to exclude utilization data for covered outpatient drugs that are subject to discounts under the 340B drug pricing program from the reports required under paragraph (s)(2) of this section when states do not require submission of managed care drug claims data from covered entities directly.

(4) The MCO, PIHP or PAHP must operate a drug utilization review program that complies with the requirements described in section 1927(g) of the Act and 42 CFR part 456, subpart K, as if such requirement applied to the MCO, PIHP, or PAHP instead of the State.

(5) The MCO, PIHP or PAHP must provide a detailed description of its drug utilization review program activities to the State on an annual basis.

(6) The MCO, PIHP or PAHP must conduct a prior authorization program that complies with the requirements of section 1927(d)(5) of the Act, as if such requirements applied to the MCO, PIHP, or PAHP instead of the State.

(t) *Requirements for MCOs, PIHPs, or PAHPs responsible for coordinating benefits for dually eligible individuals.* In a State that enters into a Coordination of Benefits Agreement with Medicare for FFS, an MCO, PIHP, or PAHP contract that includes responsibility for coordination of benefits for individuals dually eligible for Medicaid and Medicare must require the MCO, PIHP, or PAHP to enter into a Coordination of Benefits Agreement with Medicare and participate in the automated claims crossover process.

(u) *Recordkeeping requirements.* MCOs, PIHPs, and PAHPs must retain, and require subcontractors to retain, as applicable, the following information: enrollee grievance and appeal records in § 438.416, base data in § 438.5(c), MLR reports in § 438.8(k), and the data, information, and documentation specified in §§ 438.604, 438.606, 438.608, and 438.610 for a period of no less than 10 years.

(v) *Applicability date.* Sections 438.3(h) and (q) apply to the rating period for contracts with MCOs, PIHPs, PAHPs, PCCMs, and PCCM entities beginning on or after July 1, 2017. Until that applicability date, states are required to continue to comply with § 438.6(g) and (k) contained in the 42 CFR, parts 430 to 481, edition revised as of October 1, 2015.

§ 438.4 Actuarial soundness.

(a) *Actuarially sound capitation rates defined.* Actuarially sound capitation rates are projected to provide for all reasonable, appropriate, and attainable costs that are required under the terms of the contract and for the operation of the MCO, PIHP, or PAHP for the time period and the population covered under the terms of the contract, and such capitation rates are developed in accordance with the requirements in paragraph (b) of this section.

(b) *CMS review and approval of actuarially sound capitation rates.* Capitation rates for MCOs, PIHPs, and PAHPs must be reviewed and approved by CMS as actuarially sound. To be approved by CMS, capitation rates must:

(1) Have been developed in accordance with standards specified in § 438.5 and generally accepted actuarial principles and practices. Any proposed differences among capitation rates according to covered populations must be based on valid rate development standards and not based on the rate of Federal financial participation associated with the covered populations.

(2) Be appropriate for the populations to be covered and the services to be furnished under the contract.

(3) Be adequate to meet the requirements on MCOs, PIHPs, and PAHPs in §§ 438.206, 438.207, and 438.208.

(4) Be specific to payments for each rate cell under the contract.

(5) Payments from any rate cell must not cross-subsidize or be cross-subsidized by payments for any other rate cell.

(6) Be certified by an actuary as meeting the applicable requirements of this part, including that the rates have been developed in accordance with the requirements specified in § 438.3(c)(1)(ii) and (e).

(7) Meet any applicable special contract provisions as specified in § 438.6.

(8) Be provided to CMS in a format and within a timeframe that meets requirements in § 438.7.

(9) Be developed in such a way that the MCO, PIHP, or PAHP would reasonably achieve a medical loss ratio standard, as calculated under § 438.8, of at least 85 percent for the rate year. The capitation rates may be developed in such a way that the MCO, PIHP, or PAHP would reasonably achieve a medical loss ratio standard greater than 85 percent, as calculated under § 438.8, as long as the capitation rates are adequate for reasonable, appropriate, and attainable non-benefit costs.

§ 438.5 Rate development standards.

(a) *Definitions.* As used in this section and § 438.7(b), the following terms have the indicated meanings:

Budget neutral means a standard for any risk sharing mechanism that recognizes both higher and lower expected costs among contracted MCOs, PIHPs, or PAHPs under a managed care program and does not create a net aggregate gain or loss across all payments under that managed care program.

Prospective risk adjustment means a methodology to account for anticipated variation in risk levels among contracted MCOs, PIHPs, or PAHPs that is derived from historical experience of the contracted MCOs, PIHPs, or PAHPs and applied to rates for the rating period for which the certification is submitted.

Retrospective risk adjustment means a methodology to account for variation in risk levels among contracted MCOs, PIHPs, or PAHPs that is derived from experience concurrent with the rating period of the contracted MCOs, PIHPs, or PAHPs subject to the adjustment and calculated at the expiration of the rating period.

Risk adjustment is a methodology to account for the health status of enrollees via relative risk factors when predicting

or explaining costs of services covered under the contract for defined populations or for evaluating retrospectively the experience of MCOs, PIHPs, or PAHPs contracted with the State.

(b) *Process and requirements for setting actuarially sound capitation rates.* In setting actuarially sound capitation rates, the State must follow the steps below, in an appropriate order, in accordance with this section, or explain why they are not applicable:

(1) Consistent with paragraph (c) of this section, identify and develop the base utilization and price data.

(2) Consistent with paragraph (d) of this section, develop and apply trend factors, including cost and utilization, to base data that are developed from actual experience of the Medicaid population or a similar population in accordance with generally accepted actuarial practices and principles.

(3) Consistent with paragraph (e) of this section, develop the non-benefit component of the rate to account for reasonable expenses related to MCO, PIHP, or PAHP administration; taxes; licensing and regulatory fees; contribution to reserves; risk margin; cost of capital; and other operational costs associated with the MCO's, PIHP's, or PAHP's provision of State plan services to Medicaid enrollees.

(4) Consistent with paragraph (f) of this section, make appropriate and reasonable adjustments to account for changes to the base data, programmatic changes, non-benefit components, and any other adjustment necessary to establish actuarially sound rates.

(5) Take into account the MCO's, PIHP's, or PAHP's past medical loss ratio, as calculated and reported under § 438.8, in the development of the capitation rates, and consider the projected medical loss ratio in accordance with § 438.4(b)(9).

(6) Consistent with paragraph (g) of this section, if risk adjustment is applied, select a risk adjustment methodology that uses generally accepted models and apply it in a budget neutral manner across all MCOs, PIHPs, or PAHPs in the program to calculate adjustments to the payments as necessary.

(c) *Base data.* (1) States must provide all the validated encounter data, FFS data (as appropriate), and audited financial reports (as defined in § 438.3(m)) that demonstrate experience for the populations to be served by the MCO, PIHP, or PAHP to the actuary developing the capitation rates for at least the three most recent and complete years prior to the rating period.

(2) States and their actuaries must use the most appropriate data, with the basis of the data being no older than from the 3 most recent and complete years prior to the rating period, for setting capitation rates. Such base data must be derived from the Medicaid population, or, if data on the Medicaid population is not available, derived from a similar population and adjusted to make the utilization and price data comparable to data from the Medicaid population. Data must be in accordance with actuarial standards for data quality and an explanation of why that specific data is used must be provided in the rate certification.

(3) *Exception.* (i) States that are unable to base their rates on data meeting the qualifications in paragraph (c)(2) of this section that the basis of the data be no older than from the 3 most recent and complete years prior to the rating period may request approval for an exception; the request must describe why an exception is necessary and describe the actions the state intends to take to come into compliance with those requirements.

(ii) States that request an exception from the base data standards established in this section must set forth a corrective action plan to come into compliance with the base data standards no later than 2 years from the rating period for which the deficiency was identified.

(d) *Trend.* Each trend must be reasonable and developed in accordance with generally accepted actuarial principles and practices. Trend must be developed primarily from actual experience of the Medicaid population or from a similar population.

(e) *Non-benefit component of the rate.* The development of the non-benefit component of the rate must include reasonable, appropriate, and attainable expenses related to MCO, PIHP, or PAHP administration, taxes, licensing and regulatory fees, contribution to reserves, risk margin, cost of capital, and other operational costs associated with the provision of services identified in § 438.3(c)(1)(ii) to the populations covered under the contract.

(f) *Adjustments.* Each adjustment must reasonably support the development of an accurate base data set for purposes of rate setting, address appropriate programmatic changes, reflect the health status of the enrolled population, or reflect non-benefit costs, and be developed in accordance with generally accepted actuarial principles and practices.

(g) *Risk adjustment.* Prospective or retrospective risk adjustment methodologies must be developed in a

budget neutral manner consistent with generally accepted actuarial principles and practices.

§ 438.6 Special contract provisions related to payment.

(a) *Definitions.* As used in this part, the following terms have the indicated meanings:

Base amount is the starting amount, calculated according to paragraph (d)(2) of this section, available for pass-through payments to hospitals in a given contract year subject to the schedule in paragraph (d)(3) of this section.

Incentive arrangement means any payment mechanism under which a MCO, PIHP, or PAHP may receive additional funds over and above the capitation rates it was paid for meeting targets specified in the contract.

Pass-through payment is any amount required by the State to be added to the contracted payment rates, and considered in calculating the actuarially sound capitation rate, between the MCO, PIHP, or PAHP and hospitals, physicians, or nursing facilities that is not for the following purposes: A specific service or benefit provided to a specific enrollee covered under the contract; a provider payment methodology permitted under paragraphs (c)(1)(i) through (iii) of this section for services and enrollees covered under the contract; a subcapitated payment arrangement for a specific set of services and enrollees covered under the contract; GME payments; or FQHC or RHC wrap around payments.

Risk corridor means a risk sharing mechanism in which States and MCOs, PIHPs, or PAHPs may share in profits and losses under the contract outside of a predetermined threshold amount.

Withhold arrangement means any payment mechanism under which a portion of a capitation rate is withheld from an MCO, PIHP, or PAHP and a portion of or all of the withheld amount will be paid to the MCO, PIHP, or PAHP for meeting targets specified in the contract. The targets for a withhold arrangement are distinct from general operational requirements under the contract. Arrangements that withhold a portion of a capitation rate for noncompliance with general operational requirements are a penalty and not a withhold arrangement.

(b) *Basic requirements.* (1) If used in the payment arrangement between the State and the MCO, PIHP, or PAHP, all applicable risk-sharing mechanisms, such as reinsurance, risk corridors, or stop-loss limits, must be described in the contract, and must be developed in

accordance with § 438.4, the rate development standards in § 438.5, and generally accepted actuarial principles and practices.

(2) Contracts with incentive arrangements may not provide for payment in excess of 105 percent of the approved capitation payments attributable to the enrollees or services covered by the incentive arrangement, since such total payments will not be considered to be actuarially sound. For all incentive arrangements, the contract must provide that the arrangement is—

(i) For a fixed period of time and performance is measured during the rating period under the contract in which the incentive arrangement is applied.

(ii) Not to be renewed automatically.

(iii) Made available to both public and private contractors under the same terms of performance.

(iv) Does not condition MCO, PIHP, or PAHP participation in the incentive arrangement on the MCO, PIHP, or PAHP entering into or adhering to intergovernmental transfer agreements.

(v) Necessary for the specified activities, targets, performance measures, or quality-based outcomes that support program initiatives as specified in the State's quality strategy at § 438.340.

(3) Contracts that provide for a withhold arrangement must ensure that the capitation payment minus any portion of the withhold that is not reasonably achievable is actuarially sound as determined by an actuary. The total amount of the withhold, achievable or not, must be reasonable and take into consideration the MCO's, PIHP's or PAHP's financial operating needs accounting for the size and characteristics of the populations covered under the contract, as well as the MCO's, PIHP's or PAHP's capital reserves as measured by the risk-based capital level, months of claims reserve, or other appropriate measure of reserves. The data, assumptions, and methodologies used to determine the portion of the withhold that is reasonably achievable must be submitted as part of the documentation required under § 438.7(b)(6). For all withhold arrangements, the contract must provide that the arrangement is—

(i) For a fixed period of time and performance is measured during the rating period under the contract in which the withhold arrangement is applied.

(ii) Not to be renewed automatically.

(iii) Made available to both public and private contractors under the same terms of performance.

(iv) Does not condition MCO, PIHP, or PAHP participation in the withhold arrangement on the MCO, PIHP, or PAHP entering into or adhering to intergovernmental transfer agreements.

(v) Necessary for the specified activities, targets, performance measures, or quality-based outcomes that support program initiatives as specified in the State's quality strategy under § 438.340.

(c) *Delivery system and provider payment initiatives under MCO, PIHP, or PAHP contracts*—(1) *General rule.* Except as specified in this paragraph (c), in paragraph (d) of this section, in a specific provision of Title XIX, or in another regulation implementing a Title XIX provision related to payments to providers, that is applicable to managed care programs, the State may not direct the MCO's, PIHP's or PAHP's expenditures under the contract.

(i) The State may require the MCO, PIHP or PAHP to implement value-based purchasing models for provider reimbursement, such as pay for performance arrangements, bundled payments, or other service payment models intended to recognize value or outcomes over volume of services.

(ii) The State may require MCOs, PIHPs, or PAHPs to participate in a multi-payer or Medicaid-specific delivery system reform or performance improvement initiative.

(iii) The State may require the MCO, PIHP or PAHP to:

(A) Adopt a minimum fee schedule for network providers that provide a particular service under the contract; or

(B) Provide a uniform dollar or percentage increase for network providers that provide a particular service under the contract.

(C) Adopt a maximum fee schedule for network providers that provide a particular service under the contract, so long as the MCO, PIHP, or PAHP retains the ability to reasonably manage risk and has discretion in accomplishing the goals of the contract.

(2) *Process for approval.* (i) All contract arrangements that direct the MCO's, PIHP's or PAHP's expenditures under paragraphs (c)(1)(i) through (iii) of this section must be developed in accordance with § 438.4, the standards specified in § 438.5, generally accepted principles and practices, and have written approval prior to implementation. To obtain written approval, a state must demonstrate, in writing, that the arrangement—

(A) Is based on the utilization and delivery of services;

(B) Directs expenditures equally, and using the same terms of performance,

for a class of providers providing the service under the contract;

(C) Expects to advance at least one of the goals and objectives in the quality strategy in § 438.340;

(D) Has an evaluation plan that measures the degree to which the arrangement advances at least one of the goals and objectives in the quality strategy in § 438.340;

(E) Does not condition network provider participation in contract arrangements under paragraphs (c)(1)(i) through (iii) of this section on the network provider entering into or adhering to intergovernmental transfer agreements; and

(F) May not be renewed automatically.

(ii) Any contract arrangements that direct the MCO's, PIHP's or PAHP's expenditures under paragraphs (c)(1)(i) or (c)(1)(ii) of this section must also demonstrate, in writing, that the arrangement—

(A) Must make participation in the value-based purchasing initiative, delivery system reform or performance improvement initiative available, using the same terms of performance, to a class of providers providing services under the contract related to the reform or improvement initiative;

(B) Must use a common set of performance measures across all of the payers and providers;

(C) May not set the amount or frequency of the expenditures; and

(D) Does not allow the State to recoup any unspent funds allocated for these arrangements from the MCO, PIHP, or PAHP.

(d) *Pass-through payments under MCO, PIHP, and PAHP contracts.* (1) States may require MCOs, PIHPs, and PAHPs to make pass-through payments (as defined in paragraph (a) of this section) to network providers that are hospitals, physicians, and nursing facilities under the contract subject to the requirements of this paragraph (d). States may not require MCOs, PIHPs, and PAHPs to make pass-through payments other than those permitted under this paragraph.

(2) *Calculation of the base amount.* The base amount of pass-through payments is the sum of the results of paragraphs (d)(2)(i) and (ii) of this section.

(i) For inpatient and outpatient hospital services that will be provided to eligible populations through the MCO, PIHP, or PAHP contracts for the rating period that includes pass-through payments and that were provided to the eligible populations under MCO, PIHP, or PAHP contracts two years prior to the rating period, the State must determine

reasonable estimates of the aggregate difference between:

(A) The amount Medicare FFS would have paid for those inpatient and outpatient hospital services utilized by the eligible populations under the MCO, PIHP, or PAHP contracts for the 12-month period immediately two years prior to the rating period that will include pass-through payments; and

(B) The amount the MCOs, PIHPs, or PAHPs paid (not including pass through payments) for those inpatient and outpatient hospital services utilized by the eligible populations under MCO, PIHP, or PAHP contracts for the 12-month period immediately 2 years prior to the rating period that will include pass-through payments.

(ii) For inpatient and outpatient hospital services that will be provided to eligible populations through the MCO, PIHP, or PAHP contracts for the rating period that includes pass-through payments and that were provided to the eligible populations under Medicaid FFS for the 12-month period immediately 2 years prior to the rating period, the State must determine reasonable estimates of the aggregate difference between:

(A) The amount Medicare FFS would have paid for those inpatient and outpatient hospital services utilized by the eligible populations under Medicaid FFS for the 12-month period immediately 2 years prior to the rating period that will include pass-through payments; and

(B) The amount the State paid under Medicaid FFS (not including pass through payments) for those inpatient and outpatient hospital services utilized by the eligible populations for the 12-month period immediately 2 years prior to the rating period that will include pass-through payments.

(iii) The base amount must be calculated on an annual basis and is recalculated annually.

(iv) States may calculate reasonable estimates of the aggregate differences in paragraphs (d)(2)(i) and (ii) of this section in accordance with the upper payment limit requirements in 42 CFR part 447.

(3) *Schedule for the reduction of the base amount of pass-through payments for hospitals under the MCO, PIHP, or PAHP contract.* Pass-through payments for hospitals may be required under the contract but must be phased out no longer than on the 10-year schedule, beginning with contracts that start on or after July 1, 2017. Pass-through payments may not exceed a percentage of the base amount, beginning with 100 percent for contracts starting on or after July 1, 2017, and decreasing by 10

percentage points each successive year. For contracts beginning on or after July 1, 2027, the State cannot require pass-through payments for hospitals under a MCO, PIHP, or PAHP contract.

(4) *Documentation of the base amount for pass-through payments to hospitals.* All contract arrangements that direct pass-through payments under the MCO's, PIHP's or PAHP's contract for hospitals must document the calculation of the base amount in the rate certification required in § 438.7. The documentation must include the following:

(i) The data, methodologies, and assumptions used to calculate the base amount;

(ii) The aggregate amounts calculated for paragraphs (d)(2)(i)(A), (d)(2)(i)(B), (d)(2)(ii)(A), (d)(2)(ii)(B) of this section; and

(iii) The calculation of the applicable percentage of the base amount available for pass-through payments under the schedule in paragraph (d)(3) of this section.

(5) *Pass-through payments to physicians or nursing facilities.* For contracts starting on or after July 1, 2017 through contracts beginning on or after July 1, 2021, the State may require pass-through payments to physicians and nursing facilities under the MCO, PIHP, or PAHP contract. For contracts beginning on or after July 1, 2022, the State cannot require pass-through payments for physicians or nursing facilities under a MCO, PIHP, or PAHP contract.

(e) *Payments to MCOs and PIHPs for enrollees that are a patient in an institution for mental disease.* The State may make a monthly capitation payment to an MCO or PIHP for an enrollee aged 21–64 receiving inpatient treatment in an Institution for Mental Diseases, as defined in § 435.1010 of this chapter, so long as the facility is a hospital providing psychiatric or substance use disorder inpatient care or a sub-acute facility providing psychiatric or substance use disorder crisis residential services, and length of stay in the IMD is for a short term stay of no more than 15 days during the period of the monthly capitation payment. The provision of inpatient psychiatric or substance use disorder treatment in an IMD must meet the requirements for in lieu of services at § 438.3(e)(2)(i) through (iii). For purposes of rate setting, the state may use the utilization of services provided to an enrollee under this section when developing the inpatient psychiatric or substance use disorder component of the capitation rate, but must price utilization at the cost of the same

services through providers included under the State plan.

§ 438.7 Rate certification submission.

(a) *CMS review and approval of the rate certification.* States must submit to CMS for review and approval, all MCO, PIHP, and PAHP rate certifications concurrent with the review and approval process for contracts as specified in § 438.3(a).

(b) *Documentation.* The rate certification must contain the following information:

(1) *Base data.* A description of the base data used in the rate setting process (including the base data requested by the actuary, the base data that was provided by the State, and an explanation of why any base data requested was not provided by the State) and of how the actuary determined which base data set was appropriate to use for the rating period.

(2) *Trend.* Each trend factor, including trend factors for changes in the utilization and price of services, applied to develop the capitation rates must be adequately described with enough detail so CMS or an actuary applying generally accepted actuarial principles and practices can understand and evaluate the following:

(i) The calculation of each trend used for the rating period and the reasonableness of the trend for the enrolled population.

(ii) Any meaningful difference in how a trend differs between the rate cells, service categories, or eligibility categories.

(3) *Non-benefit component of the rate.* The development of the non-benefit component of the rate must be adequately described with enough detail so CMS or an actuary applying generally accepted actuarial principles and practices can identify each type of non-benefit expense that is included in the rate and evaluate the reasonableness of the cost assumptions underlying each expense. The actuary may document the non-benefit costs according to the types of non-benefit costs under § 438.5(e).

(4) *Adjustments.* All adjustments used to develop the capitation rates must be adequately described with enough detail so that CMS, or an actuary applying generally accepted actuarial principles and practices, can understand and evaluate all of the following:

(i) How each material adjustment was developed and the reasonableness of the material adjustment for the enrolled population.

(ii) The cost impact of each material adjustment and the aggregate cost impact of non-material adjustments.

(iii) Where in the rate setting process the adjustment was applied.

(iv) A list of all non-material adjustments used in the rate development process.

(5) *Risk adjustment.* (i) All prospective risk adjustment methodologies must be adequately described with enough detail so that CMS or an actuary applying generally accepted actuarial principles and practices can understand and evaluate the following:

(A) The data, and any adjustments to that data, to be used to calculate the adjustment.

(B) The model, and any adjustments to that model, to be used to calculate the adjustment.

(C) The method for calculating the relative risk factors and the reasonableness and appropriateness of the method in measuring the risk factors of the respective populations.

(D) The magnitude of the adjustment on the capitation rate per MCO, PIHP, or PAHP.

(E) An assessment of the predictive value of the methodology compared to prior rating periods.

(F) Any concerns the actuary has with the risk adjustment process.

(ii) All retrospective risk adjustment methodologies must be adequately described with enough detail so that CMS or an actuary applying generally accepted actuarial principles and practices can understand and evaluate the following:

(A) The party calculating the risk adjustment.

(B) The data, and any adjustments to that data, to be used to calculate the adjustment.

(C) The model, and any adjustments to that model, to be used to calculate the adjustment.

(D) The timing and frequency of the application of the risk adjustment.

(E) Any concerns the actuary has with the risk adjustment process.

(iii) Application of an approved risk adjustment methodology to capitation rates does not require a revised rate certification because payment of capitation rates as modified by the approved risk adjustment methodology must be within the scope of the original rate certification. The State must provide to CMS the payment terms updated by the application of the risk adjustment methodology consistent with § 438.3(c).

(6) *Special contract provisions.* A description of any of the special contract provisions related to payment in § 438.6 that are applied in the contract.

(c) *Rates paid under risk contracts.* The State, through its actuary, must

certify the final capitation rate paid per rate cell under each risk contract and document the underlying data, assumptions and methodologies supporting that specific capitation rate.

(1) The State may pay each MCO, PIHP or PAHP a capitation rate under the contract that is different than the capitation rate paid to another MCO, PIHP or PAHP, so long as each capitation rate per rate cell that is paid is independently developed and set in accordance with this part.

(2) If the State determines that a retroactive adjustment to the capitation rate is necessary, the retroactive adjustment must be supported by a rationale for the adjustment and the data, assumptions and methodologies used to develop the magnitude of the adjustment must be adequately described with enough detail to allow CMS or an actuary to determine the reasonableness of the adjustment. These retroactive adjustments must be certified by an actuary in a revised rate certification and submitted as a contract amendment to be approved by CMS. All such adjustments are also subject to Federal timely claim filing requirements.

(3) The State may increase or decrease the capitation rate per rate cell, as required in paragraph (c) of this section and § 438.4(b)(4), up to 1.5 percent without submitting a revised rate certification, as required under paragraph (a) of this section. Such changes of the capitation rate within the permissible 1.5 percent range must be consistent with a modification of the contract as required in § 438.3(c).

(d) *Provision of additional information.* The State must, upon CMS' request, provide additional information, whether part of the rate certification or additional supplemental materials, if CMS determines that information is pertinent to the approval of the certification under this part. The State must identify whether the information provided in addition to the rate certification is proffered by the State, the actuary, or another party.

§ 438.8 Medical loss ratio (MLR) standards.

(a) *Basic rule.* The State must ensure, through its contracts starting on or after July 1, 2017, that each MCO, PIHP, and PAHP calculate and report a MLR in accordance with this section. For multi-year contracts that do not start in 2017, the State must require the MCO, PIHP, or PAHP to calculate and report a MLR for the rating period that begins in 2017.

(b) *Definitions.* As used in this section, the following terms have the indicated meanings:

Credibility adjustment means an adjustment to the MLR for a partially credible MCO, PIHP, or PAHP to account for a difference between the actual and target MLRs that may be due to random statistical variation.

Full credibility means a standard for which the experience of an MCO, PIHP, or PAHP is determined to be sufficient for the calculation of a MLR with a minimal chance that the difference between the actual and target medical loss ratio is not statistically significant. An MCO, PIHP, or PAHP that is assigned full credibility (or is fully credible) will not receive a credibility adjustment to its MLR.

Member months mean the number of months an enrollee or a group of enrollees is covered by an MCO, PIHP, or PAHP over a specified time period, such as a year.

MLR reporting year means a period of 12 months consistent with the rating period selected by the State.

No credibility means a standard for which the experience of an MCO, PIHP, or PAHP is determined to be insufficient for the calculation of a MLR. An MCO, PIHP, or PAHP that is assigned no credibility (or is non-credible) will not be measured against any MLR requirements.

Non-claims costs means those expenses for administrative services that are not: Incurred claims (as defined in paragraph (e)(2) of this section); expenditures on activities that improve health care quality (as defined in paragraph (e)(3) of this section); or licensing and regulatory fees, or Federal and State taxes (as defined in paragraph (f)(2) of this section).

Partial credibility means a standard for which the experience of an MCO, PIHP, or PAHP is determined to be sufficient for the calculation of a MLR but with a non-negligible chance that the difference between the actual and target medical loss ratios is statistically significant. An MCO, PIHP, or PAHP that is assigned partial credibility (or is partially credible) will receive a credibility adjustment to its MLR.

(c) *MLR requirement.* If a State elects to mandate a minimum MLR for its MCOs, PIHPs, or PAHPs, that minimum MLR must be equal to or higher than 85 percent (the standard used for projecting actuarial soundness under § 438.4(b)) and the MLR must be calculated and reported for each MLR reporting year by the MCO, PIHP, or PAHP, consistent with this section.

(d) *Calculation of the MLR.* The MLR experienced for each MCO, PIHP, or PAHP in a MLR reporting year is the ratio of the numerator (as defined in paragraph (e) of this section) to the

denominator (as defined in paragraph (f) of this section). A MLR may be increased by a credibility adjustment, in accordance with paragraph (h) of this section.

(e) *Numerator—(1) Required elements.* The numerator of an MCO's, PIHP's, or PAHP's MLR for a MLR reporting year is the sum of the MCO's, PIHP's, or PAHP's incurred claims (as defined in (e)(2) of this section); the MCO's, PIHP's, or PAHP's expenditures for activities that improve health care quality (as defined in paragraph (e)(3) of this section); and fraud reduction activities (as defined in paragraph (e)(4) of this section).

(2) *Incurred claims.* (i) Incurred claims must include the following:

(A) Direct claims that the MCO, PIHP, or PAHP paid to providers (including under capitated contracts with network providers) for services or supplies covered under the contract and services meeting the requirements of § 438.3(e) provided to enrollees.

(B) Unpaid claims liabilities for the MLR reporting year, including claims reported that are in the process of being adjusted or claims incurred but not reported.

(C) Withholds from payments made to network providers.

(D) Claims that are recoverable for anticipated coordination of benefits.

(E) Claims payments recoveries received as a result of subrogation.

(F) Incurred but not reported claims based on past experience, and modified to reflect current conditions, such as changes in exposure or claim frequency or severity.

(G) Changes in other claims-related reserves.

(H) Reserves for contingent benefits and the medical claim portion of lawsuits.

(ii) Amounts that must be deducted from incurred claims include the following:

(A) Overpayment recoveries received from network providers.

(B) Prescription drug rebates received and accrued.

(iii) Expenditures that must be included in incurred claims include the following:

(A) The amount of incentive and bonus payments made, or expected to be made, to network providers.

(B) The amount of claims payments recovered through fraud reduction efforts, not to exceed the amount of fraud reduction expenses. The amount of fraud reduction expenses must not include activities specified in paragraph (e)(4) of this section.

(iv) Amounts that must either be included in or deducted from incurred

claims include, respectively, net payments or receipts related to State mandated solvency funds.

(v) Amounts that must be excluded from incurred claims:

(A) Non-claims costs, as defined in paragraph (b) of this section, which include the following:

(1) Amounts paid to third party vendors for secondary network savings.

(2) Amounts paid to third party vendors for network development, administrative fees, claims processing, and utilization management.

(3) Amounts paid, including amounts paid to a provider, for professional or administrative services that do not represent compensation or reimbursement for State plan services or services meeting the definition in § 438.3(e) and provided to an enrollee.

(4) Fines and penalties assessed by regulatory authorities.

(B) Amounts paid to the State as remittance under paragraph (j) of this section.

(C) Amounts paid to network providers under to § 438.6(d).

(vi) Incurred claims paid by one MCO, PIHP, or PAHP that is later assumed by another entity must be reported by the assuming MCO, PIHP, or PAHP for the entire MLR reporting year and no incurred claims for that MLR reporting year may be reported by the ceding MCO, PIHP, or PAHP.

(3) *Activities that improve health care quality.* Activities that improve health care quality must be in one of the following categories:

(i) An MCO, PIHP, or PAHP activity that meets the requirements of 45 CFR 158.150(b) and is not excluded under 45 CFR 158.150(c).

(ii) An MCO, PIHP, or PAHP activity related to any EQR-related activity as described in § 438.358(b) and (c).

(iii) Any MCO, PIHP, or PAHP expenditure that is related to Health Information Technology and meaningful use, meets the requirements placed on issuers found in 45 CFR 158.151, and is not considered incurred claims, as defined in paragraph (e)(2) of this section.

(4) *Fraud prevention activities.* MCO, PIHP, or PAHP expenditures on activities related to fraud prevention as adopted for the private market at 45 CFR part 158. Expenditures under this paragraph must not include expenses for fraud reduction efforts in paragraph (e)(2)(iii)(B) of this section.

(f) *Denominator—(1) Required elements.* The denominator of an MCO's, PIHP's, or PAHP's MLR for a MLR reporting year must equal the adjusted premium revenue. The adjusted premium revenue is the

MCO's, PIHP's, or PAHP's premium revenue (as defined in paragraph (f)(2) of this section) minus the MCO's, PIHP's, or PAHP's Federal, State, and local taxes and licensing and regulatory fees (as defined in paragraph (f)(3) of this section) and is aggregated in accordance with paragraph (i) of this section.

