

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Parts 438, 440, 456, and 457

[CMS–2333–P]

RIN 0938–AS24

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

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

ACTION: Proposed rule.

SUMMARY: This proposed rule would address application of certain requirements set forth in the Public Health Service Act, as amended by the Paul Wellstone and Pete Domenici Mental Health Parity and Addiction Equity Act of 2008, to coverage offered by Medicaid managed care organizations, Medicaid Alternative Benefit Plans, and Children's Health Insurance Programs.

DATES: To be assured consideration, comments must be received at one of the addresses provided below, no later than 5 p.m. on June 9, 2015.

ADDRESSES: In commenting, please refer to file code CMS–2333–P. Because of staff and resource limitations, we cannot accept comments by facsimile (FAX) transmission.

You may submit comments in one of four ways (please choose only one of the ways listed):

1. *Electronically.* You may submit electronic comments on this regulation to <http://www.regulations.gov>. Follow the "Submit a comment" instructions.

2. *By regular mail.* You may mail written comments to the following address ONLY: Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS–2333–P, P.O. Box 8016, Baltimore, MD 21244–8016.

Please allow sufficient time for mailed comments to be received before the close of the comment period.

3. *By express or overnight mail.* You may send written comments to the following address ONLY: Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS–2333–P, Mail Stop C4–26–05, 7500 Security Boulevard, Baltimore, MD 21244–1850.

4. *By hand or courier.* Alternatively, you may deliver (by hand or courier) your written comments ONLY to the following addresses prior to the close of the comment period:

a. For delivery in Washington, DC—Centers for Medicare & Medicaid Services, Department of Health and Human Services, Room 445–G, Hubert H. Humphrey Building, 200 Independence Avenue SW., Washington, DC 20201.

(Because access to the interior of the Hubert H. Humphrey Building is not readily available to persons without Federal government identification, commenters are encouraged to leave their comments in the CMS drop slots located in the main lobby of the building. A stamp-in clock is available for persons wishing to retain a proof of filing by stamping in and retaining an extra copy of the comments being filed.)

b. For delivery in Baltimore, MD—Centers for Medicare & Medicaid Services, Department of Health and Human Services, 7500 Security Boulevard, Baltimore, MD 21244–1850.

If you intend to deliver your comments to the Baltimore address, call telephone number (410) 786–7195 in advance to schedule your arrival with one of our staff members.

Comments erroneously mailed to the addresses indicated as appropriate for hand or courier delivery may be delayed and received after the comment period.

For information on viewing public comments, see the beginning of the **SUPPLEMENTARY INFORMATION** section.

FOR FURTHER INFORMATION CONTACT: John O'Brien or Jean Close at (410) 786–5529 (Alternative Benefit Plan), Debra Dombrowski at (312) 353–1403 (Managed Care) or Amy Lutzky (410) 786–0721.

SUPPLEMENTARY INFORMATION:

Inspection of Public Comments: All comments received before the close of the comment period are available for viewing by the public, including any personally identifiable or confidential business information that is included in a comment. We post all comments received before the close of the comment period on the following Web site as soon as possible after they have been received: <http://www.regulations.gov>. Follow the search instructions on that Web site to view public comments.

Comments received timely will also be available for public inspection as they are received, generally beginning approximately 3 weeks after publication of a document, at the headquarters of the Centers for Medicare & Medicaid Services, 7500 Security Boulevard,

Baltimore, Maryland 21244, Monday through Friday of each week from 8:30 a.m. to 4 p.m. To schedule an appointment to view public comments, phone 1–800–743–3951.

Acronyms, Abbreviations, and Short Forms

Because of the many terms to which we refer by acronym, abbreviation, or short form in this proposed rule, we are listing the acronyms, abbreviation, and short forms used and their corresponding terms in alphabetical order below.

2008 Extenders Act Tax Extenders and Alternative Minimum Tax Relief Act of 2008 (Division C)

The Act Social Security Act

The Affordable Care Act Patient Protection and Affordable Care Act (Pub. L. 111–148, enacted on March 23, 2010), as amended by the Health Care and Education Reconciliation Act of 2010 (Pub. L. 111–152)

The Departments Departments of the Treasury, Labor, and Health and Human Services

ABP Alternative Benefit Plan

BBA Balanced Budget Act of 1997

CHIP Children's Health Insurance Program

CHIPRA Children's Health Insurance Program Reauthorization Act of 2009

CMS Centers for Medicare and Medicaid Services

The Code Internal Revenue Code of 1986

DOL Department of Labor

DSM Diagnostic and Statistical Manual of Mental Disorders (current edition)

EHB Essential Health Benefit

EPSDT Early and Periodic Screening, Diagnostic and Treatment

ERISA Employee Retirement Income Security Act of 1974

FFS Fee for Service

HHS Department of Health and Human Services

ICD International Classification of Diseases

MCE Managed Care Entity

MCO Managed Care Organization

MH Mental Health

MH/SUD Mental Health or Substance Use Disorder

MHPA Mental Health Parity Act of 1996

MHPAEA Paul Wellstone and Pete Domenici Mental Health Parity and Addiction Equity Act of 2008

NQTL Nonquantitative Treatment Limitation

PAHP Prepaid Ambulatory Health Plan

PHS Act Public Health Service Act

PIHP Prepaid Inpatient Health Plan

SHO State Health Official

SUD Substance Use Disorder

Treasury Department of the Treasury

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I. Executive Summary

This proposed rule addresses the application of certain provisions added to the Public Health Service Act (PHS Act) (mental health parity requirements) by the provisions of the Paul Wellstone and Pete Domenici Mental Health Parity and Addiction Equity Act of 2008 (MHPAEA) (Pub. L. 110–343, enacted on October 3, 2008) to: (1) Medicaid managed care organizations (MCOs) as described in section 1903(m) of the Social Security Act (the Act); (2) Medicaid benchmark and benchmark-equivalent plans (referred to in this proposed rule as Medicaid Alternative Benefit Plans) as described in section 1937 of the Act; and (3) Children’s Health Insurance Program (CHIP) under title XXI of the Act.

Under section 1932(b)(8) of the Act, Medicaid MCOs are required to comply with the requirements of subpart 2 of part A of title XXVII of the PHS Act, to the same extent that those requirements apply to a health insurance issuer that offers group health insurance. Subpart 2 includes mental health parity requirements added by MHPAEA at section 2726 of the PHS Act (as renumbered; formerly section 2705 of the PHS Act). Under section 1937(b)(6) of the Act, Medicaid Alternative Benefit Plans (ABPs) that are not offered by an MCO and that provide both medical and surgical benefits and mental health or substance use disorder benefits are required to ensure that financial requirements and treatment limitations for such benefits comply with the mental health parity requirements of the PHS Act (referencing section 2705(a) of the PHS Act, which is now renumbered 2726(a) of the PHS Act), in the same

manner as such requirements apply to a group health plan. The section 1937 provision applies only to ABPs that are not offered by MCOs; ABPs offered by MCOs are already required to comply with these requirements under section 1932(b)(8) of the Act. Section 2103(c)(6) of the Act requires that state CHIP plans that provide both medical and surgical benefits and mental health or substance use disorder benefits shall ensure that financial requirements and treatment limitations for such benefits comply with mental health parity requirements of the PHS Act (referencing section 2705(a) of the PHS Act, now renumbered as section 2726(a) of the PHS Act) to the same extent as such requirements apply to a group health plan. In addition, section 2103(f)(2) of the Act requires that CHIP benchmark or benchmark equivalent plans comply with all of the requirements of subpart 2 of part A of the title XXVII of the PHS Act, which includes the mental health parity requirements of the PHS Act, insofar as such requirements apply to health insurance issuers that offer group health insurance coverage.

This proposed rule would incorporate these requirements into our regulations.

II. Background

A. Introduction

On September 26, 1996, the Congress enacted the Mental Health Parity Act of 1996 (Pub. L. 104–204) (MHPA), which required parity in aggregate lifetime and annual dollar limits for mental health benefits and medical/surgical benefits. Those mental health parity provisions were codified in section 712 of ERISA, section 2726 of the PHS Act (renumbered under section 1001 of the Affordable Care Act), and section 9812 of the Code, and applied to employment-related group health plans and health insurance coverage offered in connection with a group health plan. The Balanced Budget Act of 1997 (Pub. L. 105–33, enacted on August 5, 1997) (BBA) added sections 1932(b)(8) and 2103(f)(2) of the Act to generally apply certain aspects of MHPA, including the provisions of section 2726 of the PHS Act, to Medicaid MCOs and CHIP benefits.

MHPAEA was enacted as sections 511 and 512 of the Tax Extenders and Alternative Minimum Tax Relief Act of 2008 (Division C of Pub. L. 110–343) (the 2008 Extenders Act). MHPAEA amends the Employee Retirement Income Security Act of 1974 (ERISA), the PHS Act, and the Internal Revenue Code of 1986 (the Code). The changes made by MHPAEA consist of new standards, including parity for

substance use disorder benefits, as well as amendments to the existing mental health parity provisions enacted in MHPA.

In 2009, section 502 of the Children’s Health Insurance Program Reauthorization Act of 2009 (Pub. L. 111–3) (CHIPRA) amended section 2103(c) of the Act by adding paragraph (6), which requires that CHIP plans that provide both medical and surgical benefits and mental health or substance use disorder benefits comply with the provisions of section 2705(a) of the PHS Act, as amended by MHPAEA, in the same manner as a group health plan.

The Patient Protection and Affordable Care Act (Pub. L. 111–148) was enacted on March 23, 2010 and the Health Care and Education Reconciliation Act of 2010 (Pub. L. 111–152) was enacted on March 30, 2010 (collectively referred to as the “Affordable Care Act”). Section 1001 of the Affordable Care Act reorganized and renumbered certain provisions of the PHS Act, including renumbering section 2705 of the PHS Act as section 2726 of the PHS Act. The Affordable Care Act did not make conforming changes to cross-references to the renumbered provisions, and contained new cross-references to the former section numbers. But there was no indication that Congress intended to alter the meaning of the existing cross-references. As a result, we read the cross-references to continue to refer to the same section originally referenced, as renumbered. We believe it is clear that the new cross-references were also intended to refer to the renumbered provisions.

The Affordable Care Act expanded the application of section 2705(a) of the PHS Act, as amended by MHPAEA, and renumbered as section 2726(a) of the PHS Act, to benefits in Medicaid ABPs delivered outside of a MCO. ABPs delivered through a MCO would already have to comply with these requirements under section 1932(b)(8) of the Act.

Also, effective on March 23, 2010, section 2001(c) of the Affordable Care Act modified the benefit provisions of section 1937 of the Act. Specifically, section 2001(c) of the Affordable Care Act added mental health benefits and prescription drug coverage to the list of benefits that must be included in benchmark-equivalent coverage; required the inclusion of essential health benefits (EHBs) beginning in 2014; and directed that plans described in section 1937 of the Act (now known as ABPs) that include medical/surgical benefits and mental health or substance use disorder benefits ensure that the financial requirements and treatment limitations applicable to such mental

health or substance use disorder (MH/SUD) benefits comply with the mental health parity provisions of the PHS Act.

In 2013, we released a State Health Official (SHO) letter that provided guidance to states regarding the implementation of requirements under MHPAEA to Medicaid benchmark and benchmark-equivalent plans (referred to in the letter as ABPs) as described in section 1937 of the Act, CHIP under title XXI of the Act, and MCOs as described in section 1903(m) of the Act.¹ We previously issued a SHO letter on November 4, 2009, concerning the application of section 502 of CHIPRA.²

The Departments of Health and Human Services (HHS), Labor, and the Treasury (collectively the Departments) published interim final regulations implementing MHPAEA on February 2, 2010 (75 FR 5410), and final regulations applicable to group health plans and health insurance issuers on November 13, 2013 (78 FR 68240) (MHPAEA final regulations).³ The MHPAEA final regulations do not apply to Medicaid MCOs, ABPs, or CHIP state plans. In this proposed rule, we are proposing regulations to address how the MHPAEA requirements in section 2726 of the PHS Act, as implemented in the MHPAEA final regulations, will apply to MCOs, ABPs and CHIP.

III. Provisions of the Proposed Rule

This proposed rule generally mirrors the policies set forth in the MHPAEA final regulations to implement the statutory provisions that require MCOs, ABPs and CHIP to comply with certain requirements of section 2726 of the PHS Act (mental health parity requirements).

State Medicaid programs vary in their coverage of MH/SUD services. For example, most MH/SUD services are optional services under the traditional Medicaid benefits package, so states can choose to cover some services and not others, or can choose to cover these services but impose treatment limitations (for example, day or visit

limits). Additionally, states have the flexibility to provide services through a managed care delivery mechanism using entities other than MCOs, such as prepaid inpatient health plans (PIHPs) or prepaid ambulatory health plans (PAHPs). PIHPs and PAHPs are defined in § 438.2 as entities that provide medical services on the basis of prepaid capitation payments but provide a more limited benefit package than a comprehensive MCO defined in section 1903(m) of the Act and are subject to the requirements for managed care entities as specified in 42 CFR part 438. These entities are not described in section 1932 of the Act, which refers only to the application of mental health parity requirements to Medicaid MCOs. In many instances, states will provide the medical/surgical services through an MCO, but will not include in the MCO benefit package some or all of their MH/SUD state plan services. Instead, these services will be delivered through a PIHP or a PAHP or a non-managed care delivery system, typically fee-for-service (FFS). In many states, MCOs provide some MH/SUD services (for example, emergency department services regardless of presenting condition, or MH/SUD medications), and PIHPs, PAHPs, or FFS provide a more robust set of services for those individuals with serious mental health conditions or substance use disorders. These unique state MH/SUD delivery systems are an important distinction between Medicaid coverage and coverage available through the commercial market. Because the statutory provisions making mental health parity requirements applicable to MCOs do not explicitly address the situation in which medical/surgical benefits and MH/SUD benefits included in coverage are furnished through separate but interrelated and interdependent service delivery systems, additional guidance is needed.

As a general matter, this proposed rule would require that each MCO enrollee in a state must be provided access to a set of benefits that meets the requirements of this rule regardless of whether the MH/SUD services are provided by the MCO or through another service delivery system. We propose to apply MHPAEA in this way as we interpret section 1932(b)(8) of the Act to require that, if a state uses private health plans, or MCOs, to provide any of its state plan benefits under an MCO contract, enrollees in those MCOs (whether under a voluntary or mandatory managed care program) must receive the protections of MHPAEA parity requirements for MH/SUD services. We are concerned that the

exclusion of MH/SUD services from MCO contracts could result in the elimination of the application of section 1932(b)(8) of the Act. To ensure that the goal of parity is met, we are proposing to require, by relying on our authority in section 1902(a)(4) of the Act to specify methods “necessary for the proper and efficient operation of the state plan,” that if MH/SUD state plan services are provided to MCO enrollees through a PIHP, PAHP, or under Medicaid FFS (because such services are carved out of the MCO contract scope), MCO enrollees will still receive the MHPAEA parity protections for MH/SUD state plan services. Specifically, states that do not provide all services through the MCO will be required to provide evidence of compliance with this rule when they submit MCO contracts to the CMS Regional Office for review and approval. Contracts with PIHPs and PAHPs would also be required to provide that the PIHPs and PAHPs take steps necessary to ensure such compliance with this proposed rule. For states that offer MH/SUD services to MCO enrollees through FFS (other than when the services are part of an ABP, as discussed below), states would similarly be obligated to ensure that MH/SUD services provided on a FFS basis, when combined with services furnished by the MCO, comply with MHPAEA. In such an instance, the state would have the option of either (1) making changes to the non-ABP state plan to provide MH/SUD services through the FFS system in a manner that is on parity with the MCO-provided medical/surgical services consistent with this proposed rule or (2) including relevant MH/SUD services in the MCO contract (or PIHP or PAHP contract as applicable), in which case the managed care entity would have to comply with this proposed rule. Failure to adopt these additional requirements using our authority under section 1902(a)(4) of the Act, as well as section 1932(b)(8) of the Act would result in de facto nullification of the MHPAEA protections that are provided in section 1932(b)(8) of the Act if states carved out MH/SUD benefits from the MCO contract.

We considered alternatives such as requiring, based as well on our authority at section 1902(a)(4) of the Act, that all state plan MH/SUD services be included under MCO contracts as the way to ensure that MCO enrollees receive the full protections of MHPAEA as we believe the Congress intended in section 1932(b)(8) of the Act, again relying on our authority under section 1902(a)(4) of the Act. But, we believe that the

¹ <http://www.medicaid.gov/federal-policy-guidance/downloads/sho-13-001.pdf>.

² <http://downloads.cms.gov/cmsgov/archived-downloads/SMDL/downloads/SHO110409.pdf>.

³ The MHPAEA final regulations generally apply to group health plans and health insurance issuers on the first day of the first plan year beginning on or after July 1, 2014. The preamble to the MHPAEA final regulations stated that each plan or issuer subject to the interim final regulations, issued on February 2, 2010 (75 FR 5410), must continue to comply with the applicable provisions of the interim final regulations until the corresponding provisions of these final regulations become applicable to that plan or issuer (78 FR 68252 and 253). Note: For ease of reference, the citations to provisions of the MHPAEA final rules throughout this document will only refer to the provisions adopted by HHS in 45 CFR part 146.

approach we are proposing would allow states the most flexibility when applying mental health parity requirements to their Medicaid services across delivery systems. Given that there are many different delivery system configurations that carve out MH/SUD services, this would allow states to comport with parity requirements for MCO enrollees without completely carving out MH/SUD services from their MCO or dropping MH/SUD coverage altogether. We solicit comments on whether to require that all state plan MH/SUD services be included under MCO contracts.

We recognize that this proposed regulation would require an analysis by the state to determine if the overall delivery system complies with the provisions of this proposed rule when all services are not included in the benefit package of a single MCO. In states where the MCO has sole responsibility for offering MH/SUD services, the MCO would be responsible for undertaking the parity analysis and informing the state what changes will be needed to the MCO contract to comply with the provisions of this proposed rule. As proposed in § 438.920, states would be required to make available to the public their methods of complying with these proposed rules within 18 months after the rule is finalized.

In states where some or all MH/SUD services are provided through some combination of MCOs, PIHPs, PAHPs or FFS, the state would have the responsibility for undertaking the parity analysis across these delivery systems and determining if the benefits and any financial requirements or treatment limitations are consistent with proposed § 438.920(b). The state, based on this analysis, would take the necessary steps to ensure mental health parity compliance for its Medicaid MCO enrollees. As previously discussed, we believe that the provisions of section 1902(a)(4) of the Act authorize CMS to adopt rules that require the state to perform the parity analysis when MH/SUD services are offered across delivery systems because we believe that this administrative responsibility is necessary and essential for full implementation of section 1932(b)(8) of the Act. In addition, we are proposing at § 438.920(b) that the state make available documentation of compliance with these proposed regulations to the general public within 18 months of the effective date of this rule and post it on the state Medicaid Web site.

For beneficiaries who are not enrolled in a MCO (FFS only), and thus not covered by section 1932(b)(8) of the Act, our proposed rule would not affect

coverage (other than when the services are part of an alternative benefit plan, as discussed below). However, we encourage states to provide state plan benefits in a way that comports with the mental health parity requirements of section 2726 of the PHS Act.

We note that payment to MCOs must be actuarially sound under section 1903(m) of the Act; regulations implementing that requirement are currently codified at § 438.6 and are applicable to other managed care entities based on separate statutory authority. In particular, § 438.6(e) provides that actuarially sound rates may only be based on the cost to provide services covered under the state plan. As part of our proposal to implement the mental health parity requirements, we propose to revise § 438.6(e) to specify development of actuarially sound rates for MCOs, PIHPs and PAHPs that provide MH/SUD services may take into account the cost of providing services beyond those specified in the state plan which are necessary for the MCO, PIHP or PAHP to comply with the mental health parity requirements. Proposed § 438.6(e)⁴ would require that states base the capitation rates set for MCOs, PIHPs, and PAHPs, where MH/SUD benefits are provided under contract with these entities, on their provision of a benefit package that is compliant with these proposed parity requirements even if services go beyond what is in the state plan; the additional non-state plan services that are used to develop the capitation rates would have to be necessary to comply with the requirements of new subpart K of part 438. This would ensure that states maintain an actuarially sound rate-setting structure that provides for payment of capitation rates to managed care plans rate that reflect the full scope of benefits the managed care plans are obligated to provide. To the extent this new subpart K would obligate an MCO, PIHP or PAHP to provide services that are not otherwise included in the state plan, costs associated with services that would not be included but for the parity requirements should be part of the actuarially sound capitation rates. We believe that proposed § 438.6(e) is sufficiently specific to only permit states to include those services needed for compliance with these proposed rules. Section 438.6(e) allows a state's rate-setting structure to account for services covered by an MCO, PIHP, or

PAHP in excess of services and/or treatment limits that are listed in the state plan only to the extent that such services are necessary for the MCO, PIHP or PAHP to comply with § 438.910 of this rule. However, we are concerned about the potential for inappropriately broad readings of the regulation text and consequent use of this proposed section to include non-State plan services in rate setting for the MCO, PIHP or PAHP benefit package that are not strictly necessary for compliance with these proposed parity requirements. We request comments on this risk and how we might mitigate it, such as a need for more prescriptive language or specific oversight activities to ensure that managed care plans and states develop rates that include only state plan services and the additional services necessary for compliance with subpart K. For states that offer MH/SUD services to MCO enrollees through FFS (other than when the services are part of an alternative benefit plan, as discussed below), states would similarly be obligated to ensure that MH/SUD services provided on a FFS basis, when combined with services furnished by an MCO, comply with the proposed parity provisions in part 438, subpart K. To ensure this full implementation of section 1932(b)(8) of the Act, we rely on our authority under section 1902(a)(4) of the Act to require methods of administration necessary for the proper and efficient administration of the state plan. If a state provides MH/SUD benefits to MCO enrollees through FFS, the state would have the option of either (1) making changes to the non-ABP state plan to provide MH/SUD services through the FFS system in a manner that is on parity with the MCO-provided medical/surgical services consistent with this rule, or (2) including relevant MH/SUD services in a MCO contract (or PIHP or PAHP contract when relevant), in which case the managed care entity would have to comply with this rule.

To ensure the appropriate application of mental health parity requirements to Medicaid services, we propose to amend current regulations to apply mental health parity requirements under section 2726 of the PHS Act to services provided to enrollees of Medicaid MCOs regardless of delivery system or limitations in the state plan. Specifically, we propose amending part 438 by adding a new subpart K to extend these mental health parity requirements to MCOs, and to PIHPs and PAHPs as applicable, to ensure that all enrollees of the MCO are provided access to a MHPAEA-compliant set of services when the state plan includes

⁴ Our proposal is for this provision to be codified as part of the regulations controlling rate setting for MCOs, PIHPs and PAHPs and the paragraph designation may vary.

some MH/SUD services. Second, we are proposing to add a new provision in § 438.6 to require that all MCO contracts, and any PIHP and PAHP contracts providing services to MCO enrollees, ensure that enrollees receive services that are in compliance with the requirements of new subpart K insofar as those requirements are applicable. We would not apply mental health parity requirements to state plan services provided to beneficiaries covered only through a FFS delivery system, even if care for other beneficiaries is delivered through a managed care delivery system. However, as indicated in our 2013 SHO letter, we strongly encourage states to consider changes to the state plan benefit package to comport with the mental health parity requirements of section 2726 of the PHS Act. Several states have already implemented the necessary changes in their state plan (for example, adding SUD outpatient services and removing or aligning treatment limitations) to make their MH/SUD benefits consistent for all Medicaid beneficiaries. For clarity, we are not applying mental health parity requirements under section 2726 of the PHS Act to Medicare Parts A, B, or D services covered by Medicaid MCOs, such as those covered by integrated plans for people who are dually eligible for Medicare and Medicaid; Medicare benefits are controlled by the Medicare statute and regulations, which are not within the scope of this proposed rule.

