

(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.

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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.

III. Analysis of and Response to Public Comments on the April 6, 2004, Interim Final Rule.

We received 79 timely comments in response to the April 6, 2004, interim final rule. We received comments from drug manufacturers, pharmacies, physicians, national associations of the pharmaceutical industry, national associations of physicians, and consultants. Although we received comments on a variety of issues pertaining to the interim final rule, we are addressing only the comments that pertain to the methodology for estimating price concessions associated with ASP reporting requirements in this final rule. Those comments and our responses are summarized in this section of the final rule.

Comment: Several commenters stated that the methodology implemented by the April 6, 2004, interim final rule could result in excessive quarter-to-quarter variability in the reported ASP. The commenters suggested an alternative methodology based on a rolling average percentage of price concessions divided by total sales in dollars (described below) for making this calculation.

Response: We agree with these commenters and are adopting the alternative methodology they recommended. As a result, in § 414.804, we are revising the methodology manufacturers must use to calculate the estimates of price concessions. A manufacturer sums the volume discounts, prompt pay discounts, cash discounts, free goods that are contingent on any purchase requirement, chargebacks, and rebates (other than rebates under section 1927 of the Act) for the most recent 12-month period available associated with all sales included in the ASP reporting requirements as stated in the April 6, 2004, interim final rule. However, the manufacturer then calculates a percentage using this summed amount as the numerator and the corresponding total sales data (that is, the total in dollars for the sales subject to the ASP reporting requirement for the same 12-month period) as the denominator. This results in a 12-month rolling average price concession percentage of Total Price Concessions (12-month)/Total Sales (12-month). This percentage is then applied to the total in dollars for the sales subject to the ASP reporting requirement for the quarter being submitted to determine the price concession amount for the quarter. The price concession amount is then applied as a reduction to the total sales dollar amount, and that result (that is, Total

Sales (quarter) minus [Price Concession percentage \times Total Sales (quarter)]) is the numerator used in calculating the quarterly ASP for that National Drug Code (NDC). We are also specifying that the price concession percentage must be carried out to a sufficient number of decimal places so that the price concession amount for the quarter being reported is accurate to the nearest dollar. We included this specification because otherwise the price concession amount might be less accurate and because these calculations are administratively simple.

Example: The total price concessions (discounts, rebates, etc.) over the most recent 12-month period available associated with sales for NDC 12345-6789-01 subject to the ASP reporting requirement equal \$200,000. The total in dollars for those same sales equals \$600,000. The price concessions percentage for this period equals $200,000/600,000 = .33333$. The total in dollars for the sales subject to the ASP reporting requirement for the quarter being reported equals \$50,000 for 10,000 units sold. The manufacturer's ASP calculation for this NDC for this quarter is as follows: $\$50,000 - (.33333 \times \$50,000) = \$33,334$ (net total sales amount); $\$33,334/10,000 = \3.33 (ASP). *(The manufacturer must carry a sufficient number of decimal places in the calculation of the price concessions percentage in order to round the net total sales amount accurately to the nearest whole dollar.)

IV. Waiver of 30-Day Delay in Effective Date

We ordinarily provide an effective date 30 days after the publication of a final rule in the **Federal Register**. We can waive this procedure, however, if we find good cause that the delay is impracticable, unnecessary, or contrary to the public interest, and we incorporate a statement of this finding and its reasons in the rule issued. The provisions of this final rule are effective upon publication in the **Federal Register** because in this instance these provisions are necessary clarifications to the interim final rule that was published on April 6, 2004 (69 FR 17935). The statute requires implementation of the ASP payment methodology by January 1, 2005, which will require ASP data to be reported accurately by October 2004. In order to meet this deadline, drug manufacturers must be able to act on the information in this final rule immediately. The old methodology for estimating price concessions results in greater quarter to quarter price variation. This new methodology is more stable. Accordingly, we believe there is good cause to waive the 30-day delay in effective date.

V. Collection of Information Requirements

The requirements in § 414.804 are subject to the Paperwork Reduction Act of 1995, however, these requirements are currently approved under OMB control #0938-0921 with a current expiration date of 9/30/2007.

VI. Regulatory Statement

We have examined the impact of this rule as required by Executive Order 12866 (September 1993, Regulatory Planning and Review), the Regulatory Flexibility Act (RFA) (September 19, 1980, Pub. L. 96-354), section 1102(b) of the Social Security Act, the Unfunded Mandates Reform Act of 1995 (Pub. L. 104-4), and Executive Order 13132.

Executive Order 12866 directs 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). A regulatory impact analysis (RIA) must be prepared for major rules with economically significant effects (\$100 million or more in any 1 year). This rule does not reach the economic threshold and, thus, is not considered a major rule. The RFA requires agencies to analyze options for regulatory relief of small businesses. For purposes of the RFA, small entities include small businesses, nonprofit organizations, and government agencies. Most hospitals and most other providers and suppliers are small entities, either by nonprofit status or by having revenues of \$6 million to \$29 million in any 1 year. Individuals and States are not included in the definition of a small entity. We are not preparing an analysis for the RFA because we have determined that this rule will not have a significant economic impact on a substantial number of small entities.

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 604 for final rules 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. We are not preparing an analysis for section 1102(b) of the Act because we have determined that this final rule will not have a significant impact on the operations of a substantial number of small rural hospitals.