(2) *Premium revenue.* Premium revenue includes the following for the MLR reporting year:

(i) State capitation payments, developed in accordance with § 438.4, to the MCO, PIHP, or PAHP for all enrollees under a risk contract approved under § 438.3(a), excluding payments made under to § 438.6(d).

(ii) State-developed one time payments, for specific life events of enrollees.

(iii) Other payments to the MCO, PIHP, or PAHP approved under § 438.6(b)(3).

(iv) Unpaid cost-sharing amounts that the MCO, PIHP, or PAHP could have collected from enrollees under the contract, except those amounts the MCO, PIHP, or PAHP can show it made a reasonable, but unsuccessful, effort to collect.

(v) All changes to unearned premium reserves.

(vi) Net payments or receipts related to risk sharing mechanisms developed in accordance with § 438.5 or § 438.6.

(3) *Federal, State, and local taxes and licensing and regulatory fees.* Taxes, licensing and regulatory fees for the MLR reporting year include:

(i) Statutory assessments to defray the operating expenses of any State or Federal department.

(ii) Examination fees in lieu of premium taxes as specified by State law.

(iii) Federal taxes and assessments allocated to MCOs, PIHPs, and PAHPs, excluding Federal income taxes on investment income and capital gains and Federal employment taxes.

(iv) State and local taxes and assessments including:

(A) Any industry-wide (or subset) assessments (other than surcharges on specific claims) paid to the State or locality directly.

(B) Guaranty fund assessments.

(C) Assessments of State or locality industrial boards or other boards for operating expenses or for benefits to sick employed persons in connection with disability benefit laws or similar taxes levied by States.

(D) State or locality income, excise, and business taxes other than premium taxes and State employment and similar taxes and assessments.

(E) State or locality premium taxes plus State or locality taxes based on reserves, if in lieu of premium taxes.

(v) Payments made by an MCO, PIHP, or PAHP that are otherwise exempt from Federal income taxes, for community benefit expenditures as defined in 45 CFR 158.162(c), limited to the highest of either:

(A) Three percent of earned premium; or

(B) The highest premium tax rate in the State for which the report is being submitted, multiplied by the MCO's, PIHP's, or PAHP's earned premium in the State.

(4) *Denominator when MCO, PIHP, or PAHP is assumed.* The total amount of the denominator for a MCO, PIHP, or PAHP which is later assumed by another entity must be reported by the assuming MCO, PIHP, or PAHP for the entire MLR reporting year and no amount under this paragraph for that year may be reported by the ceding MCO, PIHP, or PAHP.

(g) *Allocation of expense—(1) General requirements.* (i) Each expense must be included under only one type of expense, unless a portion of the expense fits under the definition of, or criteria for, one type of expense and the remainder fits into a different type of expense, in which case the expense must be pro-rated between types of expenses.

(ii) Expenditures that benefit multiple contracts or populations, or contracts other than those being reported, must be reported on a pro rata basis.

(2) *Methods used to allocate expenses.*

(i) Allocation to each category must be based on a generally accepted accounting method that is expected to yield the most accurate results.

(ii) Shared expenses, including expenses under the terms of a management contract, must be apportioned pro rata to the contract incurring the expense.

(iii) Expenses that relate solely to the operation of a reporting entity, such as personnel costs associated with the adjusting and paying of claims, must be borne solely by the reporting entity and are not to be apportioned to the other entities.

(h) *Credibility adjustment.* (1) A MCO, PIHP, or PAHP may add a credibility adjustment to a calculated MLR if the MLR reporting year experience is partially credible. The credibility adjustment is added to the reported MLR calculation before calculating any remittances, if required by the State as described in paragraph (j) of this section.

(2) A MCO, PIHP, or PAHP may not add a credibility adjustment to a calculated MLR if the MLR reporting year experience is fully credible.

(3) If a MCO's, PIHP's, or PAHP's experience is non-credible, it is presumed to meet or exceed the MLR calculation standards in this section.

(4) On an annual basis, CMS will publish base credibility factors for MCOs, PIHPs, and PAHPs that are developed according to the following methodology:

(i) CMS will use the most recently available and complete managed care encounter data or FFS claims data, and enrollment data, reported by the states to CMS. This data may cover more than 1 year of experience.

(ii) CMS will calculate the credibility adjustment so that a MCO, PIHP, or PAHP receiving a capitation payment that is estimated to have a medical loss ratio of 85 percent would be expected to experience a loss ratio less than 85 percent 1 out of every 4 years, or 25 percent of the time.

(iii) The minimum number of member months necessary for a MCO's, PIHP's, or PAHP's medical loss ratio to be determined at least partially credible will be set so that the credibility adjustment would not exceed 10 percent for any partially credible MCO, PIHP, or PAHP. Any MCO, PIHP, or PAHP with enrollment less than this number of member months will be determined non-credible.

(iv) The minimum number of member months necessary for an MCO's, PIHP's, or PAHP's medical loss ratio to be determined fully credible will be set so that the minimum credibility adjustment for any partially credible MCO, PIHP, or PAHP would be greater than 1 percent. Any MCO, PIHP, or PAHP with enrollment greater than this number of member months will be determined to be fully credible.

(v) A MCO, PIHP, or PAHP with a number of enrollee member months between the levels established for non-credible and fully credible plans will be deemed partially credible, and CMS will develop adjustments, using linear interpolation, based on the number of enrollee member months.

(vi) CMS may adjust the number of enrollee member months necessary for a MCO's, PIHP's, or PAHP's experience to be non-credible, partially credible, or fully credible so that the standards are rounded for the purposes of administrative simplification. The number of member months will be rounded to 1,000 or a different degree of rounding as appropriate to ensure that the credibility thresholds are consistent with the objectives of this regulation.

(i) *Aggregation of data.* MCOs, PIHPs, or PAHPs will aggregate data for all Medicaid eligibility groups covered under the contract with the State unless

the State requires separate reporting and a separate MLR calculation for specific populations.

(j) *Remittance to the State if specific MLR is not met.* If required by the State, a MCO, PIHP, or PAHP must provide a remittance for an MLR reporting year if the MLR for that MLR reporting year does not meet the minimum MLR standard of 85 percent or higher if set by the State as described in paragraph (c) of this section.

(k) *Reporting requirements.* (1) The State, through its contracts, must require each MCO, PIHP, or PAHP to submit a report to the State that includes at least the following information for each MLR reporting year:

- (i) Total incurred claims.
- (ii) Expenditures on quality improving activities.
- (iii) Expenditures related to activities compliant with § 438.608(a)(1) through (5), (7), (8) and (b).
- (iv) Non-claims costs.
- (v) Premium revenue.
- (vi) Taxes, licensing and regulatory fees.
- (vii) Methodology(ies) for allocation of expenditures.
- (viii) Any credibility adjustment applied.
- (ix) The calculated MLR.
- (x) Any remittance owed to the State, if applicable.

(xi) A comparison of the information reported in this paragraph with the audited financial report required under § 438.3(m).

(xii) A description of the aggregation method used under paragraph (i) of this section.

(xiii) The number of member months.

(2) A MCO, PIHP, or PAHP must submit the report required in paragraph (k)(1) of this section in a timeframe and manner determined by the State, which must be within 12 months of the end of the MLR reporting year.

(3) MCOs, PIHPs, or PAHPs must require any third party vendor providing claims adjudication activities to provide all underlying data associated with MLR reporting to that MCO, PIHP, or PAHP within 180 days of the end of the MLR reporting year or within 30 days of being requested by the MCO, PIHP, or PAHP, whichever comes sooner, regardless of current contractual limitations, to calculate and validate the accuracy of MLR reporting.

(l) *Newer experience.* A State, in its discretion, may exclude a MCO, PIHP, or PAHP that is newly contracted with the State from the requirements in this section for the first year of the MCO's, PIHP's, or PAHP's operation. Such MCOs, PIHPs, or PAHPs must be required to comply with the

requirements in this section during the next MLR reporting year in which the MCO, PIHP, or PAHP is in business with the State, even if the first year was not a full 12 months.

(m) *Recalculation of MLR.* In any instance where a State makes a retroactive change to the capitation payments for a MLR reporting year where the report has already been submitted to the State, the MCO, PIHP, or PAHP must re-calculate the MLR for all MLR reporting years affected by the change and submit a new report meeting the requirements in paragraph (k) of this section.

(n) *Attestation.* MCOs, PIHPs, and PAHPs must attest to the accuracy of the calculation of the MLR in accordance with requirements of this section when submitting the report required under paragraph (k) of this section.

§ 438.9 Provisions that apply to non-emergency medical transportation PAHPs.

(a) For purposes of this section, Non-Emergency Medical Transportation (NEMT) PAHP means an entity that provides only NEMT services to enrollees under contract with the State, and on the basis of prepaid capitation payments, or other payment arrangements that do not use State plan payment rates.

(b) Unless listed in this paragraph (b), a requirement of this part does not apply to NEMT PAHPs, NEMT PAHP contracts, or States in connection with a NEMT PAHP. The following requirements and options apply to NEMT PAHPs, NEMT PAHP contracts, and States in connection with NEMT PAHPs, to the same extent that they apply to PAHPs, PAHP contracts, and States in connection with PAHPs.

(1) All contract provisions in § 438.3 except requirements for:

- (i) Physician incentive plans at § 438.3(i).
- (ii) Advance directives at § 438.3(j).
- (iii) LTSS requirements at § 438.3(o).
- (iv) MHPAEA at § 438.3(n).

(2) The actuarial soundness requirements in § 438.4.

(3) The information requirements in § 438.10.

(4) The provision against provider discrimination in § 438.12.

(5) The State responsibility provisions in §§ 438.56, 438.58, 438.60, 438.62(a), and 438.818.

(6) The provisions on enrollee rights and protections in subpart C of this part except for §§ 438.110 and 438.114.

(7) The PAHP standards in §§ 438.206(b)(1), 438.210, 438.214, 438.224, 438.230, and 438.242.

(8) An enrollee's right to a State fair hearing under subpart E of part 431 of this chapter.

(9) Prohibitions against affiliations with individuals debarred or excluded by Federal agencies in § 438.610.

(10) Requirements relating to contracts involving Indians, Indian Health Care Providers, and Indian managed care entities in § 438.14.

§ 438.10 Information requirements.

(a) *Definitions.* As used in this section, the following terms have the indicated meanings:

Limited English proficient (LEP) means potential enrollees and enrollees who do not speak English as their primary language and who have a limited ability to read, write, speak, or understand English may be LEP and may be eligible to receive language assistance for a particular type of service, benefit, or encounter.

Prevalent means a non-English language determined to be spoken by a significant number or percentage of potential enrollees and enrollees that are limited English proficient.

Readily accessible means electronic information and services which comply with modern accessibility standards such as section 508 guidelines, section 504 of the Rehabilitation Act, and W3C's Web Content Accessibility Guidelines (WCAG) 2.0 AA and successor versions.

(b) *Applicability.* The provisions of this section apply to all managed care programs which operate under any authority in the Act.

(c) *Basic rules.* (1) Each State, enrollment broker, MCO, PIHP, PAHP, PCCM, and PCCM entity must provide all required information in this section to enrollees and potential enrollees in a manner and format that may be easily understood and is readily accessible by such enrollees and potential enrollees.

(2) The State must utilize its beneficiary support system required in § 438.71.

(3) The State must operate a Web site that provides the content, either directly or by linking to individual MCO, PIHP, PAHP, or PCCM entity Web sites, specified in paragraphs (g), (h), and (i) of this section.

(4) For consistency in the information provided to enrollees, the State must develop and require each MCO, PIHP, PAHP and PCCM entity to use:

(i) Definitions for managed care terminology, including appeal, co-payment, durable medical equipment, emergency medical condition, emergency medical transportation, emergency room care, emergency services, excluded services, grievance, habilitation services and devices, health insurance, home health care, hospice services, hospitalization, hospital

outpatient care, medically necessary, network, non-participating provider, physician services, plan, preauthorization, participating provider, premium, prescription drug coverage, prescription drugs, primary care physician, primary care provider, provider, rehabilitation services and devices, skilled nursing care, specialist, and urgent care; and

(ii) Model enrollee handbooks and enrollee notices.

(5) The State must ensure, through its contracts, that each MCO, PIHP, PAHP and PCCM entity provides the required information in this section to each enrollee.

(6) Enrollee information required in this section may not be provided electronically by the State, MCO, PIHP, PAHP, PCCM, or PCCM entity unless all of the following are met:

(i) The format is readily accessible;

(ii) The information is placed in a location on the State, MCO's, PIHP's, PAHP's, or PCCM's, or PCCM entity's Web site that is prominent and readily accessible;

(iii) The information is provided in an electronic form which can be electronically retained and printed;

(iv) The information is consistent with the content and language requirements of this section; and

(v) The enrollee is informed that the information is available in paper form without charge upon request and provides it upon request within 5 business days.

(7) Each MCO, PIHP, PAHP, and PCCM entity must have in place mechanisms to help enrollees and potential enrollees understand the requirements and benefits of the plan.

(d) *Language and format.* The State must:

(1) Establish a methodology for identifying the prevalent non-English languages spoken by enrollees and potential enrollees throughout the State, and in each MCO, PIHP, PAHP, or PCCM entity service area.

(2) Make oral interpretation available in all languages and written translation available in each prevalent non-English language. All written materials for potential enrollees must include taglines in the prevalent non-English languages in the State, as well as large print, explaining the availability of written translations or oral interpretation to understand the information provided and the toll-free telephone number of the entity providing choice counseling services as required by § 438.71(a). Large print means printed in a font size no smaller than 18 point.

(3) Require each MCO, PIHP, PAHP, and PCCM entity to make its written materials that are critical to obtaining services, including, at a minimum, provider directories, enrollee handbooks, appeal and grievance notices, and denial and termination notices, available in the prevalent non-English languages in its particular service area. Written materials must also be made available in alternative formats upon request of the potential enrollee or enrollee at no cost. Auxiliary aids and services must also be made available upon request of the potential enrollee or enrollee at no cost. Written materials must include taglines in the prevalent non-English languages in the state, as well as large print, explaining the availability of written translation or oral interpretation to understand the information provided and the toll-free and TTY/TDY telephone number of the MCO's, PIHP's, PAHP's or PCCM entity's member/customer service unit. Large print means printed in a font size no smaller than 18 point.

(4) Make interpretation services available to each potential enrollee and require each MCO, PIHP, PAHP, and PCCM entity to make those services available free of charge to each enrollee. This includes oral interpretation and the use of auxiliary aids such as TTY/TDY and American Sign Language. Oral interpretation requirements apply to all non-English languages, not just those that the State identifies as prevalent.

(5) Notify potential enrollees, and require each MCO, PIHP, PAHP, and PCCM entity to notify its enrollees—

(i) That oral interpretation is available for any language and written translation is available in prevalent languages;

(ii) That auxiliary aids and services are available upon request and at no cost for enrollees with disabilities; and

(iii) How to access the services in paragraphs (d)(5)(i) and (ii) of this section.

(6) Provide, and require MCOs, PIHPs, PAHPs, PCCMs, and PCCM entities to provide, all written materials for potential enrollees and enrollees consistent with the following:

(i) Use easily understood language and format.

(ii) Use a font size no smaller than 12 point.

(iii) Be available in alternative formats and through the provision of auxiliary aids and services in an appropriate manner that takes into consideration the special needs of enrollees or potential enrollees with disabilities or limited English proficiency.

(iv) Include a large print tagline and information on how to request auxiliary aids and services, including the

provision of the materials in alternative formats. Large print means printed in a font size no smaller than 18 point.

(e) *Information for potential enrollees.*

(1) The State or its contracted representative must provide the information specified in paragraph (e)(2) of this section to each potential enrollee, either in paper or electronic form as follows:

(i) At the time the potential enrollee first becomes eligible to enroll in a voluntary managed care program, or is first required to enroll in a mandatory managed care program; and

(ii) Within a timeframe that enables the potential enrollee to use the information in choosing among available MCOs, PIHPs, PAHPs, PCCMs, or PCCM entities.

(2) The information for potential enrollees must include, at a minimum, all of the following:

(i) Information about the potential enrollee's right to disenroll consistent with the requirements of § 438.56 and which explains clearly the process for exercising this disenrollment right, as well as the alternatives available to the potential enrollee based on their specific circumstance;

(ii) The basic features of managed care;

(iii) Which populations are excluded from enrollment, subject to mandatory enrollment, or free to enroll voluntarily in the program. For mandatory and voluntary populations, the length of the enrollment period and all disenrollment opportunities available to the enrollee must also be specified;

(iv) The service area covered by each MCO, PIHP, PAHP, PCCM, or PCCM entity;

(v) Covered benefits including:

(A) Which benefits are provided by the MCO, PIHP, or PAHP; and

(B) Which, if any, benefits are provided directly by the State.

(C) For a counseling or referral service that the MCO, PIHP, or PAHP does not cover because of moral or religious objections, the State must provide information about where and how to obtain the service;

(vi) The provider directory and formulary information required in paragraphs (h) and (i) of this section;

(vii) Any cost-sharing that will be imposed by the MCO, PIHP, PAHP, PCCM, or PCCM entity consistent with those set forth in the State plan;

(viii) The requirements for each MCO, PIHP or PAHP to provide adequate access to covered services, including the network adequacy standards established in § 438.68;

(ix) The MCO, PIHP, PAHP, PCCM and PCCM entity's responsibilities for coordination of enrollee care; and

(x) To the extent available, quality and performance indicators for each MCO, PIHP, PAHP and PCCM entity, including enrollee satisfaction.

(f) *Information for all enrollees of MCOs, PIHPs, PAHPs, and PCCM entities: General requirements.* (1) The MCO, PIHP, PAHP and, when appropriate, the PCCM entity, must make a good faith effort to give written notice of termination of a contracted provider, within 15 calendar days after receipt or issuance of the termination notice, to each enrollee who received his or her primary care from, or was seen on a regular basis by, the terminated provider.

(2) The State must notify all enrollees of their right to disenroll consistent with the requirements of § 438.56 at least annually. Such notification must clearly explain the process for exercising this disenrollment right, as well as the alternatives available to the enrollee based on their specific circumstance. For States that choose to restrict disenrollment for periods of 90 days or more, States must send the notice no less than 60 calendar days before the start of each enrollment period.

(3) The MCO, PIHP, PAHP and, when appropriate, the PCCM entity must make available, upon request, any physician incentive plans in place as set forth in § 438.3(i).

(g) *Information for enrollees of MCOs, PIHPs, PAHPs and PCCM entities—Enrollee handbook.* (1) Each MCO, PIHP, PAHP and PCCM entity must provide each enrollee an enrollee handbook, within a reasonable time after receiving notice of the beneficiary's enrollment, which serves a similar function as the summary of benefits and coverage described in 45 CFR 147.200(a).

(2) The content of the enrollee handbook must include information that enables the enrollee to understand how to effectively use the managed care program. This information must include at a minimum:

(i) Benefits provided by the MCO, PIHP, PAHP or PCCM entity.

(ii) How and where to access any benefits provided by the State, including any cost sharing, and how transportation is provided.

(A) In the case of a counseling or referral service that the MCO, PIHP, PAHP, or PCCM entity does not cover because of moral or religious objections, the MCO, PIHP, PAHP, or PCCM entity must inform enrollees that the service is not covered by the MCO, PIHP, PAHP, or PCCM entity.

(B) The MCO, PIHP, PAHP, or PCCM entity must inform enrollees how they can obtain information from the State

about how to access the services described in paragraph (g)(2)(i)(A) of this section.

(iii) The amount, duration, and scope of benefits available under the contract in sufficient detail to ensure that enrollees understand the benefits to which they are entitled.

(iv) Procedures for obtaining benefits, including any requirements for service authorizations and/or referrals for specialty care and for other benefits not furnished by the enrollee's primary care provider.

(v) The extent to which, and how, after-hours and emergency coverage are provided, including:

(A) What constitutes an emergency medical condition and emergency services.

(B) The fact that prior authorization is not required for emergency services.

(C) The fact that, subject to the provisions of this section, the enrollee has a right to use any hospital or other setting for emergency care.

(vi) Any restrictions on the enrollee's freedom of choice among network providers.

(vii) The extent to which, and how, enrollees may obtain benefits, including family planning services and supplies from out-of-network providers. This includes an explanation that the MCO, PIHP, or PAHP cannot require an enrollee to obtain a referral before choosing a family planning provider.

(viii) Cost sharing, if any is imposed under the State plan.

(ix) Enrollee rights and responsibilities, including the elements specified in § 438.100.

(x) The process of selecting and changing the enrollee's primary care provider.

(xi) Grievance, appeal, and fair hearing procedures and timeframes, consistent with subpart F of this part, in a State-developed or State-approved description. Such information must include:

(A) The right to file grievances and appeals.

(B) The requirements and timeframes for filing a grievance or appeal.

(C) The availability of assistance in the filing process.

(D) The right to request a State fair hearing after the MCO, PIHP or PAHP has made a determination on an enrollee's appeal which is adverse to the enrollee.

(E) The fact that, when requested by the enrollee, benefits that the MCO, PIHP, or PAHP seeks to reduce or terminate will continue if the enrollee files an appeal or a request for State fair hearing within the timeframes specified for filing, and that the enrollee may,

consistent with state policy, be required to pay the cost of services furnished while the appeal or state fair hearing is pending if the final decision is adverse to the enrollee.

(xii) How to exercise an advance directive, as set forth in § 438.3(j). For PAHPs, information must be provided only to the extent that the PAHP includes any of the providers described in § 489.102(a) of this chapter.

(xiii) How to access auxiliary aids and services, including additional information in alternative formats or languages.

(xiv) The toll-free telephone number for member services, medical management, and any other unit providing services directly to enrollees.

(xv) Information on how to report suspected fraud or abuse;

(xvi) Any other content required by the State.

(3) Information required by this paragraph to be provided by a MCO, PIHP, PAHP or PCCM entity will be considered to be provided if the MCO, PIHP, PAHP or PCCM entity:

(i) Mails a printed copy of the information to the enrollee's mailing address;

(ii) Provides the information by email after obtaining the enrollee's agreement to receive the information by email;

(iii) Posts the information on the Web site of the MCO, PIHP, PAHP or PCCM entity and advises the enrollee in paper or electronic form that the information is available on the Internet and includes the applicable Internet address, provided that enrollees with disabilities who cannot access this information online are provided auxiliary aids and services upon request at no cost; or

(iv) Provides the information by any other method that can reasonably be expected to result in the enrollee receiving that information.

(4) The MCO, PIHP, PAHP, or PCCM entity must give each enrollee notice of any change that the State defines as significant in the information specified in this paragraph (g), at least 30 days before the intended effective date of the change.

(h) *Information for all enrollees of MCOs, PIHPs, PAHPs, and PCCM entities—Provider Directory.* (1) Each MCO, PIHP, PAHP, and when appropriate, the PCCM entity, must make available in paper form upon request and electronic form, the following information about its network providers:

(i) The provider's name as well as any group affiliation.

(ii) Street address(es).

(iii) Telephone number(s).

(iv) Web site URL, as appropriate.

(v) Specialty, as appropriate.

(vi) Whether the provider will accept new enrollees.

(vii) The provider's cultural and linguistic capabilities, including languages (including American Sign Language) offered by the provider or a skilled medical interpreter at the provider's office, and whether the provider has completed cultural competence training.

(viii) Whether the provider's office/facility has accommodations for people with physical disabilities, including offices, exam room(s) and equipment.

(2) The provider directory must include the information in paragraph (h)(1) of this section for each of the following provider types covered under the contract:

(i) Physicians, including specialists;

(ii) Hospitals;

(iii) Pharmacies;

(iv) Behavioral health providers; and

(v) LTSS providers, as appropriate.

(3) Information included in a paper provider directory must be updated at least monthly and electronic provider directories must be updated no later than 30 calendar days after the MCO, PIHP, PAHP or PCCM entity receives updated provider information.

(4) Provider directories must be made available on the MCO's, PIHP's, PAHP's, or, if applicable, PCCM entity's Web site in a machine readable file and format as specified by the Secretary.

(i) *Information for all enrollees of MCOs, PIHPs, PAHPs, and PCCM entities: Formulary.* Each MCO, PIHP, PAHP, and when appropriate, PCCM entity, must make available in electronic or paper form, the following information about its formulary:

(1) Which medications are covered (both generic and name brand).

(2) What tier each medication is on.

(3) Formulary drug lists must be made available on the MCO's, PIHP's, PAHP's, or, if applicable, PCCM entity's Web site in a machine readable file and format as specified by the Secretary.

(j) *Applicability date.* This section applies to the rating period for contracts with MCOs, PIHPs, PAHPs, PCCMs, and PCCM entities beginning on or after July 1, 2017. Until that applicability date, states are required to continue to comply with § 438.10 contained in the 42 CFR parts 430 to 481, edition revised as of October 1, 2015.

§ 438.12 Provider discrimination prohibited.

(a) *General rules.* (1) An MCO, PIHP, or PAHP may not discriminate in the participation, reimbursement, or indemnification of any provider who is acting within the scope of his or her

license or certification under applicable State law, solely on the basis of that license or certification. If an MCO, PIHP, or PAHP declines to include individual or groups of providers in its provider network, it must give the affected providers written notice of the reason for its decision.

(2) In all contracts with network providers, an MCO, PIHP, or PAHP must comply with the requirements specified in § 438.214.

(b) *Construction.* Paragraph (a) of this section may not be construed to—

(1) Require the MCO, PIHP, or PAHP to contract with providers beyond the number necessary to meet the needs of its enrollees;

(2) Preclude the MCO, PIHP, or PAHP from using different reimbursement amounts for different specialties or for different practitioners in the same specialty; or

(3) Preclude the MCO, PIHP, or PAHP from establishing measures that are designed to maintain quality of services and control costs and are consistent with its responsibilities to enrollees.

§ 438.14 Requirements that apply to MCO, PIHP, PAHP, PCCM, and PCCM entity contracts involving Indians, Indian health care providers (IHCPs), and Indian managed care entities (IMCEs).

(a) *Definitions.* As used in this section, the following terms have the indicated meanings:

Indian means any individual defined at 25 U.S.C. 1603(13), 1603(28), or 1679(a), or who has been determined eligible as an Indian, under 42 CFR 136.12. This means the individual:

(i) Is a member of a Federally recognized Indian tribe;

(ii) Resides in an urban center and meets one or more of the four criteria:

(A) Is a member of a tribe, band, or other organized group of Indians, including those tribes, bands, or groups terminated since 1940 and those recognized now or in the future by the State in which they reside, or who is a descendant, in the first or second degree, of any such member;

(B) Is an Eskimo or Aleut or other Alaska Native;

(C) Is considered by the Secretary of the Interior to be an Indian for any purpose; or

(D) Is determined to be an Indian under regulations issued by the Secretary;

(iii) Is considered by the Secretary of the Interior to be an Indian for any purpose; or

(iv) Is considered by the Secretary of Health and Human Services to be an Indian for purposes of eligibility for Indian health care services, including as

a California Indian, Eskimo, Aleut, or other Alaska Native.

Indian health care provider (IHCP) means a health care program operated by the Indian Health Service (IHS) or by an Indian Tribe, Tribal Organization, or Urban Indian Organization (otherwise known as an I/T/U) as those terms are defined in section 4 of the Indian Health Care Improvement Act (25 U.S.C. 1603).

Indian managed care entity (IMCE) means a MCO, PIHP, PAHP, PCCM, or PCCM entity that is controlled (within the meaning of the last sentence of section 1903(m)(1)(C) of the Act) by the Indian Health Service, a Tribe, Tribal Organization, or Urban Indian Organization, or a consortium, which may be composed of one or more Tribes, Tribal Organizations, or Urban Indian Organizations, and which also may include the Service.

(b) *Network and coverage requirements.* All contracts between a State and a MCO, PIHP, PAHP, and PCCM entity, to the extent that the PCCM entity has a provider network, which enroll Indians must:

(1) Require the MCO, PIHP, PAHP, or PCCM entity to demonstrate that there are sufficient IHCPs participating in the provider network of the MCO, PIHP, PAHP, or PCCM entity to ensure timely access to services available under the contract from such providers for Indian enrollees who are eligible to receive services.

(2) Require that IHCPs, whether participating or not, be paid for covered services provided to Indian enrollees who are eligible to receive services from such providers as follows:

(i) At a rate negotiated between the MCO, PIHP, PAHP, or PCCM entity, and the IHCP, or

(ii) In the absence of a negotiated rate, at a rate not less than the level and amount of payment that the MCO, PIHP, PAHP, or PCCM entity would make for the services to a participating provider which is not an IHCP; and

(iii) Make payment to all IHCPs in its network in a timely manner as required for payments to practitioners in individual or group practices under 42 CFR 447.45 and 447.46.

(3) Permit any Indian who is enrolled in a MCO, PIHP, PAHP, PCCM or PCCM entity that is not an IMCE and eligible to receive services from a IHCP primary care provider participating as a network provider, to choose that IHCP as his or her primary care provider, as long as that provider has capacity to provide the services.

(4) Permit Indian enrollees to obtain services covered under the contract between the State and the MCO, PIHP, PAHP, or PCCM entity from out-of-

network IHCPs from whom the enrollee is otherwise eligible to receive such services.

(5) In a State where timely access to covered services cannot be ensured due to few or no IHCPs, an MCO, PIHP, PAHP and PCCM entity will be considered to have met the requirement in paragraph (b)(1) of this section if—

(i) Indian enrollees are permitted by the MCO, PIHP, PAHP, or PCCM entity to access out-of-State IHCPs; or

(ii) If this circumstance is deemed to be good cause for disenrollment from both the MCO, PIHP, PAHP, or PCCM entity and the State's managed care program in accordance with § 438.56(c).

(6) MCOs, PIHPs, PAHPs, and PCCM entities, to the extent the PCCM entity has a provider network, must permit an out-of-network IHCP to refer an Indian enrollee to a network provider.

(c) *Payment requirements.* (1) When an IHCP is enrolled in Medicaid as a FQHC but not a participating provider of the MCO, PIHP, PAHP or PCCM entity, it must be paid an amount equal to the amount the MCO, PIHP, PAHP, or PCCM entity would pay a FQHC that is a network provider but is not an IHCP, including any supplemental payment from the State to make up the difference between the amount the MCO, PIHP, PAHP or PCCM entity pays and what the IHCP FQHC would have received under FFS.

(2) When an IHCP is not enrolled in Medicaid as a FQHC, regardless of whether it participates in the network of an MCO, PIHP, PAHP and PCCM entity or not, it has the right to receive its applicable encounter rate published annually in the **Federal Register** by the Indian Health Service, or in the absence of a published encounter rate, the amount it would receive if the services were provided under the State plan's FFS payment methodology.

(3) When the amount a IHCP receives from a MCO, PIHP, PAHP, or PCCM entity is less than the amount required by paragraph (c)(2) of this section, the State must make a supplemental payment to the IHCP to make up the difference between the amount the MCO, PIHP, PAHP, or PCCM entity pays and the amount the IHCP would have received under FFS or the applicable encounter rate.

(d) *Enrollment in IMCEs.* An IMCE may restrict its enrollment to Indians in the same manner as Indian Health Programs, as defined in 25 U.S.C. 1603(12), may restrict the delivery of services to Indians, without being in violation of the requirements in § 438.3(d).