The proposed rules pertaining to ABPs and CHIP cross-reference the proposed rules governing MCOs, PIHPs or PAHPs when states are using these organizations as their delivery system for ABP or CHIP benefits. Regardless of whether services are delivered in managed care or non-managed care arrangements, all Medicaid ABPs (including benchmark equivalent and Secretary-approved benchmark plans) and CHIP plans are required to meet the financial requirements and treatment limitations component of the mental health parity provisions set forth at section 2726(a) of the PHS Act.

Section 2726 of the PHS Act contains an increased cost exemption that is available for group health plans and health insurance issuers that make changes to comply with the law and incur an increased cost of at least 2 percent in the first year that mental health parity requirements apply to the plan or coverage, or an increased cost of at least 1 percent in any subsequent plan or policy year. Plans or issuer-offered coverage that comply with the parity requirements for one full plan year and that satisfy the conditions for

the increased cost exemption are exempt from the parity requirements for the following plan or policy year, and the exemption lasts for one plan or policy year.

This proposed rule does not include an increased cost exemption for MCOs, PIHPs, or PAHPs, and we do not believe that these Medicaid managed care entities will incur any net increase in costs because we are also proposing here that the actuarially sound payment methodology will take costs of compliance with parity requirements into account. As noted, we are proposing to allow states to include the cost of providing services beyond what is specified in the state plan which may include adding services or removing or aligning treatment limitations in managed care benefits into the actuarially sound rate methodology so long as those services beyond what is specified in the state plan are necessary to comply with mental health parity requirements. These changes to the managed care rate setting process would authorize states, in instances where they choose not to change their state plan, to include the cost of services beyond what is specified in the state plan into the capitation rate development to the extent the services are required to be provided by the MCO, PIHP or PAHP and outlined under contract to comply with this proposed rule. Therefore, the Medicaid program rather than the plan will bear the costs of these changes. This is different from the circumstances of the commercial market and removes the rationale for an increased cost exemption for Medicaid MCOs, PIHPs and PAHPs. In addition, we understand that few if any issuers and group health plans have sought an increased cost exemption in the commercial market. Therefore, in this proposed rule, we are not extending the cost exemption provision to the Medicaid and CHIP programs.

We recognize that state budgeting and contracting processes may necessitate additional time for compliance with these new contracting and rate setting parameters. We propose to afford states up to 18 months after the date of the publication of the final rule to comply with the finalized provisions of this proposed rule. This proposal would allow states to come into compliance with these regulations and take the actions to make the necessary budget requests to add new services or additional service units. Some states have a biannual budget cycle and may need this length of time to develop and obtain approval of these budget requests. In addition, states would need to make the necessary contract changes

to their MCOs, PIHPs, or PAHPs once the budget has been approved. Some states may choose to request approval from CMS to make changes to their non-ABP state plan for services delivered through FFS. We believe that 18 months should provide states with sufficient time to implement the necessary policy, contract and budget changes to comply with the final regulations and are proposing a delayed compliance deadline accordingly. We invite comments on this proposal regarding the delay of required compliance and the treatment of a cost-based exemption.

The statutory requirements applying mental health parity requirements to CHIP are structured differently than the statutory direction to apply those requirements to Medicaid MCOs. For CHIP programs, sections 2103(c)(6) and 2103(f)(2) of the Act generally provide that MH/SUD parity requirements apply to all delivery systems, including FFS and managed care. Except where the CHIP state plan provides full coverage of EPSDT and the MHPAEA requirements are deemed as met, the MHPAEA parity requirements apply to the CHIP state plan in the same manner as the law applies to health insurance issuers and group health plans. Our proposal reflects this in the proposed regulations for part 457.

For CHIP enrollees in an MCO, we propose to apply all mental health parity provisions of section 2726 of the PHS Act. In addition to the language at sections 2103(c)(6) and section 2103(f)(2) of the Act previously discussed, section 2103(f)(3) of the Act makes applicable to CHIP MCOs certain requirements under section 1932 of the Act, including section 1932(b)(8) of the Act which requires that MCOs comply with MHPAEA parity requirements. Furthermore, we propose to require parity in connection with coverage provided by PIHPs and PAHPs to CHIP MCO enrollees.

For ABP benefits offered only through FFS delivery systems, financial requirements and treatment limitations under section 2726(a) of the PHS Act are the only mental health parity provisions that apply (based on section 1937(b)(6) of the Act). Section 2726(a)(3)(B) of the PHS Act excludes from the definition of the term “financial requirement” aggregate lifetime or annual dollar limits on benefits, and thus these are not included in the “financial requirements and treatment limitations” parity requirements applicable to Medicaid ABPs furnished through FFS service delivery systems. (Annual and lifetime limits are addressed separately under MHPAEA from financial requirements, at sections 2726(a)(1) and (2) of the PHS

Act.). In addition, the following mental health parity provisions are not applicable to FFS delivery systems for Medicaid ABP benefits because they are not “financial or treatment limitations:” those regarding access to out-of-network providers and the increased cost exemption. For ABP benefits provided through an MCO, PIHP or PAHP, our proposal is to require compliance with the part 438 provisions addressing MHPAEA parity requirements for Medicaid managed care.

A. Meaning of Terms (§ 438.900, § 440.395, § 457.496)

The definitions of terms in this proposed rule include most terms included in the MHPAEA final regulation at 45 CFR 146.136(a). This proposed rule proposes to modify or add several terms to reflect the terminology used in the Medicaid program and CHIP statutes, regulations or policies. Some terms that are not relevant to the Medicaid program or CHIP are not included in this proposed rule. For each term described in this proposed rule, when appropriate, we have identified where we have modified, added or deleted language that deviates from those definitions in the MHPAEA final regulations. The proposed terms are as follows:

For the definition of “Aggregate lifetime dollar limit,” we are proposing to replace the words “group health plan (or health insurance coverage offered in connection with such a plan) for any coverage unit” with “MCO, PIHP or PAHP” or “ABP” to reflect the common terms for health plans in the Medicaid program. For CHIP, we are proposing to replace these words with “CHIP state plan or a Managed Care Entity (MCE).”

In § 440.395, we are proposing to add the term “Alternative Benefit Plans”.

For the definition of “Annual dollar limit,” we are proposing to replace the words “group health plan (or health insurance coverage offered in connection with such a plan) for any coverage unit” with “MCO, PIHP or PAHP” to reflect the common terms for health plans in the Medicaid program and “a CHIP state plan or a MCE” for CHIP.

We are proposing to add the definition of “Early and Periodic Screening, Diagnostic and Treatment (EPSDT) benefits”. Under section 1905(r) of the Act, EPSDT is a required benefit under the Medicaid program for categorically needy individuals under age 21. The EPSDT benefit is optional for the medically needy population and if elected for that population, the EPSDT benefit must be made available to all Medicaid eligible individuals under age

21. Under the EPSDT benefit, states must provide for screening, vision, hearing and dental services at intervals which meet reasonable standards of medical and dental practice established after consultation with recognized medical and dental organizations involved in child health care. States must also provide for medically necessary screening, vision, hearing and dental services regardless of whether such services coincide with established periodicity schedules for these services. Additionally, the Act requires that other necessary health care, diagnostic services, treatment, and other measures described in section 1905(a) of the Act to correct or ameliorate defects and physical and mental illnesses, and conditions identified by the screening services, must be provided to EPSDT beneficiaries whether or not such services are otherwise covered under the Medicaid state plan.

In the proposed ABP parity rules, we are also proposing to add the definition of “essential health benefits (EHB).” Since 2014, all non-grandfathered health insurance coverage in the individual and small group markets, Medicaid benchmark and benchmark-equivalent plans (now also known as ABPs), and Basic Health Programs (if applicable) must cover EHBs, which include items and services in 10 statutory benefit categories, that are substantially equal in scope to a typical employer health plan. Consistent with the requirements set forth in 45 CFR part 156, EHBs are comprised of (1) Ambulatory patient services; (2) Emergency services; (3) Hospitalization; (4) Maternity and newborn care; (5) Mental health and substance use disorder services, including behavioral health treatment; (6) Prescription drugs; (7) Rehabilitative and habilitative services and devices; (8) Laboratory services; (9) Preventive and wellness services and chronic disease management; and (10) Pediatric services, including oral and vision care.

We are proposing a different definition for the term “medical/surgical benefits,” to reflect that the state defines these benefits in the Medicaid and CHIP contexts. Under existing Medicaid law, the state has the responsibility of identifying what is a covered benefit for MCOs, PIHPs, PAHPs, ABPs, and CHIP; MCOs, PIHPs or PAHPs are responsible for providing the covered benefits identified by the state. This is different from the MHPAEA final regulations, where medical/surgical benefits are defined under the terms of the group health plan or health insurance coverage and in accordance with applicable federal or

state law. We are also proposing that the definition of “medical/surgical services” clearly exclude long term care services in the Medicaid and CHIP context. We believe this clarification is consistent with the intent of the MHPAEA final regulations, as the kinds of long term care services included in benefit packages for Medicaid and CHIP beneficiaries are not commonly provided in the commercial market as part of health benefits coverage. We are seeking comments on our proposal to exclude long term care services from the definition of medical/surgical services. This proposed rule further provides that states define which benefits are medical/surgical consistent with generally recognized independent standards of current medical practice (for example, the most current version of the International Classification of Diseases (ICD) or state guidelines).

We propose to define “mental health benefits” and “substance use disorder benefits”, under these regulations, as benefits for items and services for mental health conditions and substance use disorders, respectively, as defined by the state and in accordance with applicable federal and state law. Thus, our proposal here for the terms “mental health benefits” and “substance use disorder benefits” in this Medicaid and CHIP context also varies from the MHPAEA final regulations, similar to our proposed definition for medical/surgical benefits, to reflect that the state (not the MCO, PIHP or PAHP) is responsible for defining these benefits. This proposed rule also proposes that when states define what benefits are MH/SUD benefits, the definitions must be consistent with generally recognized independent standards of current medical practice. Consistent with the MHPAEA final regulations, this requirement is included to ensure that a benefit is not misclassified to avoid complying with the parity requirements. The word “generally” in the requirement “to be consistent with generally recognized independent standards of current medical practice” is not meant to imply that the standard must be a national standard, but instead that a standard is largely accepted in the relevant medical community. There are many different sources that would meet this requirement. For example, a state may follow the most current version of the Diagnostic and Statistical Manual of Mental Disorders (current edition) (DSM), ICD, or a state guideline. All of these would be considered acceptable resources to determine whether benefits for a particular condition are classified

as medical/surgical or MH/SUD benefits for purposes of these rules.

This proposed rule duplicates the definition of the term “treatment limitations” in the MHPAEA final regulations, including distinguishing between a quantitative and a nonquantitative treatment limitation (NQTL). This proposed rule proposes that the parity requirements in the statute apply to both quantitative treatment limitations and NQTLs. A quantitative treatment limitation is a restriction that is expressed numerically, such as a limit of 50 outpatient visits per year. A NQTL is a restriction that is not expressed numerically, but otherwise limits the scope or duration of benefits for treatment, such as requirements for prior authorization for services. A non-exhaustive list of NQTLs is included in proposed § 438.910(d)(2), § 440.395(b) and § 457.496. This list, as well as the application of these regulations to NQTLs, is further discussed later in this proposed rule. However, these regulations propose that a permanent exclusion of all benefits for a specific condition or disorder is not a treatment limitation.

B. Parity Requirements for Aggregate Lifetime and Annual Dollar Limits

Proposed §§ 438.905 and 457.496(c) address the parity requirements for aggregate lifetime and annual dollar limits. The application of these requirements is generally the same as under the MHPAEA final regulations (45 CFR 146.136(b)). We note that for managed care arrangements, we are using our authority in section 1902(a)(4) of the Act to require PIHPs and PAHPs to comply with mental health parity requirements for MCO enrollees.

C. Parity Requirements for Financial Requirements and Treatment Limitations

Sections 438.910, 440.395(b), and 457.496(d) of this proposed rule set forth parity requirements for financial requirements and treatment limitations.

1. Clarification of Terms

In addition to proposing the meaning of terms in § 438.900, § 440.395, and § 457.496, this proposed rule clarifies certain terms that have been given specific meanings for purposes of MHPAEA.

a. Classification of Benefits

For the purposes of this proposed rule, “classification of benefits” means a classification as described in § 438.910, § 440.395(b), and § 457.496(d). This proposed rule would

modify the classification of benefits set forth in the regulations that were adopted by the Departments, as discussed in section III.C.2.a of this proposed rule, and would provide that the parity requirements for financial requirements and treatment limitations are applied on a classification-by-classification basis.

b. Type

This proposed rule uses the term “type” to refer to financial requirements and treatment limitations of the same nature. Different types of financial requirements and treatment limitations include copayments, coinsurance, annual visit limits, and episode visit limits. States sometimes apply more than one financial requirement or treatment limitation to benefits. Also, this proposed rule specifies that a financial requirement or treatment limitation must be compared only to financial requirements or treatment limitations of the same type within a classification. For example, copayments are compared only to other copayments, and annual visit limits are compared only to other annual visit limits; copayments are not compared to coinsurance, and annual visit limits are not compared to episode visit limits.

c. Level

In this proposed rule, a “level” of a type of financial requirement or treatment limitation refers to the magnitude (such as, the dollar, percentage, day, or visit amount) of the financial requirement or treatment limitation. For example, a plan might impose a 20 unit annual limit on outpatient visits or a \$3 copayment depending on the medical/surgical or MH/SUD benefit.

2. General Parity Requirement for Financial Requirements and Treatment Limitations

The general parity requirement proposed in § 438.910(b), § 440.395(b), and § 457.496(d) of this proposed rule prohibits a MCO, PIHP, or PAHP (when providing benefits to an MCO enrollee), or ABP (when used in a non-managed care arrangement), or CHIP state plan from applying any financial requirement or treatment limitation to MH/SUD benefits in any classification that is more restrictive than the predominant financial requirement or treatment limitation of that type applied to substantially all medical/surgical benefits in the same classification. For this purpose, the general parity requirement of MHPAEA applies separately for each type of financial requirement or treatment limitation (for

example, unit limits are compared to unit limits). This general parity requirement also applies to NQTLs, which is discussed later in this proposed rule.

a. Classifications of Benefits

The MHPAEA final regulations at 45 CFR 146.136(c)(2)(ii) set forth the following classifications of benefits: Inpatient in-network; inpatient out-of-network; outpatient in-network; outpatient out-of-network; emergency care; and prescription drugs. Under those MHPAEA regulations, if a group health plan or health insurance coverage provides MH/SUD benefits in any classification of benefits, MH/SUD benefits must be provided in every classification in which medical/surgical benefits are provided. The parity requirements are applied to financial requirements and treatment limitations within each classification separately.

The benefit structure of traditional Medicaid (non-ABP state plan services), ABPs and CHIP may vary significantly from commercial health insurance coverage. For example, nursing facility long-term care services are a mandatory service in traditional Medicaid, but are not commonly provided in the commercial market as part of health benefits coverage. Additional long term care services and supports, such as personal care, home and community based services, or long term psychosocial rehabilitation programs, are also commonly included in benefit packages for all or targeted populations of Medicaid and CHIP beneficiaries, but these benefits are not typically provided in a commercial environment. Additionally, the cost-sharing structure and out-of-network coverage of Medicaid and CHIP services is often different than benefits provided in the commercial market. Therefore, issues arise over how similar or different the classifications should be for the Medicaid and CHIP programs. Our proposal follows the general structure of the classifications used in the MHPAEA final regulations with a significant distinction. For this proposed rule, we eliminated the in-network and out-of-network distinctions for the inpatient and outpatient classifications and propose four classifications: Inpatient; Outpatient; Emergency care; and Prescription drugs. We propose these classifications for the following reasons:

- Medicaid and CHIP are held to certain cost-sharing requirements for either managed care or non-managed care delivery systems. The dollar amount the beneficiary pays varies by income, and whether services are received through a network model does

not impact the amount for which the beneficiary is responsible.

- When CHIP or ABPs use a FFS delivery system or other non-managed care arrangement, payment is made for services to beneficiaries furnished by any qualified providers that have signed a Medicaid or CHIP provider agreement. Absent a waiver of section 1902(a)(23)(A) of the Act, beneficiaries have a choice from among qualified providers and are not limited to a network.

- In a Medicaid managed care environment, § 438.206(b)(4) states that if a managed care plan's provider network is unable to provide necessary services covered under the contract to a particular enrollee, the MCO, PIHP or PAHP must adequately (and on a timely basis) cover these services out-of-network for the enrollee for as long as the MCO, PIHP or PAHP is unable to provide them in network. This provision is not specific to medical/surgical services or MH/SUD services. We understand there may be continued concerns that access to out-of-network providers is provided by MCOs, PIHPs and PAHPs in compliance with MHPAEA. To address this concern, we are proposing to add access to out-of-network providers to the illustrative list of NQTLs.

For purposes of applying parity requirements to Medicaid, the classifications of benefits should relate to how states construct and manage their Medicaid benefits. All Medicaid benefits provided, with the exception of long term care services, should fall into one of the classifications of benefits.

We are proposing that parity requirements for financial requirements and treatment limitations are generally applied on a classification-by-classification basis. The four classifications proposed in this rule are the only classifications to be used for purposes of applying the parity requirements of MHPAEA to Medicaid and CHIP. Moreover, these classifications must be used for all financial requirements and treatment limitations to the extent that a MCO, PIHP, PAHP, ABP or CHIP provides benefits in a classification and imposes any separate financial requirement or treatment limitation (or separate level of a financial requirement or treatment limitation) for benefits in the classification.

The MHPAEA final regulations discussed the application of parity requirements to intermediate services (such as residential treatment, partial hospitalization, and intensive outpatient treatment) provided under the health plan. Specifically, the MHPAEA final

regulations required group health plans and issuers to assign covered intermediate MH/SUD benefits to a benefit classification in the same manner they assign comparable intermediate medical/surgical benefits to a classification. The MHPAEA final regulations do not specifically define intermediate services; nor do the Medicaid and CHIP programs define intermediate services within state plan benefits. Therefore, we are not proposing to specify an intermediate classification to be used in the parity analysis for Medicaid or CHIP programs. As in the MHPAEA final rule, we propose to allow the applicable regulated entity (the MCO, PIHP or PAHP, or state in connection with the ABP and CHIP) to assign intermediate level services to any of the classifications listed, but assignment to those classifications must be done in a consistent manner for medical/surgical services and MH/SUD services. We request comment on this approach, as well as alternatives.

Similar to the MHPAEA final rule, this proposed rule would not define what services are included in the inpatient, outpatient, or emergency care classifications. These terms are subject to the design of a state's managed care program and their meanings may differ depending on the benefit packages. State health insurance laws may define these terms and in the event that these are not defined we would expect each regulated entity within a state to define these classifications in a similar manner. Further, each regulated managed care plan (MCOs, PIHPs and PAHPs) or the state in connection with ABP or CHIP must apply these terms uniformly for both medical/surgical benefits and MH/SUD benefits.

3. Applying the General Parity Requirement to Financial Requirements and Quantitative Treatment Limitations

Sections 438.910(c), 440.395(b) and, 457.496(d) of this proposed rule address the application of the general parity requirement of MHPAEA to financial requirements and quantitative treatment limitations in MCOs, PIHPs, PAHPs, ABP or CHIP state plans.

a. Determining the Portion of Medical/Surgical Benefits Subject to a Financial Requirement or Quantitative Treatment Limitation

As noted above, the general parity requirement proposed in § 438.910(b), § 440.395(b), and § 457.496(d) of this proposed rule prohibits a MCO, PIHP, or PAHP, or ABP state plan (when used in a non-managed care arrangement), or CHIP state plan or MCE contracting with

a CHIP state plan from applying any financial requirement or treatment limitation to MH/SUD benefits in any classification that is more restrictive than the "predominant" financial requirement or treatment limitation of that type applied to "substantially all" medical/surgical benefits in the same classification. In these paragraphs of the proposed regulations, we propose standards similar to those in the MHPAEA final regulations for determining the portion of medical/surgical benefits subject to a financial requirement or quantitative treatment limitation for purposes of the parity analysis. Under this proposed rule, the portion of medical/surgical benefits in a classification subject to a financial requirement or quantitative treatment limitation would be based on the dollar amount of all payments for medical/surgical benefits in the classification expected to be paid during a specific year. For MCOs, PIHPs and PAHPs, this would be dollar amounts for payment during a contract year. For ABPs and CHIP state plans, it would be for the year starting the effective date of the approved ABP or CHIP state plan; effective dates for these plans will vary based on the date the ABP or CHIP state plan was approved by CMS. For purposes of this calculation, the MCOs, PIHPs and PAHPs (when such organizations are responsible for MH/SUD benefit) would collectively (with the assistance of the state) determine the total amount projected to be expended (including FFS) to determine the two-thirds threshold as discussed below. We are requesting comment on the approach to determine the threshold when there are multiple managed care delivery systems (for example, MCOs, PIHPs and PAHPs).

b. "Substantially all"

Similar to the MHPAEA final regulations, the first step in applying the general parity requirement of MHPAEA to a given financial requirement or quantitative treatment limitation is to determine whether a type of financial requirement or quantitative treatment limitation applies to substantially all medical/surgical benefits in a classification. This proposed rule would define "substantially all" as meaning at least two-thirds of the medical/surgical benefits in that classification as measured by the total dollar amount of payments for medical/surgical benefits in the classification expected to be paid within a measurement year. In this proposed rule, we would apply "substantially all" consistent with the MHPAEA final regulations.

c. “Predominant”

If a type of financial requirement or quantitative treatment limitation applies to substantially all medical/surgical benefits in a classification, the second step is to determine the predominant level of that type of financial requirement or quantitative treatment limitation that may be applied to MH/SUD benefits in the classification. Under this proposed rule, the level of a type of financial requirement or quantitative treatment limitation would be the predominant level if it applies to more than one-half of medical/surgical benefits subject to the financial requirement or quantitative treatment limitation in that classification. If a single level of a type of financial requirement or quantitative treatment limitation applies to more than one-half of medical/surgical benefits subject to the financial requirement or quantitative treatment limitation in a classification (based on expected payments, as discussed earlier in this proposed rule), the applicable regulated entity (under proposed §§ 438.910(b), 440.395(b), or 457.496(d)) may not apply that particular financial requirement or quantitative treatment limitation to MH/SUD benefits at a level that is higher (for example, more expensive beneficiary cost-sharing) or more restrictive than the level that has been determined to be predominant for medical/surgical benefits. As proposed in § 438.920(b), states that choose to use PIHPs, PAHPs

or the FFS delivery system to provide some of the MH/SUD benefits to MCO enrollees would be required to complete an analysis to determine if the benefits comply with these rules. For example, all projected payments for services provided to the MCO enrollees (regardless of whether the payments are made by the MCO, PIHP, PAHP or FFS) would need to be considered in determining if the level of financial requirement or treatment limitation is the predominant level. If no single level applies to more than one-half of medical/surgical benefits subject to the financial requirement or quantitative treatment limitation in a classification, multiple levels of the same type of financial requirement or quantitative treatment limitation can be combined by the state, in cases where some MH/SUD services are provided outside the MCO, or the MCO, in cases where all services are carved-in, until the portion of medical/surgical benefits subject to the financial requirement or quantitative treatment limitation exceeds one-half. For any combination of levels that applies to more than one-half of medical/surgical benefits subject to the financial requirement or quantitative treatment limitation in a classification, the state or the MCO may not apply that particular financial requirement or quantitative treatment limitation to MH/SUD benefits at a level that is more restrictive than the least restrictive level within the combination. The state or the

MCO may combine projected payments for benefits subject to the most restrictive levels first, with each less restrictive level added to the combination until the combination applies to more than one-half of the benefits subject to the financial requirement or treatment limitation. The following example illustrates the application of quantitative treatment limitations to medical/surgical and MH/SUD benefits.

