

this reason, this action is also not subject to Executive Order 13211, "Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use" (66 FR 28355, May 22, 2001). This action merely approves state law as meeting Federal requirements and imposes no additional requirements beyond those imposed by state law. Accordingly, the Administrator certifies that this rule will not have a significant economic impact on a substantial number of small entities under the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*). Because this rule approves pre-existing requirements under state law and does not impose any additional enforceable duty beyond that required by state law, it does not contain any unfunded mandate or significantly or uniquely affect small governments, as described in the Unfunded Mandates Reform Act of 1995 (Pub. L. 104-4).

This rule also does not have tribal implications because it will not have a substantial direct effect on one or more Indian tribes, on the relationship between the Federal Government and Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes, as specified by Executive Order 13175 (65 FR 67249, November 9, 2000). This action also does not have federalism implications because it does not have substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government, as specified in Executive Order 13132 (64 FR 43255, August 10, 1999). This action merely approves a state rule implementing a Federal standard, and does not alter the relationship or the distribution of power and responsibilities established in the Clean Air Act. This rule also is not subject to Executive Order 13045 "Protection of Children from Environmental Health Risks and Safety Risks" (62 FR 19885, April 23, 1997), because it is not economically significant.

In reviewing SIP submissions, EPA's role is to approve State choices, provided that they meet the criteria of the Clean Air Act. In this context, in the absence of a prior existing requirement for the State to use voluntary consensus standards (VCS), EPA has no authority to disapprove a SIP submission for failure to use VCS. It would thus be inconsistent with applicable law for EPA, when it reviews a SIP submission, to use VCS in place of a SIP submission that otherwise satisfies the provisions of the Clean Air Act. Thus, the

requirements of section 12(d) of the National Technology Transfer and Advancement Act of 1995 (15 U.S.C. 272 note) do not apply. This rule does not impose an information collection burden under the provisions of the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*).

The Congressional Review Act, 5 U.S.C. section 801 *et seq.*, as added by the Small Business Regulatory Enforcement Fairness Act of 1996, generally provides that before a rule may take effect, the agency promulgating the rule must submit a rule report, which includes a copy of the rule, to each House of the Congress and to the Comptroller General of the United States. EPA will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of the rule in the **Federal Register**. A major rule cannot take effect until 60 days after it is published in the **Federal Register**. This action is not a "major rule" as defined by 5 U.S.C. section 804(2).

Under section 307(b)(1) of the Clean Air Act, petitions for judicial review of this action must be filed in the United States Court of Appeals for the appropriate circuit by November 15, 2004. Filing a petition for reconsideration by the Administrator of this final rule does not affect the finality of this rule for the purposes of judicial review nor does it extend the time within which a petition for judicial review may be filed, and shall not postpone the effectiveness of such rule or action. This action may not be challenged later in proceedings to enforce its requirements. (*See* section 307(b)(2).)

List of Subjects in 40 CFR Part 52

Environmental protection, Air pollution control, Carbon monoxide, Intergovernmental relations, Reporting and recordkeeping requirements.

Dated: September 3, 2004.

Robert E. Roberts,
Regional Administrator, Region VIII.

■ 40 CFR part 52 is amended to read as follows:

PART 52—[AMENDED]

■ 1. The authority citation for part 52 continues to read as follows:

Authority: 42 U.S.C. 7401 *et seq.*

Subpart G—Colorado

■ 2. Section 52.349 is amended by adding paragraph (i) to read as follows:

§ 52.349 Control strategy: Carbon monoxide.

* * * * *

(i) Revisions to the Colorado State Implementation Plan, revised Carbon Monoxide Maintenance Plan for Denver, as adopted by the Colorado Air Quality Control Commission on June 19, 2003, State effective on August 30, 2003, and submitted by the Governor on October 15, 2003.

[FR Doc. 04-20793 Filed 9-15-04; 8:45 am]

BILLING CODE 6560-50-P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 63

[MD001-1001a; FRL-7813-6]

Approval of Section 112(l) Authority for Hazardous Air Pollutants; Maryland Equivalency by Permit Provisions; NESHAP for Chemical Recovery Combustion Sources at Kraft, Soda, Sulfite, and Stand-Alone Semichemical Pulp Mills

AGENCY: Environmental Protection Agency (EPA).

