AUTHENTICATED
U.S. GOVERNMENT
INFORMATION
GPO

Federal Register

Friday,
December 22, 2006

Part IV

Department of Health and Human Services

Centers for Medicare & Medicaid Services

42 CFR Part 447

Medicaid Program; Prescription Drugs; Proposed Rule

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Part 447

[CMS–2238–P]

RIN 0938–AO20

Medicaid Program; Prescription Drugs

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

ACTION: Proposed rule.

SUMMARY: This proposed rule would implement the provisions of the Deficit Reduction Act of 2005 (DRA) pertaining to prescription drugs under the Medicaid program. The DRA requires the Secretary of Health and Human Services to publish a final regulation no later than July 1, 2007. In addition, we would add to existing regulations certain established Medicaid rebate policies that are currently set forth in CMS guidance. This rule would bring together existing and new regulatory requirements in one, cohesive subpart.

DATES: To be assured consideration, comments must be received at one of the addresses provided below, no later than 5 p.m. on February 20, 2007.

ADDRESSES: In commenting, please refer to file code CMS–2238–P. 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/eRulemaking.* Click on the link ''Submit electronic comments on CMS regulations with an open comment period.'' (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–2238–P, P.O. Box 8015, Baltimore, MD 21244–8015.

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–2238–P, 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) 786–7195 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: Kimberly Howell, (410) 786–6762 (for issues related to the determination of average manufacturer price and best price).

Yolanda Reese, (410) 786–9898 (for issues related to authorized generics).

Madlyn Kruh, (410) 786–3239 (for issues related to nominal prices).

Marge Watchorn, (410) 786–4361 (for issues related to manufacturer reporting requirements).

Gail Sexton, (410) 786–4583 (for issues related to Federal upper limits).

Christina Lyon, (410) 786–3332 (for issues related to physician-administered drugs).

Bernadette Leeds, (410) 786–9463 (for issues related to the regulatory impact analysis).

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–2238–P and the specific ''issue identifier'' that precedes the section on which you choose to comment.

Inspection of Public Comments: All comments received before the close of the comment period are available for viewing by the public, including any personally identifiable or confidential business information that is included in a comment. We post all comments received before the close of the comment period on the following Web site as soon as possible after they have been received: *http://www.cms.hhs.gov/eRulemaking*. Click on the link ''Electronic Comments on CMS Regulations'' on that Web site to view public comments.

Comments received timely will also be available for public inspection as they are received, generally beginning approximately 3 weeks after publication of a document, at the headquarters of the Centers for Medicare & Medicaid Services, 7500 Security Boulevard, Baltimore, Maryland 21244, Monday through Friday of each week from 8:30 a.m. to 4 p.m. To schedule an appointment to view public comments, phone 1–800–743–3951.

I. Background

[If you choose to comment on issues in this section, please include the caption ''Background'' as the beginning of your comments.]

A. Introduction

Under the Medicaid program, States may provide coverage of outpatient drugs as an optional service under section 1905(a)(12) of the Social Security Act (the Act). Section 1903(a) of the Act provides for Federal financial participation (FFP) in State expenditures for these drugs. In order for payment to be made available under section 1903 for certain drugs, manufacturers must enter into a Medicaid drug rebate agreement as set forth in section 1927(a) of the Act. Section 1927 of the Act provides specific requirements for rebate agreements, drug pricing submission and confidentiality requirements, the formula for calculating rebate payments, and requirements for States with respect to covered outpatient drugs.

This proposed rule would implement sections 6001(a)–(d), 6002, and 6003 of the Deficit Reduction Act of 2005 (DRA), Pub. L. 109–171 (Feb. 8, 2006). It also would codify those parts of section 1927 of the Act that pertain to requirements for drug manufacturers' calculation and reporting of average

manufacturer price (AMP) and best price, and it would revise existing regulations that set upper payment limits for certain covered outpatient drugs. This proposed rule would also implement section 1903(i)(10) of the Act, as revised by the DRA, with regard to the denial of FFP in expenditures for certain physician-administered drugs. Finally, the proposed rule would address other provisions of the drug rebate program, to the extent those provisions are affected by the DRA.

The Medicaid Drug Rebate Program was established by section 4401 of the Omnibus Budget Reconciliation Act of 1990 (OBRA 90), Pub. L. 101–508 (Nov. 5, 1990) and subsequently modified by the Veterans Health Care Act of 1992 (VHCA), Pub. L. 102–585 (Nov. 4, 1992) and the Omnibus Budget Reconciliation Act of 1993, Pub. L. 103–66 (Aug. 10, 1993). These provisions were implemented primarily through the national drug rebate agreement (56 FR 7049 (Feb. 21, 1991)) and other informal program releases, which provide standards for manufacturer reporting and rebate calculations. The statutory changes that affect the provisions of this proposed rule are described below.

B. Changes Made by the Deficit Reduction Act of 2005

Section 6001(a) of the DRA amends section 1927(e) of the Act to revise the formula CMS uses to set Federal upper limits (FULs) for multiple source drugs. Effective January 1, 2007, the upper limit for multiple source drugs shall be established at 250 percent of the average manufacturer price (AMP) (as computed without regard to customary prompt pay discounts extended to wholesalers) for the least costly therapeutic equivalent.

Section 6001(b) of the DRA amends section 1927(b)(3) of the Act to create a requirement that manufacturers report certain prices to the Secretary monthly. It also requires the Secretary to provide AMP to States on a monthly basis beginning July 1, 2006 and post AMP on a Web site at least quarterly. We are aware of concerns that the AMPs released to the States beginning July 1, 2006, will not reflect changes to the definition of AMP made by the DRA and proposed in this rule. While we made the AMPs available to the States beginning July 1, 2006, States should keep these data confidential in accordance with section 1927(b)(3)(D) of the Act. Section 6001(b) of the DRA revises these confidentiality provisions to permit States to use AMP to calculate payment rates; however, these confidentiality amendments are not effective until January 1, 2007. This six-month period will give the States a chance to review the AMP data and revise their systems to address the DRA amendments.

Section 6001(c) of the DRA modifies the definition of AMP to remove customary prompt pay discounts extended to wholesalers from the AMP calculation and requires manufacturers to report these customary prompt pay discounts to the Secretary. It requires the Inspector General of the Department of Health and Human Services (IG) to review the requirements for, and the manner in which, AMP is determined and submit to the Secretary and Congress any recommendations for changes no later than June 1, 2006. Finally, it requires the Secretary to promulgate a regulation that clarifies the requirements for, and the manner in which, AMP is determined no later than July 1, 2007, taking into consideration any IG recommendations.

Section 6001(d) of the DRA requires manufacturers to report information on sales at nominal price to the Secretary for calendar quarters beginning on or after January 1, 2007. It also specifies the entities to which nominal price applies. It limits the merely nominal exclusion to sales at nominal prices to the following: A covered entity described in section 340B(a)(4) of the Public Health Service Act (PHSA), an intermediate care facility for the mentally retarded (ICF/MR), a State-owned or operated nursing facility, and any other facility or entity that the Secretary determines is a safety net provider to which sales of such drugs at a nominal price would be appropriate, based on certain factors such as type of facility or entity, services provided by the facility or entity, and patient population.

Section 6001(e) of the DRA amends section 1927 of the Act to provide for a survey of retail prices and State performance rankings. These provisions are not addressed in this proposed rule.

Section 6001(f) of the DRA makes minor amendments to section 1927(g) of the Act which are self-implementing.

Section 6001(g) of the DRA provides that the amendments in section 6001 are effective on January 1, 2007, unless otherwise noted.

Section 6002 of the DRA amends section 1903(i)(10) of the Act by prohibiting Medicaid FFP for physician-administered drugs unless States submit the utilization data described in section 1927(a) of the Act. It also amends section 1927 of the Act to require the submission of utilization data for physician-administered drugs.

Section 6003(a) of the DRA amends section 1927(b)(3)(A) of the Act to require manufacturers to include within AMP and best price all of its drugs that are sold under a new drug application (NDA) approved under section 505(c) of the Federal Food, Drug, and Cosmetic Act (FFDCA) when they report AMP and best price to the Secretary.

Section 6003(b) of the DRA amends section 1927(c)(1)(C) of the Act to clarify that manufacturers must include the lowest price available to any entity for a drug sold under an NDA approved under section 505(c) of the FFDCA when determining best price. Section 6003(b) also amends section 1927(k) to require that in the case of a manufacturer that approves, allows, or otherwise permits any of its drugs to be sold under an NDA approved under section 505(c) of the FFDCA, the AMP shall be calculated to include the average price paid for such drugs by wholesalers for drugs distributed to the retail pharmacy class of trade. Section 6003(c) of the DRA provides that the amendments made by section 6003 are effective January 1, 2007.

The statutory provisions in the DRA that affect the Medicaid Drug Rebate Program, as well as the regulatory provisions we are proposing to implement the program, are discussed in greater detail in the section entitled ''Provisions of the Proposed Regulations'' below.

C. Notice of Proposed Rulemaking Published September 19, 1995

On September 19, 1995, CMS (then the Health Care Financing Administration) published a notice of proposed rulemaking (NPRM) in the **Federal Register** (60 FR 48442 (Sept. 19, 1995)). The purpose of the 1995 NPRM was to propose regulations pertaining to the Medicaid Drug Rebate Program and to address the national rebate agreement (56 FR 7049 (Feb. 21, 1991)). On August 29, 2003, CMS finalized two of the provisions in the 1995 NPRM through a final rule with comment period (68 FR 51912). These regulations require manufacturers to retain records for data used to calculate AMP and best price for three years from when AMP and best price are reported to CMS. We also provided that manufacturers should report revisions to AMP and best price for a period not to exceed twelve quarters from the quarter in which the data are due. On November 26, 2004, we published final regulations (69 FR 68815) that require a manufacturer to retain pricing data for 10 years from the date the manufacturer reports that data to CMS and for an additional time frame where the manufacturer is the subject of an audit or government investigation. Due to the time that has elapsed since publication of the 1995 NPRM and

changes in the prescription drug industry, we do not plan to finalize the other provisions of that proposed rule, and any comments on the 1995 NPRM are outside the scope of this proposed rule. This proposed rule does not address the entire Medicaid Drug Rebate Program, but focuses primarily on the provisions of the DRA that address the Medicaid Drug Rebate Program.

II. Provisions of the Proposed Regulations

Basis and Purpose of Subpart I—Section 447.500

This subpart would implement specified provisions of sections 1927, 1903(i)(10), and 1902(a)(54) of the Act related to implementation of the DRA. It would include requirements related to State plans, FFP for drugs, and the payment for covered outpatient drugs under Medicaid. In this rule, we also propose to move the existing Medicaid drug provisions in the Federal regulations from subpart F to subpart I of 42 CFR part 447.

Definitions—Section 447.502

This section of the rule would include definitions of key terms used in 42 CFR part 447, subpart I. We propose to use definitions from several sources, including the Act, Federal regulations, program guidance, and the national rebate agreement. We invite the public to provide comments on the terms we have chosen to define as well as the proposed definitions described below.

Bona fide service fee would mean a fee paid by a manufacturer to an entity, that represents fair market value for a bona fide, itemized service actually performed on behalf of the manufacturer that a manufacturer would otherwise perform (or contract for) in the absence of the service arrangement, and that is not passed in whole or in part to a client or customer of an entity, whether or not the entity takes title to the drug.

Brand name drug would mean a single source or innovator multiple source drug.

Bundled sale would mean an arrangement regardless of physical packaging under which the rebate, discount, or other price concession is conditioned upon the purchase of the same drug or drugs of different types (that is, at the nine-digit National Drug Code (NDC) level) or some other performance requirement (e.g., the achievement of market share, inclusion or tier placement on a formulary), or where the resulting discounts or other price concessions are greater than those which would have been available had the bundled drugs been purchased separately or outside the bundled arrangement. For bundled sales, the discounts are allocated proportionately to the dollar value of the units of each drug sold under the bundled arrangement. For bundled sales where multiple drugs are discounted, the aggregate value of all the discounts should be proportionately allocated across all the drugs in the bundle.

Consumer Price Index '' Urban (CPI–U) would be defined the same as it is in the national rebate agreement, except we would replace ''U.S. Department of Commerce'' with ''U.S. Department of Labor'' to reflect that the Department of Labor is now responsible for updating the CPI–U. Therefore, the term CPI–U would mean the index of consumer prices developed and updated by the U.S. Department of Labor. For purposes of this subpart, it would be the CPI for all urban consumers (U.S. average) for the month before the beginning of the calendar quarter for which the rebate is paid.

Dispensing fee would be defined similarly to how it is defined for the Medicare Part D program in 42 CFR 423.100 in light of some of the parallels of Part D to Medicaid. We are defining this term in order to assist States in their evaluation of factors in establishing a reasonable dispensing fee to pharmacy providers. We note that while we propose to define this term, we do not intend to mandate a specific formula or methodology which the States must use to determine the dispensing fee. The formula is consistent with our regulation that defines estimated acquisition costs which give States flexibility to determine EAC. However, consistent with a recommendation made by the Office of the Inspector General (OIG) in its report, ''Determining Average Manufacturer Prices for Prescription Drugs under the Deficit Reduction Act of 2005,'' (A–06–06–00063) May 2006, we encourage States to analyze the relationship between AMP and pharmacy acquisition costs to ensure that the Medicaid program appropriately reimburses pharmacies for estimated acquisition costs.

Dispensing fee would be defined as the fee which—

(1) Is incurred at the point of sale and pays for costs other than the ingredient cost of a covered outpatient drug each time a covered outpatient drug is dispensed;

(2) Includes only pharmacy costs associated with ensuring that possession of the appropriate covered outpatient drug is transferred to a Medicaid beneficiary. Pharmacy costs include, but are not limited to, any reasonable costs associated with a pharmacist's time in checking the computer for information about an individual's coverage, performing drug utilization review and preferred drug list review activities, measurement or mixing of the covered outpatient drug, filling the container, beneficiary counseling, physically providing the completed prescription to the Medicaid beneficiary, delivery, special packaging, and overhead associated with maintaining the facility and equipment necessary to operate the pharmacy; and

(3) Does not include administrative costs incurred by the State in the operation of the covered outpatient drug benefit including systems costs for interfacing with pharmacies.

Innovator multiple source drug would be defined based on the definition in section 1927(k)(7)(A)(ii) of the Act. We would also use the definition from the national rebate agreement. Innovator multiple source drug would mean a multiple source drug that was originally marketed under an original NDA approved by the Food and Drug Administration (FDA). It would include a drug product marketed by any cross-licensed producers or distributors operating under the NDA and a covered outpatient drug approved under an NDA, Product License Approval, Establishment License Approval or Antibiotic Drug approval. We believe this definition is consistent with our understanding of the drug rebate statute and section 6003 of the DRA which includes within the definition those drugs which often receive a certain amount of patent protection and/or market exclusivity.

Manufacturer would be defined based on the definition in section 1927(k)(5) of the Act and the national rebate agreement. It would also mirror the current definition of manufacturer used by Medicare in the regulations regarding manufacturer's average sales price (ASP) data. For purposes of the Medicaid program, manufacturer would be defined as any entity that possesses legal title to the NDC for a covered drug or biological product and—

(a) Is engaged in the production, preparation, propagation, compounding, conversion, or processing of covered outpatient drug products, 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; or

(b) Is engaged in the packaging, repackaging, labeling, relabeling, or distribution of covered outpatient drug products and is not a wholesaler of drugs or a retail pharmacy licensed under State law.

(c) With respect to authorized generic products, the term ''manufacturer'' will also include the original holder of the NDA.

(d) With respect to drugs subject to private labeling arrangements, the term ''manufacturer'' will also include those entities that do not possess legal title to the NDC.