Example. Facts. A state is providing a comprehensive service package through an MCO. The MCO is currently providing coverage of services with limits that are consistent with the approved state plan. The MCO benefit package includes:

- Inpatient Hospital services for medical/surgical—30 days per year limit
- Inpatient Hospital services for MH/SUD—30 days per year limit
- Primary Care Physician Services for medical/surgical—unlimited
- Specialist Physician Services for medical/surgical—50 visits per year
- Outpatient MH services—20 visits per year limit
- Physical Therapy—20 visits per year limit
- Occupational Therapy—20 visits per year limit
- Emergency Services—Unlimited for medical/surgical or MH/SUD

The MCO projects its payments as follows for medical/surgical benefits:

TABLE 1—EXAMPLE OF QUANTITATIVE TREATMENT LIMIT

Benefit/classification—medical/surgical	Projected payment	Percent of total costs	Percent of classification subject to a limit
Inpatient Hospital	\$400x	100	100
Inpatient total	400x	100	100
Physician Services	150x	27	0
Specialist Services	250x	46	46
Physical Therapy	75x	13.5	13.5
Occupational Therapy	75x	13.5	13.5
Outpatient total	550x	100	73
Emergency Services	100x	100	0
Emergency total	100x	100	0

Example. Conclusion. In this example, the MCO would be able to maintain some level of day and visit limits on benefits in both the inpatient and outpatient MH/SUD classifications because both classifications meet the “substantially all” standard—in other words, more than two-thirds of the medical/surgical benefits in each classification are subject to those types of limits (100 percent of all medical/surgical inpatient benefits are subject to a day limit, and 73 percent of all

medical/surgical outpatient benefits are subject to a visit limit).

With regards to the level of the quantitative treatment limitation on inpatient MH/SUD services, the MCO may maintain its 30 day limit because 100 percent of all inpatient medical/surgical benefits are also subject to a 30 day limit, making it the predominant level.

However, with regards to the level of the quantitative treatment limitation on outpatient MH/SUD services, the MCO

may not maintain its current limit of 20 visits per year. Of the total amount of outpatient medical/surgical benefits subject to a visit limit (\$400x), 62.5 percent (\$250x) are subject to a 50 visit limit (specialist services), and only 37.5 percent (\$150x) are subject to a 20 visit limit (physical therapy and occupational therapy). Because the 20 visit limitation is not the predominant level (that is, it does not apply to at least 50 percent of the medical/surgical benefits in the classification subject to

the visit limit), the MCO would need to either remove the visit limits altogether on outpatient MH/SUD services or increase the visit limitation to at least 50 visits per year to align with the least restrictive level of visit limits on outpatient medical/surgical benefits.

Lastly, because there are currently unlimited emergency visits under the medical/surgical benefits, the MCO would need to maintain unlimited visits for emergency services for MH/SUD, and would not be able to impose any limits on MH/SUD unless limits were also imposed on medical/surgical services and such limits were consistent with parity requirements.

4. Special Rules for Multi-Tiered Prescription Drug Benefits and Other Benefits (§§ 438.910(c)(2), 440.395(b)(3)(ii), 457.496(d)(3)(ii))

In addition, the MHPAEA final regulations at 45 CFR 146.136(c)(3)(iii)(A) permit plans under certain circumstances to apply different levels of financial requirements to different tiers of prescription drugs and still satisfy the parity requirements. This proposed rule would allow a MCO, PIHP, PAHP, ABP or CHIP state plan to subdivide the prescription drug classification into tiers based on reasonable factors as described in the proposed regulations and without regard to whether a drug is generally prescribed for medical/surgical benefits or for MH/SUD benefits.

The MHPAEA final regulations at 45 CFR 146.136(c)(3)(iii)(C) permit a sub-classification for office visits, separate from other outpatient items and services. Other sub-classifications not specifically permitted, such as separate sub-classifications for generalists and specialists, cannot be used for purposes of determining parity. We propose to retain this approach to sub-classifications in the application of these parity requirements established in parts 438, 440 and 457 (that is, to services provided to enrollees in Medicaid MCOs, and to ABPs and CHIP). After the sub-classifications are established, a MCO, PIHP, PAHP, ABP or CHIP state plan may not impose any financial requirement or quantitative treatment limitation on MH/SUD benefits in any sub-classification (for example, office visits or non-office visits) that is more restrictive than the predominant financial requirement or quantitative treatment limitation that applies to substantially all medical/surgical benefits in the sub-classification, using the parity analysis for financial requirements and quantitative treatment limitations.

In the MHPAEA final regulations, the Departments recognized that tiered networks have become an important tool for health plan efforts to manage care and control costs. Therefore, for purposes of applying the financial requirement and treatment limitation rules under MHPAEA, the MHPAEA final regulations provide that if a plan (or health insurance coverage) provides benefits through multiple tiers of in-network providers (such as an in-network tier of preferred providers with more generous cost-sharing to participants than a separate in-network tier of participating providers in any classification), the plan may divide its benefits furnished on an in-network basis into sub-classifications that reflect those network tiers, if the tiering is done without regard to whether a provider is a MH/SUD provider or a medical/surgical provider. While network tiers may also be used in Medicaid managed care, we do not believe that the use of network tiers for the purposes of the parity analysis is needed. As discussed later in section F. of this proposed rule, Medicaid cost-sharing rules apply regardless of network status. Additionally, any quantitative treatment limitation outlined in the contract must be applied to the service broadly and therefore cannot have separate limitations based on network tiers. We recognize there may be network tiers used to commonly refer enrollees or for purposes of building the network and have varying payment rates to providers, but the use of multiple network tiers for NQTLs is discussed in section E. of this proposed rule.

D. Cumulative Financial Requirements (§ 438.910(c)(3), § 440.395(b)(3)(iii), § 457.496(d)(3)(iii))

While financial requirements such as copayments and coinsurance generally apply separately to each covered expense, other financial requirements (in particular, deductibles) accumulate across covered expenses. In the case of deductibles, generally an amount of otherwise covered expenses must be accumulated before the plan pays benefits. Financial requirements that determine whether and to what extent benefits are provided based on accumulated amounts are defined in these proposed rules as cumulative financial requirements. The MHPAEA final regulations provide that a group health plan or issuer may not apply cumulative financial requirements or cumulative quantitative treatment limitations to MH/SUD benefits in a classification that accumulate separately from any such cumulative financial requirements or cumulative quantitative

treatment limitations established for medical/surgical benefits in the same classification. As in the MHPAEA final rule at 45 CFR 146.136(c)(2)(v), we propose that any separate cumulative financial requirement (separate for mental health, substance use or medical/surgical) will not be permitted for entities subject to our proposed requirements (namely, MCOs, PIHPs and PAHPs in connection with coverage provided to MCO enrollees, and in ABP and CHIP). However, we propose to permit quantitative treatment limitations to accumulate separately for medical/surgical and MH/SUD services as long as they comply with the general parity requirement. We are proposing to allow this separate accumulation of treatment limits in Medicaid and CHIP for several reasons. First, benefits for MCO beneficiaries must be provided in at least the same amount, duration and scope as set forth in the state plan. Requiring plans to have cumulative limits across medical/surgical benefits and MH/SUD benefits within a classification may incentivize MCOs to retain the quantitative treatment limitation level applied on the medical/surgical benefits in the state plan as the total cumulative limit for both medical/surgical and MH/SUD benefits. This would comply with the requirements of parity, but would not meet the requirements of providing at least what is in the state plan. In addition, we believe that requiring quantitative treatment limitations within a classification of benefits to accumulate jointly toward a unified limit level may be operationally challenging for states with multiple delivery systems. Specifically, in Medicaid the state determines which entities will provide the specific medical/surgical and MH/SUD benefits covered under their respective contracts, including if some services will be provided under FFS. These potentially complex service delivery arrangements in Medicaid in turn determine whether the MCO or the state have the responsibility for complying with parity requirements. In commercial coverage, the parity obligations remain with the same entity—the group health plan or issuer—that determines which entities will provide each individual medical/surgical or MH/SUD benefits. Due to the difficulty that the MCO will face in administering unified treatment limits that accumulate across entities that the MCO has no contractual relationship with, we propose to permit the MCO, PIHP or PAHP to maintain separate treatment limitations, provided such limit for MH/SUD benefits is no more

restrictive than the predominant limit applied to substantially all medical/surgical benefits in a given classification.

E. Compliance With Other Cost-Sharing Rules (§ 438.910(c)(4))

States and the MCOs, PIHPs and PAHPs that contract with states are bound by the existing Medicaid and CHIP cost-sharing rules (§ 438.108 and part 457, subpart E). As previously indicated, the Medicaid program and CHIP are held to strict cost-sharing requirements for both managed care and non-managed care delivery systems. We emphasize here that all financial requirements included in a MHPAEA analysis must also be in compliance with both existing cost-sharing rules and the requirements of this proposed rule. Compliance with the parity requirements does not mean that a state, or MCO, PIHP or PAHP can violate existing cost-sharing requirements. Therefore, some cost-sharing structures in a state's Medicaid program or CHIP may need to change to be compliant with MHPAEA. To clarify this, we propose at § 438.910(c)(4) to reiterate that requirement with a cross-reference to the cost-sharing rules applicable to MCOs, PIHPs and PAHPs.

F. Nonquantitative Treatment Limitations (NQTLS) (§ 438.910(d), § 440.395(b)(4), and § 457.496(d)(4))

MCOs, PIHPs, PAHPs, ABP and CHIP state plans may impose a variety of limits affecting the scope or duration of benefits that are not expressed numerically (nonquantitative treatment limitations or NQTLS). Nonetheless, such nonquantitative provisions are also treatment limitations affecting the scope or duration of benefits. Sections 438.910(d), 440.395(b)(4), and 457.496(d)(4) of this proposed rule would prohibit the imposition of any NQTL to MH/SUD benefits unless certain requirements are met. In addition, this proposed rule provides an illustrative list of NQTLS, including medical management standards; prescription drug formulary design; standards for provider admission to participate in a network; and conditioning benefits on completion of a course of treatment.

Under the MHPAEA final regulations at 45 CFR 146.136(c)(4), an NQTL may not be imposed for MH/SUD benefits in any classification unless, under the terms of the plan (or health insurance coverage) as written and in operation, any factors used in applying the NQTL to MH/SUD benefits in a classification are comparable to and applied no more stringently than factors used in applying

the limitation for medical surgical/benefits in the classification. For these purposes, factors mean the processes, strategies, evidentiary standards, or other considerations used in determining limitations on coverage of services. The phrase “applied no more stringently” requires that any processes, strategies, evidentiary standards, or other factors that are comparable on their face be applied in the same manner to medical/surgical benefits and MH/SUD benefits.

We propose to duplicate this approach to NQTLS in the application of parity requirements to Medicaid MCOs, PIHPs and PAHPs providing services to MCO enrollees, ABPs, and CHIP state plans. For states that are using a non-managed care delivery system for their ABPs and CHIP, the state (through its ABP and CHIP state plan) may only impose an NQTL on a MH/SUD benefit in any classification if it has written and operable processes, strategies, evidentiary standards or other factors used in applying—to MH/SUD benefits in that classification—the NQTL that are comparable to or less restrictive and applied no more stringently than any processes, strategies, evidentiary standards, or other factors used in applying the limitation for medical/surgical services in that classification.

In addition, we propose to add another example of an NQTL regarding standards for accessing out-of-network providers. As discussed earlier in this proposed rule, in the context of CHIP or ABPs that use a FFS delivery system or other non-managed care arrangement, beneficiaries may choose from any qualified provider that has signed a Medicaid or CHIP provider agreement and are not limited to a network. In a Medicaid managed care environment, if a provider network is unable to provide necessary services covered under the contract to a particular enrollee, the MCO, PIHP or PAHP must adequately (and on a timely basis) cover these services out-of-network for the enrollee as long as the MCO, PIHP or PAHP is unable to provide them in-network.⁵ To address continued concerns about access to these services out-of-network when they cannot be provided in-network, these proposed rules would add this example of an NQTL, so that providing access to out-of-network providers for MH/SUD benefits in any classification would have to use the same processes, strategies, evidentiary standards, or other factors as are used in providing access to out-of-network providers for medical/surgical benefits within the same classification. If MCOs,

PIHPs or PAHPs, and ABPs provided through managed care, are found to be in compliance with § 438.206(b)(4), that would be evidence that they are in compliance with proposed § 438.910(d)(3), although the state will want to review how the plan is doing this in practice. This additional example of an NQTL is not relevant for states that are using a non-managed care delivery system for ABPs and CHIP state plan, since providers must be enrolled in Medicaid or CHIP and would not be considered out-of-network.

We note that we propose to use in § 438.910(d)(2)(iii), the example of an NQTL pertaining to network design for MCOs, PIHPs and PAHPs with multiple network tiers because although network tiers may not be used to impose financial requirements or quantitative treatment limitations in Medicaid and CHIP, we believe MCOs, PIHPs and PAHPs may still use them in developing NQTLS. For example, the MCO, PIHP or PAHP may use network tiers when recommending providers to enrollees, or how they structure their provider directories. MCOs, PIHPs and PAHPs with multiple network tiers should be constructing them and providing beneficiary access to them in a way that is consistent with the parity standard for NQTLS.

The examples below illustrate the operation of the requirements for NQTLS.

Example 1. Facts. A MCO requires prior authorization that a treatment is medically necessary for all inpatient medical/surgical benefits and for all inpatient MH/SUD benefits. In practice, inpatient benefits for medical/surgical conditions are routinely approved for 7 days, after which a treatment plan must be submitted by the patient's attending provider and approved by the MCO. Conversely, for inpatient MH/SUD benefits, routine approval is given only for 1 day, after which a treatment plan must be submitted by the beneficiary's attending provider and approved by the MCO.

Example 1. Conclusion. In this example, the MCO violates the NQTL provision of this proposed rule (§ 438.910(d)) because it is applying a stricter NQTL in practice to MH/SUD benefits than is applied to medical/surgical benefits.

Example 2. Facts. A MCO applies concurrent review to inpatient care where there are high levels of variation in length of stay (as measured by a coefficient of variation exceeding 0.8). In practice, the application of this standard affects 60 percent of MH/SUDs, but only 30 percent of medical/surgical conditions.

⁵ See § 438.206(b)(4).

Example 2. Conclusion. In this example, the MCO complies with the NQTL provisions of this proposed rule because the evidentiary standard used by the MCO is applied no more stringently for MH/SUD benefits than for medical/surgical benefits, even though it results in an overall difference in the application of concurrent review for MH/SUDs than for medical/surgical conditions.

Example 3. Facts. A MCO requires prior approval that a course of treatment is medically necessary for outpatient medical/surgical and MH/SUD benefits and uses comparable criteria in determining whether a course of treatment is medically necessary. For MH/SUD treatments that do not have prior approval, no benefits will be paid; for medical/surgical treatments that do not have prior approval, providers will only receive a 25 percent reduction in payments for these treatments from the MCO.

Example 3. Conclusion. In this example, the MCO violates the NQTL provision of this proposed rule. Although the same NQTL—medical necessity—is applied both to MH/SUD benefits and to medical/surgical benefits for outpatient services, it is not applied in a comparable way. The penalty for failure to obtain prior approval for MH/SUD benefits is not comparable to the penalty for failure to obtain prior approval for medical/surgical benefits.

Example 4. Facts. A MCO generally covers medically appropriate treatments. For both medical/surgical benefits and MH/SUD benefits, evidentiary standards used in determining whether a treatment is medically appropriate are based on recommendations made by panels of experts with appropriate training and experience in the fields of medicine involved. The evidentiary standards are applied in a manner that is based on clinically appropriate standards of care for a condition.

Example 4. Conclusion. In this example, the MCO complies with the NQTL provision of the proposed rule because the processes for developing the evidentiary standards used to determine medical appropriateness and the application of these standards to MH/SUD benefits are comparable to and are applied no more stringently than for medical/surgical benefits. This is the result even if the application of the evidentiary standards does not result in similar numbers of visits, days of coverage, or other benefits utilized for MH/SUDs as it does for any particular medical/surgical condition.

Example 5. Facts. Training and state licensing requirements often vary

among types of providers. A MCO applies a general standard that any provider must meet the highest licensing requirement related to supervised clinical experience under applicable state law in order to participate in the MCO's provider network. Therefore, the MCO requires master's-level mental health therapists to have post-degree, supervised clinical experience but does not impose this requirement on master's-level general medical providers because the scope of their licensure under applicable state law already requires supervised clinical experience. In addition, the MCO does not require post-degree, supervised clinical experience for psychiatrists or Ph.D. level psychologists since their licensing already requires supervised training.

Example 5. Conclusion. In this example, the MCO complies with the provision of this proposed rule pertaining to NQTLs. The requirement that master's-level mental health therapists must have supervised clinical experience to join the network is permissible, as long as the MCO consistently applies the same standard to all providers, even though it may have a disparate impact on certain mental health providers.

Example 6. Facts. A state contracts with an external utilization review entity to review inpatient admissions for all beneficiaries participating in its ABP. All inpatient services in the ABP are delivered on a FFS basis. The state's utilization review contractor considers a wide array of factors in designing medical management techniques for both MH/SUD and medical/surgical inpatient benefits, such as cost of treatment; high cost growth; variability in cost and quality; elasticity of demand; provider discretion in determining diagnosis, or type or length of treatment; clinical efficacy of any proposed treatment or service; licensing and accreditation of providers; and claim types with a high percentage of fraud. Based on application of these factors in a comparable fashion, prior authorization is required for some (but not all) inpatient MH/SUD benefits, as well as for some (but not all) medical/surgical benefits. The evidence considered in developing its medical management techniques includes consideration of a wide array of recognized medical literature and professional standards and protocols (including comparative effectiveness studies and clinical trials). This evidence and how it was used to develop these medical management techniques is also well documented by

the state's utilization review organization.

Example 6. Conclusion. In this example, the state and its utilization review contractor comply with the NQTL rules. Under the terms of the ABP as written and in operation, the processes, strategies, evidentiary standards, and other factors considered by the contractor in implementing the prior authorization requirement for MH/SUD inpatient benefits are comparable to, and applied no more stringently than, those applied to medical/surgical benefits.

Example 7. Facts. A MCO provides coverage for medically appropriate medical/surgical benefits, as well as MH/SUD benefits. The MCO excludes coverage for inpatient SUD services when obtained outside of the state. There is no similar exclusion for medical/surgical benefits within the same classification.

Example 7. Conclusion. In this example, the MCO violates the NQTL provisions of this proposed rule. The MCO is imposing a NQTL that restricts benefits based on geographic location. Because there is no comparable exclusion that applies to medical/surgical benefits, this exclusion may not be applied to MH/SUD benefits.

Example 8. Facts. A state's CHIP program requires prior authorization for all outpatient MH/SUD services after the ninth visit and will only approve up to 5 additional visits per authorization. For outpatient medical/surgical benefits, the state's CHIP program allows an initial visit without prior authorization. After the initial visit, benefits must be pre-approved based on the individual treatment plan recommended by the attending provider based on that individual's specific medical condition. There is no explicit, predetermined cap on the amount of additional visits approved per authorization.

Example 8. Conclusion. In this example, the state's CHIP program violates the NQTL provisions of the proposed rule. Although the same NQTL—prior authorization to determine medical appropriateness—is applied to both MH/SUD benefits and medical/surgical benefits for outpatient services, it is not applied in a comparable way. While the state CHIP plan is more generous in the number of visits initially provided without pre-authorization for MH/SUD benefits, treating all MH/SUDs in the same manner, while providing for individualized treatment of medical conditions, is not a comparable application of this NQTL.

Example 9. Facts. A state provides an ABP that is compliant with EHB

requirements, including the provision of MH/SUD services. The state aligns its ABP's outpatient benefits with those described in the state plan and applies the same prior authorization requirements. For outpatient MH/SUD services, prior authorization is required for each individual treatment session. In contrast, for outpatient medical/surgical services, a series of treatments is provided under a single authorization.

Example 9. Conclusion. In this example, the state's ABP design does not comply with the NQTL provisions of this proposed rule. Although the same NQTL—prior authorization to determine medical appropriateness—is applied to both MH/SUD benefits and medical/surgical benefits for outpatient services, it is not applied in a comparable way.

Example 10. Facts. A state's ABP requires preauthorization for all outpatient substance use disorder services. The state APB does not require preauthorization for any medical/surgical services.

Example 10. Conclusion. The state ABP does not comply with the NQTL requirements in this proposed rule. If a state plan requires preauthorization for each outpatient SUD service it cannot remain in compliance if there is no comparable limitation on medical/surgical services.

Example 11. Facts. In cases where an MCO is unable to provide necessary outpatient services to a particular enrollee, the MCO requires that the enrollee must get prior approval in order to see any outpatient out-of-network provider. The MCO approves the use of an out-of-network provider for medical/surgical outpatient services if there is not an in-network provider within 10 miles of the person's residence. Approval of an out-of-network provider for outpatient MH/SUD services is only authorized if there is not an in-network provider within 30 miles of a person's residence.

Example 11. Conclusion. In this example, the MCO violates the NQTL provisions of this proposed rule. The MCO is imposing a restriction that limits access to out-of-network providers. Although the same nonquantitative treatment limitation is applied to both the MH/SUD benefits and to medical/surgical benefits for outpatient services, it is not applied in a comparable way.

G. Application to CHIP and EPSDT Deemed Compliance (§ 457.496(b))

The CHIPRA applies MH/SUD parity requirements to the entire “state child health plan” including, but not limited to, any MCOs that contract with the

state CHIP. Specifically, section 502 of the CHIPRA requires that state child health plans ensure financial requirements and treatment limitations applicable to MH/SUD benefits comply with the requirements of section 2726(a) of the PHS Act (as renumbered) “in the same manner” as such requirements apply to a group health plan. Therefore, if a CHIP state plan provides both medical/surgical benefits and MH/SUD benefits, any treatment limitations, lifetime or annual dollar limits or financial requirements (such as out-of-pocket costs) on MH/SUD benefits must comply with the provisions of section 2726 of the PHS Act made applicable to CHIP by section 502 of the CHIPRA adding section 2103(c)(6) to the Act and by section 2103(f)(2) of the Act. Section 2103(c)(6)(B) of the Act also specifies that state CHIP plans are deemed to satisfy the requirement under section 2103(c)(6)(A) of the Act to ensure that financial requirements and treatment limitations comply with the provisions of section 2726 of the PHS Act if they provide coverage of EPSDT benefits (as defined under title XIX of the Act). For individuals receiving EPSDT services through the CHIP state plan, proposed § 457.496(b) provides that the state will be deemed to meet parity requirements for financial requirements and treatment limitations. However, states that do apply NQTLs to EPSDT services must ensure that these limitations are applied consistent with the intent of MHPAEA.

H. Availability of Information (§ 438.915, § 440.395(c), § 457.496(e))

Under the MHPAEA final regulations, the criteria for medical necessity determinations made under a group health plan or health insurance coverage for MH/SUD benefits must be made available by the plan administrator or the health insurance issuer offering such coverage in accordance with regulations to any current or potential participant, beneficiary, or contracting provider upon request. The MHPAEA final regulations also state that the reason for any denial under a group health plan or health insurance coverage of reimbursement or payment for services for MH/SUD benefits in the case of any participant or beneficiary must be made available, upon request or as otherwise required, by the plan administrator or the health insurance issuer to the participant or beneficiary in accordance with the regulations. Through this proposed rule, we are proposing to apply the requirements imposed on the health insurance issuer through the MHPAEA final regulations regarding availability of information in a similar manner to MCOs and to PIHPs and

PAHPs that provide coverage to MCO enrollees. We propose to add § 438.915(a) to provide that MCOs, PIHPs and PAHPs subject to MHPAEA requirements must make their medical necessity criteria for MH/SUD benefits available to any enrollee, potential enrollee or contracting provider upon request. MCOs, PIHPs and PAHPs found to be in compliance with § 438.236(c)—which requires dissemination by MCOs, PIHPs and PAHPs of practice guidelines to all affected providers and, upon request, to enrollees and potential enrollees—will be deemed to meet this proposed requirement. As proposed, § 438.915(b) would also require the MCO, PIHP or PAHP to make available the reason for any denial of reimbursement or payment for services for MH/SUD benefits to the enrollee. We also note that § 438.210(c) requires each contract with an MCO, PIHP, or PAHP to 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.