Subpart B—State Responsibilities

§ 438.50 State Plan requirements.

(a) *General rule.* A State plan that requires Medicaid beneficiaries to enroll in MCOs, PCCMs, or PCCM entities must comply with the provisions of this section, except when the State imposes the requirement—

(1) As part of a demonstration project under section 1115(a) of the Act; or

(2) Under a waiver granted under section 1915(b) of the Act.

(b) *State plan information.* The plan must specify—

(1) The types of entities with which the State contracts.

(2) The payment method it uses (for example, whether FFS or capitation).

(3) Whether it contracts on a comprehensive risk basis.

(4) The process the State uses to involve the public in both design and initial implementation of the managed care program and the methods it uses to ensure ongoing public involvement once the State plan has been implemented.

(c) *State plan assurances.* The plan must provide assurances that the State meets applicable requirements of the following statute and regulations:

(1) Section 1903(m) of the Act, for MCOs and MCO contracts.

(2) Section 1905(t) of the Act, for PCCMs and PCCM or PCCM entity contracts.

(3) Section 1932(a)(1)(A) of the Act, for the State's option to limit freedom of choice by requiring beneficiaries to receive their benefits through managed care entities.

(4) This part, for MCOs, PCCMs, and PCCM entities.

(5) Part 434 of this chapter, for all contracts.

(6) Section 438.4, for payments under any risk contracts, and § 447.362 of this chapter for payments under any nonrisk contracts.

(d) *Limitations on enrollment.* The State must provide assurances that, in implementing the State plan managed care option, it will not require the following groups to enroll in an MCO, PCCM or PCCM entity:

(1) Beneficiaries who are also eligible for Medicare.

(2) Indians as defined in § 438.14(a), except as permitted under § 438.14(d).

(3) Children under 19 years of age who are:

(i) Eligible for SSI under Title XVI;

(ii) Eligible under section 1902(e)(3) of the Act;

(iii) In foster care or other out-of-home placement;

(iv) Receiving foster care or adoption assistance; or

(v) Receiving services through a family-centered, community-based, coordinated care system that receives grant funds under section 501(a)(1)(D) of Title V, and is defined by the State in terms of either program participation or special health care needs.

§ 438.52 Choice of MCOs, PIHPs, PAHPs, PCCMs, and PCCM entities.

(a) *General rule.* Except as specified in paragraphs (b) and (c) of this section, a State that requires Medicaid beneficiaries to:

(1) Enroll in an MCO, PIHP, or PAHP, must give those beneficiaries a choice of at least two MCOs, PIHPs, or PAHPs.

(2) Enroll in a primary care case management system, must give those beneficiaries a choice from at least two primary care case managers employed or contracted with the State.

(3) Enroll in a PCCM entity, may limit a beneficiary to a single PCCM entity. Beneficiaries must be permitted to choose from at least two primary care case managers employed by or contracted with the PCCM entity.

(b) *Exception for rural area residents.*

(1) Under any managed care program authorized by any of the following, and subject to the requirements of paragraph (b)(2) of this section, a State may limit a rural area resident to a single MCO, PIHP, or PAHP:

(i) A State plan amendment under section 1932(a) of the Act.

(ii) A waiver under section 1115(a) of the Act.

(iii) A waiver under section 1915(b) of the Act.

(2) To comply with this paragraph (b), a State, must permit the beneficiary—

(i) To choose from at least two primary care providers; and

(ii) To obtain services from any other provider under any of the following circumstances:

(A) The service or type of provider (in terms of training, experience, and specialization) is not available within the MCO, PIHP, or PAHP network.

(B) The provider is not part of the network, but is the main source of a service to the beneficiary, provided that—

(1) The provider is given the opportunity to become a participating provider under the same requirements for participation in the MCO, PIHP, or PAHP network as other network providers of that type.

(2) If the provider chooses not to join the network, or does not meet the necessary qualification requirements to join, the enrollee will be transitioned to a participating provider within 60 calendar days (after being given an opportunity to select a provider who participates).

(C) The only plan or provider available to the beneficiary does not, because of moral or religious objections, provide the service the enrollee seeks.

(D) The beneficiary's primary care provider or other provider determines that the beneficiary needs related services that would subject the beneficiary to unnecessary risk if received separately (for example, a cesarean section and a tubal ligation) and not all of the related services are available within the network.

(E) The State determines that other circumstances warrant out-of-network treatment.

(3) As used in this paragraph (b), "rural area" is any county designated as "micro," "rural," or "County with Extreme Access Considerations (CEAC)" in the Medicare Advantage Health Services Delivery (HSD) Reference file for the applicable calendar year.

(c) *Exception for certain health insuring organizations (HIOs).* The State may limit beneficiaries to a single HIO if—

(1) The HIO is one of those described in section 1932(a)(3)(C) of the Act; and

(2) The beneficiary who enrolls in the HIO has a choice of at least two primary care providers within the entity.

(d) *Limitations on changes between primary care providers.* For an enrollee of a single MCO, PIHP, PAHP, or HIO under paragraph (b) or (c) of this section, any limitation the State imposes on his or her freedom to change between primary care providers may be no more restrictive than the limitations on disenrollment under § 438.56(c).

§ 438.54 Managed care enrollment.

(a) *Applicability.* The provisions of this section apply to all Medicaid managed care programs which operate under any authority in the Act.

(b) *General rule.* The State must have an enrollment system for its managed care programs, voluntary and mandatory, as appropriate.

(1) Voluntary managed care programs are those where one or more groups of beneficiaries as enumerated in section of 1905(a) of the Act have the option to either enroll in a MCO, PIHP, PAHP, PCCM or PCCM entity, or remain enrolled in FFS to receive Medicaid covered benefits.

(2) Mandatory managed care programs are those where one or more groups of beneficiaries as enumerated in section 1905(a) of the Act must enroll in a MCO, PIHP, PAHP, PCCM or PCCM entity to receive covered Medicaid benefits.

(c) *Voluntary managed care programs.*
(1) States that have a voluntary managed care program must have an enrollment system that:

(i) Provides an enrollment choice period during which potential enrollees may make an active choice of delivery system and, if needed, choice of an MCO, PIHP, PAHP, PCCM or PCCM entity before enrollment is effectuated; or

(ii) Employs a passive enrollment process in which the State enrolls the potential enrollee into a MCO, PIHP, PAHP, PCCM or PCCM entity and simultaneously provides a period of time for the enrollee to make an active choice of delivery system and, if needed, to maintain enrollment in the MCO, PIHP, PAHP, PCCM or PCCM entity passively assigned or to select a different MCO, PIHP, PAHP, PCCM or PCCM entity.

(2) A State must provide potential enrollees the opportunity to actively elect to receive covered services through the managed care or FFS delivery system. If the potential enrollee elects to receive covered services through the managed care delivery system, the potential enrollee must then also select a MCO, PIHP, PAHP, PCCM, or PCCM entity.

(i) If the State does not use a passive enrollment process and the potential enrollee does not make an active choice during the period allowed by the state, then the potential enrollee will continue to receive covered services through the FFS delivery system.

(ii) If the State uses a passive enrollment process, the potential enrollee must select either to accept the MCO, PIHP, PAHP, PCCM, or PCCM entity selected for them by the State's passive enrollment process, select a different MCO, PIHP, PAHP, PCCM, or PCCM entity, or elect to receive covered services through the FFS delivery system. If the potential enrollee does not make an active choice during the time allowed by the state, the potential enrollee will remain enrolled with the MCO, PIHP, PAHP, PCCM, or PCCM entity selected by the passive enrollment process.

(3) The State must provide informational notices to each potential enrollee at the time the potential enrollee first becomes eligible to enroll in a managed care program and within a timeframe that enables the potential enrollee to use the information in choosing among available delivery system and/or managed care plan options. The notices must:

(i) Clearly explain (as relevant to the State's managed care program) the implications to the potential enrollee of: not making an active choice between managed care and FFS; selecting a different MCO, PIHP, PAHP, PCCM or PCCM entity; and accepting the MCO,

PIHP, PAHP, PCCM, or PCCM entity selected by the State;

(ii) Identify the MCOs, PIHPs, PAHPs, PCCMs or PCCM entities available to the potential enrollee should they elect the managed care delivery system;

(iii) Provide clear instructions for how to make known to the State the enrollee's selection of the FFS delivery system or a MCO, PIHP, PAHP, PCCM or PCCM entity;

(iv) Provide a comprehensive explanation of the length of the enrollment period, the 90 day without cause disenrollment period, and all other disenrollment options as specified in § 438.56;

(v) Include the contact information for the beneficiary support system in § 438.71; and

(vi) Comply with the information requirements in § 438.10.

(4) The State's enrollment system must provide that beneficiaries already enrolled in an MCO, PIHP, PAHP, PCCM or PCCM entity are given priority to continue that enrollment if the MCO, PIHP, PAHP, PCCM or PCCM entity does not have the capacity to accept all those seeking enrollment under the program.

(5) If a State elects to use a passive enrollment process, the process must assign beneficiaries to a qualified MCO, PIHP, PAHP, PCCM or PCCM entity. To be a qualified MCO, PIHP, PAHP, PCCM or PCCM entity, it must:

(i) Not be subject to the intermediate sanction described in § 438.702(a)(4); and

(ii) Have capacity to enroll beneficiaries.

(6) A passive enrollment process must seek to preserve existing provider-beneficiary relationships and relationships with providers that have traditionally served Medicaid beneficiaries.

(i) An "existing provider-beneficiary relationship" is one in which the provider was a main source of Medicaid services for the beneficiary during the previous year. This may be established through State records of previous managed care enrollment or FFS experience, encounter data, or through contact with the beneficiary.

(ii) A provider is considered to have "traditionally served" Medicaid beneficiaries if it has experience in serving the Medicaid population.

(7) If the approach in paragraph (c)(6) of this section is not possible, the State must distribute the beneficiaries equitably among the MCOs, PIHPs, PAHPs, PCCMs and PCCM entities.

(i) The State may not arbitrarily exclude any MCO, PIHP, PAHP, PCCM, or PCCM entity from being considered.

(ii) The State may consider additional criteria to conduct the passive enrollment process, including the enrollment preferences of family members, previous plan assignment of the beneficiary, quality assurance and improvement performance, procurement evaluation elements, accessibility of provider offices for people with disabilities (when appropriate), and other reasonable criteria that support the objectives of the managed care program.

(8) If a passive enrollment process is used and the enrollee does not elect to be enrolled into the FFS delivery system, the State must send a notice to the enrollee:

(i) Confirming that the enrollee's time to elect to enroll in the FFS delivery system has ended and that the enrollee will remain enrolled in the managed care delivery system for the remainder of the enrollment period unless one of the disenrollment reasons specified in § 438.56 applies.

(ii) Clearly and fully explaining the enrollee's right, and process to follow, to disenroll from the passively assigned MCO, PIHP, PAHP, PCCM or PCCM entity and select a different MCO, PIHP, PAHP, PCCM or PCCM entity within 90 days from the effective date of the enrollment or for any reason specified in § 438.56(d)(2).

(iii) Within 5 calendar days of the end of the time allowed for making the delivery system selection.

(d) *Mandatory managed care programs.* (1) States must have an enrollment system for a mandatory managed care program that includes the elements specified in paragraphs (d)(2) through (8) of this section.

(2) The State's enrollment system must implement enrollment in a MCO, PIHP, PAHP, PCCM, or PCCM entity as follows:

(i) If the State does not use a passive enrollment process and the potential enrollee does not make an active choice of a MCO, PIHP, PAHP, PCCM, or PCCM entity during the period allowed by the State, the potential enrollee will be enrolled into a MCO, PIHP, PAHP, PCCM, or PCCM entity selected by the State's default process.

(ii) If the State uses a passive enrollment process, the potential enrollee must either accept the MCO, PIHP, PAHP, PCCM, or PCCM entity selected by the State's passive enrollment process or select a different MCO, PIHP, PAHP, PCCM, or PCCM entity. If the potential enrollee does not make an active choice during the time allowed by the State, the MCO, PIHP, PAHP, PCCM, or PCCM entity selected

by the passive enrollment process will remain effective.

(3) A State must provide informational notices to each potential enrollee at the time the potential enrollee first becomes eligible to enroll in a managed care program and within a timeframe that enables the potential enrollee to use the information in choosing among available managed care plans. The notices must:

(i) Include the MCOs, PIHPs, PAHPs, PCCMs, or PCCM entities available to the potential enrollee;

(ii) Provide clear instructions for how to make known to the State the enrollee's selection of a MCO, PIHP, PAHP, PCCM, or PCCM entity;

(iii) Clearly explain the implications to the potential enrollee of not making an active choice of an MCO, PIHP, PAHP, PCCM or PCCM entity as well as the implications of making an active choice of an MCO, PIHP, PAHP, PCCM or PCCM entity;

(iv) Provide a comprehensive explanation of the length of the enrollment period, the 90 day without cause disenrollment period, and all other disenrollment options as specified in § 438.56;

(v) Include the contact information for the beneficiary support system in § 438.71; and

(vi) Comply with the information requirements in § 438.10.

(4) *Priority for enrollment.* The State's enrollment system must provide that beneficiaries already enrolled in an MCO, PIHP, PAHP, PCCM or PCCM entity are given priority to continue that enrollment if the MCO, PIHP, PAHP, PCCM or PCCM entity does not have the capacity to accept all those seeking enrollment under the program.

(5) *Enrollment by default.* For potential enrollees that do not select an MCO, PIHP, PAHP, PCCM or PCCM entities during the period allowed by the state, the State must have a default enrollment process for assigning those beneficiaries to qualified MCOs, PIHPs, PAHPs, PCCMs and PCCM entities. To be a qualified MCO, PIHP, PAHP, PCCM or PCCM entity, it must:

(i) Not be subject to the intermediate sanction described in § 438.702(a)(4); and

(ii) Have capacity to enroll beneficiaries.

(6) *Passive enrollment.* For States that use a passive enrollment process, the process must assign potential enrollees to qualified MCOs, PIHPs, PAHPs, PCCMs and PCCM entities. To be a qualified MCO, PIHP, PAHP, PCCM or PCCM entity, it must:

(i) Not be subject to the intermediate sanction described in § 438.702(a)(4); and

(ii) Have capacity to enroll beneficiaries.

(7) The passive and default enrollment processes must seek to preserve existing provider-beneficiary relationships and relationships with providers that have traditionally served Medicaid beneficiaries.

(i) An “existing provider-beneficiary relationship” is one in which the provider was a main source of Medicaid services for the beneficiary during the previous year. This may be established through State records of previous managed care enrollment or FFS experience, encounter data, or through contact with the beneficiary.

(ii) A provider is considered to have “traditionally served” Medicaid beneficiaries if it has experience in serving the Medicaid population.

(8) If the approach in paragraph (d)(7) of this section is not possible, the State must distribute the beneficiaries equitably among the MCOs, PIHPs, PAHPs, PCCMs and PCCM entities available to enroll them.

(i) The State may not arbitrarily exclude any MCO, PIHP, PAHP, PCCM or PCCM entity from being considered; and

(ii) The State may consider additional criteria to conduct the default enrollment process, including the enrollment preferences of family members, previous plan assignment of the beneficiary, quality assurance and improvement performance, procurement evaluation elements, accessibility of provider offices for people with disabilities (when appropriate), and other reasonable criteria related to a beneficiary’s experience with the Medicaid program.

§ 438.56 Disenrollment: Requirements and limitations.

(a) *Applicability.* The provisions of this section apply to all managed care programs whether enrollment is mandatory or voluntary and whether the contract is with an MCO, PIHP, PAHP, PCCM, or PCCM entity.

(b) *Disenrollment requested by the MCO, PIHP, PAHP, PCCM, or PCCM entity.* All MCO, PIHP, PAHP, PCCM and PCCM entity contracts must:

(1) Specify the reasons for which the MCO, PIHP, PAHP, PCCM, or PCCM entity may request disenrollment of an enrollee.

(2) Provide that the MCO, PIHP, PAHP, PCCM, or PCCM entity may not request disenrollment because of an adverse change in the enrollee’s health status, or because of the enrollee’s

utilization of medical services, diminished mental capacity, or uncooperative or disruptive behavior resulting from his or her special needs (except when his or her continued enrollment in the MCO, PIHP, PAHP, PCCM or PCCM entity seriously impairs the entity’s ability to furnish services to either this particular enrollee or other enrollees).

(3) Specify the methods by which the MCO, PIHP, PAHP, PCCM, or PCCM entity assures the agency that it does not request disenrollment for reasons other than those permitted under the contract.

(c) *Disenrollment requested by the enrollee.* If the State chooses to limit disenrollment, its MCO, PIHP, PAHP, PCCM, and PCCM entity contracts must provide that a beneficiary may request disenrollment as follows:

(1) For cause, at any time.

(2) Without cause, at the following times:

(i) During the 90 days following the date of the beneficiary’s initial enrollment into the MCO, PIHP, PAHP, PCCM, or PCCM entity, or during the 90 days following the date the State sends the beneficiary notice of that enrollment, whichever is later.

(ii) At least once every 12 months thereafter.

(iii) Upon automatic reenrollment under paragraph (g) of this section, if the temporary loss of Medicaid eligibility has caused the beneficiary to miss the annual disenrollment opportunity.

(iv) When the State imposes the intermediate sanction specified in § 438.702(a)(4).

(d) *Procedures for disenrollment—(1) Request for disenrollment.* The beneficiary (or his or her representative) must submit an oral or written request, as required by the State—

(i) To the State (or its agent); or

(ii) To the MCO, PIHP, PAHP, PCCM, or PCCM entity, if the State permits MCOs, PIHP, PAHPs, PCCMs, and PCCM entities to process disenrollment requests.

(2) *Cause for disenrollment.* The following are cause for disenrollment:

(i) The enrollee moves out of the MCO’s, PIHP’s, PAHP’s, PCCM’s, or PCCM entity’s service area.

(ii) The plan does not, because of moral or religious objections, cover the service the enrollee seeks.

(iii) The enrollee needs related services (for example, a cesarean section and a tubal ligation) to be performed at the same time; not all related services are available within the provider network; and the enrollee’s primary care provider or another provider determines that receiving the services separately

would subject the enrollee to unnecessary risk.

(iv) For enrollees that use MLTSS, the enrollee would have to change their residential, institutional, or employment supports provider based on that provider’s change in status from an in-network to an out-of-network provider with the MCO, PIHP, or PAHP and, as a result, would experience a disruption in their residence or employment.

(v) Other reasons, including poor quality of care, lack of access to services covered under the contract, or lack of access to providers experienced in dealing with the enrollee’s care needs.

(3) *MCO, PIHP, PAHP, PCCM, or PCCM entity action on request.* (i) When the MCO’s, PIHP’s, PAHP’s, PCCM’s, or PCCM entity’s contract with the State permits the MCO, PIHP, PAHP, PCCM, or PCCM entity to process disenrollment requests, the MCO, PIHP, PAHP, PCCM, or PCCM entity may either approve a request for disenrollment by or on behalf of an enrollee or the MCO, PIHP, PAHP, PCCM, or PCCM entity must refer the request to the State.

(ii) If the MCO, PIHP, PAHP, PCCM, PCCM entity, or State agency (whichever is responsible) fails to make a disenrollment determination so that the beneficiary can be disenrolled within the timeframes specified in paragraph (e)(1) of this section, the disenrollment is considered approved.

(4) *State agency action on request.* For a request received directly from the beneficiary, or one referred by the MCO, PIHP, PAHP, PCCM, or PCCM entity, the State agency must take action to approve or disapprove the request based on the following:

(i) Reasons cited in the request.

(ii) Information provided by the MCO, PIHP, PAHP, PCCM, or PCCM entity at the agency’s request.

(iii) Any of the reasons specified in paragraph (d)(2) of this section.

(5) *Use of the MCO’s, PIHP’s, PAHP’s, PCCM’s, or PCCM’s entity’s grievance procedures.* (i) The State agency may require that the enrollee seek redress through the MCO’s, PIHP’s, PAHP’s, PCCM’s, or PCCM entity’s grievance system before making a determination on the enrollee’s request.

(ii) The grievance process, if used, must be completed in time to permit the disenrollment (if approved) to be effective in accordance with the timeframe specified in paragraph (e)(1) of this section.

(iii) If, as a result of the grievance process, the MCO, PIHP, PAHP, PCCM, or PCCM entity approves the disenrollment, the State agency is not required to make a determination in

accordance with paragraph (d)(4) of this section.

(e) *Timeframe for disenrollment determinations.* (1) Regardless of the procedures followed, the effective date of an approved disenrollment must be no later than the first day of the second month following the month in which the enrollee requests disenrollment or the MCO, PIHP, PAHP, PCCM, or PCCM entity refers the request to the State.

(2) If the MCO, PIHP, PAHP, PCCM, PCCM entity, or the State agency (whichever is responsible) fails to make the determination within the timeframes specified in paragraph (e)(1) of this section, the disenrollment is considered approved for the effective date that would have been established had the State or MCO, PIHP, PAHP, PCCM, PCCM entity complied with paragraph (e)(1) of this section.

(f) *Notice and appeals.* A State that restricts disenrollment under this section must take the following actions:

(1) Provide that enrollees and their representatives are given written notice of disenrollment rights at least 60 days before the start of each enrollment period. The notice must include an explanation of all of the enrollee's disenrollment rights as specified in this section.

(2) Ensure timely access to State fair hearing for any enrollee dissatisfied with a State agency determination that there is not good cause for disenrollment.

(g) *Automatic reenrollment: Contract requirement.* If the State plan so specifies, the contract must provide for automatic reenrollment of a beneficiary who is disenrolled solely because he or she loses Medicaid eligibility for a period of 2 months or less.

§ 438.58 Conflict of interest safeguards.

As a condition for contracting with MCOs, PIHPs, or PAHPs, a State must have in effect safeguards against conflict of interest on the part of State and local officers and employees and agents of the State who have responsibilities relating to the MCO, PIHP, or PAHP contracts or the enrollment processes specified in § 438.54(b). These safeguards must be at least as effective as the safeguards specified in section 27 of the Office of Federal Procurement Policy Act (41 U.S.C. 423).

§ 438.60 Prohibition of additional payments for services covered under MCO, PIHP or PAHP contracts.

The State agency must ensure that no payment is made to a network provider other than by the MCO, PIHP, or PAHP for services covered under the contract between the State and the MCO, PIHP,

or PAHP, except when these payments are specifically required to be made by the State in Title XIX of the Act, in 42 CFR chapter IV, or when the State agency makes direct payments to network providers for graduate medical education costs approved under the State plan.

§ 438.62 Continued services to enrollees.

(a) The State agency must arrange for Medicaid services to be provided without delay to any Medicaid enrollee of an MCO, PIHP, PAHP, PCCM, or PCCM entity the contract of which is terminated and for any Medicaid enrollee who is disenrolled from an MCO, PIHP, PAHP, PCCM, or PCCM entity for any reason other than ineligibility for Medicaid.

(b) The State must have in effect a transition of care policy to ensure continued access to services during a transition from FFS to a MCO, PIHP, PAHP, PCCM or PCCM entity or transition from one MCO, PIHP, PAHP, PCCM or PCCM entity to another when an enrollee, in the absence of continued services, would suffer serious detriment to their health or be at risk of hospitalization or institutionalization.

(1) The transition of care policy must include the following:

(i) The enrollee has access to services consistent with the access they previously had, and is permitted to retain their current provider for a period of time if that provider is not in the MCO, PIHP or PAHP network.

(ii) The enrollee is referred to appropriate providers of services that are in the network.

(iii) The State, in the case of FFS, PCCM, or PCCM entity, or the MCO, PIHP or PAHP that was previously serving the enrollee, fully and timely complies with requests for historical utilization data from the new MCO, PIHP, PAHP, PCCM, or PCCM entity in compliance with Federal and State law.

(iv) Consistent with Federal and State law, the enrollee's new provider(s) are able to obtain copies of the enrollee's medical records, as appropriate.

(v) Any other necessary procedures as specified by the Secretary to ensure continued access to services to prevent serious detriment to the enrollee's health or reduce the risk of hospitalization or institutionalization.

(2) The State must require by contract that MCOs, PIHPs, and PAHPs implement a transition of care policy consistent with the requirements in paragraph (b)(1) of this section and at least meets the State defined transition of care policy.

(3) The State must make its transition of care policy publicly available and

provide instructions to enrollees and potential enrollees on how to access continued services upon transition. At a minimum, the transition of care policy must be described in the quality strategy, under § 438.340, and explained to individuals in the materials to enrollees and potential enrollees, in accordance with § 438.10.

(c) *Applicability date.* This section applies to the rating period for contracts with MCOs, PIHPs, PAHPs, PCCMs, and PCCM entities beginning on or after July 1, 2018. Until that applicability date, states are required to continue to comply with § 438.62 contained in the 42 CFR parts 430 to 481, edition revised as of October 1, 2015.

§ 438.66 State monitoring requirements.

(a) *General requirement.* The State agency must have in effect a monitoring system for all managed care programs.

(b) The State's system must address all aspects of the managed care program, including the performance of each MCO, PIHP, PAHP, and PCCM entity (if applicable) in at least the following areas:

(1) Administration and management.

(2) Appeal and grievance systems.

(3) Claims management.

(4) Enrollee materials and customer services, including the activities of the beneficiary support system.

(5) Finance, including medical loss ratio reporting.

(6) Information systems, including encounter data reporting.

(7) Marketing.

(8) Medical management, including utilization management and case management.

(9) Program integrity.

(10) Provider network management, including provider directory standards.

(11) Availability and accessibility of services, including network adequacy standards.

(12) Quality improvement.

(13) Areas related to the delivery of LTSS not otherwise included in paragraphs (b)(1) through (12) of this section as applicable to the managed care program.

(14) All other provisions of the contract, as appropriate.

(c) The State must use data collected from its monitoring activities to improve the performance of its managed care program, including at a minimum:

(1) Enrollment and disenrollment trends in each MCO, PIHP, or PAHP.

(2) Member grievance and appeal logs.

(3) Provider complaint and appeal logs.

(4) Findings from the State's External Quality Review process.

(5) Results from any enrollee or provider satisfaction survey conducted by the State or MCO, PIHP, or PAHP.

(6) Performance on required quality measures.

(7) Medical management committee reports and minutes.

(8) The annual quality improvement plan for each MCO, PIHP, PAHP, or PCCM entity.

(9) Audited financial and encounter data submitted by each MCO, PIHP, or PAHP.

(10) The medical loss ratio summary reports required by § 438.8.

(11) Customer service performance data submitted by each MCO, PIHP, or PAHP and performance data submitted by the beneficiary support system.

(12) Any other data related to the provision of LTSS not otherwise included in paragraphs (c)(1) through (11) of this section as applicable to the managed care program.

(d)(1) The State must assess the readiness of each MCO, PIHP, PAHP or PCCM entity with which it contracts as follows:

(i) Prior to the State implementing a managed care program, whether the program is voluntary or mandatory.

(ii) When the specific MCO, PIHP, PAHP, or PCCM entity has not previously contracted with the State.

(iii) When any MCO, PIHP, PAHP, or PCCM entity currently contracting with the State will provide or arrange for the provision of covered benefits to new eligibility groups.

(2) The State must conduct a readiness review of each MCO, PIHP, PAHP, or PCCM entity with which it contracts as follows:

(i) Started at least 3 months prior to the effective date of the events described in paragraph (d)(1) of this section.

(ii) Completed in sufficient time to ensure smooth implementation of an event described in paragraph (d)(1) of this section.

(iii) Submitted to CMS for CMS to make a determination that the contract or contract amendment associated with an event described in paragraph (d)(1) of this section is approved under § 438.3(a).

(3) Readiness reviews described in paragraphs (d)(1)(i) and (ii) of this section must include both a desk review of documents and on-site reviews of each MCO, PIHP, PAHP, or PCCM entity. Readiness reviews described in paragraph (d)(1)(iii) of this section must include a desk review of documents and may, at the State's option, include an on-site review. On-site reviews must include interviews with MCO, PIHP, PAHP, or PCCM entity staff and leadership that manage key operational areas.

(4) A State's readiness review must assess the ability and capacity of the MCO, PIHP, PAHP, and PCCM entity (if applicable) to perform satisfactorily for the following areas:

(i) Operations/Administration, including—

(A) Administrative staffing and resources.

(B) Delegation and oversight of MCO, PIHP, PAHP or PCCM entity responsibilities.

(C) Enrollee and provider communications.

(D) Grievance and appeals.

(E) Member services and outreach.

(F) Provider Network Management.

(G) Program Integrity/Compliance.

(ii) Service delivery, including—

(A) Case management/care coordination/service planning.

(B) Quality improvement.

(C) Utilization review.

(iii) Financial management, including—

(A) Financial reporting and monitoring.

(B) Financial solvency.

(iv) Systems management, including—

(A) Claims management.

(B) Encounter data and enrollment information management.

(e)(1) The State must submit to CMS no later than 180 days after each contract year, a report on each managed care program administered by the State, regardless of the authority under which the program operates.

(i) The initial report will be due after the contract year following the release of CMS guidance on the content and form of the report.

(ii) For States that operate their managed care program under section 1115(a) of the Act authority, submission of an annual report that may be required by the Special Terms and Conditions of the section 1115(a) demonstration program will be deemed to satisfy the requirement of this paragraph (e)(1) provided that the report includes the information specified in paragraph (e)(2) of this section.

(2) The program report must provide information on and an assessment of the operation of the managed care program on, at a minimum, the following areas:

(i) Financial performance of each MCO, PIHP, and PAHP, including MLR experience.

(ii) Encounter data reporting by each MCO, PIHP, or PAHP.

(iii) Enrollment and service area expansion (if applicable) of each MCO, PIHP, PAHP, and PCCM entity.

(iv) Modifications to, and implementation of, MCO, PIHP, or PAHP benefits covered under the contract with the State.

(v) Grievance, appeals, and State fair hearings for the managed care program.

(vi) Availability and accessibility of covered services within the MCO, PIHP, or PAHP contracts, including network adequacy standards.

(vii) Evaluation of MCO, PIHP, or PAHP performance on quality measures, including as applicable, consumer report card, surveys, or other reasonable measures of performance.

(viii) Results of any sanctions or corrective action plans imposed by the State or other formal or informal intervention with a contracted MCO, PIHP, PAHP, or PCCM entity to improve performance.

(ix) Activities and performance of the beneficiary support system.

(x) Any other factors in the delivery of LTSS not otherwise addressed in (e)(2)(i)–(ix) of this section as applicable.

(3) The program report required in this section must be:

(i) Posted on the Web site required under § 438.10(c)(3).

(ii) Provided to the Medical Care Advisory Committee, required under § 431.12 of this chapter.

(iii) Provided to the stakeholder consultation group specified in § 438.70, to the extent that the managed care program includes LTSS.

(f) *Applicability.* States will not be held out of compliance with the requirements of paragraphs (a) through (d) of this section prior to the rating period for contracts starting on or after July 1, 2017, so long as they comply with the corresponding standard(s) codified in 42 CFR 438.66 contained in the 42 CFR, parts 430 to 481, edition revised as of October 1, 2015.

§ 438.68 Network adequacy standards.

