I. Background

[If you choose to comment on issues in this section, please include the caption “BACKGROUND” at the beginning of your comments.]

Section 303(c) of the MMA amends Title XVIII of the Social Security Act (the Act) by adding new section 1847A. This 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.

II. Provisions of the Interim Final Rule

[If you choose to comment on issues in this section, please include the caption “Provisions of the Interim Final Rule” at the beginning of your comments.]

In this interim final rule with comment period, we are adding a new subpart J (Submission of Manufacturer’s Average Sales Price Data) to Part 414 that implements section 1927(b)(3)(A)(iii) of the Act by specifying the requirements for submission of a manufacturer’s ASP data for certain drugs and biologicals covered under Part B of Title XVIII of the Act that are paid under sections 1847A, 1842(o)(1)(D), or 1881(b)(13)(A)(ii) of the Act.
A. Calculation of ASP Data

New section 1847A(c)(1) of the Act defines the manufacturer’s ASP for a National Drug Code (NDC) associated with a drug or biological to be the manufacturer’s sales to all purchasers in the United States (excluding units associated with sales exempted below) for the NDC for a quarter divided by the total number of units of that NDC sold by the manufacturer in that quarter (excluding units associated with sales exempted below). Section 1847A(c)(6)(A) of the Act adopts the definition of “manufacturer” set forth in section 1927(k)(5) of the Act. In that section, the term “manufacturer” means any entity that is engaged in the following (This term does not include a wholesaler or retailer of drugs or a retail pharmacy licensed under State law):

• Production, preparation, propagation, compounding, conversion or processing of prescription drug product, either directly or indirectly by extraction from substances of natural origin, or independently by means of chemical synthesis, or by a combination of extraction and chemical synthesis.
• Packaging, repackaging, labeling, relabeling, or distribution of prescription drug products. (Manufacturers that also engage in wholesaler activities are required to report ASP data for those drugs that they manufacture.)

In performing this calculation, manufacturers must use the NDC at the standardized 11-digit level. For the purposes of the ASP calculation, the “unit” is the product represented by the 11-digit NDC as defined in section 1847A(b)(2)(B) of the Act. In other words, the denominator is the total number of the ASP applicable sales of that NDC.

B. Sales Exempted From ASP Calculation Other Than Nominal Sales

Section 1847A(c)(2)(A) of the Act requires that in calculating the manufacturer’s ASP, a manufacturer must exclude sales that are exempt from the Medicaid best price calculation under sections 1927(c)(1)(C)(i) and 1927(c)(1)(C)(ii)(III) of the Act.

C. Sales to an Entity That Are Nominal in Amount Are Exempted From the ASP Calculation

Section 1847A(c)(2)(B) of the Act requires that sales to an entity that are nominal in amount are to be exempted from the ASP calculation. Sales to an entity that are nominal in amount are defined for purposes of section 1927(c)(1)(C)(ii)(III) of the Act for the Medicaid drug rebate program in the Medicaid drug rebate agreement.

D. Inclusion of Rebates and Other Price Concessions in the ASP Calculation

1. General Rule

Section 1847A(c)(3) of the Act requires 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).

2. Estimation Methodology

a. Use of the Most Recent 12-Month Period Available

Section 1847A(c)(5)(A) of the Act states that the ASP is to be calculated by the manufacturer on a quarterly basis. 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 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 should add 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.

b. Allocation to Individual NDCs

For situations in which a manufacturer is unable to associate volume discounts, prompt pay discounts, cash discounts, free goods that are contingent on any purchase requirement, chargebacks and rebates, with a specific NDC, the manufacturer will allocate those discounts, rebates, free goods, and chargebacks to associated NDCs. This association will be based on the percentage of sales (in dollars) attributable to each particular NDC within the group of NDCs for which the manufacturer can associate discounts, rebates, free goods, and chargebacks.

c. Future Changes to the Methodology

As we gain more experience with the ASP system, we may seek to change the methodology to estimate costs attributable to rebates and chargebacks and the scope of price concessions for years after 2004. Pursuant to section 1847A(c)(5)(A) of the Act, the Secretary may establish a uniform methodology to estimate and apply those costs. For years after 2004, the Secretary may include in the calculation of the ASP, other price concessions which may be based upon recommendations of the Inspector General that would result in a reduction of the cost to the purchaser.