The MHPAEA final regulations, at 45 CFR 146.136(d)(2), state that non-federal governmental group health plans (or health insurance coverage offered in connection with such plans) providing the reason for claim denial in a form and manner consistent with the requirements of 29 CFR 2560.503–1 for group health plans will be found in compliance with the reason for denial disclosure requirements.⁶ The provisions under 29 CFR 2560.503–1 which discuss requirements related to notices for group health plans subject to ERISA, do not apply to Medicaid, and we are not proposing to make them applicable as a condition for deemed compliance because similar requirements are already applicable. MCOs, PIHPs, PAHPs and states are required to give a “reason” for any adverse benefit determinations under requirements for notices in, respectively, § 438.404 and § 431.210. The information provided in this disclosure of the reason for the adverse benefit determination must be made in compliance with these and all other provisions of applicable federal or state law, as noted in proposed § 438.915(c).

⁶ The requirements of 29 CFR 2560.503–1 are applicable to ERISA plans, as well as all non-grandfathered group health plans and health insurance issuers in the group and individual markets, through the claims and appeals regulations adopted under the Affordable Care Act. See 78 FR 68247 for a full discussion.

For similar reasons, we are not proposing to make the claim denial requirements of 29 CFR 2560.503–1 a condition of deemed compliance for CHIP programs. CHIP enrollees have an opportunity for an external review of denials, reduction or suspension of health services under § 457.1130.

Although the statute that applies MHPAEA to ABPs does not include specific provisions regarding the availability of plan information, we propose to use our authority under section 1902(a)(4) of the Act to extend this provision to all ABPs, as well as those ABPs with services delivered through MCOs, PIHPs and all PAHP. At § 440.395(c)(1), we propose that all states delivering ABP services through a non-MCO must make available to beneficiaries and contracting providers on request the criteria for medical necessity determinations for MH/SUD benefits. Similarly, § 440.395(c)(2) would require the state to make available to the enrollee the reason for any denial of reimbursement or payment for services for MH/SUD benefits.

Current rules related to notices of adverse benefit determinations are consistent with the intent of 29 CFR 2560.503–1. This proposed rule proposes to apply provisions regarding the availability of plan information for ABP services. We request comment on any additional provisions concerning the availability of plan information or notice of adverse determinations that may be necessary to facilitate compliance with MHPAEA for MCOs, PIHPs, PAHPs, ABPs and CHIP.

I. Application to EHBs and Other ABP Benefits (§ 440.395 and § 440.347)

Section 1937(b)(6) of the Act, as added by section 2001(c) of the Affordable Care Act, and implemented through regulations at § 440.345(c) directs that ABPs that provide both medical/surgical benefits and MH or SUD benefits must comply with certain parity requirements. Further, ABPs must provide the 10 EHBs, including MH/SUD services. As states determine their ABP service package, states must use all of the EHB services from the base-benchmark plan selected by the state to define EHBs, consistent with the applicable requirements in 45 CFR part 156.

Section 1937 of the Act offers flexibility for states to provide medical assistance by designing different benefit packages, including other services beyond the EHBs for different groups of eligible individuals, as long as each benefit package contains all of the EHBs and meets certain other requirements,

including parity provisions under section 2726 of the PHS Act.

J. Application of Parity Requirements to the Medicaid State Plan

The provisions of section 2726 of the PHS Act that are incorporated through section 1932 of the Act do not apply directly to the benefit design for Medicaid non-ABP state plan services. Under this proposed rule, the requirements would apply to the benefits offered by the MCO (or, as discussed above, if benefits are carved out, to all benefits provided to MCO enrollees regardless of service delivery system) but do not apply to all Medicaid state plan benefit designs. As stated earlier in this proposed rule, states that have individuals enrolled in MCOs and have MH/SUD services offered through FFS will have the option of amending their non-ABP state plan to be consistent with these proposed regulations or offering MH/SUD services through a managed care delivery system (MCOs, PIHPs, and/or PAHPs) to be compliant with these proposed rules.

K. Scope and Applicability of the Proposed Rule (§ 438.920(a) and (b), § 440.395(d), and § 457.496(f)(1))

Sections 438.920, 440.395(d), and 457.496(f) propose to address the applicability and scope of this proposed rule. Specifically under our proposal:

- Section 438.920(a) would provide that the requirements of the subpart apply to delivery of Medicaid services when an MCO is used to deliver some or all of the Medicaid services; section 438.920(b) (also discussed below) addresses state responsibilities when the MCO delivers only some of the Medicaid services.
- Section 440.395 would apply to ABPs that are not delivered through managed care.
- Section 457.496 would apply to CHIP state plans, including when benefits are furnished under a contract with MCEs.

The MHPAEA final regulations state that if a group health plan or health insurance coverage provides MH/SUD benefits in any classification of benefits, MH/SUD benefits must be provided in every classification in which medical/surgical benefits are provided. Under our proposed amendments to part 438, for these parity standards to apply, a beneficiary must be enrolled in an MCO under a Medicaid contract. Whether the MCO provides medical/surgical or MH/SUD benefits under that contract is irrelevant.

While many Medicaid MCOs are contracted to offer benefits in each of the classifications of benefits described

in this proposed rule, there are other state-initiated “carve out” arrangements (for example, PIHPs, PAHPs or FFS) in which the MCOs are only contracted to provide benefits in one MH/SUD classification, while PIHPs, PAHPs, FFS, or a combination of all 3 provide coverage of benefits in other classifications. For example, MCOs in these carve out arrangements are likely to have contracts that include MH/SUD benefits in the prescription drug and emergency care classifications of benefits, but some or all of the MH/SUD outpatient or inpatient benefits may be offered instead through a PIHP, PAHP or FFS delivery system.

In instances where the MH/SUD services are delivered through multiple managed care delivery vehicles, we are proposing in § 438.920 that parity provisions apply across the managed care delivery systems in the Medicaid program and CHIP. MHPAEA requirements apply to the entire package of services MCO enrollees receive, whether from the MCO, PIHP, PAHP, or FFS. If states carve out some MH/SUD services from the MCO contract and furnish those services by PIHPs, PAHPs, or FFS, we are proposing to apply the foregoing MHPAEA requirement to the entire package of services MCO enrollees receive. Requiring the standards for parity to be applied to the overall package of benefits received by MCO enrollees will allow MCOs to comply with MHPAEA requirements without requiring inclusion of additional MH/SUD benefits in the MCO benefit package, as long as these MH/SUD benefits are provided elsewhere within the delivery system. In states where MH/SUD benefits are provided across multiple delivery systems (including FFS), we propose in § 438.920(b) that states would be required to review the full scope of benefits provided to MCO enrollees to ensure compliance with the proposed parity requirements. As part of complying with this regulation, we would expect states to work with their MCOs (or PIHPs and PAHPs) to determine the best method of achieving compliance with these proposed parity requirements for benefits provided to the MCO enrollees. For MH/SUD benefits offered through FFS, states would not necessarily be required to amend their non-ABP state plan to meet parity requirements, but could use their existing state plan or waiver services to achieve parity when individuals are receiving some MH/SUD benefits from a MCO (including PIHPs or PAHPs) and also some benefits through FFS. However, if a state did not have MH/

SUD benefits in every classification in which medical/surgical benefits are provided across all authorities, the state would have to choose either to offer these services through a MCO, PIHP or PAHP or amend its state plan (or a waiver of its state plan) to include these benefits to achieve compliance with proposed § 438.920(a) and (b). Applying various parity provisions across the different delivery system would allow states the most flexibility in designing delivery systems while ensuring that parity in medical/surgical and MH/SUD services is provided to MCO enrollees. Given that there are many different delivery system configurations that carve out MH/SUD services, this would allow compliance with parity requirements while reducing incentives for states to completely carve in all MH/SUD benefits to a MCO or carve out or terminate coverage of MH/SUD services.

In states where the MCO has responsibility for offering all medical/surgical and MH/SUD benefits, the MCO would be responsible for undertaking the parity analysis and informing the state what additional changes will be needed to the MCO contract to be compliant with parity requirements. In states where some or all MH/SUD benefits are provided through MCOs, PIHPs, PAHPs, or FFS, the state would have the responsibility for undertaking the parity analysis across these delivery systems and determining if the existing benefits and any financial or treatment limitations are consistent with MHPAEA. The state, based on this analysis, would have to make the necessary changes to ensure compliance with parity requirements for its Medicaid MCO enrollees. We also propose at § 438.920(b)(1) that the state provide documentation of its compliance with this analysis to the general public within 18 months of the effective date of this rule.

If states offer benefits through an ABP or CHIP state plan with various delivery systems (managed care and non-managed care), the state would need to apply the provisions of the proposed rule across the delivery systems utilized for its ABP and CHIP state plan.

For ABPs and CHIP state plans, we would also require states to apply the provisions of this proposed rule across all delivery systems to ensure that beneficiaries have access to MH/SUD benefits in every classification in which medical/surgical benefits are provided. These provisions would apply when states offer services through an ABP or CHIP state plan using only a non-managed care arrangement (FFS). If states offer services through an ABP or CHIP state plan with various delivery

systems (managed care and non-managed care), the state would need to apply the provisions of the proposed rule across the delivery systems utilized for their ABP and CHIP state plan. Provided below is an example of how this proposed rule would be applied across the delivery system in Medicaid.

Example 1. Facts. A Medicaid MCO enrollee can access Medicaid benefits in the following way at any given time during their MCO enrollment:

- The MCO comprehensive benefits include inpatient medical/surgical benefits; outpatient medical/surgical benefits; emergency for medical/surgical, MH, and SUD benefits; and prescription drugs for medical/surgical and MH/SUD benefits.
- The PIHP carve out benefits include inpatient MH benefit and the outpatient MH benefit.
- The PAHP carve out benefits include outpatient SUD benefits.
- The FFS system provides access to inpatient SUD benefits.

For purposes of this example, we assume there are no financial requirements or treatment limitations imposed on any of the benefits in any of the delivery systems noted above.

Example 1. Conclusion. In this example, the MCO, PIHP or PAHP would not need to add any additional services to its benefit package because the MCO enrollee has access to MH/SUD services through PIHPs, PAHPs and FFS and the state is responsible for undertaking the parity analysis across delivery systems and making sure the coverage complies with parity requirements under our proposed § 438.920(a) and (b). The example would apply in the same way to a CHIP enrollee.

L. Scope of Services (§ 438.920(c), § 457.496(f)(2))

We propose provisions relating to the scope of the parity requirements for Medicaid MCOs and CHIP state plans that are similar to the provisions set forth in the MHPAEA final regulations (45 CFR 146.136(e)(3)). Specifically, the proposed regulations would not require a MCO, PIHP, or PAHP to provide any MH/SUD benefits for conditions or disorders beyond the conditions or disorders that are covered as required by their contract with the state. For MCOs, PIHPs or PAHPs that provide benefits for one or more specific MH conditions or SUDs under their contracts, the proposed regulations would not require the MCO, PIHP or PAHP to provide benefits for additional MH conditions or SUDs. The proposed regulations would not affect the terms and conditions relating to the amount, duration, or

scope of MH/SUD benefits under the MCO, PIHP or PAHP contract except as specifically provided in § 438.905 and § 438.910 of the part.

M. ABP State Plan Requirements (§ 440.395(d))

We are proposing to add a section in part 440, subpart C that requires states using ABPs to provide sufficient information in ABP state plan amendment requests to assure compliance with MHPAEA. We will review ABP state plan amendments to ensure their compliance with applicable federal statutes and regulations, including MHPAEA, and EHB anti-discrimination provisions.

N. Increased Cost Exemption

As discussed above in this proposed rule, we are not proposing an increased cost exemption for MCOs, PIHPs or PAHPs. As indicated previously, we are proposing to change payment provisions in part 438 to allow states to include the cost of providing additional services or removing or aligning treatment limitations in their actuarially sound rate methodology where such costs are necessary to comply with the MHPAEA parity provisions. These proposed changes to the managed care rate setting process give states and MCOs the ability to fully comply with these mental health parity requirements by giving them flexibility to provide services compliant with this proposed regulation or remove or align service limits. We believe that the Medicaid program rather than the plan should bear the costs of these changes. We propose to provide states sufficient time to comply with this regulation: States would have up to 18 months after the date of the publication of the final rule to comply with the provisions of this regulation. This will allow states to take the actions to make the policy and budgetary changes needed for compliance.

We are not proposing to permit states delivering services through an ABP or CHIP state plan to apply for a cost exemption due to the mandatory delivery of EHB and the requirement that ABPs be compliant with MHPAEA.

O. Enforcement, Managed Care Rate Setting (§ 438.6(e)) and Contract Review and Approval (§ 438.6(n))

Medicaid and CHIP programs are administered by states in partnership with the federal government. States have the responsibility of administering the state plan in compliance with federal law, so states will be required to provide an assurance of compliance with parity requirements when submitting ABP or CHIP state plans. In

addition, we propose to require the state Medicaid agency to include contract provisions requiring compliance with parity requirements in all applicable MCO, PIHP, and PAHP contracts. As noted earlier in this proposed rule, we believe that the intent of the parity requirements implemented through section 1932(b)(8) of the Act is to provide access to services meeting parity requirements to any enrollee of a MCO in a state that provides some MH/SUD benefits through its state plan, regardless of the scope of benefits covered through the MCO itself. Therefore, states would have the responsibility of ensuring that appropriate contract language is included in all MCO contracts and any applicable PIHP or PAHP contracts under proposed § 438.6(n). We expect that states will include in the MCO, PIHP and PAHP contracts a methodology for the MCO, PIHP or PAHP that will establish and demonstrate compliance with parity requirements (including, in some instances, developing a crosswalk with other entities that are part of the service delivery system for enrollees). This methodology would have to ensure that all MCOs, PIHPs, or PAHPs included in the delivery system work together to ensure any MCO enrollee in a state is provided access to a set of benefits that meets the requirements of this rule regardless of the MH/SUD benefits provided by the MCO.

In accordance with section 1903(m) of the Act, all MCO contracts must comply with applicable requirements in section 1932 of the Act, which includes section 1932(b)(8) of the Act referencing MHPAEA provisions in the PHS Act. As we have discussed previously, if the state provides some MH/SUD benefits within its state plan, all MCO contracts must include provisions requiring compliance with parity requirements because all MCO enrollees must be provided access to MHPAEA compliant services even if the MCO itself does not provide the MH/SUD services. Therefore, if it is not shown through the MCO contract itself that an enrollee has access to MH/SUD services in each classification in which medical and surgical services are provided that are fully compliant with these parity requirements, the state will be asked to provide supplemental materials to the MCO contract or an amendment to the contract to demonstrate that the standards proposed here are met.

Further, we may defer federal financial participation (FFP) on expenditures for the MCO contract to the extent that the state has not documented that the contract would

comply with the requirements of section 1903(m) of the Act, including the requirement that the MCO contract and the MCO itself comply with applicable provisions of section 1932 of the Act. We understand that with the flexibility afforded to states to provide MH/SUD services across the delivery system there may be services outside of the MCO contract that may be needed to demonstrate compliance. If this is the case, the state would be required to show how the MCO enrollees are provided all the services needed to comply with the requirements in this proposed rule, and if the state cannot provide evidence of this compliance outside of the MCO contract, CMS would have the ability to defer FFP on the MCO contract amount until evidence of compliance is provided. Again, a state would have the option to make changes to the MCO, PIHP or PAHP contracts or make changes to its Medicaid state plan to provide evidence of compliance.

P. Applicability and Compliance
(§ 438.930, § 440.395(d), § 457.496(f))

This proposed rule would be effective based on the date of the publication of the final rule. However, MCOs, PIHPs, PAHPs and states would have 18 months to comply with the provisions of this final regulation. Specifically:

- *Managed care considerations:* Although the requirements of MHPAEA have applied to Medicaid MCOs through section 1932(b)(8) of the Act since MHPAEA was passed in 2008, Medicaid MCOs, PIHPs or PAHPs would have to comply with the specific provisions in the proposed rule in contract years starting 18 months after the publication of the final rule. New managed care contracts, or amendments, would be required to be compliant in most cases.

- *ABPs:* Although the requirements of MHPAEA have applied since January 1, 2014, states would have 18 months after the publication of the final rule to have the ABPs compliant with provisions in this proposed rule.

- *CHIP:* The requirements of MHPAEA have applied for CHIP since October 1, 2009, however, states would have 18 months after the publication date of the final rule for CHIP plans to be compliant with provisions in this proposed rule.

Q. Utilization Management

Current Medicaid regulations prescribe requirements for the control of utilization management of inpatient services in mental hospitals (§ 456.171). These regulations specifically require medical and other professionals within

the Medicaid agency (or its designee) to evaluate each beneficiary's need for admission into inpatient services in a mental hospital. There is not a similar requirement for the Medicaid agency to review medical/surgical admissions to other hospitals. States have indicated that this regulation presents challenges to achieving parity for inpatient services rendered in a mental hospital. In addition, these states have interpreted the term "mental hospitals" to include distinct part units of a general hospital, as well as freestanding institutions of mental diseases for children under the age of 21 and adults 65 years and older. This proposed rule would eliminate current language from existing regulations that require Medicaid agencies to evaluate the need for these admissions. A state could continue these evaluations, but would need to ensure that the standards and processes were consistent with the provisions in this regulation regarding nonquantitative treatment limits.

IV. Collection of Information Requirements

Under the Paperwork Reduction Act of 1995 (PRA), we are required to provide 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, section 3506(c)(2)(A) of the PRA 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 estimate of the information collection burden.
- The quality, utility, and clarity of the information to be collected.
- Recommendations to minimize the information collection burden on the affected public, including automated collection techniques.

We are soliciting public comment on each of the section 3506(c)(2)(A)–required issues for the following information collection requirements.

A. Wage Estimates

To derive average costs, we used data from the U.S. Bureau of Labor Statistics' May 2013 National Occupational Employment and Wage Estimates for all salary estimates (www.bls.gov/oes/current/oes_nat.htm). In this regard, Table 2 presents the mean hourly wage, the cost of fringe benefits (calculated at 100 percent of salary), and the adjusted hourly wage.

TABLE 2—PROPOSED HOURLY WAGE ESTIMATES

Occupation title	Occupation code	Mean hourly wage (per hr)	Fringe benefit (at 100%) (per hr)	Adjusted hourly wage (per hr)
Business Operations Specialists	13–1000	\$33.19	\$33.19	\$66.38
Medical Secretaries	43–6013	15.93	15.93	31.86

We propose to adjust all 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.

B. Proposed Information Collection Requirements (ICRs)

1. ICRs Regarding the Availability of Information and the Criteria for Medical Necessity Determinations (§§ 438.915(a), 440.395(c)(1), and 457.496(e)(1))

Proposed §§ 438.915(a), 440.395(c)(1), and 457.496(e)(1) would require that the medical necessity determination criteria used by regulated entities for MH/SUD benefits be made available to potential participants, beneficiaries, or contracting providers upon request.

In the November 13, 2013, MHPAEA final rule, the regulatory impact analysis (78 FR 68253 through 68266) quantified the costs to disclose medical necessity criteria. For consistency and comparability, we are using the same method for determining this rule's disclosure costs, with adjustments to

account for Medicaid MCOs, ABP and CHIP and the population covered.

Labor Costs for Medical Necessity Disclosures. We are unable to estimate with certainty the number of requests for medical necessity criteria disclosures that will be received by regulated entities. However, the MHPAEA final rule's impact analysis did set forth assumptions that we believe are relevant for calculating costs for the Medicaid and CHIP program. In that impact analysis, it was assumed that each plan would receive three medical necessity criteria disclosure requests for every 1,000 beneficiaries. This assumption equated to 0.003 requests per enrollee. This assumption was applied to the number of enrollees enrolled in Medicaid (33.1 million), ABP (8.7 million) and CHIP (5.7 million) to project the number of expected requests: 99,328 for MCOs; 26,100 for ABPs; and 16,975 for CHIP.

To estimate the time it will take a medical staff to respond to each request, we used the same assumption as the MHPAEA final rule. Specifically, we assumed that it took a staff member (in this case, a Medical Secretary) 5 minutes to respond to the request. In this proposed rule, this results in a total annual burden of 11,867 hours for Medicaid and CHIP programs.

The adjusted hourly rate for Medical Secretaries responding to these requests is estimated to be \$31.86/hour.

Multiplying the total annual burden of 11,867 hours by the hourly wage, yields an associated equivalent cost of about \$378,083 for all requests to Medicaid and CHIP programs.

Mailing and Supply Costs. The MHPAEA final rule's impact analysis estimated that 38 percent of the requests would be delivered electronically with *de minimis* cost. The remaining requests would require materials, printing, and postage amounting to approximately 66 cents per request. We believe that the same mailing and supply costs per request will apply to the disclosure requirements of this proposed rule.

Table 3 displays the added burden estimates, nationally and per program, for Medicaid MCOs and CHIP to comply with the proposed medical necessity determination criteria's disclosure procedures. The number of enrollees for MCOs/HIOs is based on the CMS national breakout as of July 2012 while the number for ABPs is based on the estimated enrollment growth due to Medicaid expansion ("National Health Expenditure Projections 2012–2022," CMS). CHIP enrollment is based on Medicaid and Children's Health Insurance Program (CHIP) Payment and Access Commission's 2014 estimates. The proposed requirements and burden will be submitted to OMB for approval under control number 0938–New (CMS–10556).

TABLE 3—NATIONAL AND PER PROGRAM BURDEN FOR THE PROPOSED MEDICAL NECESSITY DETERMINATION CRITERIA'S DISCLOSURE REQUIREMENTS

Plan type	Number of enrollees	Number of expected requests (.003 requests per enrollee)	Time (@5 min/ response (hr)	Labor cost (\$) @ \$31.86/hr	Mailed responses (62% of expected enrollees)	Mailing and supply cost (\$) @ \$.66/ mailing	Total cost (\$)
MCO/HIO	33,109,462	99,328	8,277	263,705	61,584	40,645	304,350
ABP	8,700,000	26,100	2,175	69,296	16,182	10,680	79,976
CHIP	5,658,460	16,975	1,415	45,082	10,525	6,947	52,029
Total	47,467,922	142,403	11,867	378,083	88,291	58,272	436,355

2. ICRs Regarding the Availability of Information and Reason for Any Denial (§§ 438.915(b), 440.395(c)(2), and 457.496(e)(2))

MHPAEA requires that the reason for any denial—under a group health plan

or health insurance coverage—of reimbursement or payment for MH/SUD benefits must be made available (upon request or as otherwise required) by the plan administrator (or the health insurance issuer) to the beneficiary in

accordance with MHPAEA regulations (45 CFR 146.136(d)(2)).

For the proposed provisions, this proposed rule would not impose any new or revised third-party disclosure requirements, and therefore, does not

require additional OMB review under the authority of the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*). The proposed text only clarifies the expectations for disclosing information concerning the denial of reimbursement or payment for MH/SUD benefits. We believe that the proposed requirements are already met by complying with existing disclosure requirements in part 438, and therefore, do not create any requirements or burden beyond what is currently approved by OMB under control number 0938–1080 (CMS–10307). We also believe that the proposed requirements are already met for CHIP by complying with existing notification and disclosure requirements in §§ 457.110 and 457.1130, and therefore, do not create any requirements or burden beyond what is currently approved by OMB under control number 0938–1148 (CMS–10398 #34) (formerly, CMS–R–211, control number 0938–0707). Furthermore, the proposed provisions do not create any new or revised third-party disclosure requirements for ABPs beyond what is currently approved by OMB under control number 0938–1188 (CMS–10434).