(a) *General rule.* A State that contracts with an MCO, PIHP or PAHP to deliver Medicaid services must develop and enforce network adequacy standards consistent with this section.

(b) *Provider-specific network adequacy standards.* (1) At a minimum, a State must develop time and distance standards for the following provider types, if covered under the contract:

(i) Primary care, adult and pediatric.

(ii) OB/GYN.

(iii) Behavioral health (mental health and substance use disorder), adult and pediatric.

(iv) Specialist, adult and pediatric.

(v) Hospital.

(vi) Pharmacy.

(vii) Pediatric dental.

(viii) Additional provider types when it promotes the objectives of the Medicaid program, as determined by CMS, for the provider type to be subject to time and distance access standards.

(2) *LTSS*. States with MCO, PIHP or PAHP contracts which cover LTSS must develop:

(i) Time and distance standards for LTSS provider types in which an enrollee must travel to the provider to receive services; and

(ii) Network adequacy standards other than time and distance standards for LTSS provider types that travel to the enrollee to deliver services.

(3) *Scope of network adequacy standards*. Network standards established in accordance with paragraphs (b)(1) and (2) of this section must include all geographic areas covered by the managed care program or, if applicable, the contract between the State and the MCO, PIHP or PAHP. States are permitted to have varying standards for the same provider type based on geographic areas.

(c) *Development of network adequacy standards*. (1) States developing network adequacy standards consistent with paragraph (b)(1) of this section must consider, at a minimum, the following elements:

(i) The anticipated Medicaid enrollment.

(ii) The expected utilization of services.

(iii) The characteristics and health care needs of specific Medicaid populations covered in the MCO, PIHP, and PAHP contract.

(iv) The numbers and types (in terms of training, experience, and specialization) of network providers required to furnish the contracted Medicaid services.

(v) The numbers of network providers who are not accepting new Medicaid patients.

(vi) The geographic location of network providers and Medicaid enrollees, considering distance, travel time, the means of transportation ordinarily used by Medicaid enrollees.

(vii) The ability of network providers to communicate with limited English proficient enrollees in their preferred language.

(viii) The ability of network providers to ensure physical access, reasonable accommodations, culturally competent communications, and accessible equipment for Medicaid enrollees with physical or mental disabilities.

(ix) The availability of triage lines or screening systems, as well as the use of telemedicine, e-visits, and/or other evolving and innovative technological solutions.

(2) States developing standards consistent with paragraph (b)(2) of this section must consider the following:

(i) All elements in paragraphs (c)(1)(i) through (ix) of this section.

(ii) Elements that would support an enrollee's choice of provider.

(iii) Strategies that would ensure the health and welfare of the enrollee and support community integration of the enrollee.

(iv) Other considerations that are in the best interest of the enrollees that need LTSS.

(d) *Exceptions process*. (1) To the extent the State permits an exception to any of the provider-specific network standards developed under this section, the standard by which the exception will be evaluated and approved must be:

(i) Specified in the MCO, PIHP or PAHP contract.

(ii) Based, at a minimum, on the number of providers in that specialty practicing in the MCO, PIHP, or PAHP service area.

(2) States that grant an exception in accordance with paragraph (d)(1) of this section to a MCO, PIHP or PAHP must monitor enrollee access to that provider type on an ongoing basis and include the findings to CMS in the managed care program assessment report required under § 438.66.

(e) *Publication of network adequacy standards*. States must publish the standards developed in accordance with paragraphs (b)(1) and (2) of this section on the Web site required by § 438.10. Upon request, network adequacy standards must also be made available at no cost to enrollees with disabilities in alternate formats or through the provision of auxiliary aids and services.

§ 438.70 Stakeholder engagement when LTSS is delivered through a managed care program.

The State must ensure the views of beneficiaries, individuals representing beneficiaries, providers, and other stakeholders are solicited and addressed during the design, implementation, and oversight of a State's managed LTSS program. The composition of the stakeholder group and frequency of meetings must be sufficient to ensure meaningful stakeholder engagement.

§ 438.71 Beneficiary support system.

(a) *General requirement*. The State must develop and implement a beneficiary support system that provides support to beneficiaries both prior to and after enrollment in a MCO, PIHP, PAHP, PCCM or PCCM entity.

(b) *Elements of the support system*. (1) A State beneficiary support system must include at a minimum:

(i) Choice counseling for all beneficiaries.

(ii) Assistance for enrollees in understanding managed care.

(iii) Assistance as specified for enrollees who use, or express a desire to

receive, LTSS in paragraph (d) of this section.

(2) The beneficiary support system must perform outreach to beneficiaries and/or authorized representatives and be accessible in multiple ways including phone, Internet, in-person, and via auxiliary aids and services when requested.

(c) *Choice counseling*. (1) Choice counseling, as defined in § 438.2, must be provided to all potential enrollees and enrollees who disenroll from a MCO, PIHP, PAHP, PCCM or PCCM entity for reasons specified in § 438.56(b) and (c).

(2) If an individual or entity provides choice counseling on the State's behalf under a memorandum of agreement or contract, it is considered an enrollment broker as defined in § 438.810(a) and must meet the independence and freedom from conflict of interest standards in § 438.810(b)(1) and (2).

(3) An entity that receives non-Medicaid funding to represent beneficiaries at hearings may provide choice counseling on behalf of the State so long as the State requires firewalls to ensure that the requirements for the provision of choice counseling are met.

(d) *Functions specific to LTSS activities*. At a minimum, the beneficiary support system must provide the following support to enrollees who use, or express a desire to receive, LTSS:

(1) An access point for complaints and concerns about MCO, PIHP, PAHP, PCCM, and PCCM entity enrollment, access to covered services, and other related matters.

(2) Education on enrollees' grievance and appeal rights within the MCO, PIHP or PAHP; the State fair hearing process; enrollee rights and responsibilities; and additional resources outside of the MCO, PIHP or PAHP.

(3) Assistance, upon request, in navigating the grievance and appeal process within the MCO, PIHP or PAHP, as well as appealing adverse benefit determinations by the MCO, PIHP, or PAHP to a State fair hearing. The system may not provide representation to the enrollee at a State fair hearing but may refer enrollees to sources of legal representation.

(4) Review and oversight of LTSS program data to provide guidance to the State Medicaid Agency on identification, remediation and resolution of systemic issues.

§ 438.74 State oversight of the minimum MLR requirement.

(a) *State reporting requirement*. (1) The State must annually submit to CMS a summary description of the report(s)

received from the MCO(s), PIHP(s), and PAHP(s) under contract with the State, according to § 438.8(k), with the rate certification required in § 438.7.

(2) The summary description must include, at a minimum, the amount of the numerator, the amount of the denominator, the MLR percentage achieved, the number of member months, and any remittances owed by each MCO, PIHP, or PAHP for that MLR reporting year.

(b) *Repayment of Federal share of remittances.* (1) If a State requires a MCO, PIHP, or PAHP to pay remittances through the contract for not meeting the minimum MLR required by the State, the State must reimburse CMS for an amount equal to the Federal share of the remittance, taking into account applicable differences in the Federal matching rate.

(2) If a remittance is owed according to paragraph (b)(1) of this section, the State must submit a separate report describing the methodology used to determine the State and Federal share of the remittance with the report required in paragraph (a) of this section.

Subpart C—Enrollee Rights and Protections

§ 438.100 Enrollee rights.

(a) *General rule.* The State must ensure that:

(1) Each MCO, PIHP, PAHP, PCCM and PCCM entity has written policies regarding the enrollee rights specified in this section; and

(2) Each MCO, PIHP, PAHP, PCCM and PCCM entity complies with any applicable Federal and State laws that pertain to enrollee rights, and ensures that its employees and contracted providers observe and protect those rights.

(b) *Specific rights—(1) Basic requirement.* The State must ensure that each managed care enrollee is guaranteed the rights as specified in paragraphs (b)(2) and (3) of this section.

(2) An enrollee of an MCO, PIHP, PAHP, PCCM, or PCCM entity has the following rights: The right to—

(i) Receive information in accordance with § 438.10.

(ii) Be treated with respect and with due consideration for his or her dignity and privacy.

(iii) Receive information on available treatment options and alternatives, presented in a manner appropriate to the enrollee's condition and ability to understand. (The information requirements for services that are not covered under the contract because of moral or religious objections are set forth in § 438.10(g)(2)(ii)(A) and (B).)

(iv) Participate in decisions regarding his or her health care, including the right to refuse treatment.

(v) Be free from any form of restraint or seclusion used as a means of coercion, discipline, convenience or retaliation, as specified in other Federal regulations on the use of restraints and seclusion.

(vi) If the privacy rule, as set forth in 45 CFR parts 160 and 164 subparts A and E, applies, request and receive a copy of his or her medical records, and request that they be amended or corrected, as specified in 45 CFR 164.524 and 164.526.

(3) An enrollee of an MCO, PIHP, or PAHP (consistent with the scope of the PAHP's contracted services) has the right to be furnished health care services in accordance with §§ 438.206 through 438.210.

(c) *Free exercise of rights.* The State must ensure that each enrollee is free to exercise his or her rights, and that the exercise of those rights does not adversely affect the way the MCO, PIHP, PAHP, PCCM or PCCM entity and its network providers or the State agency treat the enrollee.

(d) *Compliance with other Federal and State laws.* The State must ensure that each MCO, PIHP, PAHP, PCCM and PCCM entity complies with any other applicable Federal and State laws (including: Title VI of the Civil Rights Act of 1964 as implemented by regulations at 45 CFR part 80; the Age Discrimination Act of 1975 as implemented by regulations at 45 CFR part 91; the Rehabilitation Act of 1973; Title IX of the Education Amendments of 1972 (regarding education programs and activities); Titles II and III of the Americans with Disabilities Act; and section 1557 of the Patient Protection and Affordable Care Act.

§ 438.102 Provider-enrollee communications.

(a) *General rules.* (1) An MCO, PIHP, or PAHP may not prohibit, or otherwise restrict, a provider acting within the lawful scope of practice, from advising or advocating on behalf of an enrollee who is his or her patient, for the following:

(i) The enrollee's health status, medical care, or treatment options, including any alternative treatment that may be self-administered.

(ii) Any information the enrollee needs to decide among all relevant treatment options.

(iii) The risks, benefits, and consequences of treatment or non-treatment.

(iv) The enrollee's right to participate in decisions regarding his or her health

care, including the right to refuse treatment, and to express preferences about future treatment decisions.

(2) Subject to the information requirements of paragraph (b) of this section, an MCO, PIHP, or PAHP that would otherwise be required to provide, reimburse for, or provide coverage of, a counseling or referral service because of the requirement in paragraph (a)(1) of this section is not required to do so if the MCO, PIHP, or PAHP objects to the service on moral or religious grounds.

(b) *Information requirements: MCO, PIHP, and PAHP responsibility.* (1)(i) An MCO, PIHP, or PAHP that elects the option provided in paragraph (a)(2) of this section must furnish information about the services it does not cover as follows:

(A) To the State—

(1) With its application for a Medicaid contract.

(2) Whenever it adopts the policy during the term of the contract.

(B) Consistent with the provisions of § 438.10, to enrollees, within 90 days after adopting the policy for any particular service.

(ii) Although this timeframe would be sufficient to entitle the MCO, PIHP, or PAHP to the option provided in paragraph (a)(2) of this section, the overriding rule in § 438.10(g)(4) requires the State, its contracted representative, or MCO, PIHP, or PAHP to furnish the information at least 30 days before the effective date of the policy.

(2) As specified in § 438.10(g)(2)(ii)(A) and (B), the MCOs, PIHPs, and PAHPs must inform enrollees how they can obtain information from the State about how to access the service excluded under paragraph (a)(2) of this section.

(c) *Information requirements: State responsibility.* For each service excluded by an MCO, PIHP, or PAHP under paragraph (a)(2) of this section, the State must provide information on how and where to obtain the service, as specified in § 438.10.

(d) *Sanction.* An MCO that violates the prohibition of paragraph (a)(1) of this section is subject to intermediate sanctions under subpart I of this part.

§ 438.104 Marketing activities.

(a) *Definitions.* As used in this section, the following terms have the indicated meanings:

Cold-call marketing means any unsolicited personal contact by the MCO, PIHP, PAHP, PCCM or PCCM entity with a potential enrollee for the purpose of marketing as defined in this paragraph (a).

Marketing means any communication, from an MCO, PIHP, PAHP, PCCM or PCCM entity to a Medicaid beneficiary

who is not enrolled in that entity, that can reasonably be interpreted as intended to influence the beneficiary to enroll in that particular MCO's, PIHP's, PAHP's, PCCM's or PCCM entity's Medicaid product, or either to not enroll in or to disenroll from another MCO's, PIHP's, PAHP's, PCCM's or PCCM entity's Medicaid product. Marketing does not include communication to a Medicaid beneficiary from the issuer of a qualified health plan, as defined in 45 CFR 155.20, about the qualified health plan.

Marketing materials means materials that—

(i) Are produced in any medium, by or on behalf of an MCO, PIHP, PAHP, PCCM, or PCCM entity; and

(ii) Can reasonably be interpreted as intended to market the MCO, PIHP, PAHP, PCCM, or PCCM entity to potential enrollees.

MCO, PIHP, PAHP, PCCM or PCCM entity include any of the entity's employees, network providers, agents, or contractors.

Private insurance does not include a qualified health plan, as defined in 45 CFR 155.20.

(b) *Contract requirements.* Each contract with an MCO, PIHP, PAHP, PCCM, or PCCM entity must comply with the following requirements:

(1) Provide that the entity—

(i) Does not distribute any marketing materials without first obtaining State approval.

(ii) Distributes the materials to its entire service area as indicated in the contract.

(iii) Complies with the information requirements of § 438.10 to ensure that, before enrolling, the beneficiary receives, from the entity or the State, the accurate oral and written information he or she needs to make an informed decision on whether to enroll.

(iv) Does not seek to influence enrollment in conjunction with the sale or offering of any private insurance.

(v) Does not, directly or indirectly, engage in door-to-door, telephone, email, texting, or other cold-call marketing activities.

(2) Specify the methods by which the entity ensures the State agency that marketing, including plans and materials, is accurate and does not mislead, confuse, or defraud the beneficiaries or the State agency. Statements that will be considered inaccurate, false, or misleading include, but are not limited to, any assertion or statement (whether written or oral) that—

(i) The beneficiary must enroll in the MCO, PIHP, PAHP, PCCM or PCCM

entity to obtain benefits or to not lose benefits; or

(ii) The MCO, PIHP, PAHP, PCCM or PCCM entity is endorsed by CMS, the Federal or State government, or similar entity.

(c) *State agency review.* In reviewing the marketing materials submitted by the entity, the State must consult with the Medical Care Advisory Committee established under § 431.12 of this chapter or an advisory committee with similar membership.

§ 438.106 Liability for payment.

Each MCO, PIHP, and PAHP must provide that its Medicaid enrollees are not held liable for any of the following:

(a) The MCO's, PIHP's, or PAHP's debts, in the event of the entity's insolvency.

(b) Covered services provided to the enrollee, for which—

(1) The State does not pay the MCO, PIHP, or PAHP; or

(2) The State, or the MCO, PIHP, or PAHP does not pay the individual or health care provider that furnished the services under a contractual, referral, or other arrangement.

(c) Payments for covered services furnished under a contract, referral, or other arrangement, to the extent that those payments are in excess of the amount that the enrollee would owe if the MCO, PIHP, or PAHP covered the services directly.

§ 438.108 Cost sharing.

The contract must provide that any cost sharing imposed on Medicaid enrollees is in accordance with §§ 447.50 through 447.82 of this chapter.

§ 438.110 Member advisory committee.

(a) *General rule.* When LTSS are covered under a risk contract between a State and an MCO, PIHP, or PAHP, the contract must provide that each MCO, PIHP or PAHP establish and maintain a member advisory committee.

(b) *Committee composition.* The committee required in paragraph (a) of this section must include at least a reasonably representative sample of the LTSS populations, or other individuals representing those enrollees, covered under the contract with the MCO, PIHP, or PAHP.

§ 438.114 Emergency and poststabilization services.

(a) *Definitions.* As used in this section—

Emergency medical condition means a medical condition manifesting itself by acute symptoms of sufficient severity (including severe pain) that a prudent layperson, who possesses an average

knowledge of health and medicine, could reasonably expect the absence of immediate medical attention to result in the following:

(i) Placing the health of the individual (or, for a pregnant woman, the health of the woman or her unborn child) in serious jeopardy.

(ii) Serious impairment to bodily functions.

(iii) Serious dysfunction of any bodily organ or part.

Emergency services means covered inpatient and outpatient services that are as follows:

(i) Furnished by a provider that is qualified to furnish these services under this Title.

(ii) Needed to evaluate or stabilize an emergency medical condition.

Poststabilization care services means covered services, related to an emergency medical condition that are provided after an enrollee is stabilized to maintain the stabilized condition, or, under the circumstances described in paragraph (e) of this section, to improve or resolve the enrollee's condition.

(b) *Coverage and payment: General rule.* The following entities are responsible for coverage and payment of emergency services and poststabilization care services.

(1) The MCO, PIHP, or PAHP.

(2) The State, for managed care programs that contract with PCCMs or PCCM entities

(c) *Coverage and payment: Emergency services.* (1) The entities identified in paragraph (b) of this section—

(i) Must cover and pay for emergency services regardless of whether the provider that furnishes the services has a contract with the MCO, PIHP, PAHP, PCCM or PCCM entity; and

(ii) May not deny payment for treatment obtained under either of the following circumstances:

(A) An enrollee had an emergency medical condition, including cases in which the absence of immediate medical attention would not have had the outcomes specified in paragraphs (1), (2), and (3) of the definition of emergency medical condition in paragraph (a) of this section.

(B) A representative of the MCO, PIHP, PAHP, PCCM, or PCCM entity instructs the enrollee to seek emergency services.

(2) A PCCM or PCCM entity must allow enrollees to obtain emergency services outside the primary care case management system regardless of whether the case manager referred the enrollee to the provider that furnishes the services.

(d) *Additional rules for emergency services.* (1) The entities specified in paragraph (b) of this section may not—

(i) Limit what constitutes an emergency medical condition with reference to paragraph (a) of this section, on the basis of lists of diagnoses or symptoms; and

(ii) Refuse to cover emergency services based on the emergency room provider, hospital, or fiscal agent not notifying the enrollee's primary care provider, MCO, PIHP, PAHP or applicable State entity of the enrollee's screening and treatment within 10 calendar days of presentation for emergency services.

(2) An enrollee who has an emergency medical condition may not be held liable for payment of subsequent screening and treatment needed to diagnose the specific condition or stabilize the patient.

(3) The attending emergency physician, or the provider actually treating the enrollee, is responsible for determining when the enrollee is sufficiently stabilized for transfer or discharge, and that determination is binding on the entities identified in paragraph (b) of this section as responsible for coverage and payment.

(e) *Coverage and payment:*

Poststabilization care services.

Poststabilization care services are covered and paid for in accordance with provisions set forth at § 422.113(c) of this chapter. In applying those provisions, reference to "MA organization" and "financially responsible" must be read as reference to the entities responsible for Medicaid payment, as specified in paragraph (b) of this section, and payment rules governed by Title XIX of the Act and the States.

(f) *Applicability to PIHPs and PAHPs.* To the extent that services required to treat an emergency medical condition fall within the scope of the services for which the PIHP or PAHP is responsible, the rules under this section apply.

§ 438.116 Solvency standards.

(a) *Requirement for assurances.* (1) Each MCO, PIHP, and PAHP that is not a Federally qualified HMO (as defined in section 1310 of the Public Health Service Act) must provide assurances satisfactory to the State showing that its provision against the risk of insolvency is adequate to ensure that its Medicaid enrollees will not be liable for the MCO's, PIHP's, or PAHP's debts if the entity becomes insolvent.

(2) Federally qualified HMOs, as defined in section 1310 of the Public Health Service Act, are exempt from this requirement.

(b) *Other requirements*—(1) *General rule.* Except as provided in paragraph (b)(2) of this section, an MCO or PIHP,

must meet the solvency standards established by the State for private health maintenance organizations, or be licensed or certified by the State as a risk-bearing entity.

(2) *Exception.* Paragraph (b)(1) of this section does not apply to an MCO or PIHP that meets any of the following conditions:

(i) Does not provide both inpatient hospital services and physician services.

(ii) Is a public entity.

(iii) Is (or is controlled by) one or more Federally qualified health centers and meets the solvency standards established by the State for those centers.

(iv) Has its solvency guaranteed by the State.

Subpart D—MCO, PIHP and PAHP Standards

§ 438.206 Availability of services.

(a) *Basic rule.* Each State must ensure that all services covered under the State plan are available and accessible to enrollees of MCOs, PIHPs, and PAHPs in a timely manner. The State must also ensure that MCO, PIHP and PAHP provider networks for services covered under the contract meet the standards developed by the State in accordance with § 438.68.

(b) *Delivery network.* The State must ensure, through its contracts, that each MCO, PIHP and PAHP, consistent with the scope of its contracted services, meets the following requirements:

(1) Maintains and monitors a network of appropriate providers that is supported by written agreements and is sufficient to provide adequate access to all services covered under the contract for all enrollees, including those with limited English proficiency or physical or mental disabilities.

(2) Provides female enrollees with direct access to a women's health specialist within the provider network for covered care necessary to provide women's routine and preventive health care services. This is in addition to the enrollee's designated source of primary care if that source is not a women's health specialist.

(3) Provides for a second opinion from a network provider, or arranges for the enrollee to obtain one outside the network, at no cost to the enrollee.

(4) If the provider network is unable to provide necessary services, covered under the contract, to a particular enrollee, the MCO, PIHP, or PAHP must adequately and timely cover these services out of network for the enrollee, for as long as the MCO, PIHP, or PAHP's provider network is unable to provide them.

(5) Requires out-of-network providers to coordinate with the MCO, PIHP, or PAHP for payment and ensures the cost to the enrollee is no greater than it would be if the services were furnished within the network.

(6) Demonstrates that its network providers are credentialed as required by § 438.214.

(7) Demonstrates that its network includes sufficient family planning providers to ensure timely access to covered services.

(c) *Furnishing of services.* The State must ensure that each contract with a MCO, PIHP, and PAHP complies with the following requirements.

(1) *Timely access.* Each MCO, PIHP, and PAHP must do the following:

(i) Meet and require its network providers to meet State standards for timely access to care and services, taking into account the urgency of the need for services.

(ii) Ensure that the network providers offer hours of operation that are no less than the hours of operation offered to commercial enrollees or comparable to Medicaid FFS, if the provider serves only Medicaid enrollees.

(iii) Make services included in the contract available 24 hours a day, 7 days a week, when medically necessary.

(iv) Establish mechanisms to ensure compliance by network providers.

(v) Monitor network providers regularly to determine compliance.

(vi) Take corrective action if there is a failure to comply by a network provider.

(2) *Access and cultural considerations.* Each MCO, PIHP, and PAHP participates in the State's efforts to promote the delivery of services in a culturally competent manner to all enrollees, including those with limited English proficiency and diverse cultural and ethnic backgrounds, disabilities, and regardless of gender, sexual orientation or gender identity.

(3) *Accessibility considerations.* Each MCO, PIHP, and PAHP must ensure that network providers provide physical access, reasonable accommodations, and accessible equipment for Medicaid enrollees with physical or mental disabilities.

(d) *Applicability date.* This section applies to the rating period for contracts with MCOs, PIHPs, and PAHPs beginning on or after July 1, 2018. Until that applicability date, states are required to continue to comply with § 438.206 contained in the 42 CFR parts 430 to 481, edition revised as of October 1, 2015.

§ 438.207 Assurances of adequate capacity and services.

(a) *Basic rule.* The State must ensure, through its contracts, that each MCO, PIHP, and PAHP gives assurances to the State and provides supporting documentation that demonstrates that it has the capacity to serve the expected enrollment in its service area in accordance with the State's standards for access to care under this part, including the standards at § 438.68 and § 438.206(c)(1).

(b) *Nature of supporting documentation.* Each MCO, PIHP, and PAHP must submit documentation to the State, in a format specified by the State, to demonstrate that it complies with the following requirements:

(1) Offers an appropriate range of preventive, primary care, specialty services, and LTSS that is adequate for the anticipated number of enrollees for the service area.

(2) Maintains a network of providers that is sufficient in number, mix, and geographic distribution to meet the needs of the anticipated number of enrollees in the service area.

(c) *Timing of documentation.* Each MCO, PIHP, and PAHP must submit the documentation described in paragraph (b) of this section as specified by the State, but no less frequently than the following:

(1) At the time it enters into a contract with the State.

(2) On an annual basis.

(3) At any time there has been a significant change (as defined by the State) in the MCO's, PIHP's, or PAHP's operations that would affect the adequacy of capacity and services, including—

(i) Changes in MCO, PIHP, or PAHP services, benefits, geographic service area, composition of or payments to its provider network; or

(ii) Enrollment of a new population in the MCO, PIHP, or PAHP.

(d) *State review and certification to CMS.* After the State reviews the documentation submitted by the MCO, PIHP, or PAHP, the State must submit an assurance of compliance to CMS that the MCO, PIHP, or PAHP meets the State's requirements for availability of services, as set forth in § 438.68 and § 438.206. The submission to CMS must include documentation of an analysis that supports the assurance of the adequacy of the network for each contracted MCO, PIHP or PAHP related to its provider network.

(e) *CMS' right to inspect documentation.* The State must make available to CMS, upon request, all documentation collected by the State from the MCO, PIHP, or PAHP.

(f) *Applicability date.* This section applies to the rating period for contracts with MCOs, PIHPs, and PAHPs beginning on or after July 1, 2018. Until that applicability date, states are required to continue to comply with § 438.207 contained in the 42 CFR parts 430 to 481, edition revised as of October 1, 2015.

§ 438.208 Coordination and continuity of care.

(a) *Basic requirement—*(1) *General rule.* Except as specified in paragraphs (a)(2) and (3) of this section, the State must ensure through its contracts, that each MCO, PIHP, and PAHP complies with the requirements of this section.

(2) *PIHP and PAHP exception.* For PIHPs and PAHPs, the State determines, based on the scope of the entity's services, and on the way the State has organized the delivery of managed care services, whether a particular PIHP or PAHP is required to implement mechanisms for identifying, assessing, and producing a treatment plan for an individual with special health care needs, as specified in paragraph (c) of this section.

(3) *Exception for MCOs that serve dually eligible enrollees.* (i) For each MCO that serves enrollees who are also enrolled in and receive Medicare benefits from a Medicare Advantage Organization (as defined in § 422.2 of this chapter), the State determines to what extent the MCO must meet the identification, assessment, and treatment planning provisions of paragraph (c) of this section for dually eligible individuals.

(ii) The State bases its determination on the needs of the population it requires the MCO to serve.

(b) *Care and coordination of services for all MCO, PIHP, and PAHP enrollees.* Each MCO, PIHP, and PAHP must implement procedures to deliver care to and coordinate services for all MCO, PIHP, and PAHP enrollees. These procedures must meet State requirements and must do the following:

(1) Ensure that each enrollee has an ongoing source of care appropriate to his or her needs and a person or entity formally designated as primarily responsible for coordinating the services accessed by the enrollee. The enrollee must be provided information on how to contact their designated person or entity;

(2) Coordinate the services the MCO, PIHP, or PAHP furnishes to the enrollee;

(i) Between settings of care, including appropriate discharge planning for short term and long-term hospital and institutional stays;

(ii) With the services the enrollee receives from any other MCO, PIHP, or PAHP;

(iii) With the services the enrollee receives in FFS Medicaid; and

(iv) With the services the enrollee receives from community and social support providers.

(3) Provide that the MCO, PIHP or PAHP makes a best effort to conduct an initial screening of each enrollee's needs, within 90 days of the effective date of enrollment for all new enrollees, including subsequent attempts if the initial attempt to contact the enrollee is unsuccessful;

(4) Share with the State or other MCOs, PIHPs, and PAHPs serving the enrollee the results of any identification and assessment of that enrollee's needs to prevent duplication of those activities;

(5) Ensure that each provider furnishing services to enrollees maintains and shares, as appropriate, an enrollee health record in accordance with professional standards; and

(6) Ensure that in the process of coordinating care, each enrollee's privacy is protected in accordance with the privacy requirements in 45 CFR parts 160 and 164 subparts A and E, to the extent that they are applicable.

(c) *Additional services for enrollees with special health care needs or who need LTSS—*(1) *Identification.* The State must implement mechanisms to identify persons who need LTSS or persons with special health care needs to MCOs, PIHPs and PAHPs, as those persons are defined by the State. These identification mechanisms—

(i) Must be specified in the State's quality strategy under § 438.340.

(ii) May use State staff, the State's enrollment broker, or the State's MCOs, PIHPs and PAHPs.

(2) *Assessment.* Each MCO, PIHP, and PAHP must implement mechanisms to comprehensively assess each Medicaid enrollee identified by the State (through the mechanism specified in paragraph (c)(1) of this section) and identified to the MCO, PIHP, and PAHP by the State as needing LTSS or having special health care needs to identify any ongoing special conditions of the enrollee that require a course of treatment or regular care monitoring. The assessment mechanisms must use appropriate providers or individuals meeting LTSS service coordination requirements of the State or the MCO, PIHP, or PAHP as appropriate.

(3) *Treatment/service plans.* MCOs, PIHPs, or PAHPs must produce a treatment or service plan meeting the criteria in paragraphs (c)(3)(i) through (v) of this section for enrollees who

require LTSS and, if the State requires, must produce a treatment or service plan meeting the criteria in paragraphs (c)(3)(iii) through (v) of this section for enrollees with special health care needs that are determined through assessment to need a course of treatment or regular care monitoring. The treatment or service plan must be:

- (i) Developed by an individual meeting LTSS service coordination requirements with enrollee participation, and in consultation with any providers caring for the enrollee;
- (ii) Developed by a person trained in person-centered planning using a person-centered process and plan as defined in § 441.301(c)(1) and (2) of this chapter for LTSS treatment or service plans;
- (iii) Approved by the MCO, PIHP, or PAHP in a timely manner, if this approval is required by the MCO, PIHP, or PAHP;
- (iv) In accordance with any applicable State quality assurance and utilization review standards; and
- (v) Reviewed and revised upon reassessment of functional need, at least every 12 months, or when the enrollee's circumstances or needs change significantly, or at the request of the enrollee per § 441.301(c)(3) of this chapter.

(4) *Direct access to specialists.* For enrollees with special health care needs determined through an assessment (consistent with paragraph (c)(2) of this section) to need a course of treatment or regular care monitoring, each MCO, PIHP, and PAHP must have a mechanism in place to allow enrollees to directly access a specialist (for example, through a standing referral or an approved number of visits) as appropriate for the enrollee's condition and identified needs.

(d) *Applicability date.* This section applies to the rating period for contracts with MCOs, PIHPs, and PAHPs beginning on or after July 1, 2017. Until that applicability date, states are required to continue to comply with § 438.208 contained in the 42 CFR parts 430 to 481, edition revised as of October 1, 2015.

§ 438.210 Coverage and authorization of services.

(a) *Coverage.* Each contract between a State and an MCO, PIHP, or PAHP must do the following:

(1) Identify, define, and specify the amount, duration, and scope of each service that the MCO, PIHP, or PAHP is required to offer.