ACTION: Direct final rule.

SUMMARY: The EPA is approving a request from the Maryland Department of the Environment (MDE) for authority to implement and enforce state permit terms and conditions in place of those of the National Emission Standards for Hazardous Air Pollutants (NESHAP) for Chemical Recovery Combustion Sources at Kraft, Soda, Sulfite, and Stand-Alone Semichemical Pulp Mills, with respect to the operations of MeadWestvaco Company's Luke Mill, located in Luke, Maryland. Thus, the EPA is hereby granting the MDE the authority to implement and enforce alternative requirements in the form of Clean Air Act (CAA) Title V permit terms and conditions after EPA has approved the State's alternative requirements. EPA is approving this request because it has found that the MDE has satisfied the requirements.

DATES: This rule is effective on November 15, 2004 without further notice, unless EPA receives adverse written comment by October 7, 2004. If EPA receives such comments, it will publish a timely withdrawal of the direct final rule in the **Federal Register** and inform the public that the rule will not take effect.

ADDRESSES: Submit your comments, identified by MD001-1001, by one of the following methods:

A. *Federal eRulemaking Portal:* <http://www.regulations.gov>. Follow the on-line instructions for submitting comments.

B. *E-mail:* Campbell.Dave@epa.gov.

C. *Mail:* David J. Campbell, Chief, Permits and Technical Assessment Branch, Mailcode 3AP11, U.S. Environmental Protection Agency, Region III, 1650 Arch Street, Philadelphia, Pennsylvania 19103.

D. *Hand Delivery:* At the previously-listed EPA Region III address. Such deliveries are only accepted during the Docket's normal hours of operation, and special arrangements should be made for deliveries of boxed information.

Instructions: Direct your comments to Docket ID No. MD001-1001. EPA's policy is that all comments received will be included in the public docket without change, including any personal information provided, unless the comment includes information claimed to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Do not submit information that you consider to be CBI or otherwise protected through regulations.gov or e-mail. The federal regulations.gov Web site is an "anonymous access" system, which means EPA will not know your identity or contact information unless you provide it in the body of your comment. If you send an e-mail comment directly to EPA without going through regulations.gov, your e-mail address will be automatically captured and included as part of the comment that is placed in the public docket and made available on the Internet. If you submit an electronic comment, EPA recommends that you include your name and other contact information in the body of your comment and with any disk or CD-ROM you submit. If EPA cannot read your comment due to technical difficulties and cannot contact you for clarification, EPA may not be able to consider your comment. Electronic files should avoid the use of special characters, any form of encryption, and be free of any defects or viruses.

Copies of all comments should also be sent to the Maryland Department of the Environment. Copies of written comments should be sent to Thomas C. Snyder, Director, Air and Radiation Management Administration, Maryland Department of the Environment, 1800 Washington Boulevard, Baltimore, Maryland 21230. Copies of electronic comments should be sent to tsnyder@mde.state.md.us. Copies of the documents relevant to this action are available for public inspection during normal business hours at the Air

Protection Division, U.S. Environmental Protection Agency, Region III, 1650 Arch Street, Philadelphia, Pennsylvania 19103; and the Maryland Department of the Environment, 1800 Washington Boulevard, Baltimore, Maryland 21230.

FOR FURTHER INFORMATION CONTACT: Paresh R. Pandya, (215) 814-2167, or by e-mail at pandya.perry@epa.gov.

SUPPLEMENTARY INFORMATION:

I. Background

Pursuant to section 112 of the Clean Air Act (CAA), the Environmental Protection Agency (EPA) promulgates NESHAP for various categories of air pollution sources. On January 12, 2001, EPA promulgated a NESHAP for Chemical Recovery Combustion Sources at Kraft, Soda, Sulfite, and Stand-Alone Semichemical Pulp Mills, as codified at 40 CFR part 63, subpart MM, §§ 63.860 through 63.868. (*See*, 66 FR 3193.) MeadWestvaco Company operates a pulp and paper mill called the Luke Mill, located in Luke, Maryland which is subject to the requirements of this NESHAP.