3. ICRs Regarding Parity in Mental Health and Substance Use Disorder Benefits Under § 440.395 (Alternative Benefit Plan) and § 457.496 (CHIP State Plan)

The ABP State Plan Application is employed by states to identify benefits offered to Medicaid beneficiaries receiving services under section 1937 of the Act. The application requires that states identify the MH/SUD services that will be offered under the plan. The plan also collects information on any limitations (quantitative and nonquantitative treatment limitations) and financial requirements across all benefit categories (including all medical/surgical services). For states

needing to come into compliance with MHPAEA, the state is required to submit an ABP SPA amendment.

The parity requirements proposed in § 440.395 would not impose any new or revised reporting, recordkeeping, or third-party disclosure requirements, and therefore, do not require additional OMB review under the authority of the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*). The proposed provisions only clarify parity requirements and the meaning of terms for ABPs and do not create any information collection requirements or burden beyond what is currently approved by OMB under control number 0938–1188 (CMS–10434).

The single streamlined application is employed by states to determine Medicaid or CHIP eligibility. It is not used to determine benefits of any kind. However, states are required to review their respective CHIP state plans to determine if they are in compliance with MHPAEA. For states needing to come into compliance, the state must submit a CHIP SPA amendment.

The parity requirements proposed in § 457.496 would not impose any new or revised reporting, recordkeeping, or third-party disclosure requirements, and therefore, do not require additional OMB review under the authority of the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*). The information collection requirements and burden are approved by OMB under control number 0938–1148 (CMS–10398 #34) (formerly CMS–R–211, control number 0938–0707).

4. ICRs Regarding State Plan Amendments

While this proposed rule discusses a number of optional and mandatory SPA amendments, this proposed rule would not impose any new or revised SPA-specific reporting, recordkeeping, or third-party disclosure requirements and therefore, does not require additional

OMB review under the authority of the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*). The currently approved ABP SPA application was designed to capture the MHPAEA final rule classifications and identify if there are specific treatment limitations or financial requirements. The information collection requirements and burden are approved by OMB under control number 0938–1188 (CMS–10434).

5. ICRs Regarding State Health Official (SHO) Letters SHO #09–014 (November 4, 2009) and SHO #13–001 (January 16, 2013)

The January 2013 SHO letter addressed the application of the MHPAEA requirements in Medicaid and expanded upon the CMS' CHIP guidance provided in the November 2009 letter regarding section 502 of CHIPRA. The letters are discussed in section II.A. of this proposed rule as background. This proposed rule does not propose any new or revised reporting, recordkeeping, or third-party disclosure requirements pertaining to either of the letters. Consequently, the PRA does not apply.

6. ICRs Regarding Contract Requirements (§ 438.6(n))

In § 438.6(n), states would be required to include contract provisions in all applicable MCO, PIHP, and PAHP contracts to comply with part 438, subpart K. We estimate a one-time state burden of 30 minutes for a Business Operations Specialist at \$66.38/hour to amend each contract with the applicable requirements. In aggregate, we estimate 301 hours (602 contracts × 0.5 hours) and \$16,049 (301 hours × \$53.32/hr). The proposed requirements and burden will be submitted to OMB for approval under control number 0938–New (CMS–10556).

C. Summary of Proposed Burden Estimates

TABLE 4—PROPOSED ANNUAL RECORDKEEPING AND REPORTING REQUIREMENTS

Regulation Section(s) under Title 42 of the CFR	OMB Control No. (CMS ID No.)	Respondents	Total responses	Burden per response (min)	Total annual burden (hours)	Hourly labor cost of reporting (\$/hr)	Total labor cost of reporting (\$)	Total capital/maintenance costs (\$)	Total cost (\$)
438.915(a), 440.395(c)(1), and 457.496(e)(1).	0938–New (CMS–10556).	602	142,403	5	11,867	31.86	378,082	40,645	436,355
438.6(n)	36	602	30	301	66.38	19,980	0	19,980
Total	638	143,005	35	12,168	398,062	40,645	456,335

D. Submission of PRA-Related Comments

We have submitted a copy of this proposed rule to OMB for its review of

the rule's information collection requirements. These requirements are not effective until they have been approved by OMB.

To obtain copies of the supporting statement and any related forms for the proposed paperwork collections referenced above, access CMS' Web site

at <http://www.cms.hhs.gov/PaperworkReductionActof1995>; email your request, including your address, phone number, OMB control number, and CMS document identifier, to Paperwork@cms.hhs.gov; or call the Reports Clearance Office at 410-786-1326.

We invite public comments on these potential information collection requirements. If you comment on these information collection and recordkeeping requirements, please submit your comments electronically as specified in the **ADDRESSES** section of this proposed rule. Please include “CMS-2333-P,” the ICR’s OMB control number, and the CMS document ID number in your comment.

PRA-specific comments must be received by June 9, 2015.

V. Response to Comments

Because of the large number of public comments we normally receive on **Federal Register** documents, we are not able to acknowledge or respond to them individually. We will consider all comments we receive by the date and time specified in the **DATES** section of this preamble, and, when we proceed with a subsequent document, we will respond to the comments in the preamble to that document.

VI. Regulatory Impact Analysis

A. Statement of Need

This proposed rule addresses the applicability of the requirements under the MHPAEA to Medicaid non-managed care benchmark and benchmark-equivalent plans (referred to in this proposed rule as Medicaid ABPs) as described in section 1937 of the Act, CHIP under title XXI of the Act, and Medicaid MCOs as described in section 1932 of the Act.

In 2013, we released a SHO letter that provided guidance to states regarding the implementation of requirements under MHPAEA to Medicaid benchmark and benchmark-equivalent plans (referred to in this letter as ABPs), CHIP, and Medicaid MCOs.

Final regulations implementing MHPAEA were published by HHS, the Department of Labor, and the Department of Treasury in the November 13, 2013 **Federal Register**. The MHPAEA final regulations do not apply to Medicaid MCOs, ABPs, or CHIP state plans.

We believe that in absence of a regulation specific to the application of the parity requirements under MHPAEA to Medicaid and CHIP, states would not be compelled to implement the necessary changes to these programs,

resulting in an inequity between beneficiaries who have MH/SUD conditions in the commercial market (including the state and federal marketplace) and Medicaid and CHIP. Even for states that are attempting to comply with parity requirements under MHPAEA, the absence of regulation could lead to inconsistent state-specific policies based on a state’s interpretation of how policies set forth in the MHPAEA final regulations might apply in the Medicaid and CHIP contexts.

This proposed rule provides the specificity and clarity needed to effectively implement the policies set forth by MHPAEA and prevent the use of prohibited limits on coverage, including nonquantitative treatment limitations that disproportionately limit coverage of treatment for MH/SUD conditions. The Department’s assessment of the expected economic effects of this proposed rule is discussed in detail below.

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 rulemaking 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, which to the best of our ability presents the costs and benefits of the rulemaking.

Because the application of parity requirements to ABPs; MCOs and PIHPs and PAHPs providing services to MCO enrollees; and the CHIP is likely to have an effect on the economy of \$100 million or more in any given year, this proposed rule is economically significant within the meaning of section 3(f)(1) of the Executive Order As elaborated below, we believe the benefits of the rule justify the costs.

C. Anticipated Effects

This proposed rule would benefit approximately 21.6 million Medicaid beneficiaries and 850,000 CHIP beneficiaries in 2015, based on service utilization estimates from 2012 Medicaid and CHIP enrollment. We expect that a significant benefit associated with the application of the parity requirements under MHPAEA and these proposed regulations will be derived from applying parity requirements to the quantitative treatment limits such as annual or lifetime day or visit limits. Applying parity requirements to visit or stay limits will help ensure that vulnerable populations—those accessing substantial amounts of MH/SUD services—have better access to appropriate care. Among adults aged 18 through 64 with Medicaid coverage, approximately 9.6 percent have a serious mental illness, 30.5 percent have any mental illness, and 11.9 percent have a substance use disorder.⁷ Among CHIP beneficiaries, approximately 8 percent of children experience serious behavioral or emotional difficulties.⁸

⁷ Calculations were based on the Substance Abuse and Mental Health Services Administration (SAMHSA) National Survey of Drug Use and Health.

⁸ Pastor PN, Reuben CA, Duran CR. Identifying Emotional And Behavioral Problems in Children Aged 4–17 Years: United States, 2001–2007. National Health Statistics Report No. 48. Hyattsville, MD: National Center for Health Statistics; 2012.

Evidence-based treatment for severe and persistent mental illness, and for substance use disorders, often requires prolonged (possibly lifetime) treatment that consists of pharmacotherapy, supportive counseling, and often rehabilitative services. Individuals with severe MH/SUD conditions often quickly exhaust their benefits under Medicaid managed care. In addition, CHIP programs may restrict coverage, such as covering only 40 hours of psychotherapy or 5 days of detoxification per year. These coverage restrictions often result in people forgoing outpatient treatment and a higher likelihood of non-adherence to treatment regimes, which produce poor health and welfare outcomes and create the potential for increased hospitalization costs.^{9 10} For those with substance use disorders, treatment retention is of key importance when assessing outcomes, where those who stayed in treatment longer had more success in decreasing their substance use.^{11 12} In 2011, approximately 8 percent of adults with Medicaid coverage reported at least one occurrence in the past 12 months of feeling the need for mental health or substance use treatment or counseling but not receiving it.¹³ Between 2007 and 2009, approximately 72 percent of children in Medicaid with a potential mental health need did not receive mental health services.¹⁴ The most frequently cited reasons for not seeking MH/SUD treatment are cost and/or a lack of health insurance coverage, low perceived need, stigma, or structural barriers (for example, no transportation, did not know where to go).^{15 16}

⁹ Medication-Assisted Treatment for Opioid Addiction in Opioid Treatment Programs. Rockville (MD): Substance Abuse and Mental Health Services Administration (US); 2005. Treatment Improvement Protocol (TIP) Series, No. 43.

¹⁰ Trivedi AN, Swaminathan S, Mor V. Insurance parity and the use of outpatient mental health care following a psychiatric hospitalization. *JAMA*. 2008 Dec 24;300(24):2879–85.

¹¹ Simpson DD, Joe G W, Rowan-Szal G. Drug abuse treatment retention and process effects on follow-up outcomes. *Drug and Alcohol Dependence*. 1997b;47(3):227–235.

¹² Hartel DM, Schoenbaum EE. Methadone treatment protects against HIV infection: Two decades of experience in the Bronx, New York City. *Public Health Reports*. 1998;113(Suppl. 1):107–115.

¹³ Substance Abuse and Mental Health Services Administration (SAMHSA). Behavioral Health United States 2012. HHS Publication No. (SMA)13–4797. Rockville, MD: SAMHSA; 2013.

¹⁴ GAO. Children's Mental Health: Concerns Remain about Appropriate Services for Children in Medicaid and Foster Care. December 2012. <http://www.gao.gov/assets/660/650716.pdf>. Accessed June 27, 2014.

¹⁵ Affordability Most Frequent Reason for Not Receiving Mental Health Services. Rockville (MD): Substance Abuse and Mental Health Services

Removing quantitative limits on treatment may be particularly beneficial for individuals with severe mental illness and substance use disorders who may need to receive more services than the average individual.^{17 18} Improved coverage may also reduce the financial burden on individuals and families, particularly those families of children mental health service needs.¹⁹ Finally, improving coverage of MH/SUD treatment may also improve employment, productivity, and earnings among those with these conditions.²⁰ Wang, *et al*, found that implementing a care program for those identified with depression yielded not only enhanced clinical outcomes relative to depression, but also produced positive outcomes relative to decreased sick leave and increased productivity.²¹ Similarly, the State of Washington implemented a substance abuse treatment program for those receiving Aid to Families with Dependent Children (AFDC), and found that access to treatment increased both earnings for those with jobs, and increased rates of employment.²²

Application of parity requirements may also result in changes to payers' utilization management approaches, specifically when requiring preauthorization of mental health services. It was found that even when approval for continued access to mental health services was in essence guaranteed, patients sought out less treatment, perhaps believing they

Administration (US); 2013. The NSDUH Report Data Spotlight.

¹⁶ Results from the 2012 National Survey on Drug Use and Health: Summary of National Findings and Detailed Tables. Rockville (MD): Substance Abuse and Mental Health Services Administration (US); 2013.

¹⁷ Zuvekas SH, Bantnin JS, Selden TM. How would mental health parity affect the marginal price of care? *Health Serv Res*. 2001 Feb;35(6):1207–27. Review.

¹⁸ McConnell KJ. The effect of parity on expenditures for individuals with severe mental illness. *Health Serv Res*. 2013 Oct;48(5):1634–52. doi: 10.1111/1475–6773.12058. Epub 2013 Apr 5.

¹⁹ Barry CL, Busch SH. Do state parity laws reduce the financial burden on families of children with mental health care needs? *Health Serv Res*. 2007 Jun;42(3 Pt 1):1061–84.

²⁰ Dunigan R, Acevedo A, Campbell K, Garnick DW, Horgan CM, Huber A, Lee MT, Panas L, Ritter GA. Engagement in outpatient substance abuse treatment and employment outcomes. *J Behav Health Serv Res*. 2014 Jan;41(1):20–36. doi: 10.1007/s11414-013-9334–2

²¹ Wang P, Simon GE, Avorn J, Azocar F, Ludman EJ, McCulloch J, Petukhova MZ, Kessler RC. Telephone screening, outreach and care management for depressed workers and impact on clinical and work productivity outcomes. *JAMA*. 2007;298(12):1401–11.

²² Wickizer TM, Campbell K, Krupski A, Stark K. Employment outcomes among AFDC recipients treated for substance abuse in Washington State. *Milbank Q*. 2000;78(4):585–608. iv. PubMed PMID: 11191450.

“should not” access further needed treatment.²³ Hodgkin, *et al*, found that removal of utilization management approaches (including preauthorization for the first set of mental health visits) increased use of mental health services.²⁴ Cuffel, *et al*, note that there are various reasons for why an approach like preauthorization can impact provider behavior relative to mental health service. Providers may believe that the preauthorization process is too laborious and not worth their time; they may fear that those reviewing the request will penalize them for submitting a preauthorization request; they may assume that the set limits on services preclude additional requests for services; providers may believe that the initial limits are in place as an implied recommendation towards shorter treatment cycles; and some may believe requests for preauthorization simply will not be approved at all.²⁵ Liu, *et al*, found a significant correlation between preauthorization processes and the probability of ending mental health treatment prematurely.²⁶

Application of parity requirements under MHPAEA may also have benefits in terms of reduced medical costs. Mental health and physical health are interrelated, and individuals with poor mental health are likely to have physical health problems as well.^{27 28 29} Increased access to and utilization of MH/SUD benefits may result in a reduction of medical and surgical costs for individuals with mental health conditions and substance use disorders (so called “medical cost offsets”). For example, after receiving treatment, individuals with substance use

²³ Liu, X., R. Sturm, and B. J. Cuffel. 2000. “The Impact of Prior Authorization on Outpatient Utilization in Managed Behavioral Health Plans.” *Medical Care Research Review* 57: 182–95.

²⁴ Hodgkin D, Merrick EL, Horgan CM, Garnick DW, McLaughlin TJ. “Does Type of Gatekeeping Model Affect Access to Outpatient Specialty Mental Health Services?” *Health Services Research* 42. 1 (2007): 104–123.

²⁵ Cuffel, B., McCulloch, J., Wade, R., Tam, L., Brown-Mitchell, R., & Goldman, W. (2000). Patients' and providers' perceptions of outpatient treatment termination in a managed behavioral health organization. *Psychiatric Services*, 51(4), 469–473.

²⁶ Liu, X., Sturm, R., Cuffel, B. (2000) *The impact of prior authorization on outpatient utilization in managed behavioral health plans*. *Med Care Res Rev*. Jun;57(2):182–95.

²⁷ Druss BG, Walker ER. Mental disorders and medical comorbidity. *Synth Proj Res Synth Rep*. 2011 Feb;(21):1–26. Review.

²⁸ National Institute on Drug Abuse. (December 2012). *Medical Consequences of Drug Abuse*. Retrieved from <http://www.drugabuse.gov/related-topics/medical-consequences-drug-abuse>.

²⁹ Bouchery, E. E., Harwood, H. J., Sacks, J. J., Simon, C. J., & Brewer, R. D. (2011). Economic costs of excessive alcohol consumption in the US, 2006. *American Journal of Preventive Medicine*, 41(5), 516–524.

disorders may experience fewer hospitalizations and emergency room visits stemming from unintended injuries such as accidents and drug overdose. The evidence that treatment results in medical care offsets is stronger for substance abuse treatment than for mental health treatment. For example, an evaluation on the expansion of substance abuse treatment in Washington State's Medicaid program found per member per month savings of \$160 to \$385 depending on the welfare cohort.³⁰ Another study done on welfare clients in Washington State found that those accessing substance use disorder treatment had \$2500 less in medical costs than those who did not access treatment. This estimated savings equaled the cost of SUD treatment for individuals accessing SUD treatment.³¹ While a similar reduction in medical costs may be expected from mental health treatment, most empirical studies have not found a significant medical cost offset from mental health treatment.^{32 33}

1. Costs

a. Cost Associated With Increased Utilization of MH/SUD Benefits

A primary objective of Congress in enacting MHPAEA was to eliminate barriers that impeded access to and utilization of MH/SUD benefits. Cost increases and increases in capitated rates may occur as a result of increased access and utilization from the application of parity requirements and these proposed regulations, but the evidence suggests that any increases will not be large. The impact of parity requirements will depend on the extent to which MCOs, ABPs, and CHIP plans lack benefits in some classifications or manage these benefits inconsistent with such parity requirements.

In the April 30, 2010 final rule on State Flexibility for Medicaid Benefit Packages (75 FR 23068), the assumptions utilized in modeling the estimated economic impact of the associated provisions took into account

the costs of the benefit package for the new adult group served through ABPs. Coverage of these benefits was already accounted for in the April 30, 2010 final rule, and therefore, does not need to be repeated here. Because we approved ABPs only after ensuring compliance with MHPAEA, we project that this proposed regulation will result in no additional costs to ABPs.

(1) Effect of Removing Non-Compliant Quantitative Treatment Limitations

A review of Medicaid managed care benefits in all 50 states and the District of Columbia revealed that a subset of states (18 states) had Medicaid managed care plans that imposed quantitative treatment limits on outpatient visits, inpatient stays, and intermediate services (for example, intensive outpatient treatment). As indicated in the preamble, some of these quantitative treatment limits are a result of what is currently in a state's Medicaid plan.

A review of CHIP plans indicated that most are already compliant with MHPAEA. CHIP plans that include Medicaid EPSDT are already required to cover mental health and substance abuse services as needed and they are deemed compliant with MHPAEA parity requirements for financial requirements and treatment limitations. It is not permissible to apply annual or lifetime limits to the EPSDT benefit. CHIP stand-alone programs are also already compliant with MHPAEA because of changes to treatment limitations for both mental health or substance use disorder benefits and medical and surgical benefits required under the Affordable Care Act.³⁴ Among CHIP plans that are Medicaid expansion plans, we found only one to have an explicit quantitative limit.³⁵

We conducted an analysis to determine how the use of services might increase if quantitative limits on Medicaid MCO and CHIP programs were eliminated. Where quantitative limits exist that are non-compliant with parity requirements, states also have the option to align these limits for MH/SUD and medical/surgical benefits consistent with the provisions of this proposed rule. However, to estimate the highest possible cost impact that could be expected, we simulated the effect of

removing visit and day limits in states with limits for treatment users by anticipating that utilization would increase for beneficiaries who were near or exceeded current limits to equal utilization patterns observed in states without limits for Medicaid managed care beneficiaries. This simulation indicated the maximum impact of removing quantitative day and visit limits on MH/SUD services by Medicaid MCOs to be \$103 million nationwide (including federal and state costs) in undiscounted dollars in 2015. Using a similar approach, we estimated the maximum impact of removing quantitative limits on CHIP expenditures to be \$39.1 million in undiscounted dollars in 2015.

However, these estimates are the largest possible cost impacts and the actual impact is likely to be lower. One reason is that some states with quantitative limits may have mechanisms in place for beneficiaries to obtain hospital days or outpatient visits beyond the state's limit if such care is determined to be medically necessary. In practice, we anticipate a potentially lower impact than estimated currently, given that quantitative limits may already be routinely exceeded. We found that in most of the 18 states with visit limits, a number of recipients (for example, 5 to 20 percent) used services beyond the treatment limit, suggesting that exceptions to the quantitative limits may occur in these states. This does not appear to be the case in all states, because in a few states with visit limits ranging from approximately 24 to 40 visits, only 1 or 2 percent of recipients exceeded the limit.

There are no studies to date on how the application of federal parity requirements affects Medicaid spending. However information from states that have passed state-specific parity legislation (which includes application to Medicaid) provides additional support for the projected impact of these proposed regulations on service utilization and spending. For instance, an evaluation of the Oregon parity law found no significant increases in aggregate behavioral health spending or in the percent of individuals using behavioral health services associated with its implementation.³⁶ The evaluators surmised that the flexibility in quantitative limits prior to the parity law may be one reason that the

³⁰ Wickizer, T. M., Mancuso, D., & Huber, A. (2012). Evaluation of an innovative Medicaid health policy initiative to expand substance abuse treatment in Washington State. *Medical Care Research and Review*, 69(5), 540–559.

³¹ Wickizer, T. M., Krupski, A., Stark, K. D., Mancuso, D., & Campbell, K. (2006). The effect of substance abuse treatment on Medicaid expenditures among general assistance welfare clients in Washington State. *Milbank Quarterly*, 84(3), 555–576.

³² Simon GE, Katzelnick DJ. Depression, use of medical services and cost-offset effects. *J Psychosom Res*. 1997 Apr;42(4):333–44. Review.

³³ Sturm R. Economic grand rounds: The myth of medical cost offset. *Psychiatry Serv*. 2001 Jun;52(6):738–40.

³⁴ Sarata AK. Mental health parity and the Patient Protection and Affordable Care Act of 2010. Washington, DC: Congressional Research Service; 2011.

³⁵ McConnell KJ, Gast SH, Ridgely MS, Wallace N, Jacuzzi N, Rieckmann T, McFarland BH, McCarty D. Behavioral health insurance parity: Does Oregon's experience presage the national experience with the Mental Health Parity and Addiction Equity Act? *Am J Psychiatry* 2012 Jan;169(1):31–8.

³⁶ McConnell KJ, Gast SH, Ridgely MS, Wallace N, Jacuzzi N, Rieckmann T, McFarland BH, McCarty D. Behavioral health insurance parity: Does Oregon's experience presage the national experience with the Mental Health Parity and Addiction Equity Act? *Am J Psychiatry* 2012 Jan;169(1):31–8.

implementation of parity did not lead to large increases in spending. Specifically, they found that prior to the implementation of the state parity law, approximately 5 percent of beneficiaries with any behavioral health visits exceeded the specified limits of that plan.

Vermont's parity law is also very similar to MHPAEA. A study of Vermont's parity law found that the share of spending on mental and substance use disorders increased only slightly, from 2.30 percent to 2.47 percent of total spending for one health plan.³⁷

Finally, a recent evaluation of the effect of MHPAEA on the commercial market revealed a modest increase in spending on substance use disorder treatment per enrollee (\$9.99, 95 percent

CI: 2.54, 18.21), but no significant change in the percent of individuals using substance use disorder services.³⁸

(2) Effect of Classification of Services Requirements

This proposed rule requires that if the state provides for MH/SUD services under the state plan, MH/SUD services must be provided to MCO enrollees in every classification in which medical/surgical benefits are provided. After reviewing the MH/SUD services provided under Medicaid managed care plans, we identified only two states providing for MH/SUD services under the state plan in which MH/SUD services were excluded from a classification in which medical/surgical benefits are provided. In both states, the excluded services were substance abuse

inpatient services. For the purposes of this analysis, we assumed that substance abuse inpatient services would need to be included to the extent that they were provided in a distinct part or unit of a general hospital or facility with 16 or fewer beds. Using data on current use of Medicaid substance use disorder inpatient services and the cost of those services from Medicaid claims data, we estimated that the additional coverage for these services would have led to an increase of \$11.7 million nationwide in undiscounted dollars in 2012.