(2) Require that the services identified in paragraph (a)(1) of this section be furnished in an amount, duration, and

scope that is no less than the amount, duration, and scope for the same services furnished to beneficiaries under FFS Medicaid, as set forth in § 440.230 of this chapter, and for enrollees under the age of 21, as set forth in subpart B of part 440 of this chapter.

(3) Provide that the MCO, PIHP, or PAHP—

(i) Must ensure that the services are sufficient in amount, duration, or scope to reasonably achieve the purpose for which the services are furnished.

(ii) May not arbitrarily deny or reduce the amount, duration, or scope of a required service solely because of diagnosis, type of illness, or condition of the beneficiary.

(4) Permit an MCO, PIHP, or PAHP to place appropriate limits on a service—

(i) On the basis of criteria applied under the State plan, such as medical necessity; or

(ii) For the purpose of utilization control, provided that—

(A) The services furnished can reasonably achieve their purpose, as required in paragraph (a)(3)(i) of this section;

(B) The services supporting individuals with ongoing or chronic conditions or who require long-term services and supports are authorized in a manner that reflects the enrollee's ongoing need for such services and supports; and

(C) Family planning services are provided in a manner that protects and enables the enrollee's freedom to choose the method of family planning to be used consistent with § 441.20 of this chapter.

(5) Specify what constitutes "medically necessary services" in a manner that—

(i) Is no more restrictive than that used in the State Medicaid program, including quantitative and non-quantitative treatment limits, as indicated in State statutes and regulations, the State Plan, and other State policy and procedures; and

(ii) Addresses the extent to which the MCO, PIHP, or PAHP is responsible for covering services that address:

(A) The prevention, diagnosis, and treatment of an enrollee's disease, condition, and/or disorder that results in health impairments and/or disability.

(B) The ability for an enrollee to achieve age-appropriate growth and development.

(C) The ability for an enrollee to attain, maintain, or regain functional capacity.

(D) The opportunity for an enrollee receiving long-term services and supports to have access to the benefits of community living, to achieve person-

centered goals, and live and work in the setting of their choice.

(b) *Authorization of services.* For the processing of requests for initial and continuing authorizations of services, each contract must require—

(1) That the MCO, PIHP, or PAHP and its subcontractors have in place, and follow, written policies and procedures.

(2) That the MCO, PIHP, or PAHP—

(i) Have in effect mechanisms to ensure consistent application of review criteria for authorization decisions.

(ii) Consult with the requesting provider for medical services when appropriate.

(iii) Authorize LTSS based on an enrollee's current needs assessment and consistent with the person-centered service plan.

(3) That any decision to deny a service authorization request or to authorize a service in an amount, duration, or scope that is less than requested, be made by an individual who has appropriate expertise in addressing the enrollee's medical, behavioral health, or long-term services and supports needs.

(c) *Notice of adverse benefit determination.* Each contract must provide for the MCO, PIHP, or PAHP to notify the requesting provider, and give the enrollee written notice of any decision by the MCO, PIHP, or PAHP to deny a service authorization request, or to authorize a service in an amount, duration, or scope that is less than requested. For MCOs, PIHPs, and PAHPs, the enrollee's notice must meet the requirements of § 438.404.

(d) *Timeframe for decisions.* Each MCO, PIHP, or PAHP contract must provide for the following decisions and notices:

(1) *Standard authorization decisions.* For standard authorization decisions, provide notice as expeditiously as the enrollee's condition requires and within State-established timeframes that may not exceed 14 calendar days following receipt of the request for service, with a possible extension of up to 14 additional calendar days, if—

(i) The enrollee, or the provider, requests extension; or

(ii) The MCO, PIHP, or PAHP justifies (to the State agency upon request) a need for additional information and how the extension is in the enrollee's interest.

(2) *Expedited authorization decisions.*

(i) For cases in which a provider indicates, or the MCO, PIHP, or PAHP determines, that following the standard timeframe could seriously jeopardize the enrollee's life or health or ability to attain, maintain, or regain maximum function, the MCO, PIHP, or PAHP must

make an expedited authorization decision and provide notice as expeditiously as the enrollee's health condition requires and no later than 72 hours after receipt of the request for service.

(ii) The MCO, PIHP, or PAHP may extend the 72 hour time period by up to 14 calendar days if the enrollee requests an extension, or if the MCO, PIHP, or PAHP justifies (to the State agency upon request) a need for additional information and how the extension is in the enrollee's interest.

(3) *Covered outpatient drug decisions.* For all covered outpatient drug authorization decisions, provide notice as described in section 1927(d)(5)(A) of the Act.

(e) *Compensation for utilization management activities.* Each contract between a State and MCO, PIHP, or PAHP must provide that, consistent with § 438.3(i), and § 422.208 of this chapter, compensation to individuals or entities that conduct utilization management activities is not structured so as to provide incentives for the individual or entity to deny, limit, or discontinue medically necessary services to any enrollee.

(f) *Applicability date.* This section applies to the rating period for contracts with MCOs, PIHPs, and PAHPs beginning on or after July 1, 2017. Until that applicability date, states are required to continue to comply with § 438.210 contained in the 42 CFR parts 430 to 481, edition revised as of October 1, 2015.

§ 438.214 Provider selection.

(a) *General rules.* The State must ensure, through its contracts, that each MCO, PIHP, or PAHP implements written policies and procedures for selection and retention of network providers and that those policies and procedures, at a minimum, meet the requirements of this section.

(b) *Credentialing and recredentialing requirements.* (1) Each State must establish a uniform credentialing and recredentialing policy that addresses acute, primary, behavioral, substance use disorders, and LTSS providers, as appropriate, and requires each MCO, PIHP and PAHP to follow those policies. (2) Each MCO, PIHP, and PAHP must follow a documented process for credentialing and recredentialing of network providers.

(c) *Nondiscrimination.* MCO, PIHP, and PAHP network provider selection policies and procedures, consistent with § 438.12, must not discriminate against particular providers that serve high-risk populations or specialize in conditions that require costly treatment.

(d) *Excluded providers.* (1) MCOs, PIHPs, and PAHPs may not employ or contract with providers excluded from participation in Federal health care programs under either section 1128 or section 1128A of the Act.

(e) *State requirements.* Each MCO, PIHP, and PAHP must comply with any additional requirements established by the State.

§ 438.224 Confidentiality.

The State must ensure, through its contracts, that (consistent with subpart F of part 431 of this chapter), for medical records and any other health and enrollment information that identifies a particular enrollee, each MCO, PIHP, and PAHP uses and discloses such individually identifiable health information in accordance with the privacy requirements in 45 CFR parts 160 and 164, subparts A and E, to the extent that these requirements are applicable.

§ 438.228 Grievance and appeal systems.

(a) The State must ensure, through its contracts, that each MCO, PIHP, and PAHP has in effect a grievance and appeal system that meets the requirements of subpart F of this part.

(b) If the State delegates to the MCO, PIHP, or PAHP responsibility for notice of action under subpart E of part 431 of this chapter, the State must conduct random reviews of each delegated MCO, PIHP, or PAHP and its providers and subcontractors to ensure that they are notifying enrollees in a timely manner.

§ 438.230 Subcontractual relationships and delegation.

(a) *Applicability.* The requirements of this section apply to any contract or written arrangement that an MCO, PIHP, PAHP, or PCCM entity has with any subcontractor.

(b) *General rule.* The State must ensure, through its contracts with MCOs, PIHPs, PAHPs, and PCCM entities that—

(1) Notwithstanding any relationship(s) that the MCO, PIHP, PAHP, or PCCM entity may have with any subcontractor, the MCO, PIHP, PAHP, or PCCM entity maintains ultimate responsibility for adhering to and otherwise fully complying with all terms and conditions of its contract with the State; and

(2) All contracts or written arrangements between the MCO, PIHP, PAHP, or PCCM entity and any subcontractor must meet the requirements of paragraph (c) of this section.

(c) Each contract or written arrangement described in paragraph (b)(2) of this section must specify that:

(1) If any of the MCO's, PIHP's, PAHP's, or PCCM entity's activities or obligations under its contract with the State are delegated to a subcontractor—

(i) The delegated activities or obligations, and related reporting responsibilities, are specified in the contract or written agreement.

(ii) The subcontractor agrees to perform the delegated activities and reporting responsibilities specified in compliance with the MCO's, PIHP's, PAHP's, or PCCM entity's contract obligations.

(iii) The contract or written arrangement must either provide for revocation of the delegation of activities or obligations, or specify other remedies in instances where the State or the MCO, PIHP, PAHP, or PCCM entity determine that the subcontractor has not performed satisfactorily.

(2) The subcontractor agrees to comply with all applicable Medicaid laws, regulations, including applicable subregulatory guidance and contract provisions;

(3) The subcontractor agrees that—

(i) The State, CMS, the HHS Inspector General, the Comptroller General, or their designees have the right to audit, evaluate, and inspect any books, records, contracts, computer or other electronic systems of the subcontractor, or of the subcontractor's contractor, that pertain to any aspect of services and activities performed, or determination of amounts payable under the MCO's, PIHP's, or PAHP's contract with the State.

(ii) The subcontractor will make available, for purposes of an audit, evaluation, or inspection under paragraph (c)(3)(i) of this section, its premises, physical facilities, equipment, books, records, contracts, computer or other electronic systems relating to its Medicaid enrollees.

(iii) The right to audit under paragraph (c)(3)(i) of this section will exist through 10 years from the final date of the contract period or from the date of completion of any audit, whichever is later.

(iv) If the State, CMS, or the HHS Inspector General determines that there is a reasonable possibility of fraud or similar risk, the State, CMS, or the HHS Inspector General may inspect, evaluate, and audit the subcontractor at any time.

(d) *Applicability date.* This section applies to the rating period for contracts with MCOs, PIHPs, PAHPs, and PCCM entities beginning on or after July 1, 2017. Until that applicability date, states are required to continue to comply with § 438.230 contained in the 42 CFR parts 430 to 481, edition revised as of October 1, 2015.

§ 438.236 Practice guidelines.

(a) *Basic rule.* The State must ensure, through its contracts, that each MCO, PIHP, and PAHP meets the requirements of this section.

(b) *Adoption of practice guidelines.* Each MCO and, when applicable, each PIHP and PAHP adopts practice guidelines that meet the following requirements:

(1) Are based on valid and reliable clinical evidence or a consensus of providers in the particular field.

(2) Consider the needs of the MCO's, PIHP's, or PAHP's enrollees.

(3) Are adopted in consultation with contracting health care professionals.

(4) Are reviewed and updated periodically as appropriate.

(c) *Dissemination of guidelines.* Each MCO, PIHP, and PAHP disseminates the guidelines to all affected providers and, upon request, to enrollees and potential enrollees.

(d) *Application of guidelines.* Decisions for utilization management, enrollee education, coverage of services, and other areas to which the guidelines apply are consistent with the guidelines.

§ 438.242 Health information systems.

(a) *General rule.* The State must ensure, through its contracts that each MCO, PIHP, and PAHP maintains a health information system that collects, analyzes, integrates, and reports data and can achieve the objectives of this part. The systems must provide information on areas including, but not limited to, utilization, claims, grievances and appeals, and disenrollments for other than loss of Medicaid eligibility.

(b) *Basic elements of a health information system.* The State must require, at a minimum, that each MCO, PIHP, and PAHP comply with the following:

(1) Section 6504(a) of the Affordable Care Act, which requires that State claims processing and retrieval systems are able to collect data elements necessary to enable the mechanized claims processing and information retrieval systems in operation by the State to meet the requirements of section 1903(r)(1)(F) of the Act.

(2) Collect data on enrollee and provider characteristics as specified by the State, and on all services furnished to enrollees through an encounter data system or other methods as may be specified by the State.

(3) Ensure that data received from providers is accurate and complete by—

(i) Verifying the accuracy and timeliness of reported data, including data from network providers the MCO,

PIHP, or PAHP is compensating on the basis of capitation payments.

(ii) Screening the data for completeness, logic, and consistency.

(iii) Collecting data from providers in standardized formats to the extent feasible and appropriate, including secure information exchanges and technologies utilized for State Medicaid quality improvement and care coordination efforts.

(4) Make all collected data available to the State and upon request to CMS.

(c) *Enrollee encounter data.* Contracts between a State and a MCO, PIHP, or PAHP must provide for:

(1) Collection and maintenance of sufficient enrollee encounter data to identify the provider who delivers any item(s) or service(s) to enrollees.

(2) Submission of enrollee encounter data to the State at a frequency and level of detail to be specified by CMS and the State, based on program administration, oversight, and program integrity needs.

(3) Submission of all enrollee encounter data that the State is required to report to CMS under § 438.818.

(4) Specifications for submitting encounter data to the State in standardized ASC X12N 837 and NCPDP formats, and the ASC X12N 835 format as appropriate.

(d) *State review and validation of encounter data.* The State must review and validate that the encounter data collected, maintained, and submitted to the State by the MCO, PIHP, or PAHP, meets the requirements of this section. The State must have procedures and quality assurance protocols to ensure that enrollee encounter data submitted under paragraph (c) of this section is a complete and accurate representation of the services provided to the enrollees under the contract between the State and the MCO, PIHP, or PAHP.

(e) *Applicability date.* This section applies to the rating period for contracts with MCOs, PIHPs, PAHPs, and PCCM entities beginning on or after July 1, 2017. Until that applicability date, states are required to continue to comply with § 438.242 contained in the 42 CFR parts 430 to 481, edition revised as of October 1, 2015.

Subpart E—Quality Measurement and Improvement; External Quality Review**§ 438.310 Basis, scope, and applicability.**

(a) *Statutory basis.* This subpart is based on sections 1932(c), 1903(a)(3)(C)(ii), 1902(a)(4), and 1902(a)(19) of the Act.

(b) *Scope.* This subpart sets forth:

(1) Specifications for a quality assessment and performance improvement program that States must

require each contracting MCO, PIHP, and PAHP to implement and maintain.

(2) Requirements for the State review of the accreditation status of all contracting MCOs, PIHPs, and PAHPs.

(3) Specifications for a Medicaid managed care quality rating system for all States contracting with MCOs, PIHPs, and PAHPs.

(4) Specifications for a Medicaid managed care quality strategy that States contracting with MCOs, PIHPs, PAHPs, and PCCM entities (described in paragraph (c)(2) of this section) must implement to ensure the delivery of quality health care.

(5) Requirements for annual external quality reviews of each contracting MCO, PIHP, PAHP and PCCM entity (described in paragraph (c)(2) of this section) including—

(i) Criteria that States must use in selecting entities to perform the reviews.

(ii) Specifications for the activities related to external quality review.

(iii) Circumstances under which external quality review may use the results of Medicare quality reviews or private accreditation reviews.

(iv) Requirements for making the results of the reviews publicly available.

(c) *Applicability.* (1) The provisions of this subpart apply to States contracting with MCOs, PIHPs, and PAHPs for the delivery of services covered under Medicaid.

(2) The provisions of § 438.330(b)(2), (b)(3), (c), and (e), § 438.340, and § 438.350 apply to States contracting with PCCM entities whose contracts with the State provide for shared savings, incentive payments or other financial reward for the PCCM entity for improved quality outcomes.

(d) *Applicability dates.* States will not be held out of compliance with the following requirements of this subpart prior to the dates noted below so long as they comply with the corresponding standard(s) in 42 CFR part 438 contained in the 42 CFR parts 430 to 481, edition revised as of October 1, 2015:

(1) States must comply with § 438.330 and § 438.332 no later than the rating period for contracts beginning on or after July 1, 2017.

(2) States must comply with § 438.340, § 438.350, § 438.354, § 438.356, § 438.358, § 438.360, § 438.362, and § 438.364 no later than July 1, 2018.

§ 438.320 Definitions.

As used in this subpart—

Access, as it pertains to external quality review, means the timely use of services to achieve optimal outcomes, as evidenced by managed care plans

successfully demonstrating and reporting on outcome information for the availability and timeliness elements defined under § 438.68 (Network adequacy standards) and § 438.206 (Availability of services).

EQR stands for external quality review.

EQRO stands for external quality review organization.

External quality review means the analysis and evaluation by an EQRO, of aggregated information on quality, timeliness, and access to the health care services that an MCO, PIHP, PAHP, or PCCM entity (described in § 438.310(c)(2)), or their contractors furnish to Medicaid beneficiaries.

External quality review organization means an organization that meets the competence and independence requirements set forth in § 438.354, and performs external quality review, other EQR-related activities as set forth in § 438.358, or both.

Financial relationship means—

(1) A direct or indirect ownership or investment interest (including an option or nonvested interest) in any entity. This direct or indirect interest may be in the form of equity, debt, or other means, and includes any indirect ownership or investment interest no matter how many levels removed from a direct interest; or

(2) A compensation arrangement with an entity.

Health care services means all Medicaid services provided by an MCO, PIHP, or PAHP under contract with the State Medicaid agency in any setting, including but not limited to medical care, behavioral health care, and long-term services and supports.

Outcomes means changes in patient health, functional status, satisfaction or goal achievement that result from health care or supportive services.

Quality, as it pertains to external quality review, means the degree to which an MCO, PIHP, PAHP, or PCCM entity (described in § 438.310(c)(2)) increases the likelihood of desired outcomes of its enrollees through:

(1) Its structural and operational characteristics.

(2) The provision of services that are consistent with current professional, evidenced-based-knowledge.

(3) Interventions for performance improvement.

Validation means the review of information, data, and procedures to determine the extent to which they are accurate, reliable, free from bias, and in accord with standards for data collection and analysis.

§ 438.330 Quality assessment and performance improvement program.

(a) *General rules.* (1) The State must require, through its contracts, that each MCO, PIHP, and PAHP establish and implement an ongoing comprehensive quality assessment and performance improvement program for the services it furnishes to its enrollees that includes the elements identified in paragraph (b) of this section.

(2) After consulting with States and other stakeholders and providing public notice and opportunity to comment, CMS may specify performance measures and PIPs, which must be included in the standard measures identified and PIPs required by the State in accordance with paragraphs (c) and (d) of this section. A State may request an exemption from including the performance measures or PIPs established under paragraph (a)(2) of this section, by submitting a written request to CMS explaining the basis for such request.

(3) The State must require, through its contracts, that each PCCM entity described in § 438.310(c)(2) establish and implement an ongoing comprehensive quality assessment and performance improvement program for the services it furnishes to its enrollees which incorporates, at a minimum, paragraphs (b)(2) and (3) of this section and the performance measures identified by the State per paragraph (c) of this section.

(b) *Basic elements of quality assessment and performance improvement programs.* The comprehensive quality assessment and performance improvement program described in paragraph (a) of this section must include at least the following elements:

(1) Performance improvement projects in accordance with paragraph (d) of this section.

(2) Collection and submission of performance measurement data in accordance with paragraph (c) of this section.

(3) Mechanisms to detect both underutilization and overutilization of services.

(4) Mechanisms to assess the quality and appropriateness of care furnished to enrollees with special health care needs, as defined by the State in the quality strategy under § 438.340.

(5) For MCOs, PIHPs, or PAHPs providing long-term services and supports:

(i) Mechanisms to assess the quality and appropriateness of care furnished to enrollees using long-term services and supports, including assessment of care between care settings and a comparison of services and supports received with

those set forth in the enrollee's treatment/service plan, if applicable; and

(ii) Participate in efforts by the State to prevent, detect, and remediate critical incidents (consistent with assuring beneficiary health and welfare per §§ 441.302 and 441.730(a) of this chapter) that are based, at a minimum, on the requirements on the State for home and community-based waiver programs per § 441.302(h) of this chapter.

(c) *Performance measurement.* The State must—

(1)(i) Identify standard performance measures, including those performance measures that may be specified by CMS under paragraph (a)(2) of this section, relating to the performance of MCOs, PIHPs, and PAHPs; and

(ii) In addition to the measures specified in paragraph (c)(1)(i) of this section, in the case of an MCO, PIHP, or PAHP providing long-term services and supports, identify standard performance measures relating to quality of life, rebalancing, and community integration activities for individuals receiving long-term services and supports.

(2) Require that each MCO, PIHP, and PAHP annually—

(i) Measure and report to the State on its performance, using the standard measures required by the State in paragraph (c)(1) of this section;

(ii) Submit to the State data, specified by the State, which enables the State to calculate the MCO's, PIHP's, or PAHP's performance using the standard measures identified by the State under paragraph (c)(1) of this section; or

(iii) Perform a combination of the activities described in paragraphs (c)(2)(i) and (ii) of this section.

(d) *Performance improvement projects.* (1) The State must require that MCOs, PIHPs, and PAHPs conduct performance improvement projects, including any performance improvement projects required by CMS in accordance with paragraph (a)(2) of this section, that focus on both clinical and nonclinical areas.

(2) Each performance improvement project must be designed to achieve significant improvement, sustained over time, in health outcomes and enrollee satisfaction, and must include the following elements:

(i) Measurement of performance using objective quality indicators.

(ii) Implementation of interventions to achieve improvement in the access to and quality of care.

(iii) Evaluation of the effectiveness of the interventions based on the performance measures in paragraph (d)(2)(i) of this section.

(iv) Planning and initiation of activities for increasing or sustaining improvement.

(3) The State must require each MCO, PIHP, and PAHP to report the status and results of each project conducted per paragraph (d)(1) of this section to the State as requested, but not less than once per year.

(4) The State may permit an MCO, PIHP, or PAHP exclusively serving dual eligibles to substitute an MA Organization quality improvement project conducted under § 422.152(d) of this chapter for one or more of the performance improvement projects otherwise required under this section.

(e) *Program review by the State.* (1) The State must review, at least annually, the impact and effectiveness of the quality assessment and performance improvement program of each MCO, PIHP, PAHP, and PCCM entity described in § 438.310(c)(2). The review must include—

(i) The MCO's, PIHP's, PAHP's, and PCCM entity's performance on the measures on which it is required to report.

(ii) The outcomes and trended results of each MCO's, PIHP's, and PAHP's performance improvement projects.

(iii) The results of any efforts by the MCO, PIHP, or PAHP to support community integration for enrollees using long-term services and supports.

(2) The State may require that an MCO, PIHP, PAHP, or PCCM entity described in § 438.310(c)(2) develop a process to evaluate the impact and effectiveness of its own quality assessment and performance improvement program.

§ 438.332 State review of the accreditation status of MCOs, PIHPs, and PAHPs.

(a) The State must require, through its contracts, that each MCO, PIHP, and PAHP inform the State whether it has been accredited by a private independent accrediting entity.

(b) The State must require, through its contracts, that each MCO, PIHP, and PAHP that has received accreditation by a private independent accrediting entity must authorize the private independent accrediting entity to provide the State a copy of its most recent accreditation review, including:

(1) Accreditation status, survey type, and level (as applicable);

(2) Accreditation results, including recommended actions or improvements, corrective action plans, and summaries of findings; and

(3) Expiration date of the accreditation.

(c) The State must—

(1) Make the accreditation status for each contracted MCO, PIHP, and PAHP

available on the Web site required under § 438.10(c)(3), including whether each MCO, PIHP, and PAHP has been accredited and, if applicable, the name of the accrediting entity, accreditation program, and accreditation level; and

(2) Update this information at least annually.

§ 438.334 Medicaid managed care quality rating system.

(a) *General rule.* Each State contracting with an MCO, PIHP or PAHP to furnish services to Medicaid beneficiaries must—

(1) Adopt the Medicaid managed care quality rating system developed by CMS in accordance with paragraph (b) of this section; or

(2) Adopt an alternative Medicaid managed care quality rating system in accordance with paragraph (c) of this section.

(3) Implement such Medicaid managed care quality rating system within 3 years of the date of a final notice published in the **Federal Register**.

(b) *Quality rating system.* CMS, in consultation with States and other stakeholders and after providing public notice and opportunity to comment, will identify performance measures and a methodology for a Medicaid managed care quality rating system that aligns with the summary indicators of the qualified health plan quality rating system developed per 45 CFR 156.1120.

(c) *Alternative quality rating system.*

(1) A State may submit a request to CMS for approval to use an alternative Medicaid managed care quality rating system that utilizes different performance measures or applies a different methodology from that described in paragraph (b) of this section provided that—

(i) The ratings generated by the alternative Medicaid managed care quality rating system yield information regarding MCO, PIHP, and PAHP performance which is substantially comparable to that yielded by the Medicaid managed care quality rating system described in paragraph (b) of this section; and,

(ii) The state receive CMS approval prior to implementing an alternative quality rating system or modifications to an approved alternative Medicaid managed care quality rating system.

(2) Prior to submitting a request for, or modification of, an alternative Medicaid managed care quality rating system to CMS, the State must—

(i) Obtain input from the State's Medical Care Advisory Committee established under § 431.12 of this chapter; and

(ii) Provide an opportunity for public comment of at least 30 days on the proposed alternative Medicaid managed care quality rating system or modification.

(3) The State must document in the request to CMS the public comment process utilized by the State including discussion of the issues raised by the Medical Care Advisory Committee and the public. The request must document any policy revisions or modifications made in response to the comments and rationale for comments not accepted.

(d) *Quality ratings.* Each year, the State must collect data from each MCO, PIHP, and PAHP with which it contracts and issue an annual quality rating for each MCO, PIHP, and PAHP based on the data collected, using the Medicaid managed care quality rating system adopted under this section.

(e) *Availability of information.* The State must prominently display the quality rating given by the State to each MCO, PIHP, or PAHP under paragraph (d) of this section on the Web site required under § 438.10(c)(3) in a manner that complies with the standards in § 438.10(d).

§ 438.340 Managed care State quality strategy.

(a) *General rule.* Each State contracting with an MCO, PIHP, or PAHP as defined in § 438.2 or with a PCCM entity as described in § 438.310(c)(2) must draft and implement a written quality strategy for assessing and improving the quality of health care and services furnished by the MCO, PIHP, PAHP or PCCM entity.

(b) *Elements of the State quality strategy.* At a minimum, the State's quality strategy must include the following:

(1) The State-defined network adequacy and availability of services standards for MCOs, PIHPs, and PAHPs required by §§ 438.68 and 438.206 and examples of evidence-based clinical practice guidelines the State requires in accordance with § 438.236.

(2) The State's goals and objectives for continuous quality improvement which must be measurable and take into consideration the health status of all populations in the State served by the MCO, PIHP, and PAHP.

(3) A description of—

(i) The quality metrics and performance targets to be used in measuring the performance and improvement of each MCO, PIHP, and PAHP with which the State contracts, including but not limited to, the performance measures reported in accordance with § 438.330(c). The State must identify which quality measures

and performance outcomes the State will publish at least annually on the Web site required under § 438.10(c)(3); and

(ii) The performance improvement projects to be implemented in accordance with § 438.330(d), including a description of any interventions the State proposes to improve access, quality, or timeliness of care for beneficiaries enrolled in an MCO, PIHP, or PAHP.

(4) Arrangements for annual, external independent reviews, in accordance with § 438.350, of the quality outcomes and timeliness of, and access to, the services covered under each MCO, PIHP, PAHP, and PCCM entity (described in § 438.310(c)(2)) contract.

(5) A description of the State's transition of care policy required under § 438.62(b)(3).

(6) The State's plan to identify, evaluate, and reduce, to the extent practicable, health disparities based on age, race, ethnicity, sex, primary language, and disability status. States must identify this demographic information for each Medicaid enrollee and provide it to the MCO, PIHP or PAHP at the time of enrollment. For purposes of this paragraph (b)(6), "disability status" means whether the individual qualified for Medicaid on the basis of a disability.

(7) For MCOs, appropriate use of intermediate sanctions that, at a minimum, meet the requirements of subpart I of this part.

(8) A description of how the State will assess the performance and quality outcomes achieved by each PCCM entity described in § 438.310(c)(2).

(9) The mechanisms implemented by the State to comply with § 438.208(c)(1) (relating to the identification of persons who need long-term services and supports or persons with special health care needs).

(10) The information required under § 438.360(c) (relating to nonduplication of EQR activities); and

(11) The State's definition of a "significant change" for the purposes of paragraph (c)(3)(ii) of this section.

(c) *Development, evaluation, and revision.* In drafting or revising its quality strategy, the State must:

(1) Make the strategy available for public comment before submitting the strategy to CMS for review, including:

(i) Obtaining input from the Medical Care Advisory Committee (established by § 431.12 of this chapter), beneficiaries, and other stakeholders.

(ii) If the State enrolls Indians in the MCO, PIHP, or PAHP, consulting with Tribes in accordance with the State's Tribal consultation policy.

(2) Review and update the quality strategy as needed, but no less than once every 3 years.

(i) This review must include an evaluation of the effectiveness of the quality strategy conducted within the previous 3 years.

(ii) The State must make the results of the review available on the Web site required under § 438.10(c)(3).

(iii) Updates to the quality strategy must take into consideration the recommendations provided pursuant to § 438.364(a)(4).

(3) Submit to CMS the following:

(i) A copy of the initial strategy for CMS comment and feedback prior to adopting it in final.

(ii) A copy of the revised strategy whenever significant changes, as defined in the state's quality strategy per paragraph (b)(11) of this section, are made to the document, or whenever significant changes occur within the State's Medicaid program.

(d) *Availability.* The State must make the final quality strategy available on the Web site required under § 438.10(c)(3).

§ 438.350 External quality review.

Each State that contracts with MCOs, PIHPs, or PAHPs, or with PCCM entities (described in § 438.310(c)(2)) must ensure that—

(a) Except as provided in § 438.362, a qualified EQRO performs an annual EQR for each such contracting MCO, PIHP, PAHP or PCCM entity (described in § 438.310(c)(2)).

(b) The EQRO has sufficient information to use in performing the review.

(c) The information used to carry out the review must be obtained from the EQR-related activities described in § 438.358 or, if applicable, from a Medicare or private accreditation review as described in § 438.360.

(d) For each EQR-related activity, the information gathered for use in the EQR must include the elements described in § 438.364(a)(1)(i) through (iv).

(e) The information provided to the EQRO in accordance with paragraph (b) of this section is obtained through methods consistent with the protocols established by the Secretary in accordance with § 438.352.

(f) The results of the reviews are made available as specified in § 438.364.

§ 438.352 External quality review protocols.

The Secretary, in coordination with the National Governor's Association, must develop protocols for the external quality reviews required under this subpart. Each protocol issued by the Secretary must specify—

(a) The data to be gathered;
(b) The sources of the data;
(c) The activities and steps to be followed in collecting the data to promote its accuracy, validity, and reliability;

(d) The proposed method or methods for validly analyzing and interpreting the data once obtained; and

(e) Instructions, guidelines, worksheets, and other documents or tools necessary for implementing the protocol.

§ 438.354 Qualifications of external quality review organizations.

(a) *General rule.* The State must ensure that an EQRO meets the requirements of this section.

(b) *Competence.* The EQRO must have at a minimum the following:

(1) Staff with demonstrated experience and knowledge of—

(i) Medicaid beneficiaries, policies, data systems, and processes;

(ii) Managed care delivery systems, organizations, and financing;

(iii) Quality assessment and improvement methods; and

(iv) Research design and methodology, including statistical analysis.

(2) Sufficient physical, technological, and financial resources to conduct EQR or EQR-related activities.

(3) Other clinical and nonclinical skills necessary to carry out EQR or EQR-related activities and to oversee the work of any subcontractors.

