

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Part 414

[CMS-1325-IFC3]

RIN 0938-AN58

**Medicare Program; Exclusion of Vendor Purchases Made Under
the Competitive Acquisition Program (CAP) for Outpatient
Drugs and Biologicals Under Part B for the Purpose of
Calculating the Average Sales Price (ASP)**

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

ACTION: Interim final rule with comment period.

SUMMARY: This interim final rule with comment period provides clarification and solicits comments on the relationship between drugs supplied under the Competitive Acquisition Program (CAP) for Part B Drugs and Biologicals and the calculation of Average Sales Price (ASP). (For purposes of this interim final rule, the term "drug" refers to drugs and biologicals.) This interim final rule with comment period also will exclude units of drugs supplied under the CAP from ASP calculations for a period of up to 3 years, at which time the policy will be re-evaluated. In addition, this rule revises the definition of unit to reflect the exclusion of units of CAP drugs administered to

beneficiaries by participating CAP physicians.

DATES: Effective Date: [OFR: Please insert date of publication.]

Comment Date: To be assured consideration, comments must be received at one of the addresses provided below, no later than 5 p.m. on [OFR—insert date 60 days after the date of filing for public inspection at OFR.]

ADDRESSES: In commenting, please refer to file code CMS-1325-IFC3. Because of staff and resource limitations, we cannot accept comments by facsimile (FAX) transmission.

You may submit comments in one of four ways (no duplicates, please):

1. Electronically. You may submit electronic comments on specific issues in this regulation to <http://www.cms.hhs.gov/regulations/ecomments>. (Attachments should be in Microsoft Word, WordPerfect, or Excel; however, we prefer Microsoft Word.)

2. By regular mail. You may mail written comments (one original and two copies) to the following address

ONLY:

Centers for Medicare & Medicaid Services,
Department of Health and Human Services,
Attention: CMS-1325-IFC3,
P.O. Box 8017,
Baltimore, MD 21244-8017.

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 (one original and two copies) to the following address ONLY:

Centers for Medicare & Medicaid Services,
Department of Health and Human Services,
Attention: CMS-1325-IFC3,
Mail Stop C4-26-05,
7500 Security Boulevard,
Baltimore, MD 21244-1850.

4. By hand or courier. If you prefer, you may deliver (by hand or courier) your written comments (one original and two copies) before the close of the comment period to one of the following addresses. If you intend to deliver your comments to the Baltimore address, please call telephone number (410) 786-7197 in advance to schedule your arrival with one of our staff members.

Room 445-G, Hubert H. Humphrey Building,
200 Independence Avenue, SW.,
Washington, DC 20201; or
7500 Security Boulevard,
Baltimore, MD 21244-1850.

(Because access to the interior of the HHH 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.)

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

Submission of comments on paperwork requirements. You may submit comments on this document's paperwork requirements by mailing your comments to the addresses provided at the end of the "Collection of Information Requirements" section in this document.

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

FOR FURTHER INFORMATION CONTACT:

Angela Mason (410) 786-7452 (for issues related to payment for covered outpatient drugs and biologicals).

Corinne Axelrod (410) 786-5620 (for issues related to the competitive acquisition program (CAP) for Part B drugs).

SUPPLEMENTARY INFORMATION:

Submitting Comments: We welcome comments from the public on all issues set forth in this rule to assist us in fully considering issues and developing policies. You can assist us by referencing the file code CMS-1325-IFC3.

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 a public website as soon as possible after they are received. Hard copy comments received timely will 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.

This **Federal Register** document is also available from the **Federal Register** online database through GPO Access a service of the U.S. Government Printing Office. The web site address is:

<http://www.access.gpo.gov/nara/index.html>.

Information on covered outpatient drugs and biologicals can be found at:

<http://www.cms.hhs.gov/providers/drugs/asp.asp>

Information on the Competitive Acquisition Program can be found at:

<http://www.cms.hhs.gov/providers/drugs/compbid>.