Table 5 displays the total costs of removing non-compliant QTLs by service and meeting classification of services requirements in 2012.

TABLE 5—DETAILS OF ESTIMATED COSTS OF MEETING QTL AND CLASSIFICATION OF SERVICES REQUIREMENTS IN 2012

Inpatient	Outpatient	Intermediate	Administrative	Total
Mental Health—Medicaid (\$million/year)				
\$19.8	\$62.3	\$0	\$0.3	\$82.4
Mental Health—CHIP (\$million/year)				
0	30.8	0.4	0.04	31.2
Substance Use Disorder—Medicaid (\$million/year)				
11.7	0	0	0	11.7
Substance Use Disorder—CHIP (\$million/year)				
0	0	0	0	0
Total Costs of Removing Quantitative Limits in 2012 (\$million/year)				
				125.3

Note: Administrative costs are listed once for Medicaid and CHIP because the expense is all-inclusive for each program; costs are not broken down by service.

Costs for complying with parity rules for each service category were estimated based on a simulation of additional utilization states may incur as a result of removing quantitative treatment limits. For the analysis of intermediate services, we examined limits on partial hospitalization and intensive outpatient care.

These figures are calculated based on 2012 Medicaid and CHIP expenditures, which equate to approximately \$125.3

million in additional costs as a result of parity compliance. To determine the percent impact to Medicaid expenditures in 2012, we divided \$125.3 million (the additional costs of increased utilization) by \$408.8 billion (total Medicaid expenditures). Based on this calculation, Medicaid expenditures would increase by 0.03 percent each year. As total Medicaid expenditures increase over time, the cost impact of

mental health parity is expected to rise proportionally. Therefore, given that Medicaid expenditures overall are projected to equal approximately \$513.4 billion in 2015,³⁹ the predicted impact of mental health parity is expected to equal \$157.4 million in 2015, and to rise in proportion to the growth in overall Medicaid spending in future years. Costs for 2015–2019 are displayed in Table 6.

³⁷ Rosenbach M, Lake T, Young C, et al. Effects of the Vermont Mental Health and Substance Abuse Parity Law. DHHS Pub. No. SMA 03–3822, Rockville, MD: Substance Abuse and Mental Health Services Administration; 2003.

³⁸ Busch SH, Epstein AJ, Harhay MO, Fiellin DA, Un H, Leader D Jr, Barry CL. The effects of federal parity on substance use disorder treatment. *Am J Manag Care.* 2014 Jan;20(1):76–82.

³⁹ President's Budget for Fiscal Year 2015, available at <http://www.whitehouse.gov/omb/budget/>.

TABLE 6—ESTIMATED COSTS OF CMS–2333 FY 2015–2019
[In millions]

	FY 2015	FY 2016	FY 2017	FY 2018	FY 2019
Federal	94.6	102.0	108.4	114.0	120.3
State	62.8	66.8	71.2	75.0	79.4
Total	157.4	168.8	179.6	188.9	199.8

(3) Effect of Medical Cost Offsets

As described above, the cost of improving access to MH/SUD treatment may be offset by a decline in the expenditures on treatments for medical conditions resulting from substance use disorders. There is strong evidence from Medicaid programs to assume a cost offset resulting from improved access to substance use disorder benefits. In contrast, the evidence for cost offset resulting from improved access to mental health benefits is weaker. We anticipate that, on balance, costs stemming from increased utilization of substance use disorder services resulting from application of parity requirements will be largely offset by the savings from reduced medical costs, yielding very little increase in overall costs from increased utilization of substance use disorder services. However, given the difficulty of quantifying the precise cost impact of this reduced use of medical services that is expected to result from enhanced access to substance use disorder services, we have not included any cost offset in our estimates.

b. Effect of Aligning NQTLs

Under the MHPAEA final rules, medical management can be applied to MH/SUD benefits if the processes, strategies, evidentiary standards, or other factors used in applying medical management are comparable to, and are applied no more stringently than, the processes, strategies, evidentiary standards, or other factors used in applying medical management to medical and surgical benefits. It is difficult to determine whether, at baseline, Medicaid MCOs, ABPs and CHIP programs are applying medical management more stringently to MH/SUD benefits than to medical and surgical benefits. A state-by-state search of available Medicaid documents indicated that most states that use inpatient utilization management techniques for MH/SUD services, such as prior approval or continuing utilization review for inpatient stays, have similar restrictions for medical and surgical conditions. Surveys of commercial plans have also found that

inpatient managed care restrictions, such as pre-admission prior approval, are common for medical and surgical admissions.^{40 41} There may be important distinctions in the processes, strategies, evidentiary standards, or other factors between MH/SUD services and medical and surgical services, but current data do not indicate that this is the case in a way that would lead to a clear cost impact.

Moreover, if some Medicaid plans have stricter management controls for MH/SUD services than for medical services, there is scant evidence at this time as to how utilization management will evolve with the application of parity requirements and whether stricter controls would result in higher costs.⁴² For example, stricter controls may lead to underutilization of sub-acute levels of care for MH/SUD conditions, leading to the worsening of both MH/SUD conditions and medical or surgical conditions that ultimately require more costly acute levels of care. Studies of the effect of utilization review and prior approval on MH/SUD inpatient services have revealed mixed results, with some studies showing that these managed care techniques result in lower costs, quantities of treatment, or both, and other studies finding only weak or no effects, or effects that are short term.^{43 44 45 46} As noted above, the

studies of Oregon and Vermont, whose parity laws include similar restrictions on medical management, have not shown increases in costs resulting from application of these laws. There is uncertainty regarding the level of increased costs that will result from application of the parity requirement for NQTLs, but there is evidence that any increases may be small. We invite comments related to any additional evidence on the impact of aligning NQTLs for Medicaid services.

2. Transfers Resulting From Increased Access Under Medicaid

Transfer payments are monetary payments from one group to another that do not affect total resources available to society. There is a potential that application of parity requirements under MHPAEA will result in transfers among different government entities. MH/SUD services receive greater funding from public sources, such as Medicaid, federal government block grants, state government general funds, and local government funding, than do medical and surgical services.⁴⁷ Over time, MH/SUD spending has been shifting away from state and local funding, toward federal financing, especially Medicaid.⁴⁸ The potential increase in the availability of MH/SUD services under Medicaid and CHIP as a result of the MHPAEA parity requirements may result in a reduction in use of, and spending on, services financed by other public sources such as state and local governments and federal block grants.⁴⁹ Limited sound evidence exists about the size of this effect on states.

⁴⁰ Baker CA, Diaz IS. Managed care plans and managed care features: Data from the EBS to the NCS. *Compensation and Working Conditions* Spring 2011:30–6.

⁴¹ Claxton, G., DiJulio, B., Whitmore, H., Pickreign, J., McHugh, M., Finder, B., & Osei-Anto, A. (2009). Job-based health insurance: Costs climb at a moderate pace. *Health Aff* 2009; 28(6):w1002–12.

⁴² Hodgkin D. The impact of private utilization management and psychiatric care: A review of the literature. *Journal of Mental Health Administration* 1992; 19(2):143–57.

⁴³ Dickey B, Azemi H. Impact of managed care on mental health services. *Health Aff* 1992 Fall; 11(3):197–204.

⁴⁴ Frank RG, Brookmeyer R. Managed mental health care and patterns of inpatient utilization for treatment of affective disorders. *Soc Psychiatry Psychiatric Epidemiol* 1995 Aug; 30(5):220–3.

⁴⁵ Wickizer TM, Lessler D, Travis KM.. Controlling inpatient psychiatric utilization through managed care. *Am J Psychiatry* 1996; 153:339–45.

⁴⁶ Wickizer TM, Lessler D. Do treatment restrictions imposed by utilization management increase the likelihood of readmission for psychiatric patients? *Med Care* 1998; 36(6):844–50.

⁴⁷ Levit KR, Mark TL, Coffey RM, Frankel S, Santora P, Vandivort-Warren R, Malone K. Federal spending on behavioral health accelerated during recession as individuals lost employer insurance. *Health Aff* 2013 May; 32(5):952–62.

⁴⁸ Levit KR, Mark TL, Coffey RM, Frankel S, Santora P, Vandivort-Warren R, Malone K. Federal spending on behavioral health accelerated during recession as individuals lost employer insurance. *Health Aff* 2013 May; 32(5):952–62.

⁴⁹ Frank RG, Goldman HH, Hogan M. Medicaid and mental health: Be careful what you ask for. *Health Aff* 2003 Jan–Feb; 22(1):101–13.

D. Alternatives Considered

We considered several other approaches for providing guidance to states regarding the application of the MHPAEA to Medicaid MCOs, ABPs, and CHIP. As stated in the preamble of this proposed rule, under our current policies, there is no affirmative obligation to ensure that MCO enrollees receive state plan benefits in a way that fully complies with MHPAEA. This is because section 1932(b)(8) of the Act does not apply to the design of the traditional Medicaid state plan, and state plans thus may be designed in a way that does not comply with MHPAEA requirements. Under current guidance, we have said that if an MCO is simply properly applying state plan benefits, there is no violation of section 1932(b)(8) of the Act even if that benefit design does not conform to MHPAEA, because the MCO did not adopt that benefit design and thus was not at fault in its non-compliance. As explained above, we do not believe that this policy effectuates Congressional intent in enacting section 1932(b)(8) of the Act. Further, we believe that implementation of the statute requires that MCO enrollees receive benefits in a manner that complies with MHPAEA.

We considered requiring that all state plan MH/SUD services be included under MCO contracts as the way to ensure that MCO enrollees receive the full protections of MHPAEA. However, we believe the approach we are proposing would allow states the most flexibility when applying mental health parity requirements to their Medicaid services across delivery systems. Given that there are many different delivery system configurations that carve out MH/SUD services, the proposed approach would allow states to comport with parity requirements for MCO enrollees without completely carving out MH/SUD services from their MCO or dropping MH/SUD coverage altogether.

Also, under current statutes, regulations and policies, states would not be required under Federal law to apply MHPAEA provisions to PIHPs and PAHPs (many of which provide MH/SUD services) since these arrangements were not specifically addressed in section 1932(b)(8) of the Act, and MHPAEA does not directly

apply to such contracts. Consideration of these unique state MH/SUD delivery systems is an important distinction in Medicaid when compared to the commercial market. Further, because the statutory provisions making mental health parity requirements applicable to MCOs do not explicitly address these situations, additional interpretation is needed.

In addition to the delivery system issues, states would not be required to remove or align limits on services that were in the state plan for individuals enrolled in an MCO. As stated previously in this proposed regulation, these limits would be carried through in the development of rates, and cost of services outside of the state plan or a waiver of the state plan cannot be included. Without the proposed change in this rule, individuals enrolled in an MCO could still be subject to treatment limitations that are not compliant with parity requirements, which we believe is inconsistent with the intent of Congress in requiring in section 1932(b)(8) of the Act that MCOs deliver services in a manner consistent with MHPAEA requirements and the policies regarding application of MHPAEA to ABPs and CHIP that operate in a FFS arrangement. In addition, without these changes to the managed care rate setting process, it will be difficult for MCOs to comply with statutory requirements regarding financial requirements and treatment limitations.

Finally, there are mental health parity provisions that are not applicable to the FFS delivery systems for Medicaid ABP benefits. These include: Annual and lifetime dollar limits, availability of plan information, and access to out-of-network providers.

In addition, we considered the ability to provide guidance and enforce the provisions of MHPAEA's application to Medicaid and CHIP through sub-regulatory guidance. Over the past 5 years, we have used two SHO letters to provide guidance to states regarding MHPAEA and Medicaid and CHIP. While states and other stakeholders found this guidance useful, there were many questions or concerns regarding the lack of specificity regarding application of MHPAEA parity requirements to Medicaid and CHIP. There were several issues that states

raised regarding this sub-regulatory guidance. One issue was the actuarial soundness requirements, which mandate that MCO payments be based on services as covered under state plans. Another was additional clarification of NQTLs and states' concerns regarding existing federal and state policies that required utilization management strategies that were inconsistent with the intent of MHPAEA. States also raised additional questions regarding application of MHPAEA parity requirements to other delivery systems including PIHPs, PAHPs, and FFS. We do not believe that additional subregulatory guidance would provide the necessary authority for MCOs and states to implement or enforce MHPAEA parity requirements for Medicaid beneficiaries enrolled in an MCO.

We request public comment on our rationale for having regulations that are specific to Medicaid and CHIP.

E. Accounting Statement and Table

As required by OMB Circular A-4 (available at http://www.whitehouse.gov/omb/circulars_a004_a-4/), in Table 7 we have prepared an accounting statement showing the classification of the impacts associated with implementation of this proposed rule.

The projected impact on costs in 2015 was calculated by multiplying the percent anticipated increase in cost due to the application of parity requirements by expected Medicaid expenditures in 2015. Based on our analysis, the parity rule will lead to an increase of approximately 0.03 percent in total Medicaid spending each year over 10 years. In 2015, Medicaid expenditures overall are projected to equal approximately \$513.4 billion.⁵⁰ Thus, the undiscounted cost of the rule is estimated to be \$157.4 million in 2015, and to rise proportionate to the growth in overall Medicaid spending in future years. These costs are split between the federal and state governments based on the population covered and the statutory matching rate.

⁵⁰ Centers for Medicare & Medicaid Services. National Health Expenditure Projections 2012–2022. Forecast Summary. <http://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/NationalHealthExpendData/Downloads/Proj2012.pdf>. Accessed June 25, 2014.

TABLE 7—ACCOUNTING STATEMENT: CLASSIFICATION OF ESTIMATED BENEFIT, COSTS, AND TRANSFERS

Category	Estimates	Units		
		Year dollar	Discount rate %	Period covered
Transfers from Federal Government to Providers				
Annualized Monetized (\$million/year)	107.0	2015	7	2015–2019
	107.5	2015	3	2015–2019
Transfers from State Government to Providers				
Annualized Monetized (\$million/year)	70.5	2015	7	2015–2019
	70.8	2015	3	2015–2019

Note. The displayed numbers are rounded to the nearest thousand and therefore may not add up to the totals.

F. Regulatory Flexibility Act (RFA)

The RFA requires agencies to analyze options for regulatory relief for small entities, if a rule has a significant impact on a substantial number of small entities. The great majority of hospitals and most other health care providers and suppliers are small entities, either by being nonprofit organizations or by meeting the SBA definition of a small business (having revenues of less than \$7.5 million to \$38.5 million in any 1 year). States are not included in the definition of a small entity. This proposed rule does not change the rates at which providers would be reimbursed for any additional treatments and services that may be required, and MCOs, PIHPs, and PAHPs will be paid on an actuarially sound basis for any additional coverage that they will be required to provide. As indicated previously in this proposed rule, the increased costs will be borne by states and the federal government, which are not considered small entities. Therefore, the Secretary has determined that this proposed rule will not have a significant economic impact on a substantial number of small entities as that term is used in the RFA.

In addition, section 1102(b) of the Act requires us to prepare a regulatory impact analysis if a rule 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 603 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 of a metropolitan statistical area and has fewer than 100 beds. The Secretary has determined that this proposed rule will not have a significant impact on the operations of a substantial number of small rural hospitals.

G. Unfunded Mandates Reform Act (UMRA)

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. UMRA does not address the total cost of a rule. Rather, it focuses on certain categories of cost, mainly those “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. The average state share of total Medicaid spending in 2015 is projected to be 39.9 percent. The total cost impact of this rule is estimated to be \$157.4 million in 2015. Therefore, the total cost to states is projected to be approximately \$62.8 million. Therefore, this proposed rule is not subject to UMRA.

H. Federalism

Executive Order 13132 establishes certain requirements that an agency must meet when it issues a proposed rule (and subsequent final rule) that imposes substantial direct requirement costs on state and local governments, preempts state law, or otherwise has federalism implications.

In the Secretary’s view, this proposed rule has Federalism implications, because it has direct effects on the states, the relationship between the federal government and states, or on the distribution of power and responsibilities among various levels of government. However, in the Secretary’s view, the Federalism implications of this proposed rule are substantially mitigated because, with regards to

MCOs, ABPs, and CHIP, the Secretary expects that many states already offer benefits under their state plan and MCO contracts that meet or exceed the Federal mental health parity standards that would be implemented in this rule.

Throughout the process of developing these regulations, to the extent feasible within the relevant provisions of the Act, PHS Act and MHPAEA, the Secretary has attempted to balance the latitude for states to structure their state plan services and MCO contracts according to the needs and preferences of the state, and the Congress’ intent to provide uniform minimum protections to Medicaid and CHIP beneficiaries in every state. By doing so, it is the Secretary’s view that this proposed rule complies with the requirements of Executive Order 13132.

I. Conclusion

In accordance with the provisions of Executive Order 12866, this regulation was reviewed by the Office of Management and Budget.

List of Subjects

42 CFR Part 438

Grant programs-health, Medicaid, Reporting and recordkeeping requirements.

42 CFR Part 440

Grant programs-health, Medicaid reporting.

42 CFR Part 456

Administrative practice and procedure, Drugs, Grant programs-health, Health facilities, Medicaid, Reporting and recordkeeping requirements.

42 CFR Part 457

Administrative practice and procedure, Grant programs-health, Health insurance, Reporting and recordkeeping requirements.

For the reasons set forth in the preamble, the Centers for Medicare & Medicaid Services proposes to amend 42 CFR chapter IV as set forth below:

PART 438—MANAGED CARE

■ 1. The authority citation for part 438 continues to read as follows:

Authority: Sec. 1102 of the Social Security Act (42 U.S.C. 1302).

■ 2. Section 438.6 is amended by revising paragraph (e) and adding paragraph (n) to read as follows:

§ 438.6 Contract requirements.

* * * * *

(e) *Additional services that may be covered by a MCO, PIHP, or PAHP.* A MCO, PIHP, or PAHP may cover, for enrollees, services that are in addition to those covered under the state plan as follows:

(1) 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; and

(2) Any services that the MCO, PIHP, or PAHP voluntarily agrees to provide.

(3) Only the costs associated with services in paragraph (e)(1) of this section may be included when determining the payment rates under paragraph (c) of this section.

* * * * *

(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 ensure that enrollees receive services that are compliant 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.

■ 3. Subpart K is added to part 438 to read as follows:

Subpart K—Parity in Mental Health and Substance Use Disorder Benefits

Sec.

438.900 Meaning of terms.

438.905 Parity requirements for aggregate lifetime and annual dollar limits.

438.910 Parity requirements for financial requirements and treatment limitations.

438.915 Availability of information.

438.920 Applicability.

438.930 Compliance dates.

Subpart K—Parity in Mental Health and Substance Use Disorder Benefits

§ 438.900 Meaning of terms.

For purposes of this subpart, except where the context clearly indicates otherwise, the following terms have the meanings indicated:

Aggregate lifetime dollar limit means a dollar limitation on the total amount of specified benefits that may be paid under a MCO, PIHP, or PAHP.

Annual dollar limit means a dollar limitation on the total amount of specified benefits that may be paid in a 12-month period under a MCO, PIHP, or PAHP.

Cumulative financial requirements are financial requirements that determine whether or to what extent benefits are provided based on accumulated amounts and include deductibles and out-of-pocket maximums. (However, cumulative financial requirements do not include aggregate lifetime or annual dollar limits because these two terms are excluded from the meaning of financial requirements.)

Early and Periodic Screening, Diagnostic and Treatment (EPSDT) benefits are benefits defined in section 1905(r) of the Act.

Financial requirements include deductibles, copayments, coinsurance, or out-of-pocket maximums. Financial requirements do not include aggregate lifetime or annual dollar limits.

Medical/surgical benefits means benefits for items or services for medical conditions or surgical procedures, as defined by the state and in accordance with applicable federal and state law, but do not include mental health or substance use disorder benefits. Any condition defined by the state as being or as not being a medical/surgical condition must be defined to be consistent with generally recognized independent standards of current medical practice (for example, the most current version of the International Classification of Diseases (ICD) or state guidelines). Medical/surgical benefits do not include long-term care services.

Mental health benefits means benefits for items or services for mental health conditions, as defined by the state and in accordance with applicable federal and state law. Any condition defined by the state as being or as not being a mental health condition must be defined to be consistent with generally recognized independent standards of current medical practice (for example, the most current version of the Diagnostic and Statistical Manual of Mental Disorders (DSM), the most current version of the ICD, or state

guidelines). Mental health benefits do not include long-term care services.

Substance use disorder benefits means benefits for items or services for substance use disorders, as defined by the state and in accordance with applicable federal and state law. Any disorder defined by the state as being or as not being a substance use disorder must be defined to be consistent with generally recognized independent standards of current medical practice (for example, the most current version of the DSM, the most current version of the ICD, or state guidelines). Substance use disorder benefits do not include long-term care services.

Treatment limitations include limits on benefits based on the frequency of treatment, number of visits, days of coverage, days in a waiting period, or other similar limits on the scope or duration of treatment. Treatment limitations include both quantitative treatment limitations, which are expressed numerically (such as 50 outpatient visits per year), and nonquantitative treatment limitations, which otherwise limit the scope or duration of benefits for treatment under a plan or coverage. (See § 438.910(d)(2) for an illustrative list of nonquantitative treatment limitations.) A permanent exclusion of all benefits for a particular condition or disorder, however, is not a treatment limitation for purposes of this definition.

§ 438.905 Parity requirements for aggregate lifetime and annual dollar limits.

(a) *General*—(1) *General parity requirement.* Each MCO, PIHP, and PAHP providing services to MCO enrollees must comply with paragraphs (b), (c), or (e) of this section for all enrollees of a MCO in states that cover both medical/surgical benefits and mental health or substance use disorder benefits under the state plan. This section details the application of the parity requirements for aggregate lifetime and annual dollar limits.

(b) *MCOs, PIHPs, or PAHPs with no limit or limits on less than one-third of all medical/surgical benefits.* If a MCO, PIHP, or PAHP does not include an aggregate lifetime or annual dollar limit on any medical/surgical benefits or includes an aggregate lifetime or annual dollar limit that applies to less than one-third of all medical/surgical benefits provided to enrollees through a contract with the state, it may not impose an aggregate lifetime or annual dollar limit, respectively, on mental health or substance use disorder benefits.

(c) *MCOs, PIHPs, or PAHPs with a limit on at least two-thirds of all medical/surgical benefits.* If a MCO,

PIHP, or PAHP includes an aggregate lifetime or annual dollar limit on at least two-thirds of all medical/surgical benefits provided to enrollees through a contract with the state, it must either—

(1) Apply the aggregate lifetime or annual dollar limit both to the medical/surgical benefits to which the limit would otherwise apply and to mental health or substance use disorder benefits in a manner that does not distinguish between the medical/surgical benefits and mental health or substance use disorder benefits; or

(2) Not include an aggregate lifetime or annual dollar limit on mental health or substance use disorder benefits that is more restrictive than the aggregate lifetime or annual dollar limit, respectively, on medical/surgical benefits.