(c) *Independence.* The EQRO and its subcontractors must be independent from the State Medicaid agency and from the MCOs, PIHPs, PAHPs, or PCCM entities (described in § 438.310(c)(2)) that they review. To qualify as "independent"—

(1) If a State agency, department, university, or other State entity:

(i) May not have Medicaid purchasing or managed care licensing authority; and

(ii) Must be governed by a Board or similar body the majority of whose members are not government employees.

(2) An EQRO may not:

(i) Review any MCO, PIHP, PAHP, or PCCM entity (described in § 438.310(c)(2)), or a competitor operating in the State, over which the EQRO exerts control or which exerts control over the EQRO (as used in this paragraph, "control" has the meaning given the term in 48 CFR 19.101) through—

(A) Stock ownership;

(B) Stock options and convertible debentures;

(C) Voting trusts;

(D) Common management, including interlocking management; and
(E) Contractual relationships.

(ii) Deliver any health care services to Medicaid beneficiaries;

(iii) Conduct, on the State's behalf, ongoing Medicaid managed care program operations related to oversight of the quality of MCO, PIHP, PAHP, or PCCM entity (described in § 438.310(c)(2)) services, except for the related activities specified in § 438.358;

(iv) Review any MCO, PIHP, PAHP or PCCM entity (described in § 438.310(c)(2)) for which it is conducting or has conducted an accreditation review within the previous 3 years; or

(v) Have a present, or known future, direct or indirect financial relationship with an MCO, PIHP, PAHP, or PCCM entity (described in § 438.310(c)(2)) that it will review as an EQRO.

§ 438.356 State contract options for external quality review.

(a) The State—

(1) Must contract with one EQRO to conduct either EQR alone or EQR and other EQR-related activities.

(2) May contract with additional EQROs or other entities to conduct EQR-related activities as set forth in § 438.358.

(b) Each EQRO must meet the competence requirements as specified in § 438.354(b).

(c) Each EQRO is permitted to use subcontractors. The EQRO is accountable for, and must oversee, all subcontractor functions.

(d) Each EQRO and its subcontractors performing EQR or EQR-related activities must meet the requirements for independence, as specified in § 438.354(c).

(e) For each contract with an EQRO described in paragraph (a) of this section, the State must follow an open, competitive procurement process that is in accordance with State law and regulations. In addition, the State must comply with 45 CFR part 75 as it applies to State procurement of Medicaid services.

§ 438.358 Activities related to external quality review.

(a) *General rule.* (1) The State, its agent that is not an MCO, PIHP, PAHP, or PCCM entity (described in § 438.310(c)(2)), or an EQRO may perform the mandatory and optional EQR-related activities in this section.

(2) The data obtained from the mandatory and optional EQR-related activities in this section must be used for the annual EQR in § 438.350 and must include, at a minimum, the elements in § 438.364(a)(i) through (iv).

(b) *Mandatory activities.* (1) For each MCO, PIHP, or PAHP the following EQR-related activities must be performed:

(i) Validation of performance improvement projects required in accordance with § 438.330(b)(1) that were underway during the preceding 12 months.

(ii) Validation of MCO, PIHP, or PAHP performance measures required in accordance with § 438.330(b)(2) or MCO, PIHP, or PAHP performance measures calculated by the State during the preceding 12 months.

(iii) A review, conducted within the previous 3-year period, to determine the MCO's, PIHP's, or PAHP's compliance with the standards set forth in subpart D of this part and the quality assessment and performance improvement requirements described in § 438.330.

(iv) Validation of MCO, PIHP, or PAHP network adequacy during the preceding 12 months to comply with requirements set forth in § 438.68 and, if the State enrolls Indians in the MCO, PIHP, or PAHP, § 438.14(b)(1).

(2) For each PCCM entity (described in § 438.310(c)(2)), the EQR-related activities in paragraphs (b)(1)(ii) and (iii) of this section must be performed.

(c) *Optional activities.* For each MCO, PIHP, PAHP, and PCCM entity (described in § 438.310(c)(2)), the following activities may be performed by using information derived during the preceding 12 months:

(1) Validation of encounter data reported by an MCO, PIHP, PAHP, or PCCM entity (described in § 438.310(c)(2)).

(2) Administration or validation of consumer or provider surveys of quality of care.

(3) Calculation of performance measures in addition to those reported by an MCO, PIHP, PAHP, or PCCM entity (described in § 438.310(c)(2)) and validated by an EQRO in accordance with (b)(2) of this section.

(4) Conduct of performance improvement projects in addition to those conducted by an MCO, PIHP, PAHP, or PCCM entity (described in § 438.310(c)(2)) and validated by an EQRO in accordance with (b)(1) of this section.

(5) Conduct of studies on quality that focus on a particular aspect of clinical or nonclinical services at a point in time.

(6) Assist with the quality rating of MCOs, PIHPs, and PAHPs consistent with § 438.334.

(d) *Technical assistance.* The EQRO may, at the State's direction, provide technical guidance to groups of MCOs, PIHPs, PAHPs, or PCCM entities

(described in § 438.310(c)(2)) to assist them in conducting activities related to the mandatory and optional activities described in this section that provide information for the EQR and the resulting EQR technical report.

§ 438.360 Nonduplication of mandatory activities with Medicare or accreditation review.

(a) *General rule.* Consistent with guidance issued by the Secretary under § 438.352, to avoid duplication the State may use information from a Medicare or private accreditation review of an MCO, PIHP, or PAHP to provide information for the annual EQR (described in § 438.350) instead of conducting one or more of the EQR activities described in § 438.358(b)(1)(i) through (iii) (relating to the validation of performance improvement projects, validation of performance measures, and compliance review) if the following conditions are met:

(1) The MCO, PIHP, or PAHP is in compliance with the applicable Medicare Advantage standards established by CMS, as determined by CMS or its contractor for Medicare, or has obtained accreditation from a private accrediting organization recognized by CMS as applying standards at least as stringent as Medicare under the procedures in § 422.158 of this chapter;

(2) The Medicare or private accreditation review standards are comparable to standards established through the EQR protocols (§ 438.352) for the EQR activities described in § 438.358(b)(1)(i) through (iii); and

(3) The MCO, PIHP, or PAHP provides to the State all the reports, findings, and other results of the Medicare or private accreditation review activities applicable to the standards for the EQR activities.

(b) *External quality review report.* If the State uses information from a Medicare or private accreditation review in accordance with paragraph (a) of this section, the State must ensure that all such information is furnished to the EQRO for analysis and inclusion in the report described in § 438.364(a).

(c) *Quality strategy.* The State must identify in its quality strategy under § 438.340 the EQR activities for which it has exercised the option described in this section, and explain the rationale for the State's determination that the Medicare review or private accreditation activity is comparable to such EQR activities, consistent with paragraph (a)(2) of this section.

§ 438.362 Exemption from external quality review.

(a) *Basis for exemption.* The State may exempt an MCO from EQR if the following conditions are met:

(1) The MCO has a current Medicare contract under part C of Title XVIII or under section 1876 of the Act, and a current Medicaid contract under section 1903(m) of the Act.

(2) The two contracts cover all or part of the same geographic area within the State.

(3) The Medicaid contract has been in effect for at least 2 consecutive years before the effective date of the exemption and during those 2 years the MCO has been subject to EQR under this part, and found to be performing acceptably for the quality, timeliness, and access to health care services it provides to Medicaid beneficiaries.

(b) *Information on exempted MCOs.* When the State exercises this option, the State must obtain either of the following:

(1) *Information on Medicare review findings.* Each year, the State must obtain from each MCO that it exempts from EQR the most recent Medicare review findings reported on the MCO including—

(i) All data, correspondence, information, and findings pertaining to the MCO's compliance with Medicare standards for access, quality assessment and performance improvement, health services, or delegation of these activities.

(ii) All measures of the MCO's performance.

(iii) The findings and results of all performance improvement projects pertaining to Medicare enrollees.

(2) *Medicare information from a private, national accrediting organization that CMS approves and recognizes for Medicare Advantage Organization deeming.* (i) If an exempted MCO has been reviewed by a private accrediting organization, the State must require the MCO to provide the State with a copy of all findings pertaining to its most recent accreditation review if that review has been used for either of the following purposes:

(A) To fulfill certain requirements for Medicare external review under subpart D of part 422 of this chapter.

(B) To deem compliance with Medicare requirements, as provided in § 422.156 of this chapter.

(ii) These findings must include, but need not be limited to, accreditation review results of evaluation of compliance with individual accreditation standards, noted deficiencies, corrective action plans,

and summaries of unmet accreditation requirements.

§ 438.364 External quality review results.

(a) *Information that must be produced.* The State must ensure that the EQR results in an annual detailed technical report that summarizes findings on access and quality of care, including:

(1) A description of the manner in which the data from all activities conducted in accordance with § 438.358 were aggregated and analyzed, and conclusions were drawn as to the quality, timeliness, and access to the care furnished by the MCO, PIHP, PAHP, or PCCM entity (described in § 438.310(c)(2)).

(2) For each EQR-related activity conducted in accordance with § 438.358:

(i) Objectives;

(ii) Technical methods of data collection and analysis;

(iii) Description of data obtained, including validated performance measurement data for each activity conducted in accordance with § 438.358(b)(1)(i) and (ii); and

(iv) Conclusions drawn from the data.

(3) An assessment of each MCO's, PIHP's, PAHP's, or PCCM entity's (described in § 438.310(c)(2)) strengths and weaknesses for the quality, timeliness, and access to health care services furnished to Medicaid beneficiaries.

(4) Recommendations for improving the quality of health care services furnished by each MCO, PIHP, PAHP, or PCCM entity (described in § 438.310(c)(2)) including how the State can target goals and objectives in the quality strategy, under § 438.340, to better support improvement in the quality, timeliness, and access to health care services furnished to Medicaid beneficiaries.

(5) Methodologically appropriate, comparative information about all MCOs, PIHPs, PAHPs, and PCCM entities (described in § 438.310(c)(2)), consistent with guidance included in the EQR protocols issued in accordance with § 438.352(e).

(6) An assessment of the degree to which each MCO, PIHP, PAHP, or PCCM entity (described in § 438.310(c)(2)) has addressed effectively the recommendations for quality improvement made by the EQRO during the previous year's EQR.

(b) *Revision.* States may not substantively revise the content of the final EQR technical report without evidence of error or omission.

(c) *Availability of information.* (1) The State must contract with a qualified

EQRO to produce and submit to the State an annual EQR technical report in accordance with paragraph (a) of this section. The State must finalize the annual technical report by April 30th of each year.

(2) The State must—

(i) Post the most recent copy of the annual EQR technical report on the Web site required under § 438.10(c)(3) by April 30th of each year.

(ii) Provide printed or electronic copies of the information specified in paragraph (a) of this section, upon request, to interested parties such as participating health care providers, enrollees and potential enrollees of the MCO, PIHP, PAHP, or PCCM entity (described in § 438.310(c)(2)), beneficiary advocacy groups, and members of the general public.

(3) The State must make the information specified in paragraph (a) of this section available in alternative formats for persons with disabilities, when requested.

(d) *Safeguarding patient identity.* The information released under paragraph (b) of this section may not disclose the identity or other protected health information of any patient.

§ 438.370 Federal financial participation (FFP).

(a) FFP at the 75 percent rate is available in expenditures for EQR (including the production of EQR results) and the EQR-related activities set forth in § 438.358 performed on MCOs and conducted by EQROs and their subcontractors.

(b) FFP at the 50 percent rate is available in expenditures for EQR-related activities conducted by any entity that does not qualify as an EQRO, and for EQR (including the production of EQR results) and EQR-related activities performed by an EQRO on entities other than MCOs.

(c) Prior to claiming FFP at the 75 percent rate in accordance with paragraph (a) of this section, the State must submit each EQRO contract to CMS for review and approval.

Subpart F—Grievance and Appeal System**§ 438.400 Statutory basis, definitions, and applicability.**

(a) *Statutory basis.* This subpart is based on the following statutory sections:

(1) Section 1902(a)(3) of the Act requires that a State plan provide an opportunity for a fair hearing to any person whose claim for assistance is denied or not acted upon promptly.

(2) Section 1902(a)(4) of the Act requires that the State plan provide for

methods of administration that the Secretary finds necessary for the proper and efficient operation of the plan.

(3) Section 1932(b)(4) of the Act requires Medicaid managed care organizations to establish internal grievance procedures under which Medicaid enrollees, or providers acting on their behalf, may challenge the denial of coverage of, or payment for, medical assistance.

(b) *Definitions.* As used in this subpart, the following terms have the indicated meanings:

Adverse benefit determination means, in the case of an MCO, PIHP, or PAHP, any of the following:

(1) The denial or limited authorization of a requested service, including determinations based on the type or level of service, requirements for medical necessity, appropriateness, setting, or effectiveness of a covered benefit.

(2) The reduction, suspension, or termination of a previously authorized service.

(3) The denial, in whole or in part, of payment for a service.

(4) The failure to provide services in a timely manner, as defined by the State.

(5) The failure of an MCO, PIHP, or PAHP to act within the timeframes provided in § 438.408(b)(1) and (2) regarding the standard resolution of grievances and appeals.

(6) For a resident of a rural area with only one MCO, the denial of an enrollee's request to exercise his or her right, under § 438.52(b)(2)(ii), to obtain services outside the network.

(7) The denial of an enrollee's request to dispute a financial liability, including cost sharing, copayments, premiums, deductibles, coinsurance, and other enrollee financial liabilities.

Appeal means a review by an MCO, PIHP, or PAHP of an adverse benefit determination.

Grievance means an expression of dissatisfaction about any matter other than an adverse benefit determination. Grievances may include, but are not limited to, the quality of care or services provided, and aspects of interpersonal relationships such as rudeness of a provider or employee, or failure to respect the enrollee's rights regardless of whether remedial action is requested. Grievance includes an enrollee's right to dispute an extension of time proposed by the MCO, PIHP or PAHP to make an authorization decision.

Grievance and appeal system means the processes the MCO, PIHP, or PAHP implements to handle appeals of an adverse benefit determination and grievances, as well as the processes to

collect and track information about them.

State fair hearing means the process set forth in subpart E of part 431 of this chapter.

(c) *Applicability.* This subpart applies to the rating period for contracts with MCOs, PIHPs, and PAHPs beginning on or after July 1, 2017. Until that applicability date, states, MCOs, PIHPs, and PAHPs are required to continue to comply with subpart F contained in the 42 CFR parts 430 to 481, edition revised as of October 1, 2015.

§ 438.402 General requirements.

(a) *The grievance and appeal system.* Each MCO, PIHP, and PAHP must have a grievance and appeal system in place for enrollees. Non-emergency medical transportation PAHPs, as defined in § 438.9, are not subject to this subpart F.

(b) *Level of appeals.* Each MCO, PIHP, and PAHP may have only one level of appeal for enrollees.

(c) *Filing requirements—(1) Authority to file.* (i) An enrollee may file a grievance and request an appeal with the MCO, PIHP, or PAHP. An enrollee may request a State fair hearing after receiving notice under § 438.408 that the adverse benefit determination is upheld.

(A) *Deemed exhaustion of appeals processes.* In the case of an MCO, PIHP, or PAHP that fails to adhere to the notice and timing requirements in § 438.408, the enrollee is deemed to have exhausted the MCO's, PIHP's, or PAHP's appeals process. The enrollee may initiate a State fair hearing.

(B) *External medical review.* The State may offer and arrange for an external medical review if the following conditions are met.

(1) The review must be at the enrollee's option and must not be required before or used as a deterrent to proceeding to the State fair hearing.

(2) The review must be independent of both the State and MCO, PIHP, or PAHP.

(3) The review must be offered without any cost to the enrollee.

(4) The review must not extend any of the timeframes specified in § 438.408 and must not disrupt the continuation of benefits in § 438.420.

(ii) If State law permits and with the written consent of the enrollee, a provider or an authorized representative may request an appeal or file a grievance, or request a State fair hearing, on behalf of an enrollee. When the term "enrollee" is used throughout subpart F of this part, it includes providers and authorized representatives consistent with this paragraph, with the exception that providers cannot request

continuation of benefits as specified in § 438.420(b)(5).

(2) *Timing—(i) Grievance.* An enrollee may file a grievance with the MCO, PIHP, or PAHP at any time.

(ii) *Appeal.* Following receipt of a notification of an adverse benefit determination by an MCO, PIHP, or PAHP, an enrollee has 60 calendar days from the date on the adverse benefit determination notice in which to file a request for an appeal to the managed care plan.

(3) *Procedures—(i) Grievance.* The enrollee may file a grievance either orally or in writing and, as determined by the State, either with the State or with the MCO, PIHP, or PAHP.

(ii) *Appeal.* The enrollee may request an appeal either orally or in writing. Further, unless the enrollee requests an expedited resolution, an oral appeal must be followed by a written, signed appeal.

§ 438.404 Timely and adequate notice of adverse benefit determination.

(a) *Notice.* The MCO, PIHP, or PAHP must give enrollees timely and adequate notice of an adverse benefit determination in writing consistent with the requirements below and in § 438.10.

(b) *Content of notice.* The notice must explain the following:

(1) The adverse benefit determination the MCO, PIHP, or PAHP has made or intends to make.

(2) The reasons for the adverse benefit determination, including the right of the enrollee to be provided upon request and free of charge, reasonable access to and copies of all documents, records, and other information relevant to the enrollee's adverse benefit determination. Such information includes medical necessity criteria, and any processes, strategies, or evidentiary standards used in setting coverage limits.

(3) The enrollee's right to request an appeal of the MCO's, PIHP's, or PAHP's adverse benefit determination, including information on exhausting the MCO's, PIHP's, or PAHP's one level of appeal described at § 438.402(b) and the right to request a State fair hearing consistent with § 438.402(c).

(4) The procedures for exercising the rights specified in this paragraph (b).

(5) The circumstances under which an appeal process can be expedited and how to request it.

(6) The enrollee's right to have benefits continue pending resolution of the appeal, how to request that benefits be continued, and the circumstances, consistent with state policy, under which the enrollee may be required to pay the costs of these services.

(c) *Timing of notice.* The MCO, PIHP, or PAHP must mail the notice within the following timeframes:

(1) For termination, suspension, or reduction of previously authorized Medicaid-covered services, within the timeframes specified in §§ 431.211, 431.213, and 431.214 of this chapter.

(2) For denial of payment, at the time of any action affecting the claim.

(3) For standard service authorization decisions that deny or limit services, within the timeframe specified in § 438.210(d)(1).

(4) If the MCO, PIHP, or PAHP meets the criteria set forth for extending the timeframe for standard service authorization decisions consistent with § 438.210(d)(1)(ii), it must—

(i) Give the enrollee written notice of the reason for the decision to extend the timeframe and inform the enrollee of the right to file a grievance if he or she disagrees with that decision; and

(ii) Issue and carry out its determination as expeditiously as the enrollee's health condition requires and no later than the date the extension expires.

(5) For service authorization decisions not reached within the timeframes specified in § 438.210(d) (which constitutes a denial and is thus an adverse benefit determination), on the date that the timeframes expire.

(6) For expedited service authorization decisions, within the timeframes specified in § 438.210(d)(2).

§ 438.406 Handling of grievances and appeals.

(a) *General requirements.* In handling grievances and appeals, each MCO, PIHP, and PAHP must give enrollees any reasonable assistance in completing forms and taking other procedural steps related to a grievance or appeal. This includes, but is not limited to, auxiliary aids and services upon request, such as providing interpreter services and toll-free numbers that have adequate TTY/TTD and interpreter capability.

(b) *Special requirements.* An MCO's, PIHP's or PAHP's process for handling enrollee grievances and appeals of adverse benefit determinations must:

(1) Acknowledge receipt of each grievance and appeal.

(2) Ensure that the individuals who make decisions on grievances and appeals are individuals—

(i) Who were neither involved in any previous level of review or decision-making nor a subordinate of any such individual.

(ii) Who, if deciding any of the following, are individuals who have the appropriate clinical expertise, as determined by the State, in treating the enrollee's condition or disease.

(A) An appeal of a denial that is based on lack of medical necessity.

(B) A grievance regarding denial of expedited resolution of an appeal.

(C) A grievance or appeal that involves clinical issues.

(iii) Who take into account all comments, documents, records, and other information submitted by the enrollee or their representative without regard to whether such information was submitted or considered in the initial adverse benefit determination.

(3) Provide that oral inquiries seeking to appeal an adverse benefit determination are treated as appeals (to establish the earliest possible filing date for the appeal) and must be confirmed in writing, unless the enrollee or the provider requests expedited resolution.

(4) Provide the enrollee a reasonable opportunity, in person and in writing, to present evidence and testimony and make legal and factual arguments. The MCO, PIHP, or PAHP must inform the enrollee of the limited time available for this sufficiently in advance of the resolution timeframe for appeals as specified in § 438.408(b) and (c) in the case of expedited resolution.

(5) Provide the enrollee and his or her representative the enrollee's case file, including medical records, other documents and records, and any new or additional evidence considered, relied upon, or generated by the MCO, PIHP or PAHP (or at the direction of the MCO, PIHP or PAHP) in connection with the appeal of the adverse benefit determination. This information must be provided free of charge and sufficiently in advance of the resolution timeframe for appeals as specified in § 438.408(b) and (c).

(6) Include, as parties to the appeal—

(i) The enrollee and his or her representative; or

(ii) The legal representative of a deceased enrollee's estate.

§ 438.408 Resolution and notification: Grievances and appeals.

(a) *Basic rule.* Each MCO, PIHP, or PAHP must resolve each grievance and appeal, and provide notice, as expeditiously as the enrollee's health condition requires, within State-established timeframes that may not exceed the timeframes specified in this section.

(b) *Specific timeframes—(1) Standard resolution of grievances.* For standard resolution of a grievance and notice to the affected parties, the timeframe is established by the State but may not exceed 90 calendar days from the day the MCO, PIHP, or PAHP receives the grievance.

(2) *Standard resolution of appeals.* For standard resolution of an appeal and

notice to the affected parties, the State must establish a timeframe that is no longer than 30 calendar days from the day the MCO, PIHP, or PAHP receives the appeal. This timeframe may be extended under paragraph (c) of this section.

(3) *Expedited resolution of appeals.* For expedited resolution of an appeal and notice to affected parties, the State must establish a timeframe that is no longer than 72 hours after the MCO, PIHP, or PAHP receives the appeal. This timeframe may be extended under paragraph (c) of this section.

(c) *Extension of timeframes.* (1) The MCO, PIHP, or PAHP may extend the timeframes from paragraph (b) of this section by up to 14 calendar days if—

(i) The enrollee requests the extension; or

(ii) The MCO, PIHP, or PAHP shows (to the satisfaction of the State agency, upon its request) that there is need for additional information and how the delay is in the enrollee's interest.

(2) *Requirements following extension.* If the MCO, PIHP, or PAHP extends the timeframes not at the request of the enrollee, it must complete all of the following:

(i) Make reasonable efforts to give the enrollee prompt oral notice of the delay.

(ii) Within 2 calendar days give the enrollee written notice of the reason for the decision to extend the timeframe and inform the enrollee of the right to file a grievance if he or she disagrees with that decision.

(iii) Resolve the appeal as expeditiously as the enrollee's health condition requires and no later than the date the extension expires.

(3) *Deemed exhaustion of appeals processes.* In the case of an MCO, PIHP, or PAHP that fails to adhere to the notice and timing requirements in this section, the enrollee is deemed to have exhausted the MCO's, PIHP's, or PAHP's appeals process. The enrollee may initiate a State fair hearing.

(d) *Format of notice—(1) Grievances.* The State must establish the method that an MCO, PIHP, and PAHP will use to notify an enrollee of the resolution of a grievance and ensure that such methods meet, at a minimum, the standards described at § 438.10.

(2) *Appeals.* (i) For all appeals, the MCO, PIHP, or PAHP must provide written notice of resolution in a format and language that, at a minimum, meet the standards described at § 438.10.

(ii) For notice of an expedited resolution, the MCO, PIHP, or PAHP must also make reasonable efforts to provide oral notice.

(e) *Content of notice of appeal resolution.* The written notice of the resolution must include the following:

- (1) The results of the resolution process and the date it was completed.
- (2) For appeals not resolved wholly in favor of the enrollees—
 - (i) The right to request a State fair hearing, and how to do so.
 - (ii) The right to request and receive benefits while the hearing is pending, and how to make the request.
 - (iii) That the enrollee may, consistent with state policy, be held liable for the cost of those benefits if the hearing decision upholds the MCO's, PIHP's, or PAHP's adverse benefit determination.

(f) *Requirements for State fair hearings—(1) Availability.* An enrollee may request a State fair hearing only after receiving notice that the MCO, PIHP, or PAHP is upholding the adverse benefit determination.

(i) *Deemed exhaustion of appeals processes.* In the case of an MCO, PIHP, or PAHP that fails to adhere to the notice and timing requirements in § 438.408, the enrollee is deemed to have exhausted the MCO's, PIHP's, or PAHP's appeals process. The enrollee may initiate a State fair hearing.

(ii) *External medical review.* The State may offer and arrange for an external medical review if the following conditions are met.

(A) The review must be at the enrollee's option and must not be required before or used as a deterrent to proceeding to the State fair hearing.

(B) The review must be independent of both the State and MCO, PIHP, or PAHP.

(C) The review must be offered without any cost to the enrollee.

(D) The review must not extend any of the timeframes specified in § 438.408 and must not disrupt the continuation of benefits in § 438.420.

(2) *State fair hearing.* The enrollee must request a State fair hearing no later than 120 calendar days from the date of the MCO's, PIHP's, or PAHP's notice of resolution.

(3) *Parties.* The parties to the State fair hearing include the MCO, PIHP, or PAHP, as well as the enrollee and his or her representative or the representative of a deceased enrollee's estate.

§ 438.410 Expedited resolution of appeals.

(a) *General rule.* Each MCO, PIHP, and PAHP must establish and maintain an expedited review process for appeals, when the MCO, PIHP, or PAHP determines (for a request from the enrollee) or the provider indicates (in making the request on the enrollee's behalf or supporting the enrollee's request) that taking the time for a

standard resolution could seriously jeopardize the enrollee's life, physical or mental health, or ability to attain, maintain, or regain maximum function.

(b) *Punitive action.* The MCO, PIHP, or PAHP must ensure that punitive action is not taken against a provider who requests an expedited resolution or supports an enrollee's appeal.

(c) *Action following denial of a request for expedited resolution.* If the MCO, PIHP, or PAHP denies a request for expedited resolution of an appeal, it must—

(1) Transfer the appeal to the timeframe for standard resolution in accordance with § 438.408(b)(2).

(2) Follow the requirements in § 438.408(c)(2).

§ 438.414 Information about the grievance and appeal system to providers and subcontractors.

The MCO, PIHP, or PAHP must provide information specified in § 438.10(g)(2)(xi) about the grievance and appeal system to all providers and subcontractors at the time they enter into a contract.

§ 438.416 Recordkeeping requirements.

(a) The State must require MCOs, PIHPs, and PAHPs to maintain records of grievances and appeals and must review the information as part of its ongoing monitoring procedures, as well as for updates and revisions to the State quality strategy.

(b) The record of each grievance or appeal must contain, at a minimum, all of the following information:

(1) A general description of the reason for the appeal or grievance.

(2) The date received.

(3) The date of each review or, if applicable, review meeting.

(4) Resolution at each level of the appeal or grievance, if applicable.

(5) Date of resolution at each level, if applicable.

(6) Name of the covered person for whom the appeal or grievance was filed.

(c) The record must be accurately maintained in a manner accessible to the state and available upon request to CMS.

§ 438.420 Continuation of benefits while the MCO, PIHP, or PAHP appeal and the State fair hearing are pending.

(a) *Definition.* As used in this section—

Timely files means files for continuation of benefits on or before the later of the following:

(i) Within 10 calendar days of the MCO, PIHP, or PAHP sending the notice of adverse benefit determination.

(ii) The intended effective date of the MCO's, PIHP's, or PAHP's proposed adverse benefit determination.

(b) *Continuation of benefits.* The MCO, PIHP, or PAHP must continue the enrollee's benefits if all of the following occur:

(1) The enrollee files the request for an appeal timely in accordance with § 438.402(c)(1)(ii) and (c)(2)(ii);

(2) The appeal involves the termination, suspension, or reduction of previously authorized services;

(3) The services were ordered by an authorized provider;

(4) The period covered by the original authorization has not expired; and

(5) The enrollee timely files for continuation of benefits.

(c) *Duration of continued or reinstated benefits.* If, at the enrollee's request, the MCO, PIHP, or PAHP continues or reinstates the enrollee's benefits while the appeal or state fair hearing is pending, the benefits must be continued until one of the following occurs:

(1) The enrollee withdraws the appeal or request for state fair hearing.

(2) The enrollee fails to request a state fair hearing and continuation of benefits within 10 calendar days after the MCO, PIHP, or PAHP sends the notice of an adverse resolution to the enrollee's appeal under § 438.408(d)(2).

(3) A State fair hearing office issues a hearing decision adverse to the enrollee.

(d) *Enrollee responsibility for services furnished while the appeal or state fair hearing is pending.* If the final resolution of the appeal or state fair hearing is adverse to the enrollee, that is, upholds the MCO's, PIHP's, or PAHP's adverse benefit determination, the MCO, PIHP, or PAHP may, consistent with the state's usual policy on recoveries under § 431.230(b) of this chapter and as specified in the MCO's, PIHP's, or PAHP's contract, recover the cost of services furnished to the enrollee while the appeal and state fair hearing was pending, to the extent that they were furnished solely because of the requirements of this section.

§ 438.424 Effectuation of reversed appeal resolutions.

(a) *Services not furnished while the appeal is pending.* If the MCO, PIHP, or PAHP, or the State fair hearing officer reverses a decision to deny, limit, or delay services that were not furnished while the appeal was pending, the MCO, PIHP, or PAHP must authorize or provide the disputed services promptly and as expeditiously as the enrollee's health condition requires but no later than 72 hours from the date it receives notice reversing the determination.

(b) *Services furnished while the appeal is pending.* If the MCO, PIHP, or PAHP, or the State fair hearing officer reverses a decision to deny

authorization of services, and the enrollee received the disputed services while the appeal was pending, the MCO, PIHP, or PAHP, or the State must pay for those services, in accordance with State policy and regulations.

Subpart G—[Reserved]

Subpart H—Additional Program Integrity Safeguards

§ 438.600 Statutory basis, basic rule, and applicability.

(a) *Statutory basis.* This subpart is based on the following statutory sections:

(1) Section 1128 of the Act provides for the exclusion of certain individuals and entities from participation in the Medicaid program.

(2) Section 1128J(d) of the Act requires that persons who have received an overpayment under Medicaid report and return the overpayment within 60 days after the date on which the overpayment was identified.

(3) Section 1902(a)(4) of the Act requires that the State plan provide for methods of administration that the Secretary finds necessary for the proper and efficient operation of the plan.

(4) Section 1902(a)(19) of the Act requires that the State plan provide the safeguards necessary to ensure that eligibility is determined and services are provided in a manner consistent with simplicity of administration and the best interests of the beneficiaries.

(5) Section 1902(a)(27) of the Act requires States to enroll persons or institutions that provide services under the State plan.

(6) Section 1902(a)(68) of the Act requires that any entity that receives or makes annual payments under the State plan of at least \$5,000,000 must establish certain minimum written policies relating to the Federal False Claims Act.