Multiple source drug is currently defined in Federal regulations at section 42 CFR 447.301. We propose removing the definition from that section and revising the definition to reflect the DRA amendments to section 1927 of the Act. We would define the term multiple source drug to mean, with respect to a rebate period, a covered outpatient drug for which there is at least one other drug product which—

(1) Is rated as therapeutically equivalent. For the list of drug products rated as therapeutically equivalent, see the FDA's most recent publication of ''Approved Drug Products with Therapeutic Equivalence Evaluations'' which is available at *http://www.fda.gov/cder/orange/default.htm* or can be viewed at the FDA's Freedom of Information Public Reading Room at 5600 Fishers Lane, rm. 12A–30, Rockville, MD 20857;

(2) Is pharmaceutically equivalent and bioequivalent, as determined by the FDA; and

(3) Is sold or marketed in the United States during the rebate period.

National drug code (NDC) would be defined as it is used by the FDA and based on the definition used in the national rebate agreement. For purposes of this subpart, it would mean the 11-digit numerical code maintained by the FDA that indicates the labeler, product, and package size, unless otherwise specified in the regulation as being without respect to package size (9-digit numerical code).

National rebate agreement is described in section 1927 of the Act. Section 1927(b) of the Act outlines the terms of the rebate agreement, including reporting timeframes, manufacturer responsibilities, penalties, and confidentiality of pricing data. We propose that the national rebate agreement would continue to be defined as the rebate agreement developed by CMS and entered into by CMS on behalf of the Secretary or his designee and a manufacturer to implement section 1927 of the Act.

Nominal price would be defined as it is in the national rebate agreement. We propose incorporating this definition in this rule because it is the standard presently used in the Medicaid program and the Medicare Part B program, and is similar to that used by the Department of Veterans Affairs (DVA) in administering the Federal Supply Schedule (FSS). Nominal price would mean a price that is less than 10 percent of AMP in the same quarter for which the AMP is computed.

Rebate period is defined in section 1927(k)(8) of the Act as a calendar quarter or other period specified by the Secretary with respect to the payment of rebates under the national rebate agreement. The Medicaid Drug Rebate Program currently operates using a calendar quarter for the rebate period. While AMPs would be reported monthly for purposes of calculating FULs and for release to States, we can find no evidence in the legislative history of the DRA that Congress intended to change the definition of rebate period. Therefore, we would define rebate period as a calendar quarter.

Single source drug is defined in section 1927(k)(7)(A)(iv) of the Act as a covered outpatient drug which is produced or distributed under an original NDA approved by the FDA, including a drug product marketed by any cross-licensed producers or distributors operating under the NDA. It is further defined in the national rebate agreement as a covered outpatient drug approved under a Product License Approval, Establishment License Approval, or Antibiotic Drug Approval. We propose to define the term single source drug as it is defined in the statute and the national rebate agreement.

Determination of Average Manufacturer Price—Section 447.504

Background

Prior to the DRA, section 1927(k)(1) of the Act specified that the AMP with respect to a covered outpatient drug of a manufacturer for a rebate period is the average unit price paid to the manufacturer for the drug in the United States by wholesalers for drugs distributed to the retail pharmacy class of trade after deducting customary prompt pay discounts.

The national rebate agreement (56 FR 7049 (Feb. 21, 1991)) further specifies that:

- Direct sales to hospitals, health maintenance organizations (HMOs) and wholesalers, where the drug is relabeled under that distributor's national drug code number, and FSS prices are not included in the calculation of AMP;
- AMP includes cash discounts and all other price reductions (other than rebates under section 1927 of the Act), which reduce the actual price paid;
- AMP is calculated as net sales divided by the number of units sold, excluding free goods (*i.e.*, drugs or any other items given away, but not contingent on any purchase requirements), and
- Net sales means quarterly gross sales revenue less cash discounts allowed and all other price reductions (other than rebates under section 1927 of the Act) which reduce the actual price paid.

Consistent with these provisions, it has been our policy that in order to provide a reflection of market transactions, the AMP for a quarter should be adjusted by the manufacturer if cumulative discounts or other arrangements subsequently adjust the prices actually realized.

AMP should be adjusted for bundled sales (as defined above) by determining the total value of all the discounts on all drugs in the bundle and allocating those discounts proportionately to the respective AMP calculations. The aggregate discount is allocated proportionately to the dollar value of the units of each drug sold under the bundled arrangement. Where discounts are offered on multiple products in a bundle, the aggregate value of all the discounts should be proportionately allocated across all the drugs in the bundle. The average unit price means a manufacturer's quarterly sales included in AMP less all required adjustments divided by the total units sold and included in AMP by the manufacturer in a quarter.

Provisions of the DRA

Section 6001(c)(1) of the DRA amended section 1927(k)(1) of the Act to revise the definition of AMP to exclude customary prompt pay discounts to wholesalers, effective January 1, 2007. Section 6001(c)(3) of the DRA requires the OIG to review the requirements for and manner in which AMPs are determined and recommend changes to the Secretary by June 1, 2006. Section 6001(c)(3) of the DRA requires the Secretary to clarify the requirements for and the manner in which AMPs are determined by promulgating a regulation no later than July 1, 2007, taking into consideration the OIG's recommendations.

OIG Recommendations on AMP

In accordance with 6001(c)(3) of the DRA, the OIG issued its report, ''Determining Average Manufacturer Prices for Prescription Drugs under the Deficit Reduction Act of 2005,'' (A–06–06–00063), in May 2006. In this report, the OIG recommended that CMS:

- Clarify the requirements in regard to the definition of retail pharmacy class of trade and treatment of pharmacy

benefit manager (PBM) rebates and Medicaid sales and

- Consider addressing issues raised by industry groups, such as:
  - Administrative and service fees,
  - Lagged price concessions and returned goods,
  - The frequency of AMP reporting,
  - AMP restatements, and
  - Base date AMP.

The OIG also recommended that the Secretary direct CMS to:

- Issue guidance in the near future that specifically addresses the implementation of the AMP-related reimbursement provisions of the DRA and
- Encourage States to analyze the relationship between AMP and pharmacy acquisition cost to ensure that the Medicaid program appropriately reimburses pharmacies for estimated acquisition costs.

We address these recommendations as we discuss provisions of this proposed rule in the section below.

Definition of Retail Pharmacy Class of Trade and Determination of AMP

We recognize that there have been concerns expressed regarding AMP because of inconsistencies in the way manufacturers determine AMP, changes in the drug marketplace, and the introduction of newer business practices such as payment of services fees. We also realize that in light of the DRA amendments, AMP will serve two distinct purposes: For drug rebate liability and for payments. For the purpose of determining drug rebate liability, drug manufacturers would generally benefit from a broad definition of retail pharmacy class of trade which would include entities that purchase drugs at lower prices and which would lower rebate liability. Including these lower prices would decrease the AMP, decreasing manufacturers' rebate liability. The retail pharmacy industry might benefit from a narrow definition of retail pharmacy prices that would be limited to certain higher priced sales given that, in light of the DRA amendments, States might use AMP to calculate pharmacy payment rates. Excluding low-priced sales would increase AMP, increasing, in all likelihood, manufacturers' rebate payments. The pharmacy industry believes that mail order pharmacies and nursing home pharmacies (long-term care pharmacies) pay less for drugs than retail pharmacies (*e.g.*, independents and chain pharmacies), and thus the inclusion of such prices would lower AMP below the price paid by such retail pharmacies.

The statute mandates that, effective January 1, 2007, the Secretary use AMP when computing FULs. For this purpose, we would exclude certain outlier payments (see our discussion in the FULs section for a more complete description of outlier exclusions). The statute also requires that AMP be provided to States monthly and be posted on a public Web site. While there is no requirement that States use AMPs to set payment amounts, we believe the Congress intended that States have drug pricing data based on actual prices, in contrast to previously available data that did not necessarily reflect actual manufacturer prices of sales to the retail pharmacy class of trade. We considered several options to define what prices should be included in AMP. We considered including only prices of sales to retail pharmacies that dispense drugs to the general public (*e.g.*, independent and chain pharmacies) in retail pharmacy class of trade and removing prices to mail order pharmacies, nursing home pharmacies (long-term care pharmacies), and PBMs. This definition would address the retail pharmacy industry's contentions that an AMP used for reimbursement to retail pharmacies should only reflect prices of sales to those pharmacies which dispense drugs to the general public.

The exclusion of prices to mail order pharmacies, nursing home facilities (long-term care facilities), and PBMs would substantially reduce the number of transactions included in AMP. Removal of these prices would simplify AMP calculations for manufacturers because it is our understanding that certain data (*e.g.*, PBM pricing data) are difficult for manufacturers to capture. In addition, removal of these prices would address differing interpretations of CMS policy identified by the OIG and the Government Accountability Office (GAO) due to the lack of a clear definition of AMP or specific guidance regarding which retail prices should be included in AMP. However, such a removal would not be consistent with past policy, as specified in manufacturer Releases 28 and 29 (*http://www.cms.hhs.gov/MedicaidDrugRebateProgram/03_DrugMfrReleases.asp#TopOfPage*), would likely result in a higher AMP, and would result in an increase in drug manufacturers' rebate liabilities.

We also considered not revising the entities included in the retail pharmacy class of trade. However, this would not address the issues identified by the OIG in its report, ''Medicaid Drug Rebates: The Health Care Financing Administration Needs to Provide Additional Guidance to Drug Manufacturers to Better Implement the Program,'' (A–06–91–00092), November 1992 and GAO in its report ''Medicaid Drug Rebate Program—Inadequate Oversight Raises Concerns about Rebates Paid to States,'' (GAO–05–102), February 2005.

We believe, based in part on the OIG and GAO reports, that retail pharmacy class of trade means that sector of the drug marketplace, similar to the marketplace for other goods and services, which dispenses drugs to the general public and which includes all price concessions related to such goods and services. As such, we would exclude from AMP the prices of sales to nursing home pharmacies (long-term care pharmacies) because nursing home pharmacies do not dispense to the general public. We would include in AMP the prices of sales and discounts to mail order pharmacies. We considered limiting mail order pharmacy prices to only those prices that are offered to all pharmacies under similar terms and conditions. However, given our belief that such prices are simply another form of how drugs enter into the retail pharmacy class of trade, we have decided to maintain these prices in the definition. We note that even were we to incorporate this change, retail pharmacies may not be able to meet the terms and conditions placed on mail order pharmacies to be eligible for some manufacturer price concessions. CMS seeks public comment on the inclusion of all mail order pharmacy prices in our definition of retail pharmacy class of trade for purposes of inclusion in the determination of AMP.

We recognize that a major factor contributing to the determination of AMP is the treatment of PBMs. These entities have assumed a significant role in drug distribution since the enactment of the Medicaid Drug Rebate Program in 1990. We are considering how PBM rebates, discounts, or other price concessions should be recognized for purposes of AMP calculations.

A GAO report ''Medicaid Drug Rebate Program—Inadequate Oversight Raises Concerns about Rebates Paid to States,'' (GAO–05–102), in February 2005, indicated that the Medicaid Drug Rebate Program does not clearly address certain financial concessions negotiated by PBMs. The GAO recommended that we issue clear guidance on manufacturer price determination methods and the definitions of AMP and best price, and update such guidance as additional issues arise.

The issue regarding PBMs was also addressed in the recently issued OIG report, ''Determining Average

Manufacturer Prices for Prescription Drugs under the Deficit Reduction Act of 2005,'' (A–06–06–00063), in May 2006. In this report, the OIG recommended that we clarify the treatment of PBM rebates. This report says that manufacturers treat rebates and fees paid to PBMs in the calculation of AMP in three different ways. Specifically they found that manufacturers (1) did not subtract rebates or fees paid to PBMs from the AMP calculation; (2) subtracted the rebates or fees paid to PBMs; or (3) subtracted a portion of the PBMs rebates or fees from the AMP calculation.

In developing this proposed rule, we considered including all rebates, discounts and other price concessions from PBMs in the determination of AMP. We also considered excluding rebates, discounts and other price concessions from PBMs in the determination of AMP.

One of the most difficult issues with PBM discounts, rebates, or other price concessions is that manufacturers contend that they do not know what part of these discounts, rebates, or other price concessions is kept by the PBM for the cost of its activities and profit, what part is passed on to the health insurer or other insurer or other entity with which the PBM contracts, and what part, if any, that entity passes on to pharmacies. Despite the difficulties of including certain PBM rebates, discounts or other price concessions in AMP, excluding all of these price concessions could result in an artificial inflation of AMP. For this reason, we propose to include PBM rebates, discounts, or other price concessions for drugs provided to the retail pharmacy class of trade for the purpose of determining AMP; however, we invite comments on whether this proposal is operationally feasible.

As discussed more fully below, we have proposed that PBM rebates and price concessions that adjust the amount received by the manufacturer for drugs distributed to the retail pharmacy class of trade should be included in the calculation of AMP. We acknowledge that manufacturers have a variety of arrangements with PBMs and thus invite comments on all aspects of our proposal as explained below.

The rebate agreement defines AMP to include cash discounts and all other price reductions (other than rebates under section 1927 of the Act), which reduce the actual price paid to the manufacturer for drugs distributed to the retail pharmacy class of trade. As noted in Release 28 and reiterated in Release 29, manufacturers have developed a myriad of arrangements whereby specific discounts, chargebacks, or rebates are provided to PBMs which, in turn, are passed on to the purchaser. Those releases recognize that certain prices provided by manufacturers to PBMs should be included within AMP calculations. In accordance with those releases, our position has been that PBMs have no effect on the AMP calculations unless the PBM is acting as a wholesaler as defined in the rebate agreement. We are concerned, however, that this position may unduly exclude from AMP certain PBM prices and discounts which have an impact on prices paid to the manufacturer.

We believe that AMP should be calculated to reflect the net drug price recognized by the manufacturer, inclusive of any price adjustments or discounts provided directly or indirectly by the manufacturer. We are interested in comments on this proposal, including the comments on the operational difficulties of including such PBM arrangements within AMP calculations.

We recognize that the statute defines AMP as the average price paid to the manufacturer by wholesalers for drugs distributed to the retail pharmacy class of trade; however, in light of our understanding of congressional intent, we believe that the definition is meant to capture discounts and other price adjustments, regardless of whether such discounts or adjustments are provided directly or indirectly by the manufacturer. We invite comments on this definition and whether AMP should be calculated to include all adjustments that affect net drug prices.

We acknowledge that there are many PBM/manufacturer arrangements. To the extent manufacturers are offering rebates, discounts, or other price concessions to the PBM that are not bona fide service fees, we propose that these lower prices should be included in the AMP calculations. We request comments on the operational difficulties of tracking these rebates, discounts, or chargebacks provided to a PBM for purposes of calculating AMP and on the inclusion of all such price concessions in AMP. Specifically, we solicit comments on the extent to which CMS should or should not define in regulation which rebates, discounts, or price concessions provided to PBMs should be included in AMP and how best to measure these. Also, we solicit public comment on how these PBM price concessions should be reported to CMS to assure that appropriate price adjustments are captured and included in the determination of AMP.

Finally, we request comments on any other issues that we should take into account in making our final decisions. These include, but may not be limited to, possible Federal and State budgetary impacts (our savings estimates assumed no budgetary impacts as generic drugs are rarely, if ever, subject to PBM price adjustments in this context); possible future evolution in industry pricing and management practices (e.g., growth of ''preferred'' generic drugs); and possible impacts on reimbursement for brand name drugs under Medicaid. We are generally interested in comments on how and to what extent PBMs act as ''wholesalers.'' We propose to incorporate the explicitly listed exclusions in section 1927 of the Act, and in the national rebate agreement, which are direct sales to hospitals, HMOs/managed care organizations (MCOs), wholesalers where the drug is relabeled under that distributor's NDC and FSS prices.

The specific terms we propose to clarify and the proposed clarifications follow.

Retail Pharmacy Class of Trade: We propose to include in the definition of retail pharmacy class of trade any entity that purchases prescription drugs from a manufacturer or wholesaler for dispensing to the general public (e.g., retail, independent, chain and mail order pharmacies), except as otherwise specified by the statute or regulation (such as, HMOs, hospitals).