(d) *Determining one-third and two-thirds of all medical/surgical benefits.* For purposes of this section, the determination of whether the portion of medical/surgical benefits subject to an aggregate lifetime or annual dollar limit represents one-third or two-thirds of all medical/surgical benefits is based on the total dollar amount of all combinations of MCO, PIHP, and PAHP payments for medical/surgical benefits expected to be paid under the MCO, PIHP, or PAHP for a contract year (or for the portion of a contract year after a change in benefits that affects the applicability of the aggregate lifetime or annual dollar limits). Any reasonable method may be used to determine whether the dollar amount expected to be paid under the MCOs, PIHPs, and PAHPs will constitute one-third or two-thirds of the dollar amount of all payments for medical/surgical benefits.

(e) *MCO, PIHP, or PAHP not described in this section—*(1) *In general.* A MCO, PIHP, or PAHP that is not described in paragraph (b) or (c) of this section for aggregate lifetime or annual dollar limits on medical/surgical benefits, must either—

(i) Impose no aggregate lifetime or annual dollar limit, on mental health or substance use disorder benefits; or

(ii) Impose an aggregate lifetime or annual dollar limit on mental health or substance use disorder benefits that is no more restrictive than an average limit calculated for medical/surgical benefits in the following manner. The average limit is calculated by taking into account the weighted average of the aggregate lifetime or annual dollar limits, as appropriate, that are applicable to the categories of medical/surgical benefits. Limits based on delivery mechanisms, such as inpatient/outpatient treatment or normal treatment of common, low-cost

conditions (such as treatment of normal births), do not constitute categories for purposes of this paragraph (e)(1)(ii). In addition, for purposes of determining weighted averages, any benefits that are not within a category that is subject to a separately-designated dollar limit under the contract are taken into account as a single separate category by using an estimate of the upper limit on the dollar amount that a MCO, PIHP, or PAHP may reasonably be expected to incur for such benefits, taking into account any other applicable restrictions.

(2) *Weighting.* For purposes of this paragraph (e), the weighting applicable to any category of medical/surgical benefits is determined in the manner set forth in paragraph (d) of this section for determining one-third or two-thirds of all medical/surgical benefits.

§ 438.910 Parity requirements for financial requirements and treatment limitations.

(a) *Clarification of terms—*(1) *Classification of benefits.* When reference is made in this section to a classification of benefits, the term “classification” means a classification as described in paragraph (b)(2) of this section.

(2) *Type of financial requirement or treatment limitation.* When reference is made in this section to a type of financial requirement or treatment limitation, the reference to type means its nature. Different types of financial requirements include deductibles, copayments, coinsurance, and out-of-pocket maximums. Different types of quantitative treatment limitations include annual, episode, and lifetime day and visit limits. See paragraph (d)(2) of this section for an illustrative list of nonquantitative treatment limitations.

(3) *Level of a type of financial requirement or treatment limitation.* When reference is made in this section to a level of a type of financial requirement or treatment limitation, level refers to the magnitude of the type of financial requirement or treatment limitation.

(b) *General parity requirement—*(1) *General rule and scope.* Each MCO, PIHP and PAHP providing services to MCO enrollees in a state that covers both medical/surgical benefits and mental health or substance use disorder benefits under the state plan, must not apply any financial requirement or treatment limitation to mental health or substance use disorder benefits in any classification that is more restrictive than the predominant financial requirement or treatment limitation of that type applied to substantially all

medical/surgical benefits in the same classification furnished to enrollees (whether or not the benefits are furnished by the same MCO, PIHP, or PAHP). Whether a financial requirement or treatment limitation is a predominant financial requirement or treatment limitation that applies to substantially all medical/surgical benefits in a classification is determined separately for each type of financial requirement or treatment limitation. The application of the rules of this paragraph (b) to financial requirements and quantitative treatment limitations is addressed in paragraph (c) of this section; the application of the rules of this paragraph (b) to nonquantitative treatment limitations is addressed in paragraph (d) of this section.

(2) *Classifications of benefits used for applying rules.* If an MCO enrollee is provided mental health or substance use disorder benefits in any classification of benefits described in this paragraph (b)(2), mental health or substance use disorder benefits must be provided to the enrollee in every classification in which medical/surgical benefits are provided. In determining the classification in which a particular benefit belongs, a MCO, PIHP, or PAHP must apply the same standards to medical/surgical benefits and to mental health or substance use disorder benefits. To the extent that a MCO, PIHP, or PAHP provides benefits in a classification and imposes any separate financial requirement or treatment limitation (or separate level of a financial requirement or treatment limitation) for benefits in the classification, the rules of this section apply separately for that classification for all financial requirements or treatment limitations. The following classifications of benefits are the only classifications used in applying the rules of this section:

(i) *Inpatient.* Benefits furnished on an inpatient basis.

(ii) *Outpatient.* Benefits furnished on an outpatient basis. See special rules for office visits in paragraph (c)(2) of this section.

(iii) *Emergency care.* Benefits for emergency care.

(iv) *Prescription drugs.* Benefits for prescription drugs. See special rules for multi-tiered prescription drug benefits in paragraph (c)(2) of this section.

(c) *Financial requirements and quantitative treatment limitations—*(1) *Determining “substantially all” and “predominant”—*(i) *Substantially all.* For purposes of this section, a type of financial requirement or quantitative treatment limitation is considered to apply to substantially all medical/

surgical benefits in a classification of benefits if it applies to at least two-thirds of all medical/surgical benefits in that classification. If a type of financial requirement or quantitative treatment limitation does not apply to at least two-thirds of all medical/surgical benefits in a classification, then that type cannot be applied to mental health or substance use disorder benefits in that classification.

(ii) *Predominant.* (A) If a type of financial requirement or quantitative treatment limitation applies to at least two-thirds of all medical/surgical benefits in a classification as determined under paragraph (c)(1)(i) of this section, the level of the financial requirement or quantitative treatment limitation that is considered the predominant level of that type in a classification of benefits is the level that applies to more than one-half of medical/surgical benefits in that classification subject to the financial requirement or quantitative treatment limitation.

(B) If, for a type of financial requirement or quantitative treatment limitation that applies to at least two-thirds of all medical/surgical benefits in a classification, there is no single level that applies to more than one-half of medical/surgical benefits in the classification subject to the financial requirement or quantitative treatment limitation, the MCO, PIHP, or PAHP may combine levels until the combination of levels applies to more than one-half of medical/surgical benefits subject to the financial requirement or quantitative treatment limitation in the classification. The least restrictive level within the combination is considered the predominant level of that type in the classification. (For this purpose, a MCO, PIHP, or PAHP may combine the most restrictive levels first, with each less restrictive level added to the combination until the combination applies to more than one-half of the benefits subject to the financial requirement or treatment limitation.)

(iii) *Portion based on MCO, PIHP or PAHP payments.* For purposes of this section, the determination of the portion of medical/surgical benefits in a classification of benefits subject to a financial requirement or quantitative treatment limitation (or subject to any level of a financial requirement or quantitative treatment limitation) is based on the total dollar amount of all combinations of MCO, PIHP, and PAHP payments for medical/surgical benefits in the classification expected to be paid under the MCOs, PIHPs, and PAHPs for a contract year (or for the portion of a contract year after a change in benefits

that affects the applicability of the financial requirement or quantitative treatment limitation).

(iv) *Clarifications for certain threshold requirements.* For any deductible, the dollar amount of MCO, PIHP, or PAHP payments includes all payments for claims that would be subject to the deductible if it had not been satisfied. For any out-of-pocket maximum, the dollar amount of MCO, PIHP, or PAHP payments includes all payments associated with out-of-pocket payments that are taken into account towards the out-of-pocket maximum as well as all payments associated with out-of-pocket payments that would have been made towards the out-of-pocket maximum if it had not been satisfied. Similar rules apply for any other thresholds at which the rate of MCO, PIHP, or PAHP payment changes.

(v) *Determining the dollar amount of MCO, PIHP, or PAHP payments.* Subject to paragraph (c)(1)(iv) of this section, any reasonable method may be used to determine the dollar amount expected to be paid under a MCO, PIHP, or PAHP for medical/surgical benefits subject to a financial requirement or quantitative treatment limitation (or subject to any level of a financial requirement or quantitative treatment limitation).

(2) *Special rules—*(i) *Multi-tiered prescription drug benefits.* If a MCO, PIHP, or PAHP applies different levels of financial requirements to different tiers of prescription drug benefits based on reasonable factors determined in accordance with the rules in paragraph (d)(1) of this section (relating to requirements for nonquantitative treatment limitations) and without regard to whether a drug is generally prescribed for medical/surgical benefits or for mental health or substance use disorder benefits, the MCO, PIHP, or PAHP satisfies the parity requirements of this section for prescription drug benefits. Reasonable factors include cost, efficacy, generic versus brand name, and mail order versus pharmacy pick-up/delivery.

(ii) *Sub-classifications permitted for office visits, separate from other outpatient services.* For purposes of applying the financial requirement and treatment limitation rules of this section, a MCO, PIHP, or PAHP may divide its benefits furnished on an outpatient basis into the two sub-classifications described in this paragraph (c)(2)(ii). After the sub-classifications are established, the MCO, PIHP or PAHP may not impose any financial requirement or quantitative treatment limitation on mental health or substance use disorder benefits in any sub-classification that is more restrictive

than the predominant financial requirement or quantitative treatment limitation that applies to substantially all medical/surgical benefits in the sub-classification using the methodology set forth in paragraph (c)(1) of this section. Sub-classifications other than these special rules, such as separate sub-classifications for generalists and specialists, are not permitted. The two sub-classifications permitted under this paragraph (c)(2)(ii) are:

(A) Office visits (such as physician visits); and

(B) All other outpatient items and services (such as outpatient surgery, facility charges for day treatment centers, laboratory charges, or other medical items).

(3) *No separate cumulative financial requirements.* A MCO, PIHP, or PAHP may not apply any cumulative financial requirement for mental health or substance use disorder benefits in a classification that accumulates separately from any established for medical/surgical benefits in the same classification.

(4) *Compliance with other cost-sharing rules.* Each MCO, PIHP, and PAHP must meet the cost-sharing requirements in § 438.108 when applying Medicaid cost-sharing.

(d) *Nonquantitative treatment limitations—*(1) *General rule.* A MCO, PIHP, or PAHP may not impose a nonquantitative treatment limitation for mental health or substance use disorder benefits in any classification unless, under the policies and procedures of the MCO, PIHP, or PAHP as written and in operation, any processes, strategies, evidentiary standards, or other factors used in applying the nonquantitative treatment limitation to mental health or substance use disorder benefits in the classification are comparable to, and are applied no more stringently than, the processes, strategies, evidentiary standards, or other factors used in applying the limitation for medical/surgical benefits in the classification.

(2) *Illustrative list of nonquantitative treatment limitations.* Nonquantitative treatment limitations include—

(i) Medical management standards limiting or excluding benefits based on medical necessity or medical appropriateness, or based on whether the treatment is experimental or investigative;

(ii) Formulary design for prescription drugs;

(iii) For MCOs, PIHPs, or PAHPs with multiple network tiers (such as preferred providers and participating providers), network tier design;

(iv) Standards for provider admission to participate in a network, including reimbursement rates;

(v) MCO, PIHP, or PAHP methods for determining usual, customary, and reasonable charges;

(vi) Refusal to pay for higher-cost therapies until it can be shown that a lower-cost therapy is not effective (also known as fail-first policies or step therapy protocols);

(vii) Exclusions based on failure to complete a course of treatment;

(viii) Restrictions based on geographic location, facility type, provider specialty, and other criteria that limit the scope or duration of benefits for services provided under the MCO, PIHP, or PAHP; and

(ix) Standards for providing access to out-of-network providers

(3) *Application to out-of-network providers.* Any MCO, PIHP or PAHP providing access to out-of-network providers for medical/surgical benefits within a classification, must use the same processes, strategies, evidentiary standards, or other factors in determining access to out-of-network providers for MH/SUD benefits. If a MCO, PIHP or PAHP is found to be in compliance with § 438.206(b)(4), it will be deemed in compliance with the standards in this paragraph (d)(3).

§ 438.915 Availability of information.

(a) *Criteria for medical necessity determinations.* The criteria for medical necessity determinations, made by a MCO or by a PIHP or PAHP providing services to an MCO enrollee, for mental health or substance use disorder benefits must be made available by the MCO, PIHP, or PAHP administrator to any enrollee, potential enrollee, or contracting provider upon request. MCOs, PIHPs, and PAHPs operating in compliance with § 438.236(c) will be deemed compliant with the requirements in this paragraph (a).

(b) *Reason for any denial.* The reason for any denial by a MCO, PIHP, or PAHP of reimbursement or payment for services for mental health or substance use disorder benefits in the case of any enrollee must be made available by the MCO, PIHP, or PAHP administrator to the enrollee.

(c) *Provisions of other law.*

Compliance with the disclosure requirements in paragraphs (a) and (b) of this section is not determinative of compliance with any other provision of applicable federal or state law.

§ 438.920 Applicability.

(a) *MCOs, PIHPs, and PAHPs.* The requirements of this subpart apply to each MCO, PIHP, and PAHP offering

services to enrollees of a MCO, in states covering medical/surgical and MH/SUD services under the state plan. These requirements regarding coverage for services that must be provided to enrollees of an MCO apply regardless of the delivery system of the medical/surgical or MH/SUD services under the State plan.

(b) *State responsibilities.* (1) In any instance where the full scope of medical/surgical and MH/SUD services are not provided through the MCO, the State must review the MH/SUD benefits provided in the MCO, PIHP, PAHP, or FFS state plan service to ensure the full scope of services available to all enrollees of the MCO complies with the requirements in this subpart. The state must provide documentation of compliance with requirements in this subpart to the general public within 18 months of the effective date of the final rule.

(2) In any instance where the full scope of medical/surgical and MH/SUD services are not provided through the MCO, the State must ensure that the enrollees of the MCO receive services in compliance with this subpart.

(c) *Scope.* This subpart does not—

(1) Require a MCO, PIHP, or PAHP to provide any mental health benefits or substance use disorder benefits beyond what is specified in its contract, and the provision of benefits by a MCO, PIHP, or PAHP for one or more mental health conditions or substance use disorders does not require the MCO, PIHP or PAHP to provide benefits for any other mental health condition or substance use disorder;

(2) Require a MCO, PIHP, or PAHP that provides coverage for mental health or substance use disorder benefits only to the extent required under 1905(a)(4)(D) of the Act to provide additional mental health or substance use disorder benefits in any classification in accordance with this section; or

(3) Affect the terms and conditions relating to the amount, duration, or scope of mental health or substance use disorder benefits under the Medicaid MCO, PIHP, or PAHP contract except as specifically provided in §§ 438.905 and 438.910.

§ 438.930 Compliance dates.

In general, contracts with MCOs, PIHPs, and PAHPs offering Medicaid state plan services to enrollees, and those entities, must comply with the requirements of this subpart no later than the beginning of the contract year starting 18 months after the [DATE OF PUBLICATION OF THE FINAL RULE].

PART 440—SERVICES: GENERAL PROVISIONS

■ 4. The authority citation for part 440 continues to read as follows:

Authority: Sec. 1102 of the Social Security Act (42 U.S.C. 1302).

■ 5. Section 440.395 is added to read as follows:

§ 440.395 Parity in mental health and substance use disorder benefits.

(a) *Meaning of terms.* For purposes of this section, except where the context clearly indicates otherwise, the following terms have the meanings indicated:

Aggregate lifetime dollar limit means a dollar limitation on the total amount of specified benefits that may be paid under an Alternative Benefit Plan (ABP).

Annual dollar limit means a dollar limitation on the total amount of specified benefits that may be paid in a 12-month period under an ABP.

Alternative Benefit Plans (ABPs) mean benefit packages in one or more of the benchmark coverage packages described in §§ 440.330(a) through (c) and 440.335. Benefits may be delivered through managed care and non-managed care delivery systems. Consistent with the requirements of § 440.385, states must comply with the managed care provisions at section 1932 of the Act and part 438 of this chapter, if benchmark and benchmark-equivalent benefits are provided through a managed care entity.

Cumulative financial requirements are financial requirements that determine whether or to what extent benefits are provided based on accumulated amounts and include deductibles and out-of-pocket maximums. (However, cumulative financial requirements do not include aggregate lifetime or annual dollar limits because these two terms are excluded from the meaning of financial requirements.)

EPSDT means benefits defined in section 1905(r) of the Act.

Financial requirements include deductibles, copayments, coinsurance, or out-of-pocket maximums. Financial requirements do not include aggregate lifetime or annual dollar limits.

Medical/surgical benefits means benefits for items or services for medical conditions or surgical procedures, as defined by the state under the terms of the ABP and in accordance with applicable federal and state law, but does not include mental health or substance use disorder benefits. Any condition defined by the state as being or as not being a medical/surgical

condition must be defined to be consistent with generally recognized independent standards of current medical practice (for example, the most current version of the International Classification of Diseases (ICD) or state guidelines). Medical/surgical benefits do not include long-term services.

Mental health benefits means benefits for items or services for mental health conditions, as defined by the state under the terms of the ABP and in accordance with applicable federal and state law. Any condition defined by the state as being or as not being a mental health condition must be defined to be consistent with generally recognized independent standards of current medical practice (for example, the most current version of the Diagnostic and Statistical Manual of Mental Disorders (DSM), the most current version of the ICD, or state guidelines). Mental health benefits do not include long-term care services.

Substance use disorder benefits means benefits for items or services for substance use disorders, as defined by the state under the terms of the ABP and in accordance with applicable federal and state law. Any disorder defined by the state as being or as not being a substance use disorder must be defined to be consistent with generally recognized independent standards of current medical practice (for example, the most current version of the DSM, the most current version of the ICD, or state guidelines). Substance use disorder benefits do not include long-term care services.

Treatment limitations include limits on benefits based on the frequency of treatment, number of visits, days of coverage, days in a waiting period, or other similar limits on the scope or duration of treatment. Treatment limitations include both quantitative treatment limitations, which are expressed numerically (such as 50 outpatient visits per year), and nonquantitative treatment limitations, which otherwise limit the scope or duration of benefits for treatment under an ABP. (See paragraph (b)(4)(ii) of this section for an illustrative list of nonquantitative treatment limitations.) A permanent exclusion of all benefits for a particular condition or disorder, however, is not a treatment limitation for purposes of this definition.

(b) *Parity requirements for financial requirements and treatment limitations*—(1) *Clarification of terms*—(i) *Classification of benefits*. When reference is made in this paragraph (b) to a classification of benefits, the term “classification” means a classification

as described in paragraph (b)(2)(ii) of this section.

(ii) *Type of financial requirement or treatment limitation*. When reference is made in this paragraph (b) to a type of financial requirement or treatment limitation, the reference to type means its nature. Different types of financial requirements include deductibles, copayments, coinsurance, and out-of-pocket maximums. Different types of quantitative treatment limitations include annual, episode, and lifetime day and visit limits. See paragraph (b)(4)(ii) of this section for an illustrative list of nonquantitative treatment limitations.

(iii) *Level of a type of financial requirement or treatment limitation*. When reference is made in this paragraph (b) to a level of a type of financial requirement or treatment limitation, level refers to the magnitude of the type of financial requirement or treatment limitation.

(2) *General parity requirement*—(i) *General rule*. A state may not apply within an ABP any financial requirement or treatment limitation to mental health or substance use disorder benefits in any classification that is more restrictive than the predominant financial requirement or treatment limitation of that type applied to substantially all medical/surgical benefits in the same classification. Whether a financial requirement or treatment limitation is a predominant financial requirement or treatment limitation that applies to substantially all medical/surgical benefits in a classification is determined separately for each type of financial requirement or treatment limitation. The application of the rules of this paragraph (b)(2) to financial requirements and quantitative treatment limitations is addressed in paragraph (b)(3) of this section; the application of the rules of this paragraph (b)(2) to nonquantitative treatment limitations is addressed in paragraph (b)(4) of this section.

(ii) *Classifications of benefits used for applying rules*. ABPs must include mental health or substance use disorder benefits in every classification of benefits described in this paragraph (b)(2)(ii) in which medical/surgical benefits are provided. In determining the classification in which a particular benefit belongs, the state must apply the same standards to medical/surgical benefits and to mental health or substance use disorder benefits. To the extent that a state provides ABP benefits in a classification and imposes any separate financial requirement or treatment limitation (or separate level of a financial requirement or treatment

limitation) for benefits in the classification, the rules of this paragraph (b) apply separately for that classification for all financial requirements or treatment limitations. The following classifications of benefits are the only classifications used in applying the rules of this paragraph (b):

(A) *Inpatient*. Benefits furnished on an inpatient basis.

(B) *Outpatient*. Benefits furnished on an outpatient basis. See special rules for office visits in paragraph (b)(3)(ii)(B)(1) of this section.

(C) *Emergency care*. Benefits for emergency care.

(D) *Prescription drugs*. Benefits for prescription drugs. See special rules for multi-tiered prescription drug benefits in paragraph (b)(3)(ii) of this section.

(3) *Financial requirements and quantitative treatment limitations*—(i) *Determining “substantially all” and “predominant”*—(A) *Substantially all*. For purposes of this paragraph (b), a type of financial requirement or quantitative treatment limitation is considered to apply to substantially all medical/surgical benefits in a classification of benefits if it applies to at least two-thirds of all medical/surgical benefits in that classification. If a type of financial requirement or quantitative treatment limitation does not apply to at least two-thirds of all medical/surgical benefits in a classification, then that type cannot be applied to mental health or substance use disorder benefits in that classification.

(B) *Predominant*—(1) If a type of financial requirement or quantitative treatment limitation applies to at least two-thirds of all medical/surgical benefits in a classification as determined under paragraph (b)(3)(i)(A) of this section, the level of the financial requirement or quantitative treatment limitation that is considered the predominant level of that type in a classification of benefits is the level that applies to more than one-half of medical/surgical benefits in that classification subject to the financial requirement or quantitative treatment limitation.

(2) If, for a type of financial requirement or quantitative treatment limitation that applies to at least two-thirds of all medical/surgical benefits in a classification, there is no single level that applies to more than one-half of medical/surgical benefits in the classification subject to the financial requirement or quantitative treatment limitation, the state may combine levels until the combination of levels applies to more than one-half of medical/surgical benefits subject to the financial

requirement or quantitative treatment limitation in the classification. The least restrictive level within the combination is considered the predominant level of that type in the classification. (For this purpose, a state may combine the most restrictive levels first, with each less restrictive level added to the combination until the combination applies to more than one-half of the benefits subject to the financial requirement or treatment limitation.)

(C) *Portion based on ABP payments.* For purposes of this paragraph (b), the determination of the portion of medical/surgical benefits in a classification of benefits subject to a financial requirement or quantitative treatment limitation (or subject to any level of a financial requirement or quantitative treatment limitation) is based on the dollar amount of all ABP payments for medical/surgical benefits in the classification expected to be paid under the ABP for the plan year (or for the portion of the plan year after a change in ABP benefits that affects the applicability of the financial requirement or quantitative treatment limitation).

(D) *Clarifications for certain threshold requirements.* For any deductible, the dollar amount of ABP payments includes all payments for claims that would be subject to the deductible if it had not been satisfied. For any out-of-pocket maximum, the dollar amount of ABP payments includes all payments associated with out-of-pocket payments that are taken into account towards the out-of-pocket maximum as well as all payments associated with out-of-pocket payments that would have been made towards the out-of-pocket maximum if it had not been satisfied. Similar rules apply for any other thresholds at which the rate of payment changes.

(E) *Determining the dollar amount of ABP payments.* Subject to paragraph (b)(3)(i)(D) of this section, any reasonable method may be used to determine the dollar amount expected to be paid for medical/surgical benefits subject to a financial requirement or quantitative treatment limitation (or subject to any level of a financial requirement or quantitative treatment limitation).

(ii) *Special rules—(A) Multi-tiered prescription drug benefits.* If a state or plan administrator applies different levels of financial requirements to different tiers of prescription drug benefits based on reasonable factors determined in accordance with the rules in paragraph (b)(4)(i) of this section (relating to requirements for nonquantitative treatment limitations) and without regard to whether a drug is

generally prescribed for medical/surgical benefits or for mental health or substance use disorder benefits, the ABP satisfies the parity requirements of this paragraph (b) for prescription drug benefits. Reasonable factors include cost, efficacy, generic versus brand name, and mail order versus pharmacy pick-up/delivery.