(7) Section 1902(a)(77) of the Act requires that States comply with provider and supplier screening, oversight, and reporting requirements described in section 1902(kk)(1) of the Act.

(8) Section 1902(a)(80) of the Act prohibits payments for items or services provided under the State plan or under a waiver to any financial institution or entity located outside of the United States.

(9) Section 1902(kk)(7) of the Act requires States to enroll physicians or other professionals that order or refer services under the State plan.

(10) Section 1903(i) of the Act prohibits FFP for amounts expended by MCOs or PCCMs for providers excluded

by Medicare, Medicaid, or CHIP, except for emergency services.

(11) Section 1903(m) of the Act establishes conditions for payments to the State for contracts with MCOs.

(12) Section 1932(d)(1) of the Act prohibits MCOs and PCCMs from knowingly having certain types of relationships with individuals and entities debarred under Federal regulations from participating in specified activities, or with affiliates of those individuals.

(b) *Basic rule.* As a condition for receiving payment under a Medicaid managed care program, an MCO, PIHP, PAHP, PCCM or PCCM entity must comply with the requirements in §§ 438.604, 438.606, 438.608 and 438.610, as applicable.

(c) *Applicability.* States will not be held out compliance with the following requirements of this subpart prior to the dates noted below so long as they comply with the corresponding standard(s) in 42 CFR part 438 contained in the CFR, parts 430 to 481, edition revised as of October 1, 2015:

(1) States must comply with §§ 438.602(a), 438.602(c) through (h), 438.604, 438.606, 438.608(a), and 438.608(c) and (d), no later than the rating period for contracts starting on or after July 1, 2017.

(2) States must comply with § 438.602(b) and § 438.608(b) no later than the rating period for contracts beginning on or after July 1, 2018.

§ 438.602 State responsibilities.

(a) *Monitoring contractor compliance.* Consistent with § 438.66, the State must monitor the MCO's, PIHP's, PAHP's, PCCM's or PCCM entity's compliance, as applicable, with §§ 438.604, 438.606, 438.608, 438.610, 438.230, and 438.808.

(b) *Screening and enrollment and revalidation of providers.* (1) The State must screen and enroll, and periodically revalidate, all network providers of MCOs, PIHPs, and PAHPs, in accordance with the requirements of part 455, subparts B and E of this chapter. This requirement extends to PCCMs and PCCM entities to the extent the primary care case manager is not otherwise enrolled with the State to provide services to FFS beneficiaries. This provision does not require the network provider to render services to FFS beneficiaries.

(2) MCOs, PIHPs, and PAHPs may execute network provider agreements pending the outcome of the process in paragraph (b)(1) of this section of up to 120 days, but must terminate a network provider immediately upon notification from the State that the network provider cannot be enrolled, or the expiration of

one 120 day period without enrollment of the provider, and notify affected enrollees.

(c) *Ownership and control information.* The State must review the ownership and control disclosures submitted by the MCO, PIHP, PAHP, PCCM or PCCM entity, and any subcontractors as required in § 438.608(c).

(d) *Federal database checks.* Consistent with the requirements at § 455.436 of this chapter, the State must confirm the identity and determine the exclusion status of the MCO, PIHP, PAHP, PCCM or PCCM entity, any subcontractor, as well as any person with an ownership or control interest, or who is an agent or managing employee of the MCO, PIHP, PAHP, PCCM or PCCM entity through routine checks of Federal databases. This includes the Social Security Administration's Death Master File, the National Plan and Provider Enumeration System (NPPES), the List of Excluded Individuals/Entities (LEIE), the System for Award Management (SAM), and any other databases as the State or Secretary may prescribe. These databases must be consulted upon contracting and no less frequently than monthly thereafter. If the State finds a party that is excluded, it must promptly notify the MCO, PIHP, PAHP, PCCM, or PCCM entity and take action consistent with § 438.610(c).

(e) *Periodic audits.* The State must periodically, but no less frequently than once every 3 years, conduct, or contract for the conduct of, an independent audit of the accuracy, truthfulness, and completeness of the encounter and financial data submitted by, or on behalf of, each MCO, PIHP or PAHP.

(f) *Whistleblowers.* The State must receive and investigate information from whistleblowers relating to the integrity of the MCO, PIHP, PAHP, PCCM, or PCCM entity, subcontractors, or network providers receiving Federal funds under this part.

(g) *Transparency.* The State must post on its Web site, as required in § 438.10(c)(3), the following documents and reports:

(1) The MCO, PIHP, PAHP, or PCCM entity contract.

(2) The data at § 438.604(a)(5).

(3) The name and title of individuals included in § 438.604(a)(6).

(4) The results of any audits under paragraph (e) of this section.

(h) *Contracting integrity.* The State must have in place conflict of interest safeguards described in § 438.58 and must comply with the requirement described in section 1902(a)(4)(C) of the Act applicable to contracting officers, employees, or independent contractors.

(i) *Entities located outside of the U.S.* The State must ensure that the MCO, PIHP, PAHP, PCCM, or PCCM entity with which the State contracts under this part is not located outside of the United States and that no claims paid by an MCO, PIHP, or PAHP to a network provider, out-of-network provider, subcontractor or financial institution located outside of the U.S. are considered in the development of actuarially sound capitation rates.

§ 438.604 Data, information, and documentation that must be submitted.

(a) *Specified data, information, and documentation.* The State must require any MCO, PIHP, PAHP, PCCM or PCCM entity to submit to the State the following data:

(1) Encounter data in the form and manner described in § 438.818.

(2) Data on the basis of which the State certifies the actuarial soundness of capitation rates to an MCO, PIHP or PAHP under § 438.3, including base data described in § 438.5(c) that is generated by the MCO, PIHP or PAHP.

(3) Data on the basis of which the State determines the compliance of the MCO, PIHP, or PAHP with the medical loss ratio requirement described in § 438.8.

(4) Data on the basis of which the State determines that the MCO, PIHP or PAHP has made adequate provision against the risk of insolvency as required under § 438.116.

(5) Documentation described in § 438.207(b) on which the State bases its certification that the MCO, PIHP or PAHP has complied with the State's requirements for availability and accessibility of services, including the adequacy of the provider network, as set forth in § 438.206.

(6) Information on ownership and control described in § 455.104 of this chapter from MCOs, PIHPs, PAHPs, PCCMs, PCCM entities, and subcontractors as governed by § 438.230.

(7) The annual report of overpayment recoveries as required in § 438.608(d)(3).

(b) *Additional data, documentation, or information.* In addition to the data, documentation, or information specified in paragraph (a) of this section, an MCO, PIHP, PAHP, PCCM or PCCM entity must submit any other data, documentation, or information relating to the performance of the entity's obligations under this part required by the State or the Secretary.

§ 438.606 Source, content, and timing of certification.

(a) *Source of certification.* For the data, documentation, or information

specified in § 438.604, the State must require that the data, documentation or information the MCO, PIHP, PAHP, PCCM or PCCM entity submits to the State be certified by either the MCO's, PIHP's, PAHP's, PCCM's, or PCCM entity's Chief Executive Officer; Chief Financial Officer; or an individual who reports directly to the Chief Executive Officer or Chief Financial Officer with delegated authority to sign for the Chief Executive Officer or Chief Financial Officer so that the Chief Executive Officer or Chief Financial Officer is ultimately responsible for the certification.

(b) *Content of certification.* The certification provided by the individual in paragraph (a) of this section must attest that, based on best information, knowledge, and belief, the data, documentation, and information specified in § 438.604 is accurate, complete, and truthful.

(c) *Timing of certification.* The State must require the MCO, PIHP, PAHP, PCCM, or PCCM entity to submit the certification concurrently with the submission of the data, documentation, or information required in § 438.604(a) and (b).

§ 438.608 Program integrity requirements under the contract.

(a) *Administrative and management arrangements or procedures to detect and prevent fraud, waste and abuse.* The State, through its contract with the MCO, PIHP or PAHP, must require that the MCO, PIHP, or PAHP, or subcontractor to the extent that the subcontractor is delegated responsibility by the MCO, PIHP, or PAHP for coverage of services and payment of claims under the contract between the State and the MCO, PIHP, or PAHP, implement and maintain arrangements or procedures that are designed to detect and prevent fraud, waste, and abuse. The arrangements or procedures must include the following:

(1) A compliance program that includes, at a minimum, all of the following elements:

(i) Written policies, procedures, and standards of conduct that articulate the organization's commitment to comply with all applicable requirements and standards under the contract, and all applicable Federal and State requirements.

(ii) The designation of a Compliance Officer who is responsible for developing and implementing policies, procedures, and practices designed to ensure compliance with the requirements of the contract and who reports directly to the Chief Executive Officer and the board of directors.

(iii) The establishment of a Regulatory Compliance Committee on the Board of Directors and at the senior management level charged with overseeing the organization's compliance program and its compliance with the requirements under the contract.

(iv) A system for training and education for the Compliance Officer, the organization's senior management, and the organization's employees for the Federal and State standards and requirements under the contract.

(v) Effective lines of communication between the compliance officer and the organization's employees.

(vi) Enforcement of standards through well-publicized disciplinary guidelines.

(vii) Establishment and implementation of procedures and a system with dedicated staff for routine internal monitoring and auditing of compliance risks, prompt response to compliance issues as they are raised, investigation of potential compliance problems as identified in the course of self-evaluation and audits, correction of such problems promptly and thoroughly (or coordination of suspected criminal acts with law enforcement agencies) to reduce the potential for recurrence, and ongoing compliance with the requirements under the contract.

(2) Provision for prompt reporting of all overpayments identified or recovered, specifying the overpayments due to potential fraud, to the State.

(3) Provision for prompt notification to the State when it receives information about changes in an enrollee's circumstances that may affect the enrollee's eligibility including all of the following:

(i) Changes in the enrollee's residence;

(ii) The death of an enrollee.

(4) Provision for notification to the State when it receives information about a change in a network provider's circumstances that may affect the network provider's eligibility to participate in the managed care program, including the termination of the provider agreement with the MCO, PIHP or PAHP.

(5) Provision for a method to verify, by sampling or other methods, whether services that have been represented to have been delivered by network providers were received by enrollees and the application of such verification processes on a regular basis.

(6) In the case of MCOs, PIHPs, or PAHPs that make or receive annual payments under the contract of at least \$5,000,000, provision for written policies for all employees of the entity, and of any contractor or agent, that provide detailed information about the

False Claims Act and other Federal and State laws described in section 1902(a)(68) of the Act, including information about rights of employees to be protected as whistleblowers.

(7) Provision for the prompt referral of any potential fraud, waste, or abuse that the MCO, PIHP, or PAHP identifies to the State Medicaid program integrity unit or any potential fraud directly to the State Medicaid Fraud Control Unit.

(8) Provision for the MCO's, PIHP's, or PAHP's suspension of payments to a network provider for which the State determines there is a credible allegation of fraud in accordance with § 455.23 of this chapter.

(b) *Provider screening and enrollment requirements.* The State, through its contracts with a MCO, PIHP, PAHP, PCCM, or PCCM entity must ensure that all network providers are enrolled with the State as Medicaid providers consistent with the provider disclosure, screening and enrollment requirements of part 455, subparts B and E of this chapter. This provision does not require the network provider to render services to FFS beneficiaries.

(c) *Disclosures.* The State must ensure, through its contracts, that each MCO, PIHP, PAHP, PCCM, PCCM entity, and any subcontractors:

(1) Provides written disclosure of any prohibited affiliation under § 438.610.

(2) Provides written disclosures of information on ownership and control required under § 455.104 of this chapter.

(3) Reports to the State within 60 calendar days when it has identified the capitation payments or other payments in excess of amounts specified in the contract.

(d) *Treatment of recoveries made by the MCO, PIHP or PAHP of overpayments to providers.* (1) Contracts with a MCO, PIHP, or PAHP must specify:

(i) The retention policies for the treatment of recoveries of all overpayments from the MCO, PIHP, or PAHP to a provider, including specifically the retention policies for the treatment of recoveries of overpayments due to fraud, waste, or abuse.

(ii) The process, timeframes, and documentation required for reporting the recovery of all overpayments.

(iii) The process, timeframes, and documentation required for payment of recoveries of overpayments to the State in situations where the MCO, PIHP, or PAHP is not permitted to retain some or all of the recoveries of overpayments.

(iv) This provision does not apply to any amount of a recovery to be retained under False Claims Act cases or through other investigations.

(2) Each MCO, PIHP, or PAHP requires and has a mechanism for a network provider to report to the MCO, PIHP or PAHP when it has received an overpayment, to return the overpayment to the MCO, PIHP or PAHP within 60 calendar days after the date on which the overpayment was identified, and to notify the MCO, PIHP or PAHP in writing of the reason for the overpayment.

(3) Each MCO, PIHP, or PAHP must report annually to the State on their recoveries of overpayments.

(4) The State must use the results of the information and documentation collected in paragraph (d)(1) of this section and the report in paragraph (d)(3) of this section for setting actuarially sound capitation rates for each MCO, PIHP, or PAHP consistent with the requirements in § 438.4.

§ 438.610 Prohibited affiliations.

(a) An MCO, PIHP, PAHP, PCCM, or PCCM entity may not knowingly have a relationship of the type described in paragraph (c) of this section with the following:

(1) An individual or entity that is debarred, suspended, or otherwise excluded from participating in procurement activities under the Federal Acquisition Regulation or from participating in nonprocurement activities under regulations issued under Executive Order No. 12549 or under guidelines implementing Executive Order No. 12549.

(2) An individual or entity who is an affiliate, as defined in the Federal Acquisition Regulation at 48 CFR 2.101, of a person described in paragraph (a)(1) of this section.

(b) An MCO, PIHP, PAHP, PCCM, or PCCM entity may not have a relationship with an individual or entity that is excluded from participation in any Federal health care program under section 1128 or 1128A of the Act.

(c) The relationships described in paragraph (a) of this section, are as follows:

(1) A director, officer, or partner of the MCO, PIHP, PAHP, PCCM, or PCCM entity.

(2) A subcontractor of the MCO, PIHP, PAHP, PCCM, or PCCM entity, as governed by § 438.230.

(3) A person with beneficial ownership of 5 percent or more of the MCO's, PIHP's, PAHP's, PCCM's, or PCCM entity's equity.

(4) A network provider or person with an employment, consulting or other arrangement with the MCO, PIHP, PAHP, PCCM, or PCCM entity for the provision of items and services that are significant and material to the MCO's,

PIHP's, PAHP's, PCCM's, or PCCM entity's obligations under its contract with the State.

(d) If a State finds that an MCO, PIHP, PAHP, PCCM, or PCCM entity is not in compliance with paragraphs (a) and (b) of this section, the State:

(1) Must notify the Secretary of the noncompliance.

(2) May continue an existing agreement with the MCO, PIHP, PAHP, PCCM, or PCCM entity unless the Secretary directs otherwise.

(3) May not renew or otherwise extend the duration of an existing agreement with the MCO, PIHP, PAHP, PCCM, or PCCM entity unless the Secretary provides to the State and to Congress a written statement describing compelling reasons that exist for renewing or extending the agreement despite the prohibited affiliations.

(4) Nothing in this section must be construed to limit or otherwise affect any remedies available to the U.S. under sections 1128, 1128A or 1128B of the Act.

(e) *Consultation with the Inspector General.* Any action by the Secretary described in paragraphs (d)(2) or (3) of this section is taken in consultation with the Inspector General.

Subpart I—Sanctions

§ 438.700 Basis for imposition of sanctions.

(a) Each State that contracts with an MCO must, and each State that contracts with a PCCM or PCCM entity may, establish intermediate sanctions (which may include those specified in § 438.702) that it may impose if it makes any of the determinations specified in paragraphs (b) through (d) of this section. The State may base its determinations on findings from onsite surveys, enrollee or other complaints, financial status, or any other source.

(b) A State determines that an MCO acts or fails to act as follows:

(1) Fails substantially to provide medically necessary services that the MCO is required to provide, under law or under its contract with the State, to an enrollee covered under the contract.

(2) Imposes on enrollees premiums or charges that are in excess of the premiums or charges permitted under the Medicaid program.

(3) Acts to discriminate among enrollees on the basis of their health status or need for health care services. This includes termination of enrollment or refusal to reenroll a beneficiary, except as permitted under the Medicaid program, or any practice that would reasonably be expected to discourage enrollment by beneficiaries whose

medical condition or history indicates probable need for substantial future medical services.

(4) Misrepresents or falsifies information that it furnishes to CMS or to the State.

(5) Misrepresents or falsifies information that it furnishes to an enrollee, potential enrollee, or health care provider.

(6) Fails to comply with the requirements for physician incentive plans, as set forth (for Medicare) in §§ 422.208 and 422.210 of this chapter.

(c) A State determines that an MCO, PCCM or PCCM entity has distributed directly, or indirectly through any agent or independent contractor, marketing materials that have not been approved by the State or that contain false or materially misleading information.

(d) A State determines that—

(1) An MCO has violated any of the other requirements of sections 1903(m) or 1932 of the Act, or any implementing regulations.

(2) A PCCM or PCCM entity has violated any of the other applicable requirements of sections 1903 or 1905(t)(3) of the Act, or any implementing regulations.

(3) For any of the violations under paragraphs (d)(1) and (2) of this section, only the sanctions specified in § 438.702(a)(3), (4), and (5) may be imposed.

§ 438.702 Types of intermediate sanctions.

(a) The types of intermediate sanctions that a State may impose under this subpart include the following:

(1) Civil money penalties in the amounts specified in § 438.704.

(2) Appointment of temporary management for an MCO as provided in § 438.706.

(3) Granting enrollees the right to terminate enrollment without cause and notifying the affected enrollees of their right to disenroll.

(4) Suspension of all new enrollment, including default enrollment, after the date the Secretary or the State notifies the MCO of a determination of a violation of any requirement under sections 1903(m) or 1932 of the Act.

(5) Suspension of payment for beneficiaries enrolled after the effective date of the sanction and until CMS or the State is satisfied that the reason for imposition of the sanction no longer exists and is not likely to recur.

(b) State agencies retain authority to impose additional sanctions under State statutes or State regulations that address areas of noncompliance specified in § 438.700, as well as additional areas of noncompliance. Nothing in this subpart prevents State agencies from exercising that authority.

§ 438.704 Amounts of civil money penalties.

(a) *General rule.* If the State imposes civil monetary penalties as provided under § 438.702(a)(1), the maximum civil money penalty the State may impose varies depending on the nature of the MCO's, PCCM or PCCM entity's action or failure to act, as provided in this section.

(b) *Specific limits.* (1) The limit is \$25,000 for each determination under § 438.700(b)(1), (5), (6), and (c).

(2) The limit is \$100,000 for each determination under § 438.700(b)(3) or (4).

(3) The limit is \$15,000 for each beneficiary the State determines was not enrolled because of a discriminatory practice under § 438.700(b)(3). (This is subject to the overall limit of \$100,000 under paragraph (b)(2) of this section).

(c) *Specific amount.* For premiums or charges in excess of the amounts permitted under the Medicaid program, the maximum amount of the penalty is \$25,000 or double the amount of the excess charges, whichever is greater. The State must deduct from the penalty the amount of overcharge and return it to the affected enrollees.

§ 438.706 Special rules for temporary management.

(a) *Optional imposition of sanction.* If the State imposes temporary management under § 438.702(a)(2), the State may do so only if it finds (through onsite surveys, enrollee or other complaints, financial status, or any other source) any of the following:

(1) There is continued egregious behavior by the MCO, including but not limited to behavior that is described in § 438.700, or that is contrary to any requirements of sections 1903(m) and 1932 of the Act.

(2) There is substantial risk to enrollees' health.

(3) The sanction is necessary to ensure the health of the MCO's enrollees—

(i) While improvements are made to remedy violations under § 438.700.

(ii) Until there is an orderly termination or reorganization of the MCO.

(b) *Required imposition of sanction.* The State must impose temporary management (regardless of any other sanction that may be imposed) if it finds that an MCO has repeatedly failed to meet substantive requirements in sections 1903(m) or 1932 of the Act, or this subpart. The State must also grant enrollees the right to terminate enrollment without cause, as described in § 438.702(a)(3), and must notify the affected enrollees of their right to terminate enrollment.

(c) *Hearing.* The State may not delay imposition of temporary management to provide a hearing before imposing this sanction.

(d) *Duration of sanction.* The State may not terminate temporary management until it determines that the MCO can ensure that the sanctioned behavior will not recur.

§ 438.708 Termination of an MCO, PCCM or PCCM entity contract.

A State has the authority to terminate an MCO, PCCM or PCCM entity contract and enroll that entity's enrollees in other MCOs, PCCMs or PCCM entities, or provide their Medicaid benefits through other options included in the State plan, if the State determines that the MCO, PCCM or PCCM entity has failed to do either of the following:

(a) Carry out the substantive terms of its contract.

(b) Meet applicable requirements in sections 1932, 1903(m), and 1905(t) of the Act.

§ 438.710 Notice of sanction and pre-termination hearing.

(a) *Notice of sanction.* Except as provided in § 438.706(c), before imposing any of the intermediate sanctions specified in this subpart, the State must give the affected entity timely written notice that explains the following:

(1) The basis and nature of the sanction.

(2) Any other appeal rights that the State elects to provide.

(b) *Pre-termination hearing—(1) General rule.* Before terminating an MCO, PCCM or PCCM entity contract under § 438.708, the State must provide the entity a pre-termination hearing.

(2) *Procedures.* The State must do all of the following:

(i) Give the MCO, PCCM or PCCM entity written notice of its intent to terminate, the reason for termination, and the time and place of the hearing.

(ii) After the hearing, give the entity written notice of the decision affirming or reversing the proposed termination of the contract and, for an affirming decision, the effective date of termination.

(iii) For an affirming decision, give enrollees of the MCO, PCCM or PCCM entity notice of the termination and information, consistent with § 438.10, on their options for receiving Medicaid services following the effective date of termination.

§ 438.722 Disenrollment during termination hearing process.

After a State notifies an MCO, PCCM or PCCM entity that it intends to

terminate the contract, the State may do the following:

(a) Give the entity's enrollees written notice of the State's intent to terminate the contract.

(b) Allow enrollees to disenroll immediately without cause.

§ 438.724 Notice to CMS.

(a) The State must give CMS written notice whenever it imposes or lifts a sanction for one of the violations listed in § 438.700.

(b) The notice must adhere to all of the following requirements:

(1) Be given no later than 30 days after the State imposes or lifts a sanction.

(2) Specify the affected MCO, the kind of sanction, and the reason for the State's decision to impose or lift a sanction.

§ 438.726 State plan requirement.

(a) The State plan must include a plan to monitor for violations that involve the actions and failures to act specified in this part and to implement the provisions of this part.

(b) A contract with an MCO must provide that payments provided for under the contract will be denied for new enrollees when, and for so long as, payment for those enrollees is denied by CMS under § 438.730(e).

§ 438.730 Sanction by CMS: Special rules for MCOs.

(a) *Basis for sanction.* A State may recommend that CMS impose the denial of payment sanction specified in paragraph (e) of this section on an MCO with a contract under this part if the agency determines that the MCO acts or fails to act as specified in § 438.700(b)(1) through (6).

(b) *Effect of an agency determination.* (1) The State's determination becomes CMS' determination for purposes of section 1903(m)(5)(A) of the Act unless CMS reverses or modifies it within 15 days.

(2) When the State decides to recommend imposing the sanction described in paragraph (e) of this section, this recommendation becomes CMS' decision, for purposes of section 1903(m)(5)(B)(ii) of the Act, unless CMS rejects this recommendation within 15 days.

(c) *Notice of sanction.* If the State's determination becomes CMS' determination under paragraph (b)(2) of this section, the State takes all of the following actions:

(1) Gives the MCO written notice of the nature and basis of the proposed sanction.

(2) Allows the MCO 15 days from the date it receives the notice to provide

evidence that it has not acted or failed to act in the manner that is the basis for the recommended sanction.

(3) May extend the initial 15-day period for an additional 15 days if—

(i) The MCO submits a written request that includes a credible explanation of why it needs additional time.

(ii) The request is received by CMS before the end of the initial period.

(iii) CMS has not determined that the MCO's conduct poses a threat to an enrollee's health or safety.

(d) *Informal reconsideration.* (1) If the MCO submits a timely response to the notice of sanction, the State—

(i) Conducts an informal reconsideration that includes review of the evidence by a State agency official who did not participate in the original recommendation.

(ii) Gives the MCO a concise written decision setting forth the factual and legal basis for the decision.

(iii) Forwards the decision to CMS.

(2) The State's decision under paragraph (d)(1)(ii) of this section becomes CMS' decision unless CMS reverses or modifies the decision within 15 days from date of receipt by CMS.

(3) If CMS reverses or modifies the State decision, the agency sends the MCO a copy of CMS' decision.

(e) *Denial of payment.* (1) CMS, based upon the recommendation of the agency, may deny payment to the State for new enrollees of the MCO under section 1903(m)(5)(B)(ii) of the Act in the following situations:

(i) If a CMS determination that an MCO has acted or failed to act, as described in paragraphs (b)(1) through (6) of § 438.700, is affirmed on review under paragraph (d) of this section.

(ii) If the CMS determination is not timely contested by the MCO under paragraph (c) of this section.

(2) Under § 438.726(b), CMS' denial of payment for new enrollees automatically results in a denial of agency payments to the MCO for the same enrollees. (A new enrollee is an enrollee that applies for enrollment after the effective date in paragraph (f)(1) of this section.)

(f) *Effective date of sanction.* (1) If the MCO does not seek reconsideration, a sanction is effective 15 days after the date the MCO is notified under paragraph (c) of this section of the decision to impose the sanction.

(2) If the MCO seeks reconsideration, the following rules apply:

(i) Except as specified in paragraph (d)(2) of this section, the sanction is effective on the date specified in CMS' reconsideration notice.

(ii) If CMS, in consultation with the State, determines that the MCO's

conduct poses a serious threat to an enrollee's health or safety, the sanction may be made effective earlier than the date of the agency's reconsideration decision under paragraph (d)(1)(ii) of this section.

(g) *CMS' role.* (1) CMS retains the right to independently perform the functions assigned to the State under paragraphs (a) through (d) of this section.

(2) At the same time that the State sends notice to the MCO under paragraph (c)(1) of this section, CMS forwards a copy of the notice to the OIG.

(3) CMS conveys the determination described in paragraph (b) of this section to the OIG for consideration of possible imposition of civil money penalties under section 1903(m)(5)(A) of the Act and part 1003 of this title. In accordance with the provisions of part 1003, the OIG may impose civil money penalties on the MCO in addition to, or in place of, the sanctions that may be imposed under this section.

Subpart J—Conditions for Federal Financial Participation (FFP)

§ 438.802 Basic requirements.

FFP is available in expenditures for payments under an MCO contract only for the periods during which the contract—

- (a) Meets the requirements of this part; and
- (b) Is in effect.

§ 438.806 Prior approval.

(a) *Comprehensive risk contracts.* FFP is available under a comprehensive risk contract only if all of the following apply:

(1) CMS has confirmed that the contractor meets the definition of an MCO or is one of the entities described in paragraphs (b)(2) through (5) of § 438.3.

(2) The contract meets all the requirements of section 1903(m)(2)(A) of the Act, the applicable requirements of section 1932 of the Act, and the provisions of this part.

(b) *MCO contracts.* Prior approval by CMS is a condition for FFP under any MCO contract that extends for less than one full year or that has a value equal to, or greater than, the following threshold amounts:

(1) For 1998, the threshold is \$1,000,000.

(2) For subsequent years, the amount is increased by the percentage increase in the consumer price index for all urban consumers.

(c) FFP is not available in an MCO contract that does not have prior approval from CMS under paragraph (b) of this section.

§ 438.808 Exclusion of entities.

(a) *General rule.* FFP is available in payments under MCO contracts or PIHP, PAHP, PCCM, or PCCM entity contracts under a section 1915(b)(1) of the Act waiver only if the State excludes from the contracts any entities described in paragraph (b) of this section.

(b) *Entities that must be excluded.* (1) An entity that could be excluded under section 1128(b)(8) of the Act as being controlled by a sanctioned individual.

(2) An entity that has a substantial contractual relationship as defined in § 431.55(h)(3) of this chapter, either directly or indirectly, with an individual convicted of certain crimes as described in section 1128(b)(8)(B) of the Act or an individual described in § 438.610(a) and (b).

(3) An entity that employs or contracts, directly or indirectly, for the furnishing of health care, utilization review, medical social work, or administrative services, with one of the following:

(i) Any individual or entity described in § 438.610(a) and (b).

(ii) Any individual or entity that would provide those services through an individual or entity described in § 438.610(a) and (b).

§ 438.810 Expenditures for enrollment broker services.

(a) *Definitions.* As used in this section—

Enrollment activities means activities such as distributing, collecting, and processing enrollment materials and taking enrollments by phone, in person, or through electronic methods of communication.

Enrollment broker means an individual or entity that performs choice counseling or enrollment activities, or both.

Enrollment services means choice counseling, or enrollment activities, or both.

(b) *Conditions that enrollment brokers must meet.* State expenditures for the use of enrollment brokers are considered necessary for the proper and efficient operation of the State plan and thus eligible for FFP only if the broker and its subcontractors meet the following conditions:

(1) *Independence.* The broker and its subcontractors are independent of any MCO, PIHP, PAHP, PCCM, PCCM entity or other health care provider in the State in which they provide enrollment services. A broker or subcontractor is not considered “independent” if it—

(i) Is an MCO, PIHP, PAHP, PCCM, PCCM entity or other health care provider in the State;

(ii) Is owned or controlled by an MCO, PIHP, PAHP, PCCM, PCCM entity

or other health care provider in the State; or

(iii) Owns or controls an MCO, PIHP, PAHP, PCCM, PCCM entity, or other health care provider in the State.

(2) *Freedom from conflict of interest.* The broker and its subcontractor are free from conflict of interest. A broker or subcontractor is not considered free from conflict of interest if any person who is the owner, employee, or consultant of the broker or subcontractor or has any contract with them—

(i) Has any direct or indirect financial interest in any entity or health care provider that furnishes services in the State in which the broker or subcontractor provides enrollment services;

(ii) Has been excluded from participation under Title XVIII or XIX of the Act;

(iii) Has been debarred by any Federal agency; or

(iv) Has been, or is now, subject to civil money penalties under the Act.

(3) *Approval.* The initial contract or memorandum of agreement (MOA) for services performed by the broker has been reviewed and approved by CMS.

§ 438.812 Costs under risk and nonrisk contracts.

(a) Under a risk contract, the total amount the State agency pays for carrying out the contract provisions is a medical assistance cost.

(b) Under a nonrisk contract—

(1) The amount the State agency pays for the furnishing of medical services to eligible beneficiaries is a medical assistance cost; and

(2) The amount the State agency pays for the contractor’s performance of other functions is an administrative cost.

§ 438.816 Expenditures for the beneficiary support system for enrollees using LTSS.

State expenditures for the person or entity providing the services outlined in § 438.71(d) are considered necessary for the proper and efficient operation of the State plan and thus eligible for FFP only if all of the following conditions are met:

(a) Costs must be supported by an allocation methodology that appears in the State’s approved Public Assistance Cost Allocation Plan in § 433.34 of this chapter.