Section 202 of the Unfunded Mandates Reform Act of 1995 also requires that agencies assess anticipated costs and benefits before issuing any rule that may result in expenditure in any 1 year by State, local, or tribal governments, in the aggregate, or by the private sector, of \$110 million. While this final rule revises a statutory data reporting requirement for drug manufacturers, the costs associated with this requirement are expected to be below the \$110 million annual threshold established by section 202 of the Unfunded Mandates Reform Act.

Executive Order 13132 establishes certain requirements that an agency must meet when it publishes 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. Since this final rule does not impose any costs on State or local governments, the requirements of E.O. 13132 are not applicable.

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

List of Subjects in 42 CFR Part 414

Administrative practice and procedure, Health facilities, Health professions, Kidney diseases, Medicare, Reporting and recordkeeping requirements.

■ For the reasons set forth in the preamble, the Centers for Medicare & Medicaid Services amends 42 CFR Chapter IV, as set forth below:

PART 414—PAYMENT FOR PART B MEDICAL AND OTHER HEALTH SERVICES

■ 1. The authority citation for part 414 continues to read as follows:

Authority: Secs. 1102, 1871, and 1881(b)(1) of the Social Security Act (42 U.S.C. 1302, 1395hh, and 1395rr(b)(1)).

■ 2. Section § 414.804 is amended by revising paragraph (a)(3) to read as follows:

§ 414.804 Basis of payment.

(a) * * *

(3) To the extent that data on price concessions, as described in paragraph (a)(2) of this section, are available on a lagged basis, the manufacturer must estimate this amount in accordance with the methodology described in paragraphs (a)(3)(i) through (a)(3)(iv) of this section.

(i) For each such National Drug Code, the manufacturer calculates a percentage equal to the sum of the price

concessions for the most recent 12-month period available associated with sales subject to the average sales price reporting requirement divided by the total in dollars for the sales subject to the average sales price reporting requirement for the same 12-month period.

(ii) The manufacturer then multiplies the percentage described in paragraph (a)(3)(i) of this section by the total in dollars for the sales subject to the average sales price reporting requirement for the quarter being submitted. (The manufacturer must carry a sufficient number of decimal places in the calculation of the price concessions percentage in order to round accurately the net total sales amount for the quarter to the nearest whole dollar.) The result of this multiplication is then subtracted from the total in dollars for the sales subject to the average sales price reporting requirement for the quarter being submitted.

(iii) The manufacturer then uses the result of the calculation described in paragraph (a)(3)(ii) of this section as the numerator and the number of units sold in the quarter as the denominator to calculate the manufacturer's average sales price for the National Drug Code in the quarter being submitted.

(iv) *Example.* The total price concessions (discounts, rebates, etc.) over the most recent 12-month period available associated with sales for National Drug Code 12345-6789-01 subject to the ASP reporting requirement equal \$200,000. The total in dollars for the sales subject to the average sales price reporting requirement for the same period equals \$600,000. The price concessions percentage for this period equals $200,000/600,000 = .33333$. The total in dollars for the sales subject to the average sales price reporting requirement for the quarter being reported equals \$50,000 for 10,000 units sold. The manufacturer's average sales price calculation for this National Drug Code for this quarter is: $\$50,000 - (0.33333 \times \$50,000) = \$33,334$ (net total sales amount); $\$33,334/10,000 = \3.33 (average sales price).

* * * * *
(Catalog of Federal Domestic Assistance Program No. 93.774, Medicare—Supplementary Medical Insurance Program.)

Dated: August 17, 2004.

Mark McClellan,
Administrator, Centers for Medicare & Medicaid Services.

Approved: September 10, 2004.

Tommy G. Thompson,
Secretary.

[FR Doc. 04-20823 9-10-04; 4:16 pm]

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FEDERAL COMMUNICATIONS COMMISSION

47 CFR Part 64

[CG Docket Nos. 04-53 and 02-278; FCC 04-194]

Rules and Regulations Implementing the Controlling the Assault of Non-Solicited Pornography and Marketing Act of 2003; Rules and Regulations Implementing the Telephone Consumer Protection Act of 1991

AGENCY: Federal Communications Commission.

ACTION: Final rule.

SUMMARY: In this document, the Commission adopts rules to implement those aspects of the Controlling the Assault of the Non-Solicited Pornography and Marketing Act of 2003 (CAN SPAM Act) directed to the Federal Communications Commission (FCC or Commission). Also, in this document, the Commission adopts a general prohibition on sending commercial messages to any address referencing an Internet domain name associated with wireless subscriber messaging services. Furthermore, the Commission clarifies the delineation between these new rules implementing the CAN SPAM Act and our existing rules concerning messages sent to wireless telephone numbers under the Telephone Consumer Protection Act (TCPA).

DATES: Effective October 18, 2004 except § 64.3100(a)(4), (d), (e) and (f) of the Commission's rules, which contain information collection requirements under the Paperwork Reduction Act (PRA) that are not effective until approved by Office of Management and Budget (OMB). Written comments by the public on the new and modified information collections are due November 15, 2004. The Commission will publish a document in the **Federal Register** announcing the effective date for these rules.

ADDRESSES: Federal Communications Commission, 445 12th Street, SW., Washington, DC 20554. In addition to filing comments with the Secretary, a copy of any comments on the