Under section 112(l) of the CAA, EPA may approve State or local rules or programs to be implemented and enforced in place of certain otherwise applicable Federally promulgated CAA section 112 rules, emission standards, or requirements. EPA's approval of State and local rules or programs under section 112(l) is governed by regulations found at 40 CFR part 63, subpart E. (*See*, 65 FR 55810, dated September 14, 2000). Under the provisions of subpart E found at 40 CFR 63.94, a State or local air pollution control agency may seek approval, for affected sources permitted by the State or local agency under a CAA Title V permitting program developed pursuant to the EPA regulations found at 40 CFR part 70, of State or local CAA Title V permit terms and conditions to be implemented and enforced in lieu of specified existing and future Federal CAA section 112 rules, emissions standards, or requirements. This option is referred to as the equivalency by permit (EBP) option. To receive EPA approval using this option, the State or local agency must meet the requirements of 40 CFR 63.91 and 63.94.

Approval of alternative requirements under the EBP process comprises three steps. The first step is EPA granting "up-front approval" of a State's EBP program. (*See*, 40 CFR 63.94(a) and (b).) The second step is EPA review and approval of the State's proposed alternative CAA section 112 requirements in the form of pre-draft permit terms and conditions. (*See*, 40

CFR 63.94(c) and (d).) The third step is incorporation of the approved pre-draft permit terms and conditions into a specific CAA Title V permit and the CAA Title V permit issuance process itself. (*See*, 40 CFR 63.94(e).)

The first step, obtaining EPA's "up-front approval" of a State's EBP program, enables EPA to ensure that: (1) A State meets the criteria at 40 CFR 63.91(d) for up-front approval common to all approval options; (2) a legal foundation exists for a State to replace the otherwise applicable Federal section 112 requirements with alternative, Federally enforceable requirements that will be reflected in final CAA Title V permit terms and conditions; and, (3) the specific source(s) and Federal emission standard(s) for which a State will be accepting delegation under the EBP program are clearly specified.

The second step, having EPA review and approve the State's alternative CAA section 112 requirements, provides EPA with an opportunity to ensure that the State's proposed pre-draft CAA Title V permit terms and conditions reflect all of the requirements of the otherwise applicable Federal requirements and are equivalent to those requirements. The approval criteria used by EPA are set forth at 40 CFR 63.94(d). If the EPA finds that the pre-draft CAA Title V permit terms and conditions submitted by the State meet the criteria of paragraph (d), EPA approves the State's alternative requirements (by approving the pre-draft permit terms and conditions) and notifies the State in writing of the approval.

The third step, requiring incorporation of the approved pre-draft permit terms and conditions into a specific CAA Title V permit and the CAA Title V permit issuance process itself, serves to make the requirements legally effective. EPA's final approval of the State's proposed alternative requirements that substitute for the Federal standard does not occur until the completion of step three.

On March 26, 2004 (as amended on July 8, 2004) the MDE requested delegation of authority to implement and enforce State CAA Title V permit terms and requirements for MeadWestvaco Company's Luke Mill as an alternative to those of the NESHAP for Chemical Recovery Combustion Sources at Kraft, Soda, Sulfite, and Stand-Alone Semichemical Pulp Mills, found at 40 CFR, part 63, subpart MM. The MDE states in its request that it intends for the submittal to fulfill only the requirements of step one of the EBP process, pertaining to obtaining "up-front approval" of its program. The MDE explains that it will later fulfill steps

two and three of the EBP process by submitting substitute CAA Title V operating permit terms and conditions for EPA review and approval, and then proceeding with the CAA Title V permit issuance process. The MDE sought this authority pursuant to the provisions of 40 CFR 63.94 and 63.91, and the MDE submitted information addressing the requirements of those sections.

II. Analysis of State's Submittal

EPA has reviewed the MDE's submittal and has concluded that the MDE meets the requirements for "up-front approval" of its EBP program which are specified at 40 CFR 63.94(b) and 63.91(d). The requirements a State or local agency must meet can be summarized as follows: (1) Identify the source(s) for which the State seeks authority to implement and enforce alternative requirements; (2) request delegation (or have delegation) for any remaining sources required to be permitted by the State under 40 CFR part 70 that are in the same category as the source(s) for which it wishes to establish alternative requirements; (3) identify all existing and future CAA section 112 emission standards for which the State is seeking authority to implement and enforce alternative requirements; (4) demonstrate that the State has an approved CAA Title V operating permits program that permits the affected sources; and, (5) demonstrate that the State meets the general approval criteria set forth at 40 CFR 63.91(d).