(B) *Sub-classifications permitted for office visits, separate from other outpatient services.* For purposes of applying the financial requirement and treatment limitation rules of this paragraph (b), a state may divide its benefits furnished on an outpatient basis into the two sub-classifications described in this paragraph (b)(3)(ii)(B). After the sub-classifications are established, the state may not impose any financial requirement or quantitative treatment limitation on mental health or substance use disorder benefits in any sub-classification that is more restrictive than the predominant financial requirement or quantitative treatment limitation that applies to substantially all medical/surgical benefits in the sub-classification using the methodology set forth in paragraph (b)(3)(i) of this section. Sub-classifications other than these special rules, such as separate sub-classifications for generalists and specialists, are not permitted. The two sub-classifications permitted under this paragraph (b)(3)(ii)(B) are:

(1) Office visits (such as physician visits); and

(2) All other outpatient items and services (such as outpatient surgery, laboratory services, or other medical items).

(iii) *No separate cumulative financial requirements.* A state may not apply any cumulative financial requirement for mental health or substance use disorder benefits in a classification that accumulates separately from any established for medical/surgical benefits in the same classification.

(iv) *Compliance with other cost-sharing rules.* States must meet the requirements of §§ 447.50 through 447.57 of this chapter when applying Medicaid cost-sharing.

(4) *Nonquantitative treatment limitations—(i) General rule.* A state may not impose a nonquantitative treatment limitation for mental health or substance use disorder benefits in any classification unless, under the terms of the ABP as written and in operation, any processes, strategies, evidentiary standards, or other factors used in applying the nonquantitative treatment limitation to mental health or substance use disorder benefits in the classification are comparable to, and are

applied no more stringently than, the processes, strategies, evidentiary standards, or other factors used in applying the limitation for medical/surgical benefits in the classification.

(ii) *Illustrative list of nonquantitative treatment limitations.* Nonquantitative treatment limitations include—

(A) Medical management standards limiting or excluding benefits based on medical necessity or medical appropriateness, or based on whether the treatment is experimental or investigative;

(B) Formulary design for prescription drugs;

(C) Standards for provider admission to participate in a network, including reimbursement rates;

(D) Methods for determining usual, customary, and reasonable charges;

(E) Refusal to pay for higher-cost therapies until it can be shown that a lower-cost therapy is not effective (also known as fail-first policies or step therapy protocols);

(F) Exclusions based on failure to complete a course of treatment; and

(G) Restrictions based on geographic location, facility type, provider specialty, and other criteria that limit the scope or duration of benefits or services provided under the ABP.

(c) *Availability of information—(1) Criteria for medical necessity determinations.* The criteria for medical necessity determinations made by the state for beneficiaries served through the ABP for mental health or substance use disorder benefits must be made available by the state to any beneficiary or Medicaid provider upon request.

(2) *Reason for any denial.* The reason for any denial made by the state in the case of a beneficiary served through an ABP of reimbursement or payment for services for mental health or substance use disorder benefits must be made available by the state to the beneficiary.

(3) *Provisions of other law.* Compliance with the disclosure requirements in paragraphs (c)(1) and (2) of this section is not determinative of compliance with any other provision of applicable federal or state law.

(d) *Applicability—(1) Alternative Benefit Plans (ABPs).* The requirements of this section apply to states providing benefits through ABPs. For those states providing ABPs through an MCO, PIHP, or PAHP the rules of 42 CFR part 438, subpart K also apply, and approved contracts will be viewed as evidence of compliance with the requirements of this section.

(2) *Scope.* This section does not—

(i) Require a state to provide any specific mental health benefits or substance use disorder benefits;

however, in providing coverage through an ABP, the state must include the ten essential health benefits as required in § 440.347, which include mental health and substance use disorder benefits or

(ii) Affect the terms and conditions relating to the amount, duration, or scope of mental health or substance use disorder benefits under the ABP except as specifically provided in paragraph (b) of this section.

(3) *State plan requirement.* If a state plan provides for an ABP, the state must provide sufficient information in ABP state plan amendment requests to assure compliance with the requirements of this subpart.

(4) *Compliance dates*—(i) *In general.* ABP coverage offered by states must comply with the requirements of this section no later than 18 months after the publication of the final rule.

(ii) [Reserved]

PART 456—UTILIZATION CONTROL

■ 6. The authority citation for part 456 continues to read as follows:

Authority: Sec. 1102 of the Social Security Act (42 U.S.C. 1302), unless otherwise noted.

§ 456.171 [Removed and Reserved]

■ 7. Section 456.171 is removed and reserved.

PART 457—ALLOTMENTS AND GRANTS TO STATES

■ 8. The authority citation for part 457 continues to read as follows:

Authority: Section 1102 of the Social Security Act (42 U.S.C. 1302).

■ 9. Section 457.496 is added to subpart D to read as follows:

§ 457.496 Parity in mental health and substance use disorder benefits.

(a) *Meaning of terms.* For purposes of this section, except where the context clearly indicates otherwise, the following terms have the meanings indicated:

Aggregate lifetime dollar limit means a dollar limitation on the total amount of specified benefits that may be paid under a CHIP state plan or a Managed Care Entity (MCE) (as defined at § 457.10) that contracts with the CHIP state plan. CHIP state plans must meet the requirements of § 457.480.

Annual dollar limit means a dollar limitation on the total amount of specified benefits that may be paid in a 12-month period under a CHIP state plan or a MCE that contracts with a CHIP state plan. CHIP state plans must meet the requirements at § 457.480.

CHIP State Plan has the meaning assigned at § 457.50.

Cumulative financial requirements are financial requirements that determine whether or to what extent benefits are provided based on accumulated amounts and include deductibles and out-of-pocket maximums. (However, cumulative financial requirements do not include aggregate lifetime or annual dollar limits because these two terms are excluded from the meaning of financial requirements.)

Early and Periodic Screening, Diagnostic and Treatment (EPSDT) benefits has the meaning defined in section 1905(r) of the Act.

Financial requirements include deductibles, copayments, coinsurance, or out-of-pocket maximums. Financial requirements do not include aggregate lifetime or annual dollar limits.

Medical/surgical benefits means benefits for items or services for medical conditions or surgical procedures, as defined under the terms of the CHIP state plan in accordance with applicable federal and state law, but does not include mental health or substance use disorder benefits. Any condition defined by the CHIP state plan as being or not being a medical/surgical condition must be defined to be consistent with generally recognized independent standards of current medical practice (for example, the most current version of the International Classification of Diseases (ICD) or generally applicable state guidelines). Medical/surgical benefits do not include long-term care services.

Mental health benefits means benefits for items or services that treat or otherwise address mental health conditions, as defined under the terms of the CHIP state plan in accordance with applicable federal and state law, and consistent with generally recognized independent standards of current medical practice. Standards of current medical practice can be based on the most current version of the DSM, the most current version of the ICD, or generally applicable state guidelines. The term does not include long term care services.

Substance use disorder benefits means benefits for items or services for substance use disorders, as defined under the terms of the CHIP state plan in accordance with applicable federal and state law, and consistent with generally recognized independent standards of current medical practice. Standards of current medical practice can be based on the most current version of the DSM, the most current version of the ICD, or generally applicable state guidelines. The term

does not include long term care services.

Treatment limitations include limits on benefits based on the frequency of treatment, number of visits, days of coverage, days in a waiting period, or other similar limits on the scope or duration of treatment. Treatment limitations include both quantitative treatment limitations, which are expressed numerically (such as 50 outpatient visits per year), and nonquantitative treatment limitations, which otherwise limit the scope or duration of benefits for treatment under the CHIP state plan. (See paragraph (d)(4)(ii) of this section for an illustrative list of nonquantitative treatment limitations.) A permanent exclusion of all benefits for a particular condition or disorder, however, is not a treatment limitation for purposes of this definition.

(b) *State CHIP plan providing EPSDT benefits.* A state CHIP plan that provides benefits through expansion of Medicaid programs and provides EPSDT benefits is deemed to be in compliance with the parity requirements for financial requirements and treatment limitations. Annual or lifetime limits are not permissible in EPSDT benefits.

(c) *Parity requirements for aggregate lifetime and annual dollar limits.* This paragraph (c) details the application of the parity requirements for aggregate lifetime and annual dollar limits. A CHIP state plan that provides both medical/surgical benefits and mental health or substance use disorder benefits must comply with paragraph (c)(1), (2), or (4) of this section.

(1) *Plan with no limit or limits on less than one-third of all medical/surgical benefits.* If a CHIP state plan does not include an aggregate lifetime or annual dollar limit on any medical/surgical benefits or includes an aggregate lifetime or annual dollar limit that applies to less than one-third of all medical/surgical benefits, it may not impose an aggregate lifetime or annual dollar limit, respectively, on mental health or substance use disorder benefits.

(2) *CHIP state plans with a limit on at least two-thirds of all medical/surgical benefits.* If a CHIP state plan includes an aggregate lifetime or annual dollar limit on at least two-thirds of all medical/surgical benefits, it must either—

(i) Apply the aggregate lifetime or annual dollar limit both to the medical/surgical benefits to which the limit would otherwise apply and to mental health or substance use disorder benefits in a manner that does not distinguish between the medical/

surgical benefits and mental health or substance use disorder benefits; or

(ii) Not include an aggregate lifetime or annual dollar limit on mental health or substance use disorder benefits that is more restrictive than the aggregate lifetime or annual dollar limit, respectively, on medical/surgical benefits. (For cumulative limits other than aggregate lifetime or annual dollar limits, see paragraph (d)(3)(iii) of this section prohibiting separately accumulating cumulative financial requirements.)

(3) *Determining one-third and two-thirds of all medical/surgical benefits.* For purposes of this paragraph (c), the determination of whether the portion of medical/surgical benefits subject to an aggregate lifetime or annual dollar limit represents one-third or two-thirds of all medical/surgical benefits is based on the dollar amount of all plan payments for medical/surgical benefits expected to be paid under the CHIP state plan for the state plan year (or for the portion of the plan year after a change in plan benefits that affects the applicability of the aggregate lifetime or annual dollar limits). Any reasonable method may be used to determine whether the dollar amount expected to be paid under the CHIP state plan will constitute one-third or two-thirds of the dollar amount of all plan payments for medical/surgical benefits.

(4) *Plan not described in this section*—(i) *In general.* A CHIP state plan that is not described in paragraph (c)(1) or (2) of this section for aggregate lifetime or annual dollar limits on medical/surgical benefits, must either—

(A) Impose no aggregate lifetime or annual dollar limit, as appropriate, on mental health or substance use disorder benefits; or

(B) Impose an aggregate lifetime or annual dollar limit on mental health or substance use disorder benefits that is no more restrictive than an average limit calculated for medical/surgical benefits in the following manner. The average limit is calculated by taking into account the weighted average of the aggregate lifetime or annual dollar limits, as appropriate, that are applicable to the categories of medical/surgical benefits. Limits based on delivery systems, such as inpatient/outpatient treatment or normal treatment of common, low-cost conditions (such as treatment of normal births), do not constitute categories for purposes of this paragraph (c)(4)(i)(B). In addition, for purposes of determining weighted averages, any benefits that are not within a category that is subject to a separately-designated dollar limit under the plan are taken into account as

a single separate category by using an estimate of the upper limit on the dollar amount that a plan may reasonably be expected to incur for such benefits, taking into account any other applicable restrictions under the plan.

(ii) *Weighting.* For purposes of this paragraph (c)(4), the weighting applicable to any category of medical/surgical benefits is determined in the manner set forth in paragraph (c)(3) of this section for determining one-third or two-thirds of all medical/surgical benefits.

(d) *Parity requirements for financial requirements and treatment limitations*—(1) *Clarification of terms*—

(i) *Classification of benefits.* When reference is made in this paragraph (d) to a classification of benefits, the term “classification” means a classification as described in paragraph (d)(2)(ii) of this section.

(ii) *Type of financial requirement or treatment limitation.* When reference is made in this paragraph (d) to a type of financial requirement or treatment limitation, the reference to type means its nature. Different types of financial requirements include deductibles, copayments, coinsurance, and out-of-pocket maximums. Different types of quantitative treatment limitations include annual, episode, and lifetime day and visit limits. See paragraph (d)(4)(ii) of this section for an illustrative list of nonquantitative treatment limitations.

(iii) *Level of a type of financial requirement or treatment limitation.* When reference is made in this paragraph (d) to a level of a type of financial requirement or treatment limitation, level refers to the magnitude of the type of financial requirement or treatment limitation.

(2) *General parity requirement*—(i) *General rule.* A CHIP state plan or a MCE that contracts with CHIP through its state plan that provides both medical/surgical benefits and mental health or substance use disorder benefits, including when such benefits are delivered through an MCE, may not apply any financial requirement or treatment limitation to mental health or substance use disorder benefits in any classification that is more restrictive than the predominant financial requirement or treatment limitation of that type applied to substantially all medical/surgical benefits in the same classification. Whether a financial requirement or treatment limitation is a predominant financial requirement or treatment limitation that applies to substantially all medical/surgical benefits in a classification is determined separately for each type of financial

requirement or treatment limitation. The application of the rules of this paragraph (d)(2) to financial requirements and quantitative treatment limitations is addressed in paragraph (d)(3) of this section; the application of the rules of this paragraph (d)(2) to nonquantitative treatment limitations is addressed in paragraph (d)(4) of this section.

(ii) *Classifications of benefits used for applying rules.* If a CHIP state plan provides mental health or substance use disorder benefits in any classification of benefits described in this paragraph (d)(2)(ii), mental health or substance use disorder benefits must be provided in every classification in which medical/surgical benefits are provided. In determining the classification in which a particular benefit belongs, the same standards must apply to medical/surgical benefits and to mental health or substance use disorder benefits. To the extent that a CHIP state plan provides benefits in a classification and imposes any separate financial requirement or treatment limitation (or separate level of a financial requirement or treatment limitation) for benefits in the classification, the rules of this paragraph (d) apply separately for that classification for all financial requirements or treatment limitations. The following classifications of benefits are the only classifications used in applying the rules of this paragraph (d):

(A) *Inpatient.* Benefits furnished on an inpatient basis.

(B) *Outpatient.* Benefits furnished on an outpatient basis. See special rules for office visits in paragraph (d)(3)(iii) of this section.

(C) *Emergency care.* Benefits for emergency care.

(D) *Prescription drugs.* Benefits for prescription drugs. See special rules for multi-tiered prescription drug benefits in paragraph (d)(3)(iii) of this section.

(3) *Financial requirements and quantitative treatment limitations*—(i) *Determining “substantially all” and “predominant”*—(A) *Substantially all.* For purposes of this paragraph (d), a type of financial requirement or quantitative treatment limitation is considered to apply to substantially all medical/surgical benefits in a classification of benefits if it applies to at least two-thirds of all medical/surgical benefits in that classification. If a type of financial requirement or quantitative treatment limitation does not apply to at least two-thirds of all medical/surgical benefits in a classification, then that type cannot be applied to mental health or substance use disorder benefits in that classification.

(B) *Predominant.* (1) If a type of financial requirement or quantitative treatment limitation applies to at least two-thirds of all medical/surgical benefits in a classification as determined under paragraph (d)(3)(i)(A) of this section, the level of the financial requirement or quantitative treatment limitation that is considered the predominant level of that type in a classification of benefits is the level that applies to more than one-half of medical/surgical benefits in that classification subject to the financial requirement or quantitative treatment limitation.

(2) If, for a type of financial requirement or quantitative treatment limitation that applies to at least two-thirds of all medical/surgical benefits in a classification, there is no single level that applies to more than one-half of medical/surgical benefits in the classification subject to the financial requirement or quantitative treatment limitation, the CHIP state plan (or health insurance issuer) may combine levels until the combination of levels applies to more than one-half of medical/surgical benefits subject to the financial requirement or quantitative treatment limitation in the classification. The least restrictive level within the combination is considered the predominant level of that type in the classification. (For this purpose, a CHIP state plan may combine the most restrictive levels first, with each less restrictive level added to the combination until the combination applies to more than one-half of the benefits subject to the financial requirement or treatment limitation.)

(C) *Portion based on plan payments.* For purposes of this paragraph (d), the determination of the portion of medical/surgical benefits in a classification of benefits subject to a financial requirement or quantitative treatment limitation (or subject to any level of a financial requirement or quantitative treatment limitation) is based on the dollar amount of all CHIP state plan payments and combinations of MCE payments for medical/surgical benefits in the classification expected to be paid under the plan or MCE or combination that contracts with the CHIP state plan for the plan year (or for the portion of the plan year after a change in plan benefits that affects the applicability of the financial requirement or quantitative treatment limitation).

(D) *Clarifications for certain threshold requirements.* For any deductible, the dollar amount of a CHIP state plan payments includes all plan payments for claims that would be subject to the deductible if it had not been satisfied. In accordance with the cumulative cost-

sharing maximum in § 457.560, or any other out-of-pocket maximum in the CHIP state plan, the dollar amount of plan payments includes all CHIP state plan payments associated with out-of-pocket payments that are taken into account towards the out-of-pocket maximum as well as all plan payments associated with out-of-pocket payments that would have been made towards the out-of-pocket maximum if it had not been satisfied. Similar rules apply for any other thresholds at which the rate of health plan payment changes.

(E) *Determining the dollar amount of CHIP state plan payments.* Subject to paragraph (d)(3)(i)(D) of this section, any reasonable method may be used to determine the dollar amount expected to be paid under a CHIP state plan for medical/surgical benefits subject to a financial requirement or quantitative treatment limitation (or subject to any level of a financial requirement or quantitative treatment limitation).

(ii) *Special rules—(A) Multi-tiered prescription drug benefits.* If a CHIP state plan applies different levels of financial requirements to different tiers of prescription drug benefits based on reasonable factors determined in accordance with the rules in paragraph (d)(4)(i) of this section (relating to requirements for nonquantitative treatment limitations) and without regard to whether a drug is generally prescribed for medical/surgical benefits or for mental health or substance use disorder benefits, the health plan satisfies the parity requirements of this paragraph (d) for prescription drug benefits. Reasonable factors include cost, efficacy, generic versus brand name, and mail order versus pharmacy pick-up/delivery.

(B) *Sub-classifications permitted for office visits, separate from other outpatient services.* For purposes of applying the financial requirement and treatment limitation rules of this paragraph (d), a CHIP state plan may divide its benefits furnished on an outpatient basis into the two sub-classifications described in this paragraph (d)(3)(ii)(B). After the sub-classifications are established, the CHIP state plan may not impose any financial requirement or quantitative treatment limitation on mental health or substance use disorder benefits in any sub-classification that is more restrictive than the predominant financial requirement or quantitative treatment limitation that applies to substantially all medical/surgical benefits in the sub-classification using the methodology set forth in paragraph (d)(3)(i) of this section. Sub-classifications other than these special rules, such as separate sub-

classifications for generalists and specialists, are not permitted. The two sub-classifications permitted under this paragraph (d)(3)(ii)(B) are:

(1) Office visits (such as physician visits); and

(2) All other outpatient items and services (such as outpatient surgery, facility charges for day treatment centers, laboratory charges, or other medical items).

(iii) *No separate cumulative financial requirements.* A CHIP state plan may not apply any cumulative financial requirement for mental health or substance use disorder benefits in a classification that accumulates separately from any established for medical/surgical benefits in the same classification.

(4) *Nonquantitative treatment limitations—(i) General rule.* A CHIP state plan may not impose a nonquantitative treatment limitation for mental health or substance use disorder benefits in any classification unless, under the terms of the CHIP state plan as written and in operation, any processes, strategies, evidentiary standards, or other factors used in applying the nonquantitative treatment limitation to mental health or substance use disorder benefits in the classification are comparable to, and are applied no more stringently than, the processes, strategies, evidentiary standards, or other factors used in applying the limitation for medical/surgical benefits in the classification.

(ii) *Illustrative list of nonquantitative treatment limitations.* Nonquantitative treatment limitations include—

(A) Medical management standards limiting or excluding benefits based on medical necessity or medical appropriateness, or based on whether the treatment is experimental or investigative;

(B) Formulary design for prescription drugs;

(C) For plans with multiple network tiers (such as preferred providers and participating providers), network tier design;

(D) Standards for provider admission to participate in a network, including reimbursement rates;

(E) Plan methods for determining usual, customary, and reasonable charges;

(F) Refusal to pay for higher-cost therapies until it can be shown that a lower-cost therapy is not effective (also known as fail-first policies or step therapy protocols);

(G) Exclusions based on failure to complete a course of treatment; and

(H) Restrictions based on geographic location, facility type, provider

specialty, and other criteria that limit the scope or duration of benefits for services provided under the plan or coverage.

(I) Standards for providing access to out-of-network providers

(5) *Application to out-of-network providers.* Any CHIP state plan providing access to out-of-network providers for medical/surgical benefits within a classification must use the same processes, strategies, evidentiary standards, or other factors in determining access to out-of-network providers for mental health and substance use disorder benefits. If the CHIP state plan is found to be in compliance with § 438.206(b)(4) of this chapter, they will be deemed in compliance with the standards in this paragraph (d)(5).

(e) *Availability of plan information—*
(1) *Criteria for medical necessity determinations.* The criteria for medical necessity determinations made under a CHIP state plan including when benefits are furnished through a MCE contractor for mental health or substance use disorder benefits must be made available by the plan administrator (or the state offering the coverage) to any current enrollee or potential enrollee or contracting provider upon request. Health plans operating in compliance with § 438.236(c) of this chapter will be determined compliant with the requirements in this paragraph (e).

(2) *Reason for any denial.* The reason for any denial under a health plan of reimbursement or payment for services for mental health or substance use disorder benefits in the case of any enrollee must be made available by the plan administrator or the state to the enrollee.

(3) *Provisions of other law.* Compliance with the disclosure requirements in paragraphs (e)(1) and (2) of this section is not determinative of compliance with any other provision of applicable federal or state law.

(f) *Applicability—*(1) *CHIP state plans.* The requirements of this section apply to CHIP state plans offering medical/surgical benefits and mental health or substance use disorder benefits to their enrollees including when benefits are furnished under a contract with MCEs. If, under an arrangement or arrangements to provide CHIP state plan benefits any enrollee can simultaneously receive coverage for medical/surgical benefits and coverage for mental health or substance use disorder benefits, then the requirements of this section apply separately for each combination of medical/surgical benefits and of mental health or substance use disorder benefits that any enrollee can simultaneously receive from the state Medicaid agency.

(2) *Scope.* This section does not—

(i) Require a CHIP state plan or a MCE that contracts with a CHIP state plan to

provide any mental health benefits or substance use disorder benefits, and the provision of benefits by a CHIP state plan or a MCE that contracts with a CHIP state plan for one or more mental health conditions or substance use disorders does not require the plan or health insurance coverage under this section to provide benefits for any other mental health condition or substance use disorder;

(ii) Affect the terms and conditions relating to the amount, duration, or scope of mental health or substance use disorder benefits under the CHIP state plan or a MCE that contracts with a CHIP state plan except as specifically provided in paragraphs (c) and (d) of this section.

(g) *Compliance dates—*(i) *In general.* CHIP state plans (including those that contract with a MCE) must comply with the requirements of this section no later than [DATE 18 MONTHS AFTER THE PUBLICATION OF THE FINAL RULE].

(ii) [Reserved]

Dated: March 18, 2015.

Andrew M. Slavitt,

Acting Administrator, Centers for Medicare & Medicaid Services.

Dated: April 1, 2015.

Sylvia M. Burwell,

Secretary, Department of Health and Human Services.

[FR Doc. 2015-08135 Filed 4-6-15; 4:15 pm]

BILLING CODE 4120-01-P