Some of the issues discussed in this preamble affect the payment policies, but do not require changes to the regulations in the Code of Federal Regulations.

Information on the regulation's impact appears throughout the preamble and is not exclusively in section IV.

I. Background

A. Average Sales Price (ASP)

Section 303(c) of the Medicare Modernization Act (MMA) revised the drug payment methodology by creating a new pricing system based on a drug's ASP. Effective January 2005, Medicare pays for the vast majority of Part B covered drugs and biologicals using a drug payment methodology based on the ASP. In accordance with section

1847A of the Social Security Act (the Act), manufacturers submit the ASP data for their products to us on a quarterly basis. These data include the manufacturer's total sales (in dollars) and number of units of a drug to all purchasers in the United States in a calendar quarter (excluding certain sales exempted by statute), with limited exceptions. The sales price is net of discounts such as 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). The Medicare payment rate is based on 106 percent of the ASP, less applicable deductible and coinsurance, and is updated quarterly.

B. Competitive Acquisition Program (CAP)

Section 303(d) of the MMA provides for an alternative payment methodology to the ASP for certain Part B covered drugs that are not paid on a cost or prospective payment basis. The MMA amended Title XVIII of the Social Security Act by adding a new section 1847B, which established a competitive acquisition program for the acquisition of and payment for competitively-biddable Part B covered drugs. This program is anticipated to begin on July 1, 2006. At that time, physicians will have a choice between--(1) obtaining these drugs from entities selected to participate

in the CAP in a competitive bidding process; or (2) acquiring and billing for Part B covered drugs under the ASP system. The provisions for acquiring and billing for drugs through the CAP were first described in the March 4, 2005 proposed rule (70 FR 10746).

In response to the March 4, 2005 proposed rule, many commenters requested clarification about whether the prices determined under the CAP will be taken into account in computing the ASP under section 1847A of the Act. Most commenters recommended that purchases made under the CAP be excluded from the ASP calculation, although one commenter noted that the CAP was not included in the section 1847A(c)(2) of the Act list of sales that are exempt from the ASP calculation and, therefore, could not be excluded. Our response in the Competitive Acquisition Program of Outpatient Drugs and Biologicals under Part B interim final rule with comment period published July 6, 2005 (70 FR 39022) was that because the CAP was not included in the section 1847A(c)(2) of the Act list of sales that are exempt from the ASP calculation, we believed that sales to vendors made under the CAP must be included in the ASP.

We received similar comments on the July 6, 2005 CAP interim final rule with comment period reiterating concern about including purchases made by vendors under the CAP in

the ASP calculations and requesting that we change our interpretation of our statutory authority. Several commenters provided detailed legal arguments supporting the exclusion of purchases by vendors made under the CAP from the calculation of ASP.

Some commenters argued that we could use our demonstration authority to exclude CAP prices from ASP. Other commenters took the position that we could use our authority to establish CAP drug categories to establish a category of drugs that are excluded from the ASP calculation. Several commenters argued that sales to approved CAP vendors should be considered excluded from the determination of "best price" under section 1927(c)(1)(C) of the Act and, by virtue of this exclusion, be excluded from the calculation of ASP. One commenter contended that sales to CAP vendors are excluded from best price because CAP vendors do not fit squarely into the list of entities contained in the definition of "best price" in section 1927(c)(1)(C)(i) of the Act. Another commenter suggested that approved CAP vendors, as Medicare contractors, should be considered Federal purchasers exempt from the determination of best price under section 1927(c)(1)(C)(i)(I-II) of the Act.

Finally, several commenters stated that the intent of

the Congress was to create two different and separate structures, with separate pricing, to provide physicians with a choice of programs. These commenters reference the language contained in section 1847A(a)(2) of the Act, which states that section 1847A "shall not apply in the case of a physician who elects under subsection (a)(1)(A)(ii) of section 1847B for that section to apply instead of this section for the payment for drugs and biologicals," and in section 1847B(a)(1)(A), which states that "this section shall not apply in the case of a physician who elects section 1847A to apply." These commenters argue that this language, which is contained in both the ASP and CAP statutes, clearly indicates that the Congress intended the two programs to operate independently. These commenters assert that as independent programs, the pricing methodologies under ASP and the CAP should not be linked. These commenters further believe that including CAP prices in the calculation of ASP would undermine the CAP program by virtually eliminating any incentive that a manufacturer might have to offer discounts to CAP vendors.