EPA lists each requirement below and after each requirement explains its reasons for concluding that the MDE meets the requirement:

A. Identify the Source(s) for Which the State Is Seeking Authority To Implement and Enforce Alternative Requirements

The MDE identified MeadWestvaco Company's Luke Mill, a pulp and paper mill located in Luke, Maryland, as the source for which it is seeking authority to implement and enforce alternative requirements. According to the MDE, MeadWestvaco Company's Luke Mill is the only operating pulp and paper mill in Maryland subject to 40 CFR part 63, subpart MM. MeadWestvaco Company's Luke Mill is situated on the border of both Maryland and West Virginia. The portion of the Luke mill that is located in West Virginia is also subject to the requirements of 40 CFR part 63, subpart MM. However, this Direct Final Rule does not grant Maryland or West Virginia the authority to implement the EBP process in West Virginia. For this Direct Final Rule, the EBP process will

only apply to MeadWestvaco's Luke Mill units that are subject to subpart MM and located in Maryland only.

B. Request or Have Delegation for any Remaining Sources Required To Be Issued CAA Title V Permits by the State and That Are in the Same Category as the Source(s) for Which it Seeks To Establish Alternative Requirements

The MDE is currently delegated the authority to implement and enforce the Federal requirements of 40 CFR part 63, subpart MM for Chemical Recovery Combustion Sources at Kraft, Soda, Sulfite, and Stand-Alone Semicheical Pulp Mills. Subpart MM applies to "the owner or operator of each Kraft, Soda, Sulfite, or Stand-Alone Semicheical Pulp Mill that is a major source of hazardous air pollutants * * *" (See, 40 CFR 63.860). On November 3, 1999, EPA delegated to the MDE the authority to implement and enforce EPA's NESHAP standards for affected sources of hazardous air pollutants (HAPs), as defined in 40 CFR part 63, for all source categories which are located at major sources. EPA also delegated to the MDE the authority to implement and enforce all future EPA NESHAP standards applicable to such sources, on the condition that the MDE legally adopt such new standards with only approved wording changes and that the MDE provide notice to EPA of such adoption. The MDE subsequently adopted additional MACT standards which became effective on November 24, 2003. In a letter dated January 13, 2004, MDE notified EPA that they had adopted these additional MACT standards. The additional standards that the State adopted included 40 CFR part 63, subpart MM.

C. Identify All Existing and Future Federal Section 112 Rules for Which the State Is Seeking Authority To Implement and Enforce Alternative Requirements

In its March 26, 2004 (as amended on July 8, 2004) submittal, the MDE requested only the authority to implement and enforce State permit requirements for MeadWestvaco Company's Luke Mill as alternatives to the Federal requirements applicable to that Mill found at 40 CFR part 63, subpart MM. The MDE confirmed that there are no other existing and future Federal CAA section 112 rules for which the State is seeking authority to implement and enforce alternative requirements.

D. Demonstrate That the State has an Approved CAA Title V Permits Program and That the Program Permits the Affected Source(s)

EPA granted final full approval to Maryland's CAA Title V operating permits program on February 14, 2003 (68 FR 1974), and under this approved program the MDE has the authority to issue CAA Title V permits to all major stationary sources. In its March 26, 2004 (as amended on July 8, 2004) submittal, the MDE confirmed that MeadWestvaco Company's Luke Mill is a CAA Title V source and that it is subject to the State's CAA Title V permits program. The MDE noted the MeadWestvaco Company had submitted a CAA Title V permit application, and that the MDE was reviewing this application.

E. Demonstrate That the State Meets the General Approval Criteria Found at 40 CFR 63.91(d)

The provisions of 40 CFR 63.91(d) specify that "Interim or final CAA Title V program approval will satisfy the criteria set forth in § 63.91(d), up-front approval criteria." As discussed in item D. above, EPA has fully approved Maryland's CAA Title V operating permits program.