E. Reporting of ASP Data to CMS

1. Format

 Manufacturers must report the ASP data to us in Microsoft Excel using the template provided in Addendum A. Manufacturers are required to calculate and report the ASP information to us at the 11-digit NDC level, along with the associated units used in the calculation of the ASP. As we gain more experience with the ASP system, we may seek to modify these requirements in the future.

2. Contacts

As indicated in Addendum B, manufacturers must submit the names of one or more individuals that we may contact if we have questions or issues with respect to the data submission.

3. Certification by the Chief Executive Officer or Chief Financial Officer

Due to the consequences of failing to submit accurate and timely ASP data, each quarterly ASP data submission must be certified by one of the following: the manufacturer’s Chief Executive Officer (CEO), the manufacturer’s Chief Financial Officer (CFO), or an individual who has delegated authority to sign for, and who reports directly to, the manufacturer’s CEO or CFO.

F. Penalties Associated With the Failure To Submit Timely and Accurate ASP Data

Section 1847A(d)(4) of the Act specifies the penalties for misrepresentations associated with ASP data. If the Secretary determines that a manufacturer has made a misrepresentation in the reporting of ASP data, a civil money penalty in an amount of up to $10,000 may be applied for each price misrepresentation and for each day in which the price misrepresentation was applied. Section 1927 of the Act, as amended by section 303(f)(4) of the MMA, specifies the penalties associated with the manufacturer’s failure to submit timely information or the submission of false information.

III. 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.

IV. Waiver of Proposed Rulemaking

We ordinarily publish a notice of proposed rulemaking in the Federal Register and invite public comment on the proposed rule. The notice of proposed rulemaking includes a reference to the legal authority under which the rule is proposed, and the terms and substance of the proposed rule or a description of the subjects and issues involved. This procedure can be waived, however, if an agency finds good cause that a notice-and-comment procedure is impracticable, unnecessary, or contrary to the public interest and incorporates a statement of the finding and its reasons in the rule issued. In addition, the Administrative Procedure Act normally requires a 30-day delay in the effective date of a final rule. Furthermore, the Congressional Review Act generally requires an agency to delay the effective date of a major rule by 60-days in order to allow for congressional review of the agency action. Section 1871 of the Act provides for publication of a notice of proposed rulemaking and opportunity for public comment before CMS issues a final rule. However, section 1871(b)(2)(B) of the Act provides an exception when a law establishes a specific deadline for implementation of a provision and the deadline is less than 150 days after the law’s date of enactment. The MMA was enacted by Congress on November 25, 2003, and signed into law by the President on December 8, 2003. The provisions of this interim final rule with comment period are required to be implemented by April 30, 2004. Therefore, these provisions are subject to waiver of proposed rulemaking and public comment in accordance with section 1871(b)(2)(B) of the Act.

Even if section 1871(b)(2)(B) of the Act were not directly applicable here, we would find good cause to waive the requirement for publication of a notice of proposed rulemaking and public comment on the grounds that it is impracticable, unnecessary, and contrary to the public interest. This interim final rule with comment period sets forth non-discretionary provisions of MMA with respect to the calculation and submission of ASP data for certain Medicare Part B drugs and biologicals. Because the rule is generally ministerial, we believe that pursuing notice and comment is unnecessary. Moreover, because that process would delay the implementation of congressionally-mandated submissions of drug payment-related data, we find that pursuing that process would be both impracticable and contrary to the public interest.

With respect to the requirement of a 60-day delay in the effective date of any final rule pursuant to the Congressional Review Act (CRA), see 5 U.S.C. section 801, the CRA provides that the 60-day delayed effective date shall not apply to any rule “which an agency for good cause finds * * * that notice and public procedure thereon are impracticable, unnecessary, or contrary to the public interest.” (5 U.S.C. section 808(2)). For the reasons set forth above, we believe that additional notice and comment rulemaking on this subject would be impracticable, unnecessary, or contrary to the public interest. Therefore, we do not believe that the CRA requires a 60-day delay in the effective date of this interim final rule with comment period.