II. Provisions of the Interim Final Rule

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

Although we did not take a position on whether sales of CAP drugs should be part of the computation of the ASP, we were not convinced that we had the statutory authority to exclude sales of CAP drugs from the calculation of ASP. However, in response to the comments that we received on this issue, we revisited our analysis of our statutory authority. We do not find the commenters' arguments above regarding demonstration authority, best price, or the definition of categories entirely persuasive. However, we recognize the commenters' concerns about the effect of including CAP prices in the calculation of ASP and agree that the best outcome for both the ASP methodology and the CAP programs would be one in which prices under CAP did not affect payment amounts under the ASP methodology. In particular, we find compelling the commenters' arguments about the separation of the ASP and CAP programs and that the two programs are intended to be alternatives to each other. We acknowledge the possibility that the Congress intended the programs to be completely independent of each other. Therefore, as a result of our reassessment, and in accordance with our statutory authority, including our authority under section 1847A(b)(2)(B) of the Act to establish methods for counting units, we have decided to exclude, for the initial 3-year contract period under the

CAP, units of CAP drugs that are administered to beneficiaries by participating CAP physicians. In light of Congress's intent to give physicians a choice between the two programs, we believe the relationship between the CAP and the ASP methodology represents a unique circumstance. We believe it is appropriate to implement this exclusion from the ASP calculation because this exclusion is necessary for implementing the CAP, a program that the Congress has expressly identified as an alternative to the ASP payment methodology. We intend to examine the effect of this exclusion and, if necessary, revisit our decision at the end of the initial 3-year period of the CAP.

Because CAP prices will not be included in the ASP calculation for at least the first 3 years of the CAP, we are revising §414.802 (definition of unit) to reflect the exclusion of units of CAP drugs administered to beneficiaries by participating CAP physicians.

Manufacturers also must exclude rebates and lagged price concessions attributable to units of CAP drugs administered to a beneficiary by a participating CAP physician when using the estimation methodology specified in §414.804. (To assist manufacturers in the implementation of this exclusion, we are requiring approved CAP vendors to provide manufacturers with information

necessary to determine which sales to the approved CAP vendor are sales of CAP drugs that are excluded from the ASP calculation. This requirement will be reflected in the approved CAP vendor's contract with CMS.) We welcome further comment on the exclusion of CAP drug units from the calculation of the ASP. We also seek comment on accounting for this exclusion when estimating lagged price concessions. We will provide additional guidance regarding lagged price concessions in a future ASP document. For the reasons stated in section IV. of this preamble, these changes to the calculation of the ASP are effective upon publication of this interim final rule with comment period. However, because there will not be any excludable CAP units until the CAP begins, which we expect to occur on July 1, 2006, this exclusion will not affect manufacturers' calculation of ASP until the third quarter of 2006.

After the initial 3-year period of the CAP, we will evaluate the impact on approved CAP vendors, manufacturers, and others of excluding units supplied under the CAP from the calculation of ASP. If there appears to be a reason not to continue to exclude units supplied under the CAP from the calculation of ASP, we will undertake rulemaking to describe our findings and conclusions and to seek public comment.

III. Response to Comments

Because of the large number of 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 substances 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.