III. Final Action

EPA is granting the MDE "up-front" approval of an EBP program under which the MDE may establish and enforce alternative State requirements for MeadWestvaco Company's Luke Mill in lieu of those of the NESHAP for Chemical Recovery Combustion Sources at Kraft, Soda, Sulfite, and Stand-Alone Semicheical Pulp Mills, found at 40 CFR part 63, subpart MM. The MDE may only establish alternative requirements for the Luke Mill which are equivalent to and at least as stringent as the otherwise applicable Federal requirements. (See, 40 CFR 63.94(d).) The MDE must, in order to establish alternative requirements for the Luke Mill under its EPA approved EBP program: (1) Submit to EPA for review pre-draft CAA Title V permit terms specifying alternative requirements which are at least as stringent as the otherwise applicable Federal requirements, (2) obtain EPA's written approval of the alternative pre-draft CAA Title V permit requirements, and (3) issue a CAA Title V permit for the Luke Mill which contains the approved alternative requirements. (See, 40 CFR 63.94(c) and (e).) Until EPA has approved the alternative permit terms and conditions and the MDE has issued a final CAA Title V permit incorporating them, MeadWestvaco Company's Luke

Mill will remain subject to the Federal NESHAP requirements found at 40 CFR part 63, subpart MM.

EPA is publishing this rule without prior proposal because the Agency views this as a noncontroversial amendment and anticipates no adverse comment. However, in the "Proposed Rules" section of today's **Federal Register**, EPA is publishing a separate document that will serve as the proposal to approve if adverse comments are filed. This rule will be effective on November 15, 2004 without further notice unless EPA receives adverse comment by October 7, 2004. If EPA receives adverse comment, EPA will publish a timely withdrawal in the **Federal Register** informing the public that the rule will not take effect. EPA will address all public comments in a subsequent final rule based on the proposed rule. EPA will not institute a second comment period on this action. Any parties interested in commenting must do so at this time.

IV. Statutory and Executive Order Reviews

A. General Requirements

Under Executive Order 12866 (58 FR 51735, October 4, 1993), this action is not a "significant regulatory action" and therefore is not subject to review by the Office of Management and Budget. For this reason, this action is also not subject to Executive Order 13211, "Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use" (66 FR 28355, May 22, 2001). This action merely approves state law as meeting Federal requirements and imposes no additional requirements beyond those imposed by state law. Accordingly, the Administrator certifies that this rule will not have a significant economic impact on a substantial number of small entities under the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*). Because this rule approves pre-existing requirements under state law and does not impose any additional enforceable duty beyond that required by state law, it does not contain any unfunded mandate or significantly or uniquely affect small governments, as described in the Unfunded Mandates Reform Act of 1995 (Pub. L. 104-4). This rule also does not have tribal implications because it will not have a substantial direct effect on one or more Indian tribes, on the relationship between the Federal Government and Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes, as specified by Executive Order 13175 (65

FR 67249, November 9, 2000). This action also does not have Federalism implications because it does not have substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government, as specified in Executive Order 13132 (64 FR 43255, August 10, 1999). This action merely approves a state rule implementing a Federal standard, and does not alter the relationship or the distribution of power and responsibilities established in the CAA. This rule also is not subject to Executive Order 13045 "Protection of Children from Environmental Health Risks and Safety Risks" (62 FR 19885, April 23, 1997), because it is not economically significant.

EPA's role in reviewing this submittal is to approve a State request for authority to establish State permit terms and conditions to be implemented and enforced in lieu of specified existing and future Federal rules, emissions standards or requirements promulgated under CAA section 112, for those affected sources permitted by the State under a program meeting the requirements of CAA part 70, provided that the request meets the criteria of the CAA. In this context, in the absence of a prior existing requirement for a State to use voluntary consensus standards (VCS), EPA has no authority to disapprove a State's submission for failure to use VCS. It would thus be inconsistent with applicable law for EPA, in reviewing this submission, to use VCS in place of a State submission that otherwise satisfies the provisions of the CAA. Thus, the requirements of section 12(d) of the National Technology Transfer and Advancement Act of 1995 (15 U.S.C. 272) do not apply. This rule does not impose an information collection burden under the provisions of the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*).