(b) The costs do not duplicate payment for activities that are already being offered or should be provided by other entities or paid by other programs.

(c) The person or entity providing the services must meet the requirements in § 438.810(b)(1) and (2).

(d) The initial contract or MOA for services performed has been reviewed and approved by CMS.

§ 438.818 Enrollee encounter data.

(a) FFP is available for expenditures under an MCO, PIHP, or PAHP contract only if the State meets the following conditions for providing enrollee encounter data to CMS:

(1) Enrollee encounter data reports must comply with the Health Insurance Portability and Accountability Act of 1996 (HIPAA) security and privacy standards and be submitted in the format required by the Medicaid Statistical Information System or format required by any successor system to the Medicaid Statistical Information System.

(2) States must ensure that enrollee encounter data is validated for accuracy and completeness as required under § 438.242 before submitting data to CMS. States must also validate that the data submitted to CMS is a complete and accurate representation of the information submitted to the State by the MCOs, PIHPs, and PAHPs.

(3) States must cooperate with CMS to fully comply with all encounter data reporting requirements of the Medicaid Statistical Information System or any successor system.

(b) CMS will assess a State’s submission to determine if it complies with current criteria for accuracy and completeness.

(c) If, after being notified of compliance issues under paragraph (b) of this section the State is unable to make a data submission compliant, CMS will take appropriate steps to defer and/or disallow FFP on all or part of an MCO, PIHP, or PAHP contract in a manner based on the enrollee and specific service type of the noncompliant data. Any deferral and/or disallowance of FFP will be effectuated utilizing the processes specified in §§ 430.40 and 430.42 of this chapter.

PART 440—SERVICES: GENERAL PROVISIONS

■ 11. The authority citation for part 440 continues to read as follows:

Authority: Sec. 1102 of the Social Security Act (42 U.S.C. 1302).

■ 12. Section 440.262 is added to read as follows:

§ 440.262 Access and cultural considerations.

The State must have methods to promote access and delivery of services in a culturally competent manner to all beneficiaries, including those with limited English proficiency, diverse

cultural and ethnic backgrounds, disabilities, and regardless of gender, sexual orientation or gender identity. These methods must ensure that beneficiaries have access to covered services that are delivered in a manner that meet their unique needs.

PART 457—ALLOTMENTS AND GRANTS TO STATES

■ 13. The authority citation for part 457 continues to read as follows:

Authority: Section 1102 of the Social Security Act (42 U.S.C. 1302).

■ 14. Section 457.10 is amended by:

■ a. Adding the definitions of “actuarially sound principles”, “comprehensive risk contract”, “external quality review”, and “external quality review organization” in alphabetical order.

■ b. Revising the definition of “fee-for-service entity”.

■ c. Adding the definitions of “managed care organization”, “prepaid ambulatory health plan”, “prepaid inpatient health plan”, “primary care case management”, “primary care case management entity”, “primary care case manager”, “provider”, and “risk contract” in alphabetical order.

The additions and revision read as follows:

§ 457.10 Definitions and use of terms.

* * * * *

Actuarially sound principles means generally accepted actuarial principles and practices that are applied to determine aggregate utilization patterns, are appropriate for the population and services to be covered, and have been certified by actuaries who meet the qualification standards established by the Actuarial Standards Board.

* * * * *

Comprehensive risk contract means a risk contract between the State and an MCO that covers comprehensive services, that is, inpatient hospital services and any of the following services, or any three or more of the following services:

- (1) Outpatient hospital services.
- (2) Rural health clinic services.
- (3) Federally Qualified Health Center (FQHC) services.
- (4) Other laboratory and X-ray services.
- (5) Nursing facility (NF) services.
- (6) Early and periodic screening, diagnostic, and treatment (EPSDT) services.
- (7) Family planning services.
- (8) Physician services.
- (9) Home health services.

* * * * *

External quality review (EQR) means the analysis and evaluation by an EQRO, of aggregated information on quality, timeliness, and access to the health care services that an MCO, PIHP, or PAHP, or their contractors furnish to CHIP beneficiaries.

External quality review organization (EQRO) means an organization that meets the competence and independence requirements set forth in § 438.354 of this chapter, and holds a contract with a State to perform external quality review, other EQR-related activities as set forth in § 438.358 of this chapter, or both.

* * * * *

Fee-for-service entity means any individual or entity that furnishes services under the program on a fee-for-service basis, including health insurance services.

* * * * *

Federally qualified HMO means an HMO that CMS has determined is a qualified HMO under section 2791(b)(3) of the Public Health Service Act.

Managed care organization (MCO) means an entity that has, or is seeking to qualify for, a comprehensive risk contract under this part, and that is—

- (1) A Federally qualified HMO that meets the requirements of subpart I of part 489 of this chapter; or
- (2) Makes the services it provides to its CHIP enrollees as accessible (in terms of timeliness, amount, duration, and scope) as those services are to other CHIP beneficiaries within the area served by the entity and

(3) Meets the solvency standards of § 438.116 of this chapter.

* * * * *

Prepaid ambulatory health plan (PAHP) means an entity that—

- (1) Provides services to enrollees under contract with the State, and on the basis of prepaid capitation payments, or other payment arrangements that do not use State plan payment rates.
- (2) Does not provide or arrange for, and is not otherwise responsible for the provision of any inpatient hospital or institutional services for its enrollees.

(3) Does not have a comprehensive risk contract.

Prepaid inpatient health plan (PIHP) means an entity that—

- (1) Provides services to enrollees under contract with the State, and on the basis of prepaid capitation payments, or other payment arrangements that do not use State plan payment rates.
- (2) Provides, arranges for, or otherwise has responsibility for the provision of any inpatient hospital or institutional services for its enrollees.

(3) Does not have a comprehensive risk contract.

* * * * *

Primary care case management means a system under which:

(1) A PCCM contracts with the State to furnish case management services (which include the location, coordination and monitoring of primary health care services) to CHIP beneficiaries; or

(2) A PCCM entity contracts with the State to provide a defined set of functions to CHIP beneficiaries.

Primary care case management entity (PCCM entity) means an organization that provides any of the following functions, in addition to primary care case management services, for the State:

(1) Provision of intensive telephonic or face-to-face case management, including operation of a nurse triage advice line.

(2) Development of enrollee care plans.

(3) Execution of contracts with and/or oversight responsibilities for the activities of fee-for-service providers in the fee-for-service program.

(4) Provision of payments to fee-for-service providers on behalf of the State.

(5) Provision of enrollee outreach and education activities.

(6) Operation of a customer service call center.

(7) Review of provider claims, utilization and practice patterns to conduct provider profiling and/or practice improvement.

(8) Implementation of quality improvement activities including administering enrollee satisfaction surveys or collecting data necessary for performance measurement of providers.

(9) Coordination with behavioral health systems/providers.

(10) Coordination with long-term services and supports systems/providers.

Primary care case manager (PCCM) means a physician, a physician group practice or, at State option, any of the following in addition to primary care case management services:

- (1) A physician assistant.
- (2) A nurse practitioner.
- (3) A certified nurse-midwife.

* * * * *

Provider means any individual or entity that is engaged in the delivery of services, or ordering or referring for those services, and is legally authorized to do so by the State in which it delivers the services.

* * * * *

Risk contract means a contract under which the contractor—

- (1) Assumes risk for the cost of the services covered under the contract.

(2) Incurs loss if the cost of furnishing the services exceeds the payments under the contract.

* * * * *

■ 15. Section 457.204 is amended by revising paragraph (a) to read as follows:

§ 457.204 Withholding of payment for failure to comply with Federal requirements.

(a) *Basis for withholding.* CMS withholds payments to the State, in whole or in part, only if, after giving the State notice, a reasonable opportunity for correction, and an opportunity for a hearing, the Administrator finds—

(1) That the State plan is in substantial noncompliance with the requirements of Title XXI of the Act or the regulations in this part; or

(2) That the State is conducting its program in substantial noncompliance with either the State plan or the requirements of Title XXI of the Act or the regulations in this part. (Hearings are generally not called until a reasonable effort has been made to resolve the issues through conferences and discussions. These efforts may be continued even if a date and place have been set for the hearing.)

(3) For purposes of this paragraph (a), substantial non-compliance includes, but is not limited to, failure to comply with requirements that significantly affect federal or state oversight or state reporting.

* * * * *

§ 457.902 [Removed]

■ 16. Section 457.902 is removed.

■ 17. Section 457.940 is revised to read as follows:

§ 457.940 Procurement standards.

(a) A State must submit to CMS a written assurance that Title XXI services will be provided in an effective and efficient manner. The State must submit the assurance—

(1) With the initial State plan; or

(2) For States with approved plans, with the first request to amend the approved plan.

(b) A State must provide for free and open competition, to the maximum extent practical, in the bidding of all procurement contracts for coverage or other services in accordance with the procurement requirements of 45 CFR part 75, as applicable.

(c) All contracts under this part must include provisions that define a sound and complete procurement contract, as required by 45 CFR part 75, as applicable.

■ 18. Section 457.950 is amended by revising paragraph (a) to read as follows:

§ 457.950 Contract and payment requirements including certification of payment-related information.

(a) *MCOs, PAHPs, PIHPs, PCCMs, and PCCM entities.* The contract requirements for MCOs, PAHPs, PIHPs, PCCMs, and PCCM entities are provided in § 457.1201.

* * * * *

■ 19. Subpart L is added to part 457 to read as follows:

Subpart L—Managed Care

Sec.

General Provisions

- 457.1200 Basis, scope, and applicability.
- 457.1201 Standard contract requirements.
- 457.1203 Rate development standards and medical loss ratio.
- 457.1206 Non-emergency medical transportation PAHPs.
- 457.1207 Information requirements.
- 457.1208 Provider discrimination prohibited.
- 457.1209 Requirements that apply to MCO, PIHP, PAHP, PCCM, and PCCM entity contracts involving Indians, Indian health care provider (IHCP), and Indian managed care entities (IMCE).

State Responsibilities

- 457.1210 Enrollment process.
- 457.1212 Disenrollment.
- 457.1214 Conflict of interest safeguards.
- 457.1216 Continued services to enrollees.
- 457.1218 Network adequacy standards.

Enrollee Rights and Protections

- 457.1220 Enrollee rights.
- 457.1222 Provider-enrollee communication.
- 457.1224 Marketing activities.
- 457.1226 Liability for payment.
- 457.1228 Emergency and poststabilization services.

MCO, PIHP, and PAHP Standards

- 457.1230 Access standards.
- 457.1233 Structure and operation standards.

Quality Measurement and Improvement; External Quality Review

- 457.1240 Quality measurement and improvement.
- 457.1250 External quality review.

Grievance System

- 457.1260 Grievance system.

Sanctions

- 457.1270 Sanctions.

Subpart L—Managed Care

General Provisions

§ 457.1200 Basis, scope, and applicability.

(a) *Statutory basis.* This subpart implements the following sections of the Act:

(1) Section 2101(a) of the Act, which provides that the purpose of Title XXI is to provide funds to States to enable

them to initiate and expand the provision of child health assistance to uninsured, low-income children in an effective and efficient manner.

(2) Section 2103(f)(3) and 2107(e)(1)(M) of the Act, which apply certain provisions of Title XIX related to Medicaid managed care to CHIP.

(3) Sections 2107(b) and 2107(e)(2) of the Act, which relate to program integrity.

(b) *Scope.* This subpart sets forth requirements for the provision of services through MCOs, PIHPs, PAHPs, and PCCM entities, as defined in § 457.10.

(c) *Applicability.* The requirements of this subpart apply to child health assistance provided under a separate child health program operating a managed care delivery system. Regulations relating to managed care that are applicable to a Medicaid expansion program are found at part 438 of this chapter.

§ 457.1201 Standard contract requirements.

(a) *CMS review.* The State must submit all MCO, PAHP, PIHP, PCCM, and PCCM entity contracts for review in the form and manner established by CMS.

(b) *Entities eligible for comprehensive risk contracts.* The State may enter into a comprehensive risk contract only with the entities specified in § 438.3(b)(1) through (3) of this chapter.

(c) *Payment.* The final capitation rates for all MCO, PIHP or PAHP contracts must be identified and developed, and payment must be made in accordance with § 438.3(c) of this chapter, except that the requirement for preapproval of contracts does not apply, and contract rates must be submitted to CMS upon request of the Secretary.

(d) *Enrollment discrimination prohibited.* Contracts with MCOs, PAHPs, PIHPs, PCCMs and PCCM entities must comply with prohibitions on enrollment discrimination in accordance with § 438.3(d) of this chapter, except that § 438.3(d)(2) of this chapter (related to voluntary enrollment) does not apply.

(e) *Services that may be covered by an MCO, PIHP, or PAHP.* An MCO, PIHP, or PAHP may cover, for enrollees, services that are not covered under the State plan in accordance with § 438.3(e) of this chapter.

(f) *Compliance with applicable laws and conflict of interest safeguards.* Contracts with MCOs, PAHPs, PIHPs, PCCMs or PCCM entities must comply with Federal laws and regulations in accordance with § 438.3(f) of this chapter.

(g) *Inspection and audit of records and access to facilities.* Contracts with MCOs, PIHPs, PAHPs, PCCMs or PCCM entities must allow for the inspection and audit of records and access to facilities in accordance with § 438.3(h) of this chapter.

(h) *Physician incentive plans.* If a contract with an MCO, PAHP, or PIHP provides for a physician incentive plan, it must comply with § 438.3(i) of this chapter (which cross references §§ 422.208 and 422.210 of this chapter).

(i) *Subcontractual relationships and delegations.* The state must ensure, through its contracts with MCOs, PIHPs, and PAHPs, that any contract or written agreement that the MCO, PIHP, or PAHP has with any individual or entity that relates directly or indirectly to the performance of the MCOs, PIHPs, or PAHPs obligations under its contract comply with § 457.1233(b) (which cross references § 438.230 of this chapter).

(j) *Choice of network provider.* The contract must allow each enrollee to choose his or her network provider in accordance with § 438.3(l) of this chapter.

(k) *Audited financial reports.* Contracts with MCOs, PAHPs, and PIHPs must comply with the requirements for submission of audited financial reports in § 438.3(m) of this chapter.

(l) *Parity in mental health and substance use disorder benefits.*

Contracts with MCOs, PAHPs, and PIHPs must comply with the requirements of § 438.3(n).

(m) *Additional rules for contracts with PCCMs.* Contracts with PCCMs must comply with the requirements of § 438.3(q) of this chapter, except that the right to disenroll is in accordance with § 457.1212.

(n) *Additional rules for contracts with PCCM entities.* (1) States must submit PCCM entity contracts to CMS for review.

(2) Contracts with PCCMs must comply with the requirements of paragraph (o) of this section; § 457.1207; § 457.1240(b) (cross-referencing § 438.330(b)(3), (c), and (e) of this chapter); § 457.1240(e) (cross-referencing § 438.340 of this chapter); and § 457.1250(a) (cross-referencing § 438.350 of this chapter).

(o) *Attestations.* Contracts with MCO, PAHP, PIHP, PCCM or PCCM entities must include an attestation to the accuracy, completeness, and truthfulness of claims and payment data, under penalty of perjury.

(p) *Guarantee not to avoid costs.* Contracts with an MCO, PAHP, PIHP, PCCM or PCCM entities must include a guarantee that the MCO, PAHP, PIHP,

PCCM or PCCM entity will not avoid costs for services covered in its contract by referring enrollees to publicly supported health care resources.

(q) *Recordkeeping requirements.*

Contracts with MCOs, PIHPs, and PAHPs, must comply with the recordkeeping requirements of § 438.3(u) of this chapter.

§ 457.1203 Rate development standards and medical loss ratio.

(a) A state must use payment rates based on public or private payment rates for comparable services for comparable populations, consistent with actuarially sound principles as defined at § 457.10. This requirement for using actuarially sound principles to develop payment rates does not prohibit a state from (implementing value-based purchasing models for provider reimbursement, such as pay for performance arrangements, bundled payments, or other service payment models intended to recognize value or outcomes over volume of services; such alternate payment models should be developed using actuarially sound principles to the extent applicable.

(b) A State may establish higher rates than permitted under paragraph (a) of this section if such rates are necessary to ensure sufficient provider participation or provider access or to enroll providers who demonstrate exceptional efficiency or quality in the provision of services.

(c) The rates must be designed to reasonably achieve a medical loss ratio standard, calculated in accordance with the provisions of § 438.8 of this chapter, that—

(1) Is equal to at least 85 percent for the rate year; and

(2) Provides for reasonable administrative costs.

(d) The State must provide to CMS, if requested, a description of the manner in which rates were developed in accordance with the requirements of paragraphs (a), (b), or (c) of this section.

(e) The state must comply with the requirements related to medical loss ratios in accordance with the terms of § 438.74 of this chapter, except that the description of the reports received from the MCOs PIHPs and PAHPs under to § 438.8(k) of this chapter will be submitted independently, and not with the actuarial certification described in § 438.7 of this chapter.

(f) The state must ensure, through its contracts, that each MCO, PIHP, and PAHP complies with the requirements § 438.8 of this chapter.

§ 457.1206 Non-emergency medical transportation PAHPs.

(a) For purposes of this section Non-Emergency Medical Transportation (NEMT) Prepaid Ambulatory Health Plan (PAHP) means an entity that provides only NEMT services to enrollees under contract with the State, and on the basis of prepaid capitation payments, or other payment arrangements that do not use State plan payment rates.

(b) The following requirements and options apply to NEMT PAHPs, NEMT PAHP contracts, and States in connection with NEMT PAHPs, to the same extent that they apply to PAHPs, PAHP contracts, and States in connection with PAHPs.

(1) All contract provisions in § 457.1201 except those set forth in § 457.1201(h) (related to physician incentive plans) § 457.1201(l) (related to mental health parity).

(2) The information requirements in § 457.1207.

(3) The provision against provider discrimination in § 457.1208.

(4) The State responsibility provisions in §§ 457.1212 and 457.1214, and § 438.62(a) of this chapter, as cross-referenced in § 457.1216.

(5) The provisions on enrollee rights and protections in §§ 457.1220, 457.1222, 457.1224, and 457.1226.

(6) The PAHP standards in § 438.206(b)(1) of this chapter, as cross-referenced by §§ 457.1230(a), 457.1230(d), and 457.1233(a), (b) and (d).

(7) An enrollee's right to a State review under subpart K of this part.

(8) Prohibitions against affiliations with individuals debarred or excluded by Federal agencies in § 438.610 of this chapter, as cross referenced by § 457.1285.

(9) Requirements relating to contracts involving Indians, Indian Health Care Providers, and Indian managed care entities in § 457.1209.

§ 457.1207 Information requirements.

The State must provide, or ensure its contracted MCO, PAHP, PIHP, PCCM and PCCM entities provide, all enrollment notices, informational materials, and instructional materials related to enrollees and potential enrollees in accordance with the terms of § 438.10 of this chapter.

§ 457.1208 Provider discrimination prohibited.

The state must ensure through its contracts that each MCO, PIHP, and PAHP follow the requirements related to the prohibition on provider discrimination in § 438.12 of this chapter.

§ 457.1209 Requirements that apply to MCO, PIHP, PAHP, PCCM, and PCCM entity contracts involving Indians, Indian health care provider (IHCP), and Indian managed care entities (IMCE).

The State must follow, and ensure through its contracts, that each MCO, PIHP, PAHP, PCCM, and PCCM entity follows, the requirements related to Indians, IHCPs, and IMCEs in accordance with the terms of § 438.14 of this chapter.

State Responsibilities

§ 457.1210 Enrollment process.

(a) *Default enrollment process.* (1) If a state uses a default enrollment process to assign beneficiaries to a MCO, PIHP, PAHP, PCCM, or PCCM entity, the process must:

(i) Assign beneficiaries to a qualified MCO, PIHP, PAHP, PCCM or PCCM entity. To be qualified, the MCO, PIHP, PAHP, PCCM or PCCM entity must:

(A) Not be subject to the intermediate sanction described in § 438.702(a)(4) of this chapter.

(B) Have capacity to enroll beneficiaries.

(ii) Maximize continuation of existing provider-beneficiary relationships. An “existing provider-beneficiary relationship” is one in which the provider was the main source of CHIP services for the beneficiary during the previous year. This may be established through State records of previous managed care enrollment or fee-for-service experience, encounter data, or through contact with the beneficiary.

(iii) If the approach in paragraph (a)(1)(ii) of this section is not possible, the State must distribute the beneficiaries equitably among the MCOs, PIHPs, PAHPs, PCCMs and PCCM entities. The State may not arbitrarily exclude any MCO, PIHP, PAHP, PCCM or PCCM entity from being considered.

(2) The State may consider additional reasonable criteria to conduct the default enrollment process, including the previous plan assignment of the beneficiary, quality assurance and improvement performance, procurement evaluation elements, accessibility of provider offices for people with disabilities (when appropriate), and other reasonable criteria that support the objectives of the managed care program.

(3) The State must send a confirmation of the enrollee’s managed care enrollment to the enrollee within 5 calendar days of the date such enrollment is processed by the State. The confirmation must clearly explain the enrollee’s right to disenroll within

90 days from the effective date of the enrollment.

(b) *Priority for enrollment.* The state must have an enrollment system under which beneficiaries already enrolled in an MCO, PIHP, PAHP, PCCM, or PCCM entity are given priority to continue that enrollment if the MCO, PIHP, PAHP, PCCM, or PCCM entity does not have the capacity to accept all those seeking enrollment under the program.

(c) *Informational notices.* A State must provide an informational notice to each potential enrollee who may enroll in an MCO, PIHP, PAHP, PCCM, or PCCM entity. Such notice must:

(1) Include the MCOs, PIHPs, PAHPs, PCCMs, or PCCM entities available to the potential enrollee;

(2) Explains how to select an MCO, PIHP, PAHP, PCCM, or PCCM entity;

(3) Explain the implications of making or not making an active choice of an MCO, PIHP, PAHP, PCCM or PCCM entity;

(4) Explains the length of the enrollment period as well as the disenrollment policies in § 457.1212; and

(5) Comply with the information requirements in § 457.1207 and accessibility standards established under § 457.340.

§ 457.1212 Disenrollment.

The State must comply with and ensure, through its contracts, that each MCO, PAHP, PIHP, PCCM and PCCM entity complies with the disenrollment requirements in accordance with the terms of § 438.56 of this chapter, except that references to fair hearings should be read to refer to reviews as described in subpart K of this part.

§ 457.1214 Conflict of interest safeguards.

The State must have in effect safeguards against conflict of interest in accordance with the terms of § 438.58 of this chapter.

§ 457.1216 Continued services to enrollees.

The State must follow the requirements related to continued services to enrollees in accordance with the terms of § 438.62 of this chapter.

§ 457.1218 Network adequacy standards.

The State must develop network adequacy standards in accordance with the terms of § 438.68 of this chapter, and, ensure through its contracts, that each MCO, PAHP, and PIHP meets such standards.

Enrollee Rights and Protections

§ 457.1220 Enrollee rights.

The State must ensure, through its contracts, that each MCO, PIHP, PAHP,

PCCM, and PCCM entity follow the enrollee rights requirements in accordance with the terms of § 438.100 of this chapter.

§ 457.1222 Provider-enrollee communication.

The State must ensure, through its contracts, that each MCO, PIHP, and PAHP protects communications between providers and enrollees in accordance with the terms of § 438.102 of this chapter.

§ 457.1224 Marketing activities.

The State must ensure, through its contracts, that each MCO, PIHP, PAHP, PCCM, and PCCM entity follows the requirements related to marketing activities in accordance with the terms of § 438.104 of this chapter, except § 438.104(c) of this chapter related to state agency review does not apply.

§ 457.1226 Liability for payment.

The State must ensure, through its contracts, that enrollees of MCOs, PIHPs, and PAHPs are not held liable for services or debts of the MCO, PIHP, or PAHPs in accordance with the terms of § 438.106 of this chapter.

§ 457.1228 Emergency and poststabilization services.

The State must ensure that emergency services, as defined in § 457.10 of this chapter, are available and accessible to enrollees in accordance with the terms of § 438.114 of this chapter.

MCO, PIHP, and PAHP Standards

§ 457.1230 Access standards.

(a) *Availability of services.* The State must ensure that the services are available and accessible to enrollees in accordance with the terms of § 438.206 of this chapter.

(b) *Assurances of adequate capacity and services.* The State must ensure, through its contracts, that each MCO, PIHP and PAHP has adequate capacity to serve the expected enrollment in accordance with the terms of § 438.207 of this chapter.

(c) *Coordination and continuity of care.* The State must ensure, through its contracts, that each MCO, PIHP and PAHP complies with the coordination and continuity of care requirements in accordance with the terms of § 438.208 of this chapter.

(d) *Coverage and authorization of services.* The State must ensure, through its contracts, that each MCO, PIHP or PAHP complies with the coverage and authorization of services requirements in accordance with the terms of § 438.210 of this chapter, except that the following do not apply: § 438.210(a)(5)

of this chapter (related to medical necessity standard); and § 438.210(b)(2)(iii) of this chapter (related to authorizing LTSS).

§ 457.1233 Structure and operation standards.

(a) *Provider selection.* The State must ensure, through its contracts, that each MCO, PIHP or PAHP complies with the provider selection requirements as provided in § 438.214 of this chapter.

(b) *Subcontractual relationships and delegation.* The State must ensure, through its contracts, that each MCO, PIHP and PAHP complies with the subcontractual relationships and delegation requirements as provided in § 438.230 of this chapter.

(c) *Practice guidelines.* The state must ensure, through its contracts, that each MCO and, when applicable, each PIHP and PAHP, complies with the practice guidelines requirements as provided in § 438.236 of this chapter.

(d) *Health information systems.* The State must ensure, through its contracts, that each MCO, PIHP, and PAHP complies with the health information systems requirements as provided in § 438.242 of this chapter.

(e) *Privacy protections.* The state must ensure, through its contracts, that each MCO, PIHP, and PAHP complies with the privacy protections as provided in § 457.1110.

Quality Measurement and Improvement; External Quality Review

§ 457.1240 Quality measurement and improvement.

(a) *Scope.* This section sets forth requirements related to quality assessment and performance improvement that the State must meet in contracting with an MCO, PIHP, PAHP, or certain PCCM entities.

(b) *Quality assessment and performance improvement program.* The State must require, through its contracts, that each MCO, PIHP, and PAHP must establish and implement an ongoing comprehensive quality assessment and performance improvement program for the services it furnishes to its enrollees as provided in § 438.330 of this chapter, except that the terms of § 438.330(d)(4) of this chapter (related to dual eligibles) do not apply. In the case of a contract with a PCCM entity described in paragraph (f) of this section, § 438.330(b)(3), (c), and (e) of this chapter apply.

(c) *State review of the accreditation status of MCOs, PIHPs, and PAHPs.* The State must review the accreditation status of each MCO, PIHP, and PAHP in accordance with the requirements as set forth in § 438.332 of this chapter.

(d) *Managed care quality rating system.* The State must determine a quality rating or ratings for each MCO, PIHP, and PAHP in accordance with the requirements set forth in § 438.334 of this chapter.

(e) *Managed care quality strategy.* The State must draft and implement a written quality strategy for assessing and improving the quality of health care and services furnished CHIP enrollees as described in § 438.340 of this chapter. In the case of a contract with a PCCM entity described in paragraph (f) of this section, § 438.340 (e) of this chapter apply.

(f) *Applicability to PCCM entities.* For purposes of paragraphs (b) and (e) of this section and § 457.1250(a), a PCCM entity described in this paragraph is a PCCM entity whose contract with the State provides for shared savings, incentive payments or other financial reward for improved quality outcomes.

§ 457.1250 External quality review.

(a) Each State that contracts with MCOs, PIHPs, or PAHPs must follow all applicable external quality review requirements as set forth in §§ 438.350, 438.352, 438.354, 438.356, 438.358, 438.360 (only with respect to nonduplication of EQR activities with private accreditation) and 438.364 of this chapter. In the case of a contract with a PCCM entity described in § 457.1240(f), § 438.350 of this chapter applies.

(b) A State may amend an existing EQRO contract to include the performance of EQR-related activities and/or EQR in accordance with paragraph (a) of this section.

Grievance System

§ 457.1260 Grievance system.

The State must ensure that its contracted MCOs, PIHPs, and PAHPs comply with the grievance and appeals requirements and procedures in accordance with the terms of subpart F of part 438 of this chapter, except that the terms of § 438.420 of this chapter do not apply and that references to fair hearings should be read to refer to reviews as described in subpart K of this part.

Sanctions

§ 457.1270 Sanctions.

The State must comply, and ensure that its contracted MCOs comply, with the sanctions requirements in accordance with the terms of subpart I of part 438 of this chapter.

§ 457.955 [Redesignated as § 457.1280]

■ 20. Section 457.955 is redesignated as § 457.1280 and transferred from subpart I to subpart L.

■ 21. Newly redesignated § 457.1280 is amended by revising the section heading and paragraphs (a), (b)(1), (b)(2), (b)(3), and (d) to read as follows:

§ 457.1280 Conditions necessary to contract as an MCO, PAHP, or PIHP.

(a) The State must assure that any entity seeking to contract as an MCO, PAHP, or PIHP under a separate child health program has administrative and management arrangements or procedures designed to safeguard against fraud and abuse.

(b) * * *

(1) Enforce MCO, PAHP, and PIHP compliance with all applicable Federal and State statutes, regulations, and standards.

(2) Prohibit MCOs, PAHPs, and PIHPs from conducting any unsolicited personal contact with a potential enrollee by an employee or agent of the MCO, PAHP, or PIHP for the purpose of influencing the individual to enroll with the entity.

(3) Include a mechanism for MCOs, PAHPs, and PIHPs to report to the State, to CMS, or to the Office of Inspector General (OIG) as appropriate, information on violations of law by subcontractors, providers, or enrollees of an MCO, PAHP, or PIHP and other individuals.

* * * * *

(d) The State may inspect, evaluate, and audit MCOs, PIHPs, and PAHPs at any time, as necessary, in instances where the State determines that there is a reasonable possibility of fraudulent or abusive activity.

■ 22. Section 457.1285 is added to subpart L to read as follows:

§ 457.1285 Program integrity safeguards.

The state must comply with the program integrity safeguards in accordance with the terms of subpart H of part 438, except that the terms of § 438.604(a)(2) of this chapter do not apply.

PART 495—STANDARDS FOR THE ELECTRONIC HEALTH RECORD TECHNOLOGY INCENTIVE PROGRAM

■ 23. The authority citation for part 495 continues to read as follows:

Authority: Secs. 1102 and 1871 of the Social Security Act (42 U.S.C. 1302 and 1395hh).

§ 495.332 [Amended]

■ 24. In § 495.332, amend paragraph (d)(2) by removing the reference “§ 438.6(v)(5)(iii)” and adding in its place the reference “§ 438.6(b)(2)”.

§ 495.366 [Amended]

■ 25. In § 495.366, amend paragraph (e)(7) by removing the reference “§ 438.6(c)(5)(iii)” and adding in its place the reference “§ 438.6(b)(2)”.

Dated: March 9, 2016.

Andrew M. Slavitt,

Acting Administrator, Centers for Medicare & Medicaid Services.

Dated: April 19, 2016.

Sylvia M. Burwell,

Secretary, Department of Health and Human Services.

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