PBM Price Concessions: We proposed to include any rebates, discounts or other price adjustments provided by the manufacturer to the PBM that affect the net price recognized by the manufacturer for drugs provided to entities in the retail pharmacy class of trade.

Customary Prompt Pay Discounts: Prior to the DRA, neither the statute nor the national rebate agreement defined customary prompt pay discounts. The DRA revises the definition of AMP to exclude customary prompt pay discounts extended to wholesalers; however, it does not revise or define customary prompt pay discounts. We propose to define customary prompt pay discounts as any discount off the purchase price of a drug routinely offered by the manufacturer to a wholesaler for prompt payment of purchased drugs within a specified time of the payment due date.

Treatment of Medicaid Sales: The OIG recommended that we should address whether AMP should include Medicaid prices of sales; i.e., prices of sales where the end payer for the drug is the Medicaid program. In its May 2006 report, the OIG noted confusion on this

issue and recommended that we clarify that these prices of sales are to be included in AMP. It is our position that these sales are included in AMP because they are not expressly excluded in the statute. In this proposed rule, we would also clarify that prices to State Children's Health Insurance Program Title XIX (SCHIP) through an expanded Medicaid program are covered under the provisions of section 1927 of the Act and generally subsumed in Medicaid sales. As a general matter, Medicaid does not directly purchase drugs from manufacturers or wholesalers but instead reimburses pharmacies for these drugs. Therefore, Medicaid sales are determined by the entities that are actually in the sales chain and because Medicaid reimburses pharmacies for drugs for Medicaid beneficiaries, integrated into the chain of sales otherwise included in AMP.

In this proposed rule, we would clarify that the units associated with Medicaid sales should be included as part of the total units in the AMP calculation. We have proposed that AMP be calculated to include all sales and associated discounts and other price concessions provided by the manufacturer for drugs distributed to the retail pharmacy class of trade unless the sale, discount, or other price concession is specifically excluded by the statute or regulation or is provided to an entity excluded by statute or regulation. Therefore, we would clarify that rebates paid to States under the Medicaid Drug Rebate Program should be excluded from AMP calculations but that price concessions associated with the sales of drugs in the retail pharmacy class of trade which are provided to Medicaid patients should be included.

In this proposed rule, we also propose to clarify how the prices of sales to State Children's Health Insurance Program Title XXI (SCHIP) non-Medicaid expansion programs should be treated. Like the Medicaid program, SCHIP non-Medicaid expansion programs do not directly purchase drugs. Because such programs are not part of the Medicaid program, they are not covered under the provisions of section 1927 of the Act. As with Medicaid sales, these sales are included in AMP to the extent they concern sales at the retail pharmacy class of trade. Therefore, these sales should not be backed out of the AMP calculation to the extent that such sales are included within sales provided to the retail pharmacy class of trade. Rebates and units associated with those sales should also be included in the calculation of AMP.

Treatment of Medicare Part D sales: We would clarify that the treatment of prices of sales through a Medicare Part D prescription drug plan (PDP), a Medicare Advantage prescription drug plan (MA–PD), or a qualified retiree prescription drug plan for covered Part D drugs provided on behalf of Part D eligible individuals should be included in the AMP calculation. Like the Medicaid program, PDPs and MA–PDs do not directly purchase drugs, but are usually third party payers. As with Medicaid sales, these sales are included in AMP to the extent they are sales to the retail pharmacy class of trade. Therefore, we believe these prices of sales should not be backed out of the AMP. Rebates paid by the manufacturer to the PDP or MA–PD should be included in the calculation of AMP.

SPAP price concessions: In this proposed rule, we also propose to clarify how the prices to State pharmaceutical assistance programs (SPAPs) should be treated. Like the Medicaid program, PDPs, and MA–PDs, SPAPs do not directly purchase drugs, but are generally third-party payers. As with Medicaid sales, these sales are included in AMP to the extent the sales are to an entity included in the retail pharmacy class of trade. Therefore, we propose that SPAP sales should not be backed out of the AMP calculation. Rebates paid by the manufacturer to the SPAP should be included in the calculation of AMP.

Prices to other Federal Programs: We propose that any prices on or after October 1, 1992, to the IHS, the DVA, a State home receiving funds under section 1741 of title 38, United States Code, the Department of Defense (DoD), the Public Health Service (PHS), or a covered entity described in subsection 1927(a)(5)(B) of the Act (including inpatient prices charged to hospitals described in section 340B(a)(4)(L) of the PHSA); any prices charged under the FSS of the GSA; and any depot prices (including Tricare) and single award contract prices, as defined by the Secretary, of any agency of the Federal government are excluded from the calculation of AMP. We propose that the prices to these entities should be excluded from AMP because the prices to these entities are not available to the retail pharmacy class of trade.

Administrative and Service Fees: Current Medicaid drug rebate policy is that administrative fees which include service fees and distribution fees, incentives, promotional fees, chargebacks and all discounts or rebates, other than rebates under the Medicaid drug program, should be included in the calculation of AMP, if those sales are to an entity included in the calculation of AMP. The OIG has noted in its report, ''Determining Average Manufacturer Prices for Prescription Drugs under the Deficit Reduction Act of 2005,'' (A–06–06–00063), May 2006, that confusion exists about the treatment of fees, such as service fees negotiated between a manufacturer and pharmaceutical distributor. Some believe that these fees should not be included in AMP because the manufacturer does not know if the fees act to reduce the price paid by the end purchasers. Others believe such fees should be included in the calculation, which would reduce AMP because they serve as a price concession. For the same reason as for sales to PBMs, we propose that all fees except fees paid for bona fide services should be included in AMP. We propose that bona fide service fees means fees paid by a manufacturer to an entity, which represent fair market value for a bona fide, itemized service actually performed on behalf of the manufacturer that the manufacturer would otherwise perform (or contract for) in the absence of the service arrangement, and which are not passed in whole or in part to a client or customer of an entity, whether or not the entity takes title to the drug. Medicare Part B also adopted this definition in its final rule with comment period that was published on December 1, 2006 (71 FR 69623–70251) that implemented the ASP provisions enacted in the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA). We are not proposing to define fair market value. However, CMS invites comments from the public regarding an appropriate definition for fair market value.

Direct Patient Sales: In response to manufacturers' questions, CMS has stated previously that covered outpatient drugs sold to patients through direct programs should be included in the calculation of AMP. These sales are usually for specialty drugs through a direct distribution arrangement, where the manufacturer retains ownership of the drug and pays either an administrative or service fee to a third party for functions such as the storage, delivery and billing of the drug. Some manufacturers have contended that direct patient sales for covered outpatient drugs sold by a manufacturer through a direct distribution channel should not qualify for inclusion in the calculation of AMP because the Medicaid rebate statute and the national rebate agreement do not address covered outpatient drugs that are not sold to wholesalers and/or not distributed in the retail pharmacy class of trade. We believe that the distributor is acting as

a wholesaler and these sales are to the retail pharmacy class of trade. In light of this, we propose in this regulation that these sales and the rebates associated with these sales to patients through direct programs would be included in AMP. CMS invites comments from the public on this proposed policy.

Returned Goods: Current Medicaid Drug Rebate Program policy is that returned goods are credited back to the manufacturer in either the quarter of sale or quarter of receipt. This has caused difficulty for some manufacturers when these returns have substantially reduced AMP in a quarter or resulted in a negative AMP. In light of these concerns, we propose to exclude returned goods from the calculation of AMP when returned in good faith. CMS considers that goods are being returned in good faith when they are being returned pursuant to manufacturer policies which are not designed to manipulate or artificially inflate or deflate AMP. The Medicare Part B program excludes returned goods from the calculation of ASP. The exclusion of returned goods will allow the manufacturer to calculate and report an AMP that is more reflective of its true pricing policies to the retail pharmacy class of trade in the reporting period. It lessens the administrative burden and problems associated with allocating the returned goods back to the reporting period in which they were sold, as well as eliminating artificially low, zero or negative AMPs that may result from these adjustments.

Manufacturer Coupons: In this proposed rule, we propose to clarify how manufacturer coupons should be treated. The treatment of manufacturer coupons has been problematic for CMS as well as some manufacturers. In this rule, we propose to include coupons redeemed by any entity other than the consumer in the calculation of AMP. We believe that the redemption of coupons by the consumer directly to the manufacturer is not included in the retail pharmacy class of trade. In this proposed rule, we propose to exclude coupons redeemed by the consumer directly to the manufacturer from the calculation of AMP. CMS invites comments from the public on this proposed policy.

Future Clarifications of AMP: Based on past comments from the GAO and the OIG and recommendations of the OIG in its May 2006 report on AMP, we believe that we need to have the ability to clarify the definition of AMP in an expedited manner in order to address the evolving marketplace for the sale of drugs. We plan to address future clarifications of AMP through the issuance of program releases and by posting the clarifications on the CMS Web site as needed.

Requirements for Average Manufacturer Price

To implement the provisions set forth in sections 6001 and 6003 of the DRA related to AMP, we propose a new § 447.504. In § 447.504(a), we propose a revised definition of AMP and clarify that AMP is determined without regard to customary prompt pay discounts extended to wholesalers. In § 447.504(b), we propose to define average unit price. In § 447.504(c), we propose to define customary prompt pay discount. In § 447.504(d), we propose to define net sales. In § 447.504(e), we propose to define retail pharmacy class of trade. In § 447.504(f), we propose to define wholesaler. In § 447.504(g), we would describe in detail the sales, rebates, discounts, or other price concessions that must be included in AMP. In § 447.504(h), we would describe the sales, rebates, discounts, or other price concessions that must be excluded from AMP. In § 447.504(i), we would provide further clarification about how manufacturers should account for price reductions and other pricing arrangements which should be included in the calculation of AMP.

Determination of Best Price—Section 447.505

Prior to the DRA, section 1927(c)(1)(C) of the Act provided that manufacturers must include in their best price calculation, for a single source or innovator multiple source drug, the lowest price available from the manufacturers during the rebate period to any wholesaler, retailer, provider, HMO, non-profit entity, or governmental entity within the United States except for those entities specifically excluded by statute. Excluded from best price are prices charged on or after October 1, 1992, to the IHS, the DVA, a State home receiving funds under section 1741 of title 38, United States Code, the DoD, the PHS, or a covered entity described in section 1927(a)(5)(B) of the Act (including inpatient prices charged to hospitals described in section 340B(a)(4)(L) of the PHSA); any prices charged under the FSS of the GSA; any prices used under an SPAP; any depot prices (including Tricare) and single award contract prices, as defined by the Secretary, of any agency of the Federal Government; and prices to a Medicare Part D PDP, an MA–PD, or a qualified retiree prescription drug plan for covered Part D drugs provided on behalf of Part D eligible individuals.

The statute further specifies that:

- Best price includes cash discounts, free goods that are contingent on any purchase requirement, volume discounts and rebates (other than rebates under section 1927 of the Act), which reduce the price paid;
- Best price must be determined on a unit basis without regard to special packaging, labeling or identifiers on the dosage form or product or package;
- Best price must not take into account prices that are merely nominal in amount.

Consistent with these provisions and the national rebate agreement, it has been our policy that in order to reflect market transactions, the best price for a rebate period should be adjusted by the manufacturer if cumulative discounts or other arrangements subsequently adjust the prices actually realized.

Best price should be adjusted for any bundled sale. The drugs in a ''bundle'' do not have to be physically packaged together to constitute a ''bundle,'' just part of the same bundled transaction.

Section 1927(c)(1)(C)(ii)(I) of the Act specifies that best price must include free goods that are contingent on any purchase requirement. Thus, only those free goods that are not contingent on any purchase requirements may be excluded from best price.

Section 103(e) of the MMA modified the definition of best price by excluding prices which are negotiated by a PDP under part D of title XVIII of the Act, by any MA–PD plan under part C of such title with respect to covered part D drugs, or by a qualified retiree prescription drug plan (as defined in section 1860D–22(a)(2) of the Act) with respect to such drugs on behalf of individuals entitled to benefits under part A or enrolled under part B of such title. Section 1002(a) of the MMA modified section 1927(c)(1)(C)(i)(I) of the Act by clarifying that inpatient prices charged to hospitals described in section 340B(a)(4)(L) of the PHSA are exempt from best price.

Section 6003 of the DRA amended section 1927(c)(1)(C) of the Act by revising the definition of best price to clarify that the best price includes the lowest price available to any entity for any such drug of a manufacturer that is sold under an NDA approved under section 505(c) of the FFDCA.

In accordance with our understanding of congressional intent, in this proposed rule we propose to define best price with respect to a single source drug or innovator multiple source drug of a manufacturer, including any drug sold under an NDA approved under section

505(c) of the FFDCA, as the lowest price available from the manufacturer during the rebate period to any entity in the United States in any pricing structure (including capitated payments) in the same quarter for which the AMP is computed. It continues to be our policy that best price reflects the lowest price at which the manufacturer sells a covered outpatient drug to any purchaser, except those prices specifically exempted by law. We propose to define provider as a hospital; HMO, including an MCO or PBM; or other entity that treats individuals for illnesses or injuries or provides services or items in the provisions of health care.

As with the determination of AMP, the DRA does not establish a mechanism to clarify how best price is to be determined should new entities be formed after this regulation takes effect. We believe that we need to have the ability to clarify best price in an expedited manner in order to address the evolving marketplace for the sale of drugs. We plan to address future clarifications to best price through the issuance of program releases and by posting the clarifications on the CMS Web site as needed. Even though the DRA did not require CMS to clarify the requirements for best price, we determined that it is reasonable to propose these provisions in this proposed rule, consistent with long-standing Medicaid Drug Rebate Program policy, the MMA, and our understanding of congressional intent with respect to best price as revised by the DRA.

We propose to incorporate the explicitly listed exclusions in section 1927 of the Act, which are prices charged on or after October 1, 1992, to the IHS, the DVA, a State home receiving funds under section 1741 of title 38, United States Code, the DoD, the PHS, or a covered entity described in section 1927(a)(5)(B) of the Act (including inpatient prices charged to hospitals described in section 340B(a)(4)(L) of the PHSA); any prices charged under the FSS of the GSA; any prices paid under an SPAP; any depot prices (including Tricare) and single award contract prices, as defined by the Secretary, of any agency of the Federal Government; and payments made by a Medicare Part D PDP, an MA–PD, or a qualified retiree prescription drug plan for covered Part D drugs provided on behalf of Part D eligible individuals. We propose to codify this policy and require that manufacturers exclude the prices to these entities from best price. Because best price represents the lowest price available from the manufacturer to any entity with respect to a single source drug or innovator multiple source drug of a manufacturer, including an authorized generic, any price concession associated with that sale should be netted out of the price received by the manufacturer in calculating best price and best price should be adjusted by the manufacturer if other arrangements subsequently adjust the prices actually realized. We propose to consider any price adjustment which ultimately affects those prices which are actually realized by the manufacturer as ''other arrangements'' and that such adjustment should be included in the calculation of best price, except to the extent that such adjustments qualify as bona fide service fees.

Consistent with our understanding of congressional intent, we propose that best price be calculated to include all sales, discounts, and other price concessions provided by the manufacturer for covered outpatient drugs to any entity unless the manufacturer can demonstrate that the sale, discount, or other price concession is specifically excluded by statute or is provided to an entity not included in the rebate calculation. To the extent that an entity is not included in the best price calculation, both sales and associated discounts or other price concessions provided to such an entity should be excluded from the calculation. The specific terms we propose to clarify and the proposed clarification follow.

The Medicaid drug rebate agreement defines best price, in part, as the lowest price at which the manufacturer sells the covered outpatient drug to any purchaser in the United States. We propose to codify this policy in this proposed rule.

Customary Prompt Pay Discounts: The DRA revises the definition of AMP to exclude customary prompt pay discounts to wholesalers; however, we can find no evidence in the legislative history of the DRA that Congress intended to change the definition of best price to exclude customary prompt pay discounts. Therefore, we propose in this regulation to include customary prompt pay discounts in best price.