B. Submission to Congress and the Comptroller General

The Congressional Review Act, 5 U.S.C. 801 *et seq.*, as added by the Small Business Regulatory Enforcement Fairness Act of 1996, generally provides that before a rule may take effect, the agency promulgating the rule must submit a rule report, which includes a copy of the rule, to each House of the Congress and to the Comptroller General of the United States. Section 804 exempts from section 801 the following types of rules: (1) Rules of particular applicability; (2) rules relating to agency management or personnel; and (3) rules of agency organization, procedure, or

practice that do not substantially affect the rights or obligations of non-agency parties. 5 U.S.C. 804(3). EPA is not required to submit a rule report regarding today's action under section 801 because this is a rule of particular applicability establishing source-specific requirements for MeadWestvaco Company's Luke Mill located in Luke, Maryland.

C. Petitions for Judicial Review

Under section 307(b)(1) of the Clean Air Act, petitions for judicial review of this action must be filed in the United States Court of Appeals for the appropriate circuit by November 15, 2004. Filing a petition for reconsideration by the Administrator of this final rule does not affect the finality of this rule for the purposes of judicial review nor does it extend the time within which a petition for judicial review may be filed, and shall not postpone the effectiveness of such rule or action. This action granting the MDE "up-front" approval of an EBP program under which the MDE may establish and enforce alternative State requirements for MeadWestvaco Company's Luke Mill in lieu of those of the NESHAP for Chemical Recovery Combustion Sources at Kraft, Soda, Sulfite, and Stand-Alone Semicheical Pulp Mills found at 40 CFR part 63, subpart MM may not be challenged later in proceedings to enforce its requirements. (See section 307(b)(2).)

List of Subjects in 40 CFR Part 63

Environmental protection, Administrative practice and procedure, Air pollution control, Hazardous substances, Intergovernmental relations, Paper and paper products industry, Reporting and recordkeeping requirements.

Dated: September 7, 2004.

Donald S Welsh,

Regional Administrator, Region III.

■ 40 CFR part 63 is amended as follows:

PART 63—[AMENDED]

■ 1. The authority citation for part 63 continues to read as follows:

Authority: 42 U.S.C. 7401 *et seq.*

Subpart E—Approval of State Programs and Delegation of Federal Authorities

■ 2. Section 63.99 is amended by adding paragraph (a)(20)(iii) to read as follows:

§ 63.99 Delegated Federal authorities.

- (a) * * *
- (20) * * *

(iii) EPA has granted the Maryland Department of the Environment (MDE) "up-front" approval to implement an Equivalency by Permit (EBP) program under which the MDE may establish and enforce alternative State requirements for MeadWestvaco Company's Luke Mill in lieu of those of the National Emissions Standard for Hazardous Air Pollutants (NESHAP) for Chemical Recovery Combustion Sources at Kraft, Soda, Sulfite, and Stand-Alone Semichemical Pulp Mills found at 40 CFR part 63, subpart MM. The MDE may only establish alternative requirements for the Luke Mill which are equivalent to and at least as stringent as the otherwise applicable Federal requirements. The MDE must, in order to establish alternative requirements for the Luke Mill under its EPA approved EBP program: submit to EPA for review pre-draft Clean Air Act (CAA) Title V permit terms specifying alternative requirements which are at least as stringent as the otherwise applicable Federal requirements, obtain EPA's written approval of the alternative pre-draft CAA Title V permit requirements, and issue a CAA Title V permit for the Luke Mill which contains the approved alternative requirements. Until EPA has approved the alternative permit terms and conditions and the MDE has issued a final CAA Title V permit incorporating them, MeadWestvaco Company's Luke Mill will remain subject to the Federal NESHAP requirements found at 40 CFR part 63, subpart MM.

* * * * *

[FR Doc. 04-20898 Filed 9-15-04; 8:45 am]

BILLING CODE 6560-50-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Part 414

[CMS-1380-F]

RIN 0938-AN05

Medicare Program; Manufacturer Submission of Manufacturer's Average Sales Price (ASP) Data for Medicare Part B Drugs and Biologicals

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

ACTION: Final rule.