V. Collection of Information Requirements

Under the Paperwork Reduction Act of 1995, we are required to provide 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. In order to fairly evaluate whether an information collection should be approved by OMB, section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 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, however, requesting an emergency review of the information collection referenced below. In compliance with the requirement of section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, we have submitted to the Office of Management and Budget (OMB) the following requirements for emergency review. We are requesting an emergency review because the collection of this information is needed before the expiration of the normal time limits under OMB’s regulations at 5 CFR Part 1320. This is necessary to ensure compliance with a statutory deadline. We cannot reasonably comply with the normal clearance procedures because of an anticipated event.

CMS is requesting OMB review and approval of this collection by April 23, 2004, with a 180-day approval period. Written comments and recommendations will be accepted from the public if received by the individuals designated below by April 16, 2004. During this 180-day period, we will publish a separate Federal Register notice announcing the initiation of an extensive 60-day agency review and public comment period on these requirements.

We are soliciting public comment on each of these issues for the following sections of this document that contain information collection requirements:

- In summary, this interim final rule with comment period requires manufacturers of Medicare Part B covered drugs and biologicals paid under sections 1847A, 1842(o)(1)(D), or 1881(b)(13)(A)(ii) of the Act to submit manufacturer’s quarterly ASP data to CMS beginning April 30, 2004. This interim final rule with comment period lays out the requirements and provides the template manufacturers should use to report their ASP data to CMS. The burden associated with the requirements in this rule is the time and effort required by manufacturers of Medicare Part B drugs and biologicals to prepare and submit the required data to CMS. We estimate that it will take approximately 4 hours for each submission. We also estimate that this requirement will affect approximately 120 manufacturers. Therefore, we estimate the total reporting burden to be approximately 480 hours per quarter for a total of 1920 hours annually.

- As required by section 3504(b) of the Paperwork Reduction Act of 1995, we have submitted a copy of this document to OMB for its review of these information collection requirements. If you comment on these information collection and recordkeeping requirements, please mail copies directly to the following: Centers for Medicare & Medicaid Services, Office of Strategic Operations and Regulatory Affairs, Regulations Development and Issuances Group, Attn: Dawn Willingham, CMS–1200–IFC, Room C5–14–03, 7500 Security Boulevard, Baltimore, MD 21244–1850; and Office of Information and Regulatory Affairs, Office of Management and Budget, Room 10235, New Executive Office Building, Washington, DC 20503, Attn: Brenda Aguilar, CMS Desk Officer, baguilar@omb.eop.gov. Fax (202) 395–6974.

VI. Regulatory Impact

We have examined the impact of this rule as required by Executive Order 12866 (September 1993, Regulatory Planning and Review), the Regulatory
Manufacturers must comply with the requirements for submission of a manufacturer's average sales price (ASP) data for certain drugs and biologicals covered under Title XVIII of the Social Security Act (42 U.S.C. 1395hh, and 1395rr(b)(1)). The requirements for submission of ASP data are contained in section 1847A of the Social Security Act (42 U.S.C. 1395hh). The ASP data must be submitted on a quarterly basis for each 11-digit National Drug code (NDC) and include the following information:

- Production, preparation, conversion, or processing of the product,
- Sales to wholesalers and retailers,
- Sales to mail order customers,
- Sales to other government agencies,
- Free goods that are contingent on any purchase requirement,
- Chargebacks and rebates (other than rebates under the Medicaid drug rebate program),
- 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),
- 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),
- 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).