PBM Price Concessions: We recognize that a major factor contributing to the determination of best price includes the treatment of PBMs. These entities have assumed a significant role in drug distribution since the enactment of the Medicaid Drug Rebate Program in 1990.

As noted in Release 28 and reiterated in Release 29, manufacturers have developed a myriad of arrangements whereby specific discounts, chargebacks, or rebates are provided to PBMs which, in turn, are passed on to the purchaser. In such situations where discounts, chargebacks, or rebates are used to adjust drug prices at the wholesaler or retail level, such adjustments are included in the best price calculation.

A GAO report, ''Medicaid Drug Rebate Program—Inadequate Oversight Raises Concerns about Rebates Paid to States,'' (GAO–05–102), in February 2005, indicated that the Medicaid Drug Rebate Program does not clearly address certain financial concessions negotiated by PBMs. The GAO recommended that we issue clear guidance on manufacturer price determination methods and the definitions of AMP and best price, and update such guidance as additional issues arise.

The issue regarding PBMs was also addressed in the recently issued OIG report, ''Determining Average Manufacturer Prices for Prescription Drugs under the Deficit Reduction Act of 2005,'' (A–06–06–00063), in May 2006. In this report, the OIG recommended that we clarify the treatment of PBM rebates.

One of the most difficult issues with PBM discounts, price concessions, or rebates is that manufacturers contend that they do not know what part of these discounts, price concessions, or rebates are kept by the PBM for the cost of their activities and profit, what part is passed on to the health insurer or other insurer or other entity with which the PBM contracts, and what part that entity passes on to pharmacies.

Despite the difficulties of including certain PBM rebates, discounts or other price concessions in best price, excluding these price concessions could result in an artificial inflation of best price. We propose to include PBM rebates, discounts, or other price concessions for the purpose of determining best price.

To the extent manufacturers are offering PBMs rebates, discounts, or other price concessions, these lower prices should be included in the best price calculations. Therefore, where the use of the PBM by manufacturers affects the price available from the manufacturer, these lower prices should be reflected in best price calculations. We acknowledge that there are many PBM/manufacturer arrangements.

We believe that PBMs often obtain rebates, discounts, or other price concessions which adjust prices, either directly or indirectly. Unless the fees/discounts qualify as bona fide service fees (which are excluded), the PBM rebates, discounts, or chargebacks should be included in best price. We propose to consider these rebates,

discounts, or chargebacks in best price calculations. CMS invites public comment on the inclusion of certain PBM price concessions in the determination of best price. Also, we solicit public comment on how these PBM price concessions should be reported to CMS to assure that appropriate price concessions are captured and included in the determination of best price.

We propose to incorporate the explicitly listed exclusions in section 1927 of the Act and in the national rebate agreement. Because best price represents the prices available from the manufacturer for prescription drugs, best price should be adjusted by the manufacturer if other arrangements subsequently adjust the prices actually realized. We propose to consider that any price adjustment which ultimately affects those prices which are actually realized by the manufacturer as ''other arrangements'' and that such an adjustment should be included in the calculation of best price. The specific terms we propose to clarify and the proposed clarifications follow.

Administrative and Service Fees: We propose that administrative fees which include service fees and distribution fees, incentives, promotional fees, chargebacks and all discounts or rebates, other than rebates under the Medicaid Drug Rebate Program, should be included in the calculation of best price, if those sales are to an entity included in the calculation of best price. As previously discussed, the OIG has noted in its report, ''Determining Average Manufacturer Prices for Prescription Drugs under the Deficit Reduction Act of 2005,'' (A–06–06–00063), May 2006 that confusion exists about the treatment of fees, such as service fees negotiated between a manufacturer and pharmaceutical distributor for AMP and best price. We believe that price adjustments which ultimately affect those prices which are actually available from the manufacturer should be included in best price. We propose that manufacturers should include all such fees except bona fide service fees provided at fair market value in the best price calculation.

Treatment of Medicare Part D Prices: In this proposed rule, we propose to clarify the treatment of prices which are negotiated by a Medicare Part D PDP, an MA–PD, or a qualified retiree prescription drug plan for covered Part D drugs provided on behalf of Part D eligible individuals. We propose that these prices are exempt from the best price. Section 1860D–2(d)(1)(C) of the Act specifically states that ''prices negotiated by a prescription drug plan, by an MA–PD plan with respect to covered part D drugs, or by a qualified retiree prescription drug plan (as defined in section 1860D–22(a)(2)) with respect to such drugs on behalf of Part D eligible individuals, shall (notwithstanding any other provision of law) not be taken into account for the purposes of establishing the best price under section 1927(c)(1)(C).'' Therefore, while we propose that the prices listed above be included for the purpose of calculating AMP, we propose that prices negotiated by a PDP, an MA–PD, or a qualified retiree prescription drug plan for covered Part D drugs provided on behalf of Part D eligible individuals not be taken into account for the purpose of establishing best price.

Manufacturer Coupons: In this proposed rule, we propose to clarify how manufacturer coupons should be treated for the purpose of establishing best price. We believe that the redemption of coupons by any entity other than the consumer to the manufacturer ultimately affects the price paid by the entity (*e.g.*, retail pharmacy). In this rule, we propose to include coupons redeemed by any entity other than the consumer in the calculation of best price. We believe that the redemption of coupons by the consumer directly to the manufacturer does not affect the price paid by any entity whose sales are included in best price. In this proposed rule, we propose to exclude coupons redeemed by the consumer directly to the manufacturer from the calculation of best price. CMS invites comments from the public on this proposed policy.

Medicaid Rebates and Supplemental Rebates: Section 1927(c)(1)(C)(ii)(I) of the Act and the national rebate agreement provide that any rebates paid by manufacturers under section 1927 of the Act are to be excluded from the calculation of best price. Therefore, we propose to exclude Medicaid rebates from best price. Likewise, we consider rebates paid under CMS-authorized separate (supplemental) Medicaid drug rebate agreements with States to meet this requirement and propose that these rebates be excluded from best price. In accordance with section 1927 of the Act pertaining to the determination of best price and our understanding of congressional intent, we propose a new § 447.505. In § 447.505(a), we would provide a general definition of the term best price. In § 447.505(b), we propose to define provider. In § 447.505(c), we would specify the sales and prices which must be included in best price. In § 447.505(d), we would specify which sales and prices must be excluded from best price. In § 447.505(e), we would further clarify the price reductions and other pricing arrangements included in the calculation of best price.

Authorized Generic Drugs—Section 447.506

Under current law, drug manufacturers participating in the Medicaid Drug Rebate Program are required to report the AMP for each covered outpatient drug offered under the Medicaid program and the best price for each single source or innovator multiple source drug available to any wholesaler, retailer, provider, HMO, non-profit entity, or governmental entity with certain exceptions.

For purposes of the Medicaid Drug Rebate Program, an authorized generic is any drug product marketed under the innovator or brand manufacturer's original NDA, but labeled with a different NDC than the innovator or brand product. According to our reading of the statute, authorized generics are single source or innovator multiple source drugs for the purpose of computing the drug rebate and are classified based on whether the drug is being sold or marketed pursuant to an NDA. Responsibility for the rebate rests with the manufacturer selling or marketing the drug to the retail pharmacy class of trade.

This rule would implement section 6003 of the DRA. We propose to adopt the term ''authorized generic'' and define this term with respect to the Medicaid Drug Rebate Program, as any drug sold, licensed or marketed under a new drug application approved by the FDA under section 505(c) of the FFDCA that is marketed, sold or distributed directly or indirectly under a different product code, labeler code, trade name, trademark, or packaging (other than repackaging the listed drug for use in institutions) than the listed drug.

Section 6003 of the DRA amended section 1927(b)(3)(A) of the Act to include drugs approved under section 505(c) of the FFDCA in the reporting requirements for the primary manufacturer (NDA holder) for AMP and best price. We propose to interpret the language of section 6003 of the DRA to include in the best price and AMP calculations of the branded drugs, the authorized generic drugs that have been marketed by another manufacturer or subsidiary of the brand manufacturer (or NDA holder). We believe that to limit the applicability of this regulation to the sellers of authorized generic drugs would allow manufacturers to circumvent the intent of the provision by licensing rather than selling the rights to such drugs. This is why we propose a broad definition of authorized

generic drugs rather than a more narrow definition of such drugs. We propose to require the NDA holder to include sales of the authorized generic product marketed by the secondary manufacturer or the brand manufacturer's subsidiary in its calculation of AMP and best price. We welcome comments on this issue.

The secondary manufacturer or subsidiary of the brand manufacturer would continue to pay the single source or innovator multiple source rebate for the authorized generic drug products based on utilization under its own NDC number, as required under current law. We welcome comments on these issues.

In § 447.506(a), we would define the term authorized generic drug for the purposes of the Medicaid Drug Rebate Program.

In § 447.506(b), we would require the sales of authorized generic drugs that have been sold or licensed to another manufacturer to be included by the primary manufacturer as part of its calculation of AMP for the single source or innovator multiple source drug (including all such drugs that are sold under an NDA approved under section 505(c) of the FFDCA).

In § 447.506(c), we would require that sales of authorized generic drugs by the secondary manufacturer that buys or licenses the right to sell the drugs be included by the primary manufacturer in sales used to determine the best price for the single source or innovator multiple source drug approved under section 505(c) of the FFDCA during the rebate period to any manufacturer, wholesaler, retailer, provider, HMO, non-profit entity, or governmental entity within the United States. The primary manufacturer must include in its calculation of best price all sales of the authorized generic drug which have been sold or marketed by a secondary manufacturer or by a subsidiary of the brand manufacturer.

Exclusion From Best Price of Certain Sales at a Nominal Price—Section 447.508

Pursuant to the terms of the national rebate agreement, manufacturers excluded from their best price calculations outpatient drug prices below 10 percent of the AMP. The rebate agreement did not specify whether this nominal price exception applied to all purchasers or to a subset of purchasers. Medicaid has used this definition since the start of the Medicaid Drug Rebate Program and Medicare Part B also adopted it in its April 6, 2004 interim final rule with comment period (69 FR 17935) that implemented the ASP provisions enacted in the MMA. It is also similar to the definition of nominal price in the VHCA. We propose to continue to define nominal prices as prices at less than 10 percent of the AMP in that same quarter; however, in accordance with the DRA, we further propose to specify that the nominal price exception applies only when certain entities are the purchasers.

Section 6001(d)(2) of the DRA modified section 1927(c)(1) of the Act to limit the nominal price exclusion from best price to exclude only sales to certain entities and safety net providers. Specifically, it excluded from best price those nominal price sales to 340B covered entities as described in section 340B(a)(4) of the PHSA, ICFs/MR, and State-owned or operated nursing facilities. In addition, the Secretary has authority to identify as safety net providers other facilities or entities to which sales at a nominal price will be excluded from best price if he deems them eligible safety net providers based on four factors: the type of facility or entity, the services provided by the facility or entity, the patient population served by the facility or entity and the number of other facilities or entities eligible to purchase at nominal prices in the same service area.

Section 340B(a)(4) of the PHSA defines entities covered under that provision. Covered entities include: A federally qualified health center as defined in section 1905(l)(2)(B) of the Act; an entity receiving a grant under section 340A of the PHSA; a family planning project receiving a grant or contract under Section 1001 of the PHSA (42 U.S.C. § 300); an entity receiving a grant under subpart II of part C of title XXVI of the PHSA (relating to categorical grants for outpatient early intervention services for HIV disease); a State-operated AIDS drug purchasing assistance program receiving financial assistance under title XXVI of the PHSA; a black lung clinic receiving funds under section 427(a) of the Black Lung Benefits Act; a comprehensive hemophilia diagnostic treatment center receiving a grant under section 501(a)(2) of the Act; a Native Hawaiian Health Center receiving funds under the Native Hawaiian Health Care Act of 1988; an urban Indian organization receiving funds under the title V of the Indian Health Care Improvement Act, any entity receiving assistance under title XXVI of the PHSA (other than a State or unit of local government or an entity receiving a grant under subpart II of part C of title XXVI of the PHSA), but only if the entity is certified by the Secretary pursuant to section 340B(a)(7) of the PHSA; an entity receiving funds under section 318 of the PHSA (relating to treatment of sexually transmitted diseases) or section 317(j)(2) of the PHSA (relating to treatment of tuberculosis) through a State or unit of local government, but only if the entity is certified by the Secretary pursuant to section 340B(a)(7) of the PHSA; a subsection (d) hospital (as defined in section 1886(d)(1)(B) of the Act that (i) is owned or operated by a unit of State or local government, is a public or private non-profit corporation which is formally granted governmental powers by a unit of State or local government, or is a private non-profit hospital which has a contract with a State or local government to provide health care services to low income individuals who are not entitled to benefits under title XVIII of the Act or eligible for assistance under the State plan under this title, (ii) for the most recent cost reporting period that ended before the calendar quarter involved, had a disproportionate share adjustment percentage (as determined under section 1886(d)(5)(F) of the Act) greater than 11.75 percent or was described in section 1886(d)(5)(F)(i)(II) of the Act, and (iii) does not obtain covered outpatient drugs through a group purchasing organization or other group purchasing arrangement. We do not believe it necessary to elaborate further on these entities. We propose to define ICF/MR, for purposes of the nominal price exclusion from best price, to mean an institution for the mentally retarded or persons with related conditions that provides services as set forth in 42 CFR 440.150. Additionally, we propose to define nursing facility as a facility that provides those services set forth in 42 CFR 440.155.

The statute allows the Secretary to determine other facilities or entities to be safety net providers to whom sales of drugs at a nominal price would be excluded from best price. The Secretary's determination would be based on the four factors noted above established by the DRA. We considered using this authority to expand this exclusion to other safety-net providers. We considered proposing that we use the broader definition of safety net provider used by the Institute of Medicine (IOM). In its report, ''America's Health Care Safety Net, Intact but Endangered,'' the IOM defines safety-net providers as ''providers that by mandate or mission organize and deliver a significant level of healthcare and other health-related services to the uninsured, Medicaid and other vulnerable patients.'' We also considered proposing how the Secretary might use the four factors to allow the

nominal price exclusion to best price to apply to other safety net providers. However, we believe that the entities specified in the statute are sufficiently inclusive and capture the appropriate safety net providers. Therefore, we have chosen not to propose to expand the entities subject to this provision at this time. Additionally, we believe that adding other entities or facilities would have an undesirable effect on the best price by expanding the entities for which manufacturers can receive the best price exclusion beyond those specifically mandated by the DRA and lowering manufacturer rebates to the Medicaid Program. Because the statute gives the Secretary discretion not to expand the list of entities, we do not propose to do so at this time in this rule.

CMS has concerns that despite the fact that the DRA limits the nominal price exclusion to specific entities, the nominal price exclusion will continue to be used as a marketing tool. Historically, patients frequently remain on the same drug regimen following discharge from a hospital. Physicians may be hesitant to switch a patient to a different brand and risk destabilizing the patient once discharged from the hospital. We believe that using nominal price for marketing is not within the spirit and letter of the law. We are considering crafting further guidance to address this issue. CMS invites comments from the public to assist us in ensuring that all aspects of this issue are fully considered.

In accordance with the provisions of the DRA, the restriction on nominal price sales shall not apply to sales by a manufacturer of covered outpatient drugs that are sold under a DVA master agreement under section 8126 of title 38, United States Code.

We propose a new § 447.508 in which we would specify those entities to which a manufacturer of covered outpatient drugs may sell at nominal price and provide for the exclusion of such sales from best price.

Requirements for Manufacturers—Section 447.510

On August 29, 2003, CMS finalized two of the provisions in the 1995 NPRM through a final rule with comment period (68 FR 51912). We required manufacturers to retain records for data used to calculate AMP and best price for three years from when AMP and best price are reported to CMS. We also required manufacturers to report revisions to AMP and best price for a period not to exceed twelve quarters from the quarter in which the data are due. On January 6, 2004, we published an interim final rule with comment period replacing the three-year recordkeeping requirement with a ten-year requirement on a temporary basis (69 FR 508 (Jan. 6, 2004)). We also required that manufacturers retain records beyond the ten-year period if the records were subject to certain audits or government investigations. On November 26, 2004, we published final regulations (69 FR 68815) that require that a manufacturer retain pricing data for ten years from the date the manufacturer reports that period's data to CMS. We propose to move the recordkeeping requirements at § 447.534(h) to § 447.510(f) and revise them by adding the requirement that manufacturers must also retain records used in calculating the customary prompt pay discounts and nominal prices reported to CMS.

Existing regulations at § 447.534(i) require manufacturers to report revisions to AMP and best price for a period not to exceed twelve quarters from the quarter in which the data were due. We propose to move this provision to § 447.510(b) and revise it to require manufacturers to also report revisions to customary prompt pay discounts and nominal prices for the same period.

In order to reflect the changes to AMP as set forth in the DRA, we propose allowing manufacturers to recalculate base date AMP in accordance with the definition of AMP in § 447.504(e) of this subpart. Base date AMP is used in the calculation of the additional rebate described in section 1927(c)(2) of the Act. This additional rebate is defined as the difference between the quarterly AMP reported to CMS and the base date AMP trended forward using the CPI–-U. We propose this amendment so that the additional rebate would not increase due to changes in the definition of AMP. We propose giving manufacturers an opportunity to submit a revised base date AMP with their data submission for the first full calendar quarter following the publication of the final rule. We propose to allow manufacturers the option to decide whether they will recalculate and submit to CMS a base date AMP based on the new definition of AMP or submit their existing base date AMP. We are giving manufacturers this option because we are aware that some manufacturers may not have the data needed to recalculate base date AMP or may find the administrative burden to be more costly than the savings gained.

Under section 1927(b)(3)(A) of the Act and the terms of the national rebate agreement, manufacturers that sign the national rebate agreement must supply CMS with a list of all product data (e.g., date entered market, drug category of single source, innovator multiple source, or noninnovator multiple source) and pricing information for their covered outpatient drugs. In accordance with the statute, the rule would require manufacturers to report AMP and best price to CMS not later than thirty days after the end of the rebate period.

Section 6001(b)(1) of the DRA amended section 1927(b)(3)(A)(i) of the Act by adding ''month of a'' before ''rebate period.'' Section 6003(a) of the DRA restructured section 1927(b)(3)(A)(i) of the Act. The statute, as amended by these provisions, can be read in different ways. One interpretation is that the revisions made by section 6003(a) of the DRA supersede the revisions made by section 6001(b)(1) of the DRA, effectively eliminating the requirement that manufacturers report data to CMS on a monthly basis. However, we do not believe that this reading is the better reading of the statute or consistent with congressional intent. It is unreasonable to presume that Congress would simultaneously establish and render meaningless a new provision of law and we do not propose to adopt this interpretation. Another interpretation is that the revisions made by section 6001(b)(1) of the DRA, when read with the amendments made by section 6003 of the DRA, create a new requirement that AMP, best price, and customary prompt pay discounts be reported on a monthly basis. However, there is no compelling evidence in the legislative history which indicates that Congress intended to change the rebate period from quarterly to monthly. Best price is reported to CMS quarterly for purposes of our calculation of the unit rebate amount for single source and innovator multiple source drugs. While Congress clearly intended that AMPs be reported and disclosed to States on a monthly basis, it did not establish any similar monthly use for best price or customary prompt pay discounts. For these reasons, we propose to interpret section 6001(b) of the DRA to require that manufacturers report only AMP to CMS on a monthly basis beginning January 1, 2007. To implement this provision, we would require in § 447.510(d) that manufacturers must submit monthly AMP to CMS not later than 30 days after each month. We would also require manufacturers to report quarterly AMP, best price, and customary prompt pay discounts on a quarterly basis.

We propose that the monthly AMP will be calculated the same as the quarterly AMP, with the following exceptions. The time frame represented by the monthly AMP would be one calendar month instead of a calendar

quarter and once reported, would not be subject to revision later than 30 days after each month. Because we recognize that industry pricing practices sometimes result in rebates or other price concessions being given by manufacturers to purchasers at the end of a calendar quarter, if the monthly AMP were calculated simply using sales in that month, these pricing practices might result in fluctuations between the AMP for the first two months and the AMP for the third month in a calendar quarter. In order to maximize the usefulness of the monthly AMP and minimize volatility in the prices, we propose allowing manufacturers to rely on estimates regarding the impact of their end-of-quarter rebates or other price concessions and allocate these rebates or other price concessions in the monthly AMPs reported to CMS throughout the quarter. We considered applying this same methodology to other cumulative rebates or other price concessions over longer periods of time, but are not certain that such rebates or other prices concessions could be allocated with respect to monthly AMP calculations. We invite comments on allowing the use of 12-month rolling average estimates of all lagged discounts for both the monthly and quarterly AMP. We also considered allowing manufacturers to calculate the monthly AMP based on updates of the most recent three-month period (i.e., a rolling three-month AMP). While this methodology may minimize volatility in the data, we believe it would be fairly complex for manufacturers to operationalize. We encourage comments on the appropriate methodology for calculating monthly AMP.

Section 6001(b)(2)(C) of the DRA amended the confidentiality requirements at section 1927(b)(3)(D) of the Act by adding an exception for AMP disclosure through a Web site accessible to the public. The statute does not specify that this exception only applies to monthly AMP; therefore, we also propose to make the quarterly AMP publicly available. We note that the quarterly AMP would not necessarily be identical to the monthly AMP due to the potential differences in AMP from one timeframe to the next.

Section 6001(d)(1) of the DRA modified section 1927(b)(3)(A)(iii) of the Act by adding a requirement that manufacturers report nominal prices for calendar quarters beginning on or after January 1, 2007 to the Secretary. To implement this provision, we propose to require that manufacturers report nominal price exception data to CMS on a quarterly basis. We further propose that nominal price exception data shall be reported as an aggregate dollar amount which includes all nominal price sales to the entities listed in § 447.508(a) of this subpart for the rebate period.

Section 1927(b)(3)(C) of the Act describes penalties for manufacturers that provide false information or fail to provide timely information to CMS. In light of these requirements, we propose to require that manufacturers certify the pricing reports they submit to CMS in accordance with § 447.510. We propose to adopt the certification requirements established by the Medicare Part B Program for ASP in the interim final rule with comment period published on April 6, 2004. Each manufacturer's pricing reports would be certified by the manufacturer's Chief Executive Officer (CEO), 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.

We propose that all product and pricing data, whether submitted on a quarterly or monthly basis, be submitted to CMS in an electronic format. When the Medicaid Drug Rebate Program was first implemented in 1991, electronic data transfer was one of three data submission options as the use of such electronic media was not yet as commonplace as it is today. Due to the new monthly data reporting requirements and additional quarterly data reporting requirements, we propose to require manufacturers to use one uniform data transmission format to transmit and collect these data. CMS will issue operational instructions to provide additional guidance regarding the new electronic data submission requirements.

Aggregate Upper Limits of Payment—Section 447.512

We propose that the existing § 447.331 be revised and redesignated as a new § 447.512. We propose to revise subsection (a) to clarify that the upper limit for multiple source drugs applies in the aggregate. We also propose to update several cross-references to provisions in subpart I.

Upper Limits for Multiple Source Drugs—Section 447.514

We propose that the existing § 447.332 be revised in a new § 447.514.

A. Upper Limits for Multiple Source Drugs

Existing regulations at 42 CFR 447.331, 447.332 and 447.334 address upper limits for payment of drugs covered under the Medicaid program. We propose to redesignate existing regulations at §§ 447.331, 447.332, and 447.334 as new regulations at §§ 447.512, 447.514, and 447.516, respectively.

Existing regulations at § 447.332(a)(1)(i) state that an upper limit for a multiple source drug may be established if all of the formulations of the drug approved by the FDA have been evaluated as therapeutically equivalent in the current edition of the FDA's publication, ''Approved Drug Products with Therapeutic Equivalence Evaluations.''

Section 1927(e)(4) of the Act, as amended by OBRA 90, expanded the criteria for multiple source drugs subject to FUL reimbursement. Specifically, the statute required CMS to establish an upper payment limit for each multiple source drug when there are at least three therapeutically and pharmaceutically equivalent multiple source drugs, regardless of whether all additional formulations are rated as such. Effective January 1, 2007, the DRA changed the requirement such that a FUL must be established for each multiple source drug for which the FDA has rated two or more products as therapeutically equivalent.

Currently, if all formulations of a multiple source drug are identified as A-rated in the FDA's publication, ''Approved Drug Products with Therapeutic Equivalence Evaluations,'' at least two formulations must be listed in that publication for CMS to establish a FUL for that drug. If all formulations of a multiple source drug are not A-rated, there must be at least three A-rated versions of the drug listed in ''Approved Drug Products with Therapeutic Equivalence Evaluations'' for CMS to establish a FUL for the drug. If a product meets the FDA criteria described above, we confirm that at least three suppliers (i.e., manufacturers, wholesalers, re-packagers, re-labelers or any other entity from which a drug can be purchased) list the drug in published compendia of cost information for drugs available for sale nationally (e.g., Red Book, First DataBank, or Medi-Span). Then, using these pricing compendia, we select the lowest price (e.g., the average wholesale price, wholesale acquisition cost, or direct price) from among the A-rated formulations of a particular drug and apply the formula described in existing § 447.332 to determine the FUL for that drug. FUL lists and changes to those lists based on the methodology set forth in the statute and regulations are issued periodically through Medicaid program issuances and are posted on the CMS Web site.

By the term, ''therapeutically equivalent,'' we mean drugs that are identified as A-rated in the current edition of the FDA's publication, ''Approved Drug Products with Therapeutic Equivalence Evaluations'' (including supplements or successor publications). We propose that the FUL will be established, as per section 1927(e)(4) of the Act, only using an ''A'' rated drug. However, we propose to continue our current practice of applying the FUL to all drug formulations, including those drug versions not proven to be therapeutically equivalent, (e.g., B-rated drugs). We believe it is appropriate to apply the FUL to B-rated drugs in order not to encourage pharmacies to substitute B-rated drugs to avoid the FUL in the case where B-rated drugs would be excluded from the FUL. Current regulation does not prohibit or exclude B-rated drugs from the FUL reimbursement.

We propose revising the methodology we use to establish FULs for multiple source drugs based on the modifications made by the DRA. Specifically, sections 6001(a)(3) and (4) of the DRA changed the definition of multiple source drug established in section 1927(k)(7)(A)(i) of the Act to mean, with respect to a rebate period, a covered outpatient drug for which there is at least one other drug product which is rated as therapeutically equivalent (under the FDA's most recent publication of ''Approved Drug Products with Therapeutic Equivalence Evaluations''). Also, section 6001(a)(1) of the DRA changed the requirement for a FUL to be established for each multiple source drug for which the FDA has rated three or more products therapeutically and pharmaceutically equivalent to a requirement for a FUL when the FDA has established such a rating for two or more products. Therefore, we propose in § 447.514(a)(1)(ii) that a FUL will be set when at least two suppliers (e.g., manufacturers, wholesalers, re-packagers, or re-labelers) list the drug in a nationally available pricing compendia (e.g., Red Book, First DataBank, or Medi-Span).

Existing regulations at § 447.332(b) specify that the agency's payments for multiple source drugs identified and listed must not exceed, in the aggregate, payment levels determined by applying, for each drug entity, a reasonable dispensing fee established by the agency, plus an amount that is equal to 150 percent of the published price for the least costly therapeutic equivalent (using all available national pricing compendia) that can be purchased by pharmacies in quantities of 100 tablets or capsules (or, if the drug is not commonly available in quantities of 100, the package size commonly listed) or, in the case of liquids, the commonly listed size.

Section 6001(a)(2) of the DRA added section 1927(e)(5) to the Act that changed the formula used to establish the FUL for multiple source drugs. Effective January 1, 2007, the upper limit for multiple source drugs shall be established at 250 percent of the AMP (as computed without regard to customary prompt pay discounts extended to wholesalers) for the least costly therapeutic equivalent. The currently reported AMP is based on the nine-digit NDC and is specific only to the product code, combining all package sizes of the drug into the same computation of AMP. We propose to continue to use the AMP calculated at the nine-digit NDC for the FUL calculation. In accordance with the DRA amendments, we will no longer take the individual 11-digit NDC, and thereby the most commonly used package size into consideration when computing the FUL because the currently reported AMP does not differentiate among package sizes.

We considered using the 11-digit NDC to calculate the AMP, which would require manufacturers to report the AMP at the 11-digit NDC for each package size and that doing so would offer other advantages to the program for FULs and other purposes. An AMP at the 11-digit NDC would allow us to compute a FUL based on the most common package size as specified in current regulations. We do not believe computing an AMP at the 11-digit NDC would be significantly more difficult than computing the AMP at the nine-digit NDC as the data from each of the 11-digit NDCs is combined into the current AMP. The AMP at the 11-digit NDC would also align with State Medicaid drug payments that are based on the package size. It would also allow us to more closely examine manufacturer price calculations and allow the States and the public to know the AMP for the drug for each package size. It would also allow 340B covered entities, which are entitled to buy drugs at a discount that is in part based on calculations related to AMP, to know what the pricing is for each package size, as 340B ceiling prices are established per package size. Calculating the AMP at the 11-digit NDC level permits greater transparency, and may increase accuracy and reduce errors for the 340B covered entities where prices are established for a package-size product rather than a per unit cost using the product's weighted average AMP.

However, the legislation did not change the level at which manufacturers are to report AMP, and we find no evidence in the legislative history that the Congress intended that AMP should be restructured to collect it by 11-digit NDCs. We are proposing to use the currently reported 9-digit AMP for calculating the FUL. Changing the current method of calculating the AMP would require manufacturers to make significant changes to their reporting systems and have an unknown effect on the calculation of rebates in the existing Medicaid Drug Rebate Program. In State Medicaid payment systems that consider a number of different factors in deriving payment rates, we also believe it would offer minimal advantages. Furthermore, we expect that because the AMP is marked up 250 percent, the resultant reimbursement should be sufficient to reimburse the pharmacy for the drug regardless of the package size the pharmacy purchased and that to the extent it does have an impact, it would encourage pharmacies to buy the most economical package size.

We specifically ask for comments on the alternative approach of using the 11-digit NDC to calculate the AMP. We will consider comments on the merits of using both approaches in calculating the AMP for the FUL.

In computing the FUL, we propose that the monthly AMP submitted by the manufacturer will be used. Using the monthly AMP will provide for the timeliest pricing data and allow revisions to the FUL list on a monthly basis. It will also permit us to update the FULs on a timely basis in accordance with the provisions of section 1927(f)(1)(B) of the Act, wherein the Secretary, after receiving notification that a therapeutically equivalent drug product is generally available, shall determine within 7 days if that drug product should have a FUL.

Section 6001(c)(1) of the DRA redefines AMP to exclude customary prompt pay discounts extended to wholesalers. Due to this change in the computation, and the requirement that monthly AMP first be reported as of January 1, 2007, we propose that a FUL update of drugs, using the new methodology first be published when the revised AMPs are available and processed.

We propose to adopt additional criteria to ensure that the FUL will be set at an adequate price to ensure that a drug is available for sale nationally as presently provided in our regulations. When establishing a FUL, we propose to disregard the AMP of an NDC which has been terminated. The AMP of a terminated NDC will not be used to set

the FUL beginning with the first day of the month after the actual termination date reported by the manufacturer. This refinement may not capture all outlier AMPs that would offset the availability of drugs at the FUL price. It is possible that a product that is not discontinued may be available on a limited basis at a very low price. As a further safeguard to ensure that a drug is nationally available at the FUL price and that a very low AMP is not used by us to set a FUL that is lower than the AMP for other therapeutically and pharmaceutically equivalent multiple source drugs, we propose to set the FUL based on the lowest AMP that is not less than 30 percent of the next highest AMP for that drug. That is to say, that the AMP of the lowest priced therapeutically equivalent drug will be used to establish the FUL, except in cases where this AMP is more than 70 percent below the second lowest AMP. In those cases, the second lowest AMP will be used in the FUL calculation. We propose to use this percentage calculation as a benchmark to prevent an outlier price from determining the FUL, but invite comments as to whether this percentage is an appropriate measure to use. We did consider other options, such as 60 percent below the next highest AMP so that at least drugs of two different manufacturers would be in the FULs group, but we were concerned that this percentage was insufficient to encourage competition where the cost of a particular drug was dropping rapidly. We also considered a test of a drug priced 90 percent below the next lowest priced drug, in line with how we look on nominal prices, as an indicator that the manufacturer was offering this drug on a not-for-profit basis. However, we note that nominal price relates to best price for some sales and it is unlikely a manufacturer would sell all of its drugs at this price. We welcome suggestions about other means to address outliers and whether outliers should be addressed at all.

We are proposing an exception to the 30 percent carve-out policy when the FUL group only includes the innovator single source drug and the first new generic in the market, including an authorized generic. In this event, we would not apply the 30-percent rule as we believe the DRA intends that a FUL be set when new generic drugs become generally available so as to encourage greater utilization of a generic drug when the price is set less than its brand name counterpart.

We invite comments from the public on all issues set forth in this subpart. We invite suggestions on how best to accomplish the goal of ensuring that the use of AMP in calculating the FUL will ensure that a drug is available nationally at the FUL price. Please submit data supporting your proposal when available.

Upper Limits for Drugs Furnished as Part of Services—Section 447.516

We propose that the existing § 447.334 be redesignated as a new § 447.516.

State Plan Requirements, Findings and Assurances—Section 447.518

We propose that the existing § 447.333 be redesignated as a new § 447.518.

FFP: Conditions Relating to Physician-Administered Drugs—Section 447.520

Prior to the DRA, many States did not collect rebates on physician-administered drugs when they were not identified by NDC number because the NDC number is necessary for States to bill manufacturers for rebates. In its report, ''Medicaid Rebates for Physician Administered Drugs'' (April 2004, OEI–03–02–00660), the OIG reported that, by 2003, 24 States either required providers to bill using NDC numbers or identified NDC numbers using a Healthcare Common Procedure Coding System (HCPCS)-to-NDC crosswalk for physician-administered drugs in order to collect rebates. Four of the 24 States were able to collect rebates for all physician-administered drugs, both single source and multiple source drugs (one State only collected these rebates from targeted providers). Section 6002 of the DRA added sections 1927(a)(7) and 1903(i)(10)(C) to the Act to require that States collect rebates on certain physician-administered drugs in order for FFP to be available for these drugs.

Section 1927(a)(7)(A) of the Act requires that, effective January 1, 2006, in order for FFP to be available, States must require the submission of utilization data for single source physician-administered drugs using HCPCS codes or NDC numbers. (HCPCS codes are numeric and alpha-numeric codes assigned by CMS to every medical or surgical supply, service, orthotic, prosthetic and generic or brand name drug for the purpose of reporting healthcare transactions for claims billing. Physician-administered drugs are assigned alpha-numeric HCPCS codes, and are commonly referred to as J-codes. However, physician-administered drugs are also coded using other letters of the alphabet. For this reason, we will refer to the coding system, HCPCS, as opposed to one set of alpha-numeric codes in our discussion of section 6002 requirements.) If States collect HCPCS codes for single source drugs, they can crosswalk these codes to NDC numbers because most HCPCS codes for single source drugs include only one NDC in order to collect rebates.

Section 1927(a)(7)(C) of the Act requires that, beginning January 1, 2007, States must provide for the submission of claims data with respect to physician-administered drugs (both single source and multiple source drugs) using NDC numbers, unless the Secretary specifies that an alternative coding system can be used. The Secretary does not plan to specify an alternative coding system because we believe that NDC numbers are well established in the medical community and provide States the most useful information to collect rebates.

Section 1927(a)(7)(B) of the Act requires the Secretary, by January 1, 2007, to publish a list of the 20 multiple source physician-administered drugs with the highest dollar volume dispensed under the Medicaid program. We propose that the list will be developed by the Secretary using data from the Medicaid Statistical Information System and published on the CMS Web site.

Section 1927(a)(7)(B)(ii) of the Act (when read with other DRA amendments) requires that, effective January 1, 2008, in order for FFP to be available, States must provide for the submission of claims for physician-administered multiple source drugs using NDC numbers for those drugs with the highest dollar volume listed by the Secretary.

We propose, for the purpose of this section, that the term ''physician-administered drugs'' be defined as covered outpatient drugs under section 1927(k)(2) of the Act (many are also covered by Medicare Part B) that are typically furnished incident to a physician's service. These drugs are usually injectable or intravenous drugs administered by a medical professional in a physician's office or other outpatient clinical setting. Examples include injectables: Lupron acetate for depot suspension (primarily used to treat prostate cancer), epoetin alpha (injectable drug primarily used to treat cancer), anti-emetic drugs (injectable drug primarily used to treat nausea resulting from chemotherapy), intravenous drugs primarily used to treat cancer (paclitaxel and docetaxel), infliximab primarily used to treat rheumatoid arthritis, and rituximab primarily used to treat non-Hodgkin's lymphoma. We believe that some oral self-administered drugs (administered in an outpatient clinical setting), such as oral anti-cancer drugs, oral anti-emetic

drugs should also be included in the designation of physician-administered drugs consistent with Part B policy and sections 1861(s)(2)(Q) and (T) of the Act.

Section 1927(a)(7)(D) of the Act allows the Secretary to grant States extensions if they need additional time to implement or modify reporting systems to comply with this section. We are not proposing any criteria for reviewing these extension requests as we expect that most, if not all States will be able to meet the statutory deadlines for collection of NDC numbers on claims. Most States are already collecting rebates for single source drugs that are provided in a physician's office. For multiple source drugs, the States have nearly two years following enactment of the DRA before FFP would be denied for the 20 multiple source drugs specified by the Secretary as having the highest dollar volume.

We expect that States will require physicians to submit all claims using NDC numbers, as using multiple billing systems would be burdensome for physicians and States. This will also advantage States because rebates will be collectible on all physician-administered drugs.

For States not currently billing manufacturers for rebates on single source drugs, we believe that the Medicare Part B crosswalk may be helpful to crosswalk HCPCS codes to NDC numbers. This crosswalk may be found on the CMS Web site at *http://new.cms.hhs.gov/McrPartBDrugAvgSalesPrice/02_aspfiles.asp.*

To implement the provisions set forth in section 6002, we propose a new § 447.520. In § 447.520(a), we would require States to require that claims for physician-administered drugs be submitted using codes that identify the drugs sufficiently to bill a manufacturer for rebates in order for the State to receive FFP. In § 447.520(b), we would require States to require providers to submit claims using NDC numbers. In § 447.520(c), we would allow States that require additional time to comply with the requirements of this section to apply to the Secretary for an extension.

III. Collection of Information Requirements

Under the Paperwork Reduction Act of 1995 (PRA), we are required to provide 60-day notice in the **Federal Register** and solicit public comment before a collection of information requirement is submitted to the Office of Management and Budget (OMB) for review and approval. In order to fairly evaluate whether an information collection should be approved by the OMB, section 3506(c)(2)(A) of the PRA requires that we solicit comment on the following issues:

- The need for the information collection and its usefulness in carrying out the proper functions of our agency.
- The accuracy of our estimate of the information collection burden.
- The quality, utility, and clarity of the information to be collected.
- Recommendations to minimize the information collection burden on the affected public, including automated collection techniques.

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

Requirements for Manufacturers (§ 447.510)

Proposed § 447.510 states that a manufacturer must report, electronically, product and pricing information to CMS not later than 30 days after the end of the rebate period. In addition, customary prompt pay discounts and nominal prices must be reported quarterly. Detailed information pertaining to the manufacturer's reporting requirements is located under §§ 447.510(a), (b), (c), (d), and (e).

The burden associated with these new requirements is the time and effort it would take for a drug manufacturer to gather product and pricing information and submit it to CMS in an electronic format. We estimate that these requirements would affect the approximately 550 drug manufacturers that currently participate in the Medicaid Drug Rebate Program. Our current reporting and recordkeeping hour burden for each manufacturer in the Medicaid Drug Rebate Program is 71 hours per quarter or 284 hours annually. We believe the new reporting requirements will require less than half of this time. Specifically, we believe it would take each manufacturer 31 hours per quarter or 124 hours annually to report additional new information to CMS. The total estimated burden on all drug manufacturers associated with the new requirements under § 447.510 is 68,200 annual hours.

Section 447.510(f) requires a manufacturer to retain records for ten years from the date the manufacturer reports data to CMS for that rebate period. The ten-year time frame applies to a manufacturer's quarterly and monthly submissions of pricing data, as well as any revised quarterly pricing data subsequently submitted to CMS. As stated under § 447.510(f)(2), there are certain instances when records must be maintained beyond the ten-year period.

While this requirement is subject to the PRA, the retention of quarterly data it is not a new requirement. While this requirement will now also apply to monthly AMP data, we believe a similar set of data is now retained to support the quarterly retention requirement. Therefore, we believe this regulation imposes no additional burden on the drug manufacturer.

FFP: Conditions Relating to Physician-Administered Drugs. (§ 447.520)

Section 447.520 requires providers, effective January 1, 2007, to submit claims to the State for physician-administered single source drugs and the 20 multiple source drugs identified by the Secretary using NDC numbers.

Assuming all States impose this requirement, the burden associated with this requirement is the time and effort it would take for a physician's office, hospital outpatient department or other entity (e.g., non profit facilities) to include the NDC on claims submitted to the State. We estimate this requirement would affect an excess of 20,000 physicians, hospitals with outpatient departments and other entities that would submit approximately 3,910,000 claims annually. We believe this would take approximately 15 seconds per claim. We estimated the cost based on the average annual wage and benefits paid for office and administrative support services in 2006 of $21.14 per hour (*http://www.bls.gov/news.release/pdf/ecec.pdf*). The per claim cost would be under 9 cents.

Section 447.520(c) allows States requiring additional time to comply with the requirements of this section to apply for an extension. The burden associated with this requirement is the time and effort it would take for each State to apply for a one-time extension. We estimate that it would take five hours for each State to apply for the extension; however, we believe that no State will apply. Therefore, we believe this requirement to be exempt as specified at 5 CFR 1320.3(c)(4).

We have submitted a copy of this proposed rule to the OMB for its review of the information collection requirements described above. These requirements are not effective until they have been approved by the OMB.

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, Division of Regulations Development, Attn: Melissa Musotto, [CMS–2238–P], 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: Katherine Astrich, CMS Desk Officer, CMS–2238–P, *katherine_astrich@omb.eop.gov.* Fax (202) 395–6974.

IV. 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'' February 20, 2007, and, when we proceed with a subsequent document, we will respond to the comments in the preamble to that document.

V. Regulatory Impact Analysis

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

A. Overall Impact

We have examined the impacts 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 Act, the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4), Executive Order 13132, and the Congressional Review Act (CRA, 5 U.S.C. 804(2)).

Executive Order 12866 (as amended by Executive Order 13258, which merely reassigns responsibility of duties) 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). We believe this rule will have an economically significant effect. We believe the rule would save $8.4 billion over the next five years ($4.93 billion Federal savings and $3.52 billion State savings as shown in the table below). This figure represents a 5.6 percent reduction in total Medicaid drug expenditures in Federal fiscal years 2007–2011. We consider this proposed rule to be a major rule for purposes of the CRA.

STATE AND FEDERAL SAVINGS OVER 5 YEARS

[In millions]

DRA section and provision	FFY Federal State	2007	2008	2009	2010	2011	2007–11 Total savings
Section 6001—Federal Upper Payment Limits and Other Provisions.	Federal	$465	$750	$1,075	$1,155	$1,250	$4,695
	State	330	535	765	825	890	3,345
	Total	795	1,285	1,840	1,980	2,140	8,040
Section 6002—Rebates on Physician-Administered Drugs.	Federal	18	19	20	22	24	103
	State	13	14	15	16	18	76
	Total	31	33	35	38	42	179
Section 6003—Authorized Generics in Rebate Best Price.	Federal	10	25	28	32	36	131
	State	7	19	21	24	27	98
	Total	17	44	49	56	63	229
Total Savings for FFY	Federal	493	794	1,123	1209	1310	4,929
	State	350	568	801	865	935	3,519
	Total	843	1,362	1,924	2074	2245	8,448

All savings estimates were developed by the Office of the Actuary in CMS. We note that the Congressional Budget Office, in its estimates of the budgetary effects of these provisions of the DRA, reached an almost identical estimate for these years, about $4.8 billion in Federal outlay reduction compared to the CMS estimate of $4.9 billion.

Savings estimates for section 6001 of the DRA—FULs and other provisions—were derived from simulations of the new FULs performed using price and utilization data from the Medicaid Drug Rebate Program combined with generic group codes from First DataBank. Percent savings from these simulations were applied to projected Medicaid prescription drug spending developed for the President's fiscal year 2007 budget. Savings were phased in over three years to allow for implementation lags. On the previous chart, the estimate for FFY 2007 through FFY 2010 includes $5 million for the retail price survey.

The savings estimates for section 6002 of the DRA—rebates on physician-administered drugs—are based on the 2004 OIG report, ''Medicaid Rebates for Physician-Administered Drugs.'' A key finding of the report is the amount of additional rebates that could have been collected in 2001 if all States had collected rebates on physician-administered drugs. This amount was then projected forward using historical data (2001–2005) and projections consistent with the 2007 President's Budget forecast for Medicaid spending to develop the total estimated impact.

The savings estimates for section 6003 of the DRA—Reporting of authorized generics for Medicaid rebates—are based on the consensus of Medicaid experts and the review of available and relevant data. After estimating the impact of the proposal in the first year of implementation, the total impact was projected using assumptions consistent with the 2007 President's Budget

forecast for Medicaid spending as well as adjustments given that the proposal is limited to a subset of the prescription drug market.

None of the estimates include Federal or State administrative costs. We believe these costs would be small as they involve changes in work processes rather than new activities. The resulting program savings would be many times these costs.

The RFA requires agencies to analyze options for regulatory relief of small businesses and other small entities if a proposed or final rule would have a ''significant impact on a substantive number of small entities.'' For purposes of the RFA, small entities include small businesses, non-profit organizations, and small governmental jurisdictions. Individuals and States are not included in the definition of a small entity. For purposes of the RFA, three types of small business entities are potentially affected by this regulation. They are small pharmaceutical manufacturers participating in the Medicaid Drug Rebate Program, small retail pharmacies, and physicians and other practitioners (including small hospitals or other entities such as non-profit providers) that bill Medicaid for physician-administered drugs. We will discuss each type of business in turn.

According to the Small Business Administration's (SBA) size standards, drug manufacturers are small businesses if they have fewer than 500 employees (*http://www.sba.gov/size/sizetable2002.html*). Approximately 550 drug manufacturers participate in the Medicaid Drug Rebate Program. We believe that most of these manufacturers are small businesses. We anticipate that this rule would have a small impact on small drug manufacturers. The rule would require all drug manufacturers participating in the Medicaid Drug Rebate Program to submit pricing information (AMP) on each of their drug products on a monthly basis. Currently drug manufacturers are required to submit similar information quarterly. In addition, drug manufacturers would be required to submit two additional pricing data elements—customary prompt pay discounts and nominal prices—on each of their drugs on a quarterly basis. We believe that drug manufacturers currently have these data; therefore, the new requirement does not require new data collection. Rather, it simply requires that existing information be reported to CMS. For this reason, we believe the burden to be minimal. In addition, the proposed regulation would affect the level of rebates due from manufacturers. The DRA provides that customary prompt pay discounts be excluded from AMP. This would result in higher AMPs and, consequently, higher rebate payments. We have been told informally by manufacturers that customary prompt pay discounts are generally about 2 percent. We have found no independent source to confirm this percentage. We also do not know what percent of sales qualify for customary prompt pay discounts. Based on this limited information, we believe that the removal of customary prompt pay discounts would cost manufacturers up to $160 million (2 percent of $8 billion in rebate payments annually). In this proposed regulation we also would remove sales to nursing home pharmacies from AMP. We have been told by industry representatives that nursing home pharmacies receive larger discounts than other sectors, thus resulting in an increase in AMP from this change. However, because we have no independent data on the cost of drugs to nursing home pharmacies, we cannot quantify the effect of this provision other than to say that we believe it would increase rebates owed by drug manufacturers.

According to the SBA's size standards, a retail pharmacy is a small business if it has revenues of $ 6.5 million or less in 1 year (*http://www.sba.gov/size/sizetable2002.html*). The SBA estimates that there are about 18,000 small pharmacies. These pharmacies would be affected by this regulation as the law will result in lower FULs for most drugs subject to the limits, thus reducing Medicaid payments to pharmacies for drugs. The revision to the FULs would generally reduce those limits and, thereby, reduce Medicaid payment for drugs subject to the limits. The savings for section 6001 of the DRA reflect this statutory change. The other provisions concerning payment for drugs would provide States two new data points to use to set payment rates. Beginning in January 2007, States may use AMP and retail survey prices in their payment methodologies. The savings for section 6001 of the DRA do not reflect decreases to State payments for drugs not on the FUL list. As analyzed in detail below, we believe that these legislatively mandated section 6001 savings will potentially have a ''significant impact'' on some small, independent pharmacies. The analysis in this section, together with the remainder of the preamble, constitutes an Initial Regulatory Flexibility Analysis (IRFA) for purposes of compliance with the RFA.

According to the SBA's size standards, physician practices are small businesses if they have revenues of $9 million or less in 1 year (*http://www.sba.gov/size/sizetable2002.html*). Nearly all of the approximately 20,000 physician's practices that specialize in oncology, rheumatology and urology may experience some administrative burden due to new requirements that claims include the NDC for drugs administered by these physicians. These practices would be required to transfer the NDC code for drugs administered by a physician to the electronic or paper claim. We estimate that 3,910,000 claims would be submitted a year. We derived this number by multiplying the 23 million annual Part B claims by the percentage (17) of Medicare beneficiaries who are also Medicaid beneficiaries. We believe most of the Medicaid beneficiaries who receive physician-administered drugs are also in Medicare. We then assume that it would take 15 seconds per claim. Multiplying 3,910,000 by 15 seconds equals 58,650,000 seconds or 16,292 hours (58,650,000/3600 seconds per hour). We multiplied 16,292 hours by the hourly wage and benefit rate of $21.14 for office and administrative staff published by the Department of Labor, Bureau of Labor Statistics for March 2006 to estimate the annual cost to be $344,000. We divided the total cost of $344,000 by the 3,910,000 claims to estimate the cost per claim would be under 9 cents. Calculated another way, the annual cost per physician practice would be under $20 ($344,000 divided by 20,000 equals about $17). Accordingly, we believe that there is no ''significant impact'' on these physicians.

According to the SBA's size standards, hospitals are small businesses if they have yearly revenue of $31.5 million or less (*http://www.sba.gov/size/sizetable2002.html*). As with physician practices, outpatient units of hospitals would need to include NDCs on claims for physician-administered drugs. Outpatient hospital claims for physician-administered drugs are included in the 3,910,000 annual total claims discussed in the previous paragraph. However, we believe that these costs could be reduced or eliminated with a one-time systems change to capture this code in the billing system. In any case, the total cost of this change to hospitals would be small, and we believe that there is no ''significant impact'' on hospitals.

Other small entities such as non-profit providers may also be affected by this provision. We do not have data to quantify how many of the 3,910,000 annual total claims are submitted by

these entities. In any case, the cost would be under 9 cents per claim.

Section 1102(b) of the Act requires us to prepare an RIA if a rule may have a significant impact on the operations of a substantial number of small rural hospitals. This analysis must conform to the provisions of section 603 of the RFA. For purposes of section 1102(b) of the Act, we define a small rural hospital as a hospital that is located outside of a Core-Based Statistical Area and has fewer than 100 beds. There are approximately 700 small rural hospitals that meet this definition. We do not know how many of these hospitals have outpatient departments. However, we believe that this rule would not have a significant impact on small rural hospitals because the only provision that would affect small rural hospitals is the requirement for those hospitals to include the NDC on bills for drugs administered by physicians in the outpatient department. As the national annual cost of this provision is estimated at $344,000, the impact on small rural hospitals would be minimal.

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 on States and private entities require spending in any one year of $100 million in 1995 dollars, updated annually for inflation. That threshold level is currently approximately $125 million. This proposed rule would mandate that drug manufacturers provide information on drug prices, and that these data be used in calculating FULs. However, our estimate of costs to manufacturers (see next section) falls far below the threshold and we anticipate this rule would save States $3.5 billion over the 5-year period from October 1, 2006 through September 30, 2011.

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. Since this proposed rule would impose only minimal new administrative burden on States and yield substantial savings to States, we believe that these costs can be absorbed by States from the substantial savings they would accrue.

B. Anticipated Effects

1. Effects on Drug Manufacturers

As previously indicated, approximately 550 drug manufacturers participate in the Medicaid Drug Rebate program. The rule would require all drug manufacturers participating in the Medicaid Drug Rebate Program to submit pricing information (AMP) on each of their drug products on a monthly basis. Currently drug manufacturers are required to submit similar information quarterly. In addition, drug manufacturers would be required to submit two additional pricing data elements—customary prompt pay discounts and nominal prices—on each of their drugs on a quarterly basis. We believe that drug manufacturers currently have these data; therefore, the new requirement would not require new data collection. Rather it simply requires that existing information be reported to CMS. For this reason, we believe the burden to be minimal. The estimated startup burden to the manufacturers is $27.5 million for a one-time systems upgrade, or $50,000 for each of the 550 manufacturers that participate in the Medicaid Drug Rebate Program. To estimate the ongoing burden, we expect that the manufacturers would each spend 208 hours annually (114,400 total hours annually) in complying with these requirements. The estimated annual operational expenses are $5.7 million, which is 114,400 total annual hours multiplied by $37.50 per labor hour in wages and benefits, or $4.3 million in labor burden, plus $1.4 million in technical support.

In addition, the proposed regulation would affect the level of rebates due from manufacturers. The DRA provides that customary prompt pay discounts be excluded from AMP. This would result in higher AMPs and, consequently, higher rebate payments. We have been told informally by manufacturers that customary prompt pay discounts are generally about two percent. We have found no independent source to confirm this percentage. We also do not know what percent of sales qualify for customary prompt pay discounts. Based on this limited information, we believe that the removal of customary prompt pay discounts would cost manufacturers up to $160 million (2 percent of $8 billion in rebate payments annually). In this proposed regulation, we also would remove sales to nursing home pharmacies from AMP. We have been told by industry representatives that nursing home pharmacies receive larger discounts than other sectors, thus resulting in an increase in AMP. However, because we have no independent data on the cost of drugs to nursing home pharmacies, we cannot quantify the effect of this provision other than to say that we believe it would increase rebates owed by drug manufacturers.

2. Effects on State Medicaid Programs

States share in the savings from this rule. As noted in the table above, we estimate five-year State savings of over $3.5 billion. State administrative costs associated with this regulation are minor as States currently pay based on a FUL for drugs subject to that limit, determine their drug reimbursement rates, and collect claims information on physician-administered drugs.

3. Effects on Retail Pharmacies

Retail pharmacies would be affected by this regulation, as the law will result in lower FULs for most drugs subject to the limits, thus reducing Medicaid payments to pharmacies for drugs. The revision to the FULs would generally reduce those limits and, thereby, reduce Medicaid payment for drugs subject to the limits. The savings for section 6001 of the DRA reflect this statutory change. The other provisions concerning payment for drugs would provide States two new data points to use to set payment rates. Beginning in January 2007, States may use AMP and retail survey prices in their payment methodologies. The savings for section 6001 of the DRA do not reflect decreases to State payments for drugs not on the FUL list that may result if States change their payment methodologies.

The savings to the Medicaid program would largely be realized through lower payments to pharmacies. As shown earlier in this analysis, the annual effect of lower FULs and related changes will likely reduce pharmacy revenues by about $800 million in 2007, increasing to a $2 billion reduction annually by 2011. These reductions, while large in absolute terms, represent only a small fraction of overall pharmacy revenues. According to recent data summarized by the National Association of Chain Drug Stores (*http://www.nacds.org/wmspage.cfm?parm1=507*), total retail prescription sales in the United States, including chain drug stores, independent drug stores, supermarket, and mail order, totaled about $230 billion in 2005. Assuming, conservatively, that sales will rise at only five percent a year, 2007 sales would be over $250 billion and 2011 sales well over $300 billion. Thus, the effect of this proposed rule would be to reduce retail prescription drug revenues by less than one percent, on average. Actual revenue losses would be even smaller for two reasons. First, almost all of these stores sell goods other than prescription drugs, and overall sales average more than twice as much as

prescription drug sales. Second, pharmacies have the ability to mitigate the effects of the proposed rule by changing purchasing practices. The 250 percent FUL will typically be lower than the prices available to pharmacies only when one or more very low cost generic drugs are included in the calculation. Pharmacies will often be able to switch their purchasing to the lowest cost drugs and mitigate the effect of the sales loss by lowering costs.

Although it is clear that the effects will be small on the great majority of pharmacies, whether chain or independent, we are unable to estimate quantitatively effects on ''small'' pharmacies, particularly those in low-income areas where there are high concentrations of Medicaid beneficiaries. We request any information that may help us better assess those effects before we make final decisions. Because of these uncertainties, we have concluded that this proposed rule is likely to have a ''significant impact'' on some pharmacies.

4. Effects on Physicians

This regulation would affect physician practices that provide and bill Medicaid for physician-administered drugs. This includes about 20,000 physicians as well as hospitals with outpatient departments. The effect on physicians is the same as discussed in section A—Overall Impact above for small businesses because all or nearly all physician offices are small businesses.

5. Effects on Hospitals

This regulation would affect hospitals with outpatient departments that provide and bill Medicaid for physician-administered drugs. As discussed above, hospitals with outpatient departments would need to include the NDC on claims for physician-administered drugs. We believe this would need to be done manually or would require a one-time systems change. We believe the cost of adding the NDC to each claim would be minimal. We are not able to estimate the cost to make this change. We also note that CMS has encouraged States to collect information on physician-administered drug claims to enable them to collect rebates. Some States have required that NDCs be included on claims and others are in the process of doing so. We expect that, in the absence of the DRA requirement, the number of States requiring NDCs on these claims would have increased.

6. Effects on Small Business Entities

As previously discussed, for purposes of the RFA, three types of small business entities are potentially affected by this regulation. This regulation would affect small pharmaceutical manufacturers participating in the Medicaid Drug Rebate Program, small retail pharmacies, and physicians and other practitioners (including small hospitals or other entities such as non-profit providers).

According to the SBA's size standards, we believe that most of the 550 pharmaceutical manufacturers in the Medicaid Drug Rebate Program are small businesses. We previously indicated that this rule impacts drug manufacturers by requiring them to submit pricing information (AMP) on each of their drug products on a monthly basis with an estimated impact that is minimal. The rule would also increase the amount of drug rebates that manufacturers would pay as a result of removing customary prompt pay discounts and nursing home sales from AMP, which is used in the rebate calculation. The exclusion of customary prompt pay discounts would cost manufacturers up to $160 million (2 percent of $8 billion in rebate payments annually). Additional detail regarding the effects of this proposed rule for the determination of drug prices and calculation of drug rebate liability for drug manufacturers is described in the preamble under ''Definition of Retail Pharmacy Class of Trade and Determination of AMP.''

We estimate that 18,000 small retail pharmacies would be affected by this regulation. However, we are unable to specifically estimate quantitative effects on small retail pharmacies, particularly those in low income areas where there are high concentrations of Medicaid beneficiaries. We request any information that may help us better assess those effects before we make final decisions. The preamble under ''Definition of Retail Pharmacy Class of Trade and Determination of AMP'' provides additional information regarding the entities included in the retail pharmacy class of trade and the discounts or other price concessions for drugs provided to the retail pharmacy class of trade. As shown earlier, the annual effect of lower FULs and related changes will likely reduce overall pharmacy revenues by about $800 million in 2007, increasing to a $2 billion reduction annually by 2011.

Nearly all of the approximately 20,000 physician practices that specialize in oncology, rheumatology and urology are considered small businesses. The rule would impose some administrative burden on these practices due to new requirements that claims include the NDC for physician-administered drugs. As shown earlier, we believe that the annual cost per claim would be under 9 cents and the annual cost per physician practice would be under $20. Accordingly, we believe that there is no significant impact on these physician practices.

We also previously indicated that this rule would not have a significant impact on the operations of small rural hospitals. There are approximately 700 small rural hospitals that meet the small business standard. As previously discussed, small rural hospitals would need to include the NDC on claims for physician-administered drugs through outpatient departments. We do not have data to quantify how many of the overall claims for physician-administered drugs are submitted by these 700 small rural hospitals. In any case, the cost would be under 9 cents per claim.

The following chart depicts the number of small entities and the estimated economic impact for each category of small entity affected by this rule.

Small entity	Number affected by rule	Estimated economic impact
Pharmaceutical Manufacturers in Medicaid Drug Rebate Program.	550	$160 million (2 percent of $8 billion) higher rebates result from removal of customary prompt pay discounts from rebate calculations. Independent cost data not available for excluded nursing home drug sales that are expected to increase rebate cost.
Small Retail Pharmacies	18,000	Reduces overall pharmacy revenues by about $800 million in 2007 increasing to $2 billion annually by 2011. Unable to quantitatively estimate effects on small retail pharmacies, particularly in low income areas.

Small entity	Number affected by rule	Estimated economic impact
Physicians in their Offices, Hospital Outpatient Settings or Other Entities (e.g., Non-profit Facilities) that Specialize in Oncology, Rheumatology and Urology.	20,000	Under 9 cents per claim to enter NDC number. About $17 annual cost per physician practice to enter NDC number on claims for physician-administered drugs. Total estimated impact is $344,000.
Small Rural Hospitals	700	Minimal impact.

C. Alternatives Considered

We considered a number of different policies and approaches during the development of the proposed rule.

With regard to the definition of AMP, we considered one definition for quarterly AMP and a different definition for monthly AMP. However, we believe the better reading of statute is for AMP to be defined the same way for quarterly or monthly reporting.

We also considered redefining the entities included in ''retail pharmacy class of trade'' for purposes of the definition of AMP. Options considered included whether to include or exclude sales to nursing home pharmacies, PBMs, and mail order pharmacies. We chose to propose to exclude sales to nursing home pharmacies.

We considered retaining the current base date AMP rather than allowing manufacturers to recalculate their base date AMP to reflect the revised definition of AMP. However, we decided that retaining the current base date AMP is unwarranted because it would create a financial burden on manufacturers that was not intended by section 6001 of the DRA.

We considered several options concerning the timeframe to be covered by the monthly AMP. We considered requiring manufacturers to report the same quarterly AMP three times over the quarter, and reflect any changes to the quarterly AMP vis-à-vis the monthly reports. However, we did not believe that this timeframe would provide useful pricing information to States. We also considered establishing a rolling three-month period for the monthly AMP. While this may yield updated pricing information, we felt this would be too burdensome for manufacturers to implement.

We considered proposing to extend the nominal price exclusion from best price to other facilities or entities that the Secretary determines to be safety net providers to which sales of drugs at nominal prices would be appropriate. However, we were concerned that expanding the list of entities eligible for nominal pricing would drive up best price, which would effectively lower the amount of rebates manufacturers pay for Medicaid drugs.

We considered using a non-weighted AMP, which is specific to a package size, to establish the FUL. However, we decided to continue to base AMP on all package sizes for each drug. We did not find any indication that the Congress intended to change how package size is used for AMP. Such a change would be burdensome on manufacturers and would have no impact on how States pay for drugs.

We considered not making an exception to using the lowest AMP for drugs in a FUL group to establish the upper limit for the group. However, we were concerned that low outlier prices might result in only one drug being available at or near the FUL price and that a sufficient supply of the drug to meet the national Medicaid need may not be available at that price.

As discussed extensively earlier in the preamble, we believe that mail order sales and the activities of PBMs are an important part of the wholesale and retail markets for drugs. They reflect the realities of today's marketplace for consumers of prescription drugs. However, there are difficulties in dealing with both segments of the market and we specifically request comments on ways to handle these components of the marketplace. We also welcome comments on any options that would maintain the overall savings of the proposed rule, appropriately encompass the entire retail marketplace, and reduce burden on small pharmacies.

D. Other Requirements in the Regulatory Flexibility Act

The RFA lists five general requirements for an IRFA and four categories of burden-reducing alternatives. We know of no relevant Federal rules that duplicate, overlap, or conflict with the proposed rule. The preceding analysis, together with the rest of this preamble, addresses all these general requirements.

We have not, however, addressed the various categories of burden reduction listed in the RFA as appropriate for IRFAs. These alternatives, such as an exemption from coverage for small entities, establishment of less onerous requirements for small entities, or use of performance rather than design standards, simply do not appear to apply in a situation where uniform payment standards are being established. However, we welcome comments with suggestions for improvements we can make, consistent with the statute, to minimize any unnecessary burdens on pharmacies or other affected entities.

E. Accounting Statement

As required by OMB's Circular A–4 (available at *http://www.whitehouse.gov/omb/circulars/a004/a-4.pdf*), in the table below, we have prepared an accounting statement showing the classification of the expenditures associated with the provisions of this proposed rule. This table provides our best estimate of the decreases in Medicaid payments under sections 6001 '' 6003 of the DRA. All expenditures are classified as transfers to the Federal and State Medicaid programs from retail pharmacies and drug manufacturers.

ACCOUNTING STATEMENT: CLASSIFICATION OF ESTIMATED EXPENDITURES, FROM CY 2007 TO CY 2011

[In millions/year]

Category	Transfers	Discount rate (percent)	From whom to whom?
Federal Annualized Monetized Transfers.	$957.8	7	Retail Pharmacies and Drug Manufacturers to the Federal Government.

ACCOUNTING STATEMENT: CLASSIFICATION OF ESTIMATED EXPENDITURES, FROM CY 2007 TO CY 2011—Continued

[In millions/year]

Category	Transfers	Discount rate (percent)	From whom to whom?
Other Annualized Monetized Transfers.	973.6	3	Retail Pharmacies and Drug Manufacturers to the State Governments.
	683.8	7	
	695.1	3	

F. Conclusion

We estimate savings from this regulation of $8.4 billion over five years, $4.9 billion to the Federal Government and $3.5 billion to the States. Most of these savings result from a change in how the FULs on multiple source drugs are calculated and from a change in how authorized generic drugs are treated for AMP and best price. The majority of the savings would come from lower reimbursement to retail pharmacies. The provision on physician-administered drugs does not change the legal liability of drug manufacturers for paying rebates but would make it easier for States to collect these rebates.

While the effects of this regulation are substantial, they are a result of changes to the law.

In accordance with the provisions of Executive Order 12866, this regulation was reviewed by the OMB.

List of Subjects in 42 CFR Part 447

Accounting, Administrative practice and procedure, Drugs, Grant programs—health, Health facilities, Health professions, Medicaid, Reporting and recordkeeping requirements, Rural areas.

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

PART 447—PAYMENTS FOR SERVICES

1. The authority citation for part 447 continues to read as follows:

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

Subpart F—Payment Methods for Other Institutional and Non-institutional Services

2. Section 447.300 is revised to read as follows:

§ 447.300 Basis and purpose.

In this subpart, § 447.302 through § 447.325 and § 447.361 implement section 1902(a)(30) of the Act, which requires that payments be consistent with efficiency, economy and quality of care. Section 447.371 implements section 1902(a)(13)(F) of the Act, which requires that the State plan provide for payment for rural health clinic services in accordance with regulations prescribed by the Secretary.

§ 447.301 [Removed]

3. Section 447.301 is removed.

§ 447.331 [Removed]

4. Section 447.331 is removed.

§ 447.332 [Removed]

5. Section 447.332 is removed.

§ 447.333 [Removed]

6. Section 447.333 is removed.

§ 447.334 [Removed]

7. Section 447.334 is removed.

8. Subpart I is revised to read as follows:

Subpart I—Payment for Drugs

Sec.
447.500 Basis and purpose.
447.502 Definitions.
447.504 Determination of AMP.
447.505 Determination of best price.
447.506 Authorized generic drugs.
447.508 Exclusion from best price of certain sales at a nominal price.
447.510 Requirements for manufacturers.
447.512 Drugs: Aggregate upper limits of payment.
447.514 Upper limits for multiple source drugs.
447.516 Upper limits for drugs furnished as part of services.
447.518 State plan requirements, findings and assurances.
447.520 FFP: Conditions relating to physician-administered drugs.

Subpart I—Payment for Drugs

§ 447.500 Basis and purpose.

(a) *Basis.* This subpart—

(1) Interprets those provisions of section 1927 of the Act that set forth requirements for drug manufacturers' calculating and reporting average manufacturer prices (AMPs) and that set upper payment limits for covered outpatient drugs.

(2) Implements section 1903(i)(10) of the Act with regard to the denial of Federal financial participation (FFP) in expenditures for certain physician-administered drugs.

(3) Implements section 1902(a)(54) of the Act with regard to a State plan that provides covered outpatient drugs.

(b) *Purpose.* This subpart specifies certain requirements in the Deficit Reduction Act of 2005 and other requirements pertaining to Medicaid payment for drugs.

§ 447.502 Definitions.

Bona fide service fees mean fees paid by a manufacturer to an entity, that represent fair market value for a bona fide, itemized service actually performed on behalf of the manufacturer that the manufacturer would otherwise perform (or contract for) in the absence of the service arrangement, and that are not passed on in whole or in part to a client or customer of an entity, whether or not the entity takes title to the drug.

Brand name drug means a single source or innovator multiple source drug.

Bundled sale means an arrangement regardless of physical packaging under which the rebate, discount, or other price concession is conditioned upon the purchase of the same drug or drugs of different types (that is, at the nine-digit National Drug Code (NDC) level) or some other performance requirement (for example, the achievement of market share, inclusion or tier placement on a formulary), or, where the resulting discounts or other price concessions are greater than those which would have been available had the bundled drugs been purchased separately or outside the bundled arrangement. For bundled sales, the discounts are allocated proportionally to the dollar value of the units of each drug sold under the bundled arrangement. For bundled sales where multiple drugs are discounted, the aggregate value of all the discounts should be proportionately allocated across all the drugs in the bundle.

Consumer Price Index—Urban (CPI–U) means the index of consumer prices developed and updated by the U.S. Department of Labor. It is the CPI for all urban consumers (U.S. average) for the month before the beginning of the

calendar quarter for which the rebate is paid.

Dispensing fee means the fee which—

(1) Is incurred at the point of sale and pays for costs in excess of the ingredient cost of a covered outpatient drug each time a covered outpatient drug is dispensed;

(2) Includes only pharmacy costs associated with ensuring that possession of the appropriate covered outpatient drug is transferred to a Medicaid recipient. Pharmacy costs include, but are not limited to, any reasonable costs associated with a pharmacist's time in checking the computer for information about an individual's coverage, performing drug utilization review and preferred drug list review activities, measurement or mixing of the covered outpatient drug, filling the container, beneficiary counseling, physically providing the completed prescription to the Medicaid beneficiary, delivery, special packaging, and overhead associated with maintaining the facility and equipment necessary to operate the pharmacy; and

(3) Does not include administrative costs incurred by the State in the operation of the covered outpatient drug benefit including systems costs for interfacing with pharmacies.

Estimated acquisition cost means the agency's best estimate of the price generally and currently paid by providers for a drug marketed or sold by a particular manufacturer or labeler in the package size of drug most frequently purchased by providers.

Innovator multiple source drug means a multiple source drug that was originally marketed under an original new drug application (NDA) approved by the Food and Drug Administration (FDA). It includes a drug product marketed by any cross-licensed producers or distributors operating under the NDA and a covered outpatient drug approved under a product license approval, establishment license approval or antibiotic drug approval.

Manufacturer means any entity that possesses legal title to the NDC for a covered drug or biological product and—

(1) Is engaged in the production, preparation, propagation, compounding, conversion, or processing of covered outpatient drug products, 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; or

(2) Is engaged in the packaging, repackaging, labeling, relabeling, or distribution of covered outpatient drug products and is not a wholesale distributor of drugs or a retail pharmacy licensed under State law.

(3) With respect to authorized generic products, the term ''manufacturer'' will also include the original holder of the NDA.

(4) With respect to drugs subject to private labeling arrangements, the term ''manufacturer'' will also include the entity that does not possess legal title to the NDC.

Multiple source drug means, with respect to a rebate period, a covered outpatient drug for which there is at least one other drug product which—

(1) Is rated as therapeutically equivalent. For the list of drug products rated as therapeutically equivalent, see the FDA's most recent publication of ''Approved Drug Products with Therapeutic Equivalence Evaluations'' which is available at *http://www.fda.gov/cder/orange/default.htm* or can be viewed at the FDA's Freedom of Information Public Reading Room at 5600 Fishers Lane, rm. 12A–30, Rockville, MD 20857;

(2) Is pharmaceutically equivalent and bioequivalent, as determined by the FDA; and

(3) Is sold or marketed in the United States during the rebate period.

National drug code (NDC) means the 11-digit numerical code maintained by the FDA that indicates the labeler, product, and package size, unless otherwise specified in this part as being without respect to package size (*i.e.*, the nine-digit numerical code).

National rebate agreement means the rebate agreement developed by CMS and entered into by CMS on behalf of the Secretary or his designee and a manufacturer to implement section 1927 of the Act.

Nominal price means a price that is less than 10 percent of the AMP in the same quarter for which the AMP is computed.

Rebate period means a calendar quarter.

Single source drug means a covered outpatient drug that is produced or distributed under an original NDA approved by the FDA, including a drug product marketed by any cross-licensed producers or distributors operating under the NDA. It also includes a covered outpatient drug approved under a product license approval, establishment license approval, or antibiotic drug approval.

§ 447.504 Determination of AMP.

(a) *AMP* means, with respect to a covered outpatient drug of a manufacturer (including those sold under an NDA approved under section 505(c) of the Federal Food, Drug, and Cosmetic Act (FFDCA)) for a calendar quarter, the average price received by the manufacturer for the drug in the United States from wholesalers for drugs distributed to the retail pharmacy class of trade. AMP shall be determined without regard to customary prompt pay discounts extended to wholesalers. AMP shall be calculated to include all sales and associated discounts and other price concessions provided by the manufacturer for drugs distributed to the retail pharmacy class of trade unless the sale, discount, or other price concession is specifically excluded by statute or regulation or is provided to an entity specifically excluded by statute or regulation.

(b) *Average unit price* means a manufacturer's quarterly sales included in AMP less all required adjustments divided by the total units sold and included in AMP by the manufacturer in a quarter.

(c) *Customary prompt pay discount* means any discount off the purchase price of a drug routinely offered by the manufacturer to a wholesaler for prompt payment of purchased drugs within a specified time.

(d) *Net sales* means quarterly gross sales revenue less cash discounts allowed and all other price reductions (other than rebates under section 1927 of the Act or price reductions specifically excluded by statute or regulations) which reduce the amount received by the manufacturer.

(e) *Retail pharmacy class of trade* means any independent pharmacy, chain pharmacy, mail order pharmacy, pharmacy benefit manager (PBM), or other outlet that purchases, or arranges for the purchase of, drugs from a manufacturer, wholesaler, distributor, or other licensed entity and subsequently sells or provides the drugs to the general public.

(f) *Wholesaler* means any entity (including a pharmacy, chain of pharmacies, or PBM) to which the manufacturer sells, or arranges for the sale of, the covered outpatient drugs, but that does not relabel or repackage the covered outpatient drug.

(g) *Sales, rebates, discounts, or other price concessions included in AMP.* Except with respect to those sales identified in paragraph (h) of this section, AMP for covered outpatient drugs shall include—

(1) Sales to wholesalers, except for those sales that can be identified with adequate documentation as being subsequently sold to any of the excluded entities as specified in paragraph (h) of this section;

(2) Sales to other manufacturers who act as wholesalers and do not

repackage/relabel under the purchaser's NDC, including private labeling agreements;

(3) Sales (direct and indirect) to hospitals, where the drug is used in the outpatient pharmacy;

(4) Sales at nominal prices to any entity except a covered entity described in section 340B(a)(4) of the Public Health Service Act (PHSA), an intermediate care facility for the mentally retarded (ICF/MR) providing services as set forth in § 440.150 of this chapter, or a State-owned or operated nursing facility providing services as set forth in § 440.155 of this chapter;

(5) Sales to retail pharmacies including discounts or other price concessions that adjust prices either directly or indirectly on sales of drugs to the retail pharmacy class of trade;

(6) Discounts, rebates, or other price concessions to PBMs associated with sales for drugs provided to the retail pharmacy class of trade;

(7) Sales directly to patients;

(8) Sales to outpatient clinics;

(9) Sales to mail order pharmacies;

(10) Rebates, discounts, or other price concessions (other than rebates under section 1927 of the Act or as otherwise specified in the statute or regulations) associated with sales of drugs provided to the retail pharmacy class of trade;

(11) Manufacturer coupons redeemed by any entity other than the consumer that are associated with sales of drugs provided to the retail pharmacy class of trade; and

(12) Sales and associated rebates, discounts and other price concessions under the Medicare Part D, Medicare Advantage Prescription Drug Program (MA–PD), State Children's Health Insurance Program (SCHIP), State pharmaceutical assistance programs (SPAPs), and Medicaid programs that are associated with sales of drugs provided to the retail pharmacy class of trade (except for rebates under section 1927 of the Act or as otherwise specified in the statute or regulations).

(h) *Sales, rebates, discounts, or other price concessions excluded from AMP.* AMP excludes—

(1) Any prices on or after October 1, 1992, to the Indian Health Service (IHS), the Department of Veterans Affairs (DVA), a State home receiving funds under 38 U.S.C. 1741, the Department of Defense (DoD), the Public Health Service (PHS), or a covered entity described in subsection (a)(5)(B) of the Act (including inpatient prices charged to hospitals described in section 340B(a)(4)(L) of the PHSA);

(2) Any prices charged under the Federal Supply Schedule (FSS) of the General Services Administration (GSA);

(3) Any depot prices (including Tricare) and single award contract prices, as defined by the Secretary, of any agency of the Federal Government;

(4) Sales to hospitals (direct and indirect), where the drug is used in the inpatient setting;

(5) Sales to health maintenance organizations (HMOs), including managed care organizations (MCOs);

(6) Sales to long-term care facilities, including nursing home pharmacies;

(7) Sales to wholesalers where the drug is distributed to the non-retail pharmacy class of trade;

(8) Sales to wholesalers or distributors where the drug is relabeled under the wholesalers' or distributors' NDC number;

(9) Manufacturer coupons redeemed by a consumer;

(10) Free goods, not contingent upon any purchase requirement;

(11) Bona fide service fees;

(12) Customary prompt pay discounts extended to wholesalers; and

(13) Returned goods when returned in good faith.

(i) *Further clarification of AMP calculation.* (1) AMP includes cash discounts, free goods that are contingent on any purchase requirement, volume discounts, PBM price concessions, chargebacks, incentives, administrative fees, service fees, (except bona-fide service fees), distribution fees, and any other discounts or price reduction and rebates, other than rebates under section 1927 of the Act, which reduce the price received by the manufacturer for drugs distributed to the retail