SUMMARY: On April 6, 2004, we published an interim final rule in the **Federal Register** implementing the provisions of the Medicare Prescription

Drug, Improvement, and Modernization Act of 2003 (MMA) related to the calculation and submission of manufacturer's average sales price (ASP) data on certain Medicare Part B drugs and biologicals by manufacturers. This final rule responds to the public comments received on the interim final rule concerning the methodology for estimating price concessions associated with manufacturers' ASP reporting requirements. Other issues and comments relating to the interim final rule will be addressed at a future time.

DATES: These regulations are effective September 16, 2004.

FOR FURTHER INFORMATION CONTACT: Marjorie Baldo, (410) 786-0548.

SUPPLEMENTARY INFORMATION:

I. Background

Section 303(c) of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) amends Title XVIII of the Social Security Act (the Act) by adding new section 1847A. This new section establishes the use of the ASP methodology for payment for drugs and biologicals described in section 1842(o)(1)(C) of the Act furnished on or after January 1, 2005. For calendar quarters beginning on or after January 1, 2004, the statute requires manufacturers to report manufacturer's ASP data to CMS for Medicare Part B drugs and biologicals paid under sections 1842(o)(1)(D), 1847A, or 1881(b)(13)(A)(ii) of the Act. Manufacturers are required to submit their quarterly ASP data to us beginning April 30, 2004. Reports are due not later than 30 days after the last day of each calendar quarter. The types of Medicare Part B covered drugs and biologicals paid under sections 1842(o)(1)(D), 1847A, or 1881(b)(13)(A)(ii) of the Act include drugs furnished incident to a physician's service, drugs furnished under the durable medical equipment (DME) benefit, certain oral anti-cancer drugs, and oral immunosuppressive drugs.

All Medicare Part B covered drugs and biologicals paid under sections 1842(o)(1)(D), 1847A, or 1881(b)(13)(A)(ii) of the Act are subject to the ASP reporting requirements. Certain drugs and biologicals (for example, radiopharmaceuticals) are not paid under these sections of the Act and are not subject to the ASP reporting requirements.

As stated in the summary of this final rule, the April 6, 2004, interim final rule implemented the manufacturer ASP reporting requirements of section 303(i)(4) of the MMA, effective April 30,

2004. In this final rule, we are addressing those comments concerning price concession calculation issues because we believe a clearer understanding of the issues is required in order that manufacturers report ASP data accurately and consistently in time for the submissions due in October 2004. The October data will be used to calculate the payment allowances effective January 1, 2005. The 2005 ASP based payment system was displayed at the Office of the Federal Register on July 27, 2004, and published on August 5, 2004, in the **Federal Register** (69 FR 47488).

II. Provisions of the Final Rule

In the April 6, 2004, interim final rule published in the **Federal Register** (69 FR 17935), we implemented the requirement in section 1847A(c)(3) of the Act, which provides that in calculating the manufacturer's ASP, a manufacturer must include volume discounts, prompt pay discounts, cash discounts, free goods that are contingent on any purchase requirement, chargebacks, and rebates (other than rebates under the Medicaid drug rebate program).

To the extent that data on volume discounts, prompt pay discounts, cash discounts, free goods that are contingent on any purchase requirement, chargebacks, and rebates are available on a lagged basis, the rule provides the following methodology: The manufacturer is required to apply a methodology based on the most recent 12-month period available to estimate costs attributable to these price concessions. Specifically, a manufacturer would sum the volume discounts, prompt pay discounts, cash discounts, free goods that are contingent on any purchase requirement, chargebacks, and rebates for the most recent 12-month period available and divide by 4 to determine the estimate to apply in calculating the manufacturer's ASP for the quarter being submitted. Manufacturers are required to report ASP data to us within 30 days after the last day of the calendar quarter in accordance with section 1927(b)(3)(A) of the Act.

Since publication of the interim final rule, manufacturers have expressed concerns regarding the estimation methodology for pricing concessions. As discussed in section III of this final rule, they have noted that the methodology may result in a disproportionate allocation of pricing concessions within quarterly ASP submissions. In response to these concerns, we have decided to revise the estimation methodology in this final rule.