The ASP data must be submitted within 90 days of the end of the quarter. The data must be submitted on a quarterly basis for each 11-digit NDC and include the following information:

- Production, preparation, conversion, or processing of the product,
- Sales to wholesalers and retailers,
- Sales to mail order customers,
- Sales to other government agencies,
- Free goods that are contingent on any purchase requirement,
- Chargebacks and rebates (other than rebates under the Medicaid drug rebate program),
- 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).
(5) The manufacturer’s average sales price must be calculated by the manufacturer every calendar quarter and submitted to CMS within 30 days of the close of the quarter. The first quarter submission must be submitted by April 30, 2004. Subsequent reports are due not later than 30 days after the last day of each calendar quarter.

(6) Each report must be certified by one of the following:
   (i) The manufacturer’s Chief Executive Officer (CEO).
   (ii) The manufacturer’s Chief Financial Officer (CFO).
   (iii) An individual who has delegated authority to sign for, and who reports directly to, the manufacturer’s CEO or CFO.

§414.806 Penalties associated with the failure to submit timely and accurate ASP data.

Section 1847A(d)(4) specifies the penalties associated with misrepresentations associated with ASP data. If the Secretary determines that a manufacturer has made a misrepresentation in the reporting of ASP data, a civil money penalty in an amount of up to $10,000 may be applied for each price misrepresentation and for each day in which the price misrepresentation was applied. Section 1927(b)(3)(C) of the Act, as amended by section 303(i)(4) of the MMA, specifies the penalties associated with a manufacturer’s failure to submit timely information or the submission of false information.

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


Dennis G. Smith,
Acting Administrator, Centers for Medicare & Medicaid Services.


Tommy G. Thompson,
Secretary.

BILLING CODE 4120–01–P
## Addendum A

<table>
<thead>
<tr>
<th>Manufacturer's Name</th>
<th>National Drug Code</th>
<th>Manufacturer's Average Sales Price</th>
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## Addendum B
### The Centers for Medicare & Medicaid Services
#### Average Sales Price Data

Name of Drug or Biological Manufacturer (as “manufacturer” is defined in section 1927(k)(5) of the Social Security Act):

Legal Address:

Manufacturer Contact(s):

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I certify that the reported Average Sales Prices were calculated accurately and that all information and statements made in this submission are true, complete, and current to the best of my knowledge and belief and are made in good faith. I understand that information contained in this submission may be used for Medicare reimbursement purposes.

Name of CEO, CFO or Authorizing Official:

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According to the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number. The valid OMB control number for this information collection is 0938-0921. The time required to complete this information collection is estimated to average 1 hour per response, including the time to review instructions, search existing data resources, gather the data needed, and complete and review the information collection. If you have comments concerning the accuracy of the time estimate(s) or suggestions for improving this form, please write to: CMS, 7500 Security Boulevard, Attn: PRA Reports Clearance Officer, Baltimore, Maryland 21244-1850.

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FEDERAL MARITIME COMMISSION

46 CFR Part 515

[Docket No. 04–02]

Optional Rider for Proof of Additional NVOCC Financial Responsibility

AGENCY: Federal Maritime Commission.

ACTION: Final rule.

SUMMARY: The Federal Maritime Commission amends its regulations governing proof of financial responsibility for ocean transportation intermediaries to allow an optional rider to be filed with a licensed non-vessel-operating common carrier’s proof of financial responsibility to provide additional proof of financial responsibility for such carriers serving the U.S. oceanborne trade with the People’s Republic of China.


FOR FURTHER INFORMATION CONTACT: Amy W. Larson, General Counsel, Federal Maritime Commission, 800 North Capitol Street, NW., Room 1018, Washington, DC 20573–0001, (202) 523–5740, E-mail: GeneralCounsel@fmc.gov. Sandra A. Kusumoto, Director, Bureau of Consumer Complaints and Licensing, Federal Maritime Commission, 800 North Capitol Street, NW., Room 970, Washington, DC 20573–0001, (202) 523–5787, E-mail: otibonds@fmc.gov.

SUPPLEMENTARY INFORMATION:

I. Background

This rulemaking proceeding was initiated on January 23, 2004, with the issuance by the Federal Maritime Commission (“FMC” or “Commission”) of a Notice of Proposed Rulemaking (“NPR”), 69 FR 4271 (January 29, 2004). Comments on the NPR were to be due on February 20, 2004, but requests for