We find good cause to waive the requirement for publication of a notice of proposed rulemaking and public comment on the grounds that it is contrary to the public interest. We have re-examined our statutory authority and

have determined that both the CAP and ASP payment methodologies are best served by excluding units supplied under the CAP from the calculation of ASP for an initial period of 3 years. We believe that excluding CAP drug units from the ASP calculation will give manufacturers an incentive to provide discounts to approved CAP vendors that will, in turn, result in lower prices under the CAP. However, unless it is implemented immediately, any beneficial effects of this policy could not be achieved, because it would not be effective in time to allow vendor applicants to take it into consideration as they prepare their CAP bids. In order to comply with the statutory mandate that the CAP begin in 2006, the bidding process for the CAP must commence in time to allow vendors sufficient time to formulate their bids, to allow us to assess the bids and vendor applications and select the approved CAP vendors, and to allow physicians a meaningful opportunity to review and select an approved CAP vendor. For this reason, it is necessary that policies affecting the CAP bidding process be in place now.

In addition, the Administrative Procedure Act normally requires a 30-day delay in the effective date of a final rule. This delay may be waived if an agency for good cause finds that the delay is impracticable, unnecessary or

contrary to the public interest, and incorporates a statement of the finding and the reasons in the rule issued. (5 U.S.C. 553(d)(3))

We find that good cause exists to waive the 30-day delay so that this rule takes effect immediately upon publication in the **Federal Register**. As noted above, to comply with the statutory mandate that the CAP begin in 2006, it will be necessary for us to have contracts in place with approved CAP vendors in time to give physicians a meaningful opportunity to review and select an available approved CAP vendor in their competitive acquisition areas. An effective date of [**OFR: please insert date of publication**] will ensure that the selection of CAP vendors can proceed and will afford the approved CAP vendors needed time to prepare for the enrollment of physicians and education of beneficiaries concerning the CAP program in time for the anticipated CAP start date, July 1, 2006.

V. Collection of Information Requirements

Under the Paperwork Reduction Act of 1995, 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. 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 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 paid under sections 1847A, 1842(o)(1)(D), or 1881(b)(13)(A)(iii) of the Act to exclude all units supplied under the CAP from their calculation of ASP as well as adjust for this exclusion in their estimation of rebates and lagged price concessions using the estimation methodology. This interim final rule with comment period

lays out the specifications for complying with these requirements.

The burden associated with the requirements in this rule is the time and effort required by manufacturers of Medicare Part B drugs to prepare and submit the required data to CMS. While these requirements are subject to the PRA, this requirement is currently approved under OMB control number 0938-0921, with a current expiration date of September 30, 2007.

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: William Parham, CMS-1325-IFC3, Room C4-26-05,
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,
baquilar@omb.eop.gov. Fax (202) 395-6974.

VI. Regulatory Impact

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

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). Because this rule clarifies the reporting requirements for ASP data and does not affect actual payment, it 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 Core-Based Statistical Area and has fewer than 100 beds. We are not preparing an analysis of section 1102(b) of the Act because we have determined that this 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 whose mandates require

spending in any 1 year of \$100 million in 1995 dollars, updated annually for inflation. That threshold level is currently approximately \$120 million. While this interim final rule with comment period does implement a new data reporting requirement for drug manufacturers, the costs associated with this requirement are expected to be below the \$120 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 promulgates 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. This regulation does not impose any costs on State or local governments, and there is no direct effect on States, or the relationship between the national government and the States, or the distribution of power or responsibilities between the national and State or local governments, and, therefore, 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 this 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)).

Subpart J--Submission of Manufacturer's Average Sales Price Data

2. Section 414.802 is amended by revising the definition of "unit," to read as follows:

§414.802 Definitions.

* * * * *

Unit means the product represented by the 11-digit National Drug Code. During the first 3 years of the CAP (as defined in §414.902), the method of counting units excludes units of CAP drugs (as defined in §414.902) administered to a beneficiary by a participating CAP physician (as defined in §414.902).

(Catalog of Federal Domestic Assistance Program No. 93.773,
Medicare--Hospital Insurance; and Program No. 93.774,
Medicare--Supplementary Medical Insurance Program)

Dated: _____

Mark B. McClellan,

Administrator,

Centers for Medicare & Medicaid

Services.

Approved: _____

Michael O. Leavitt,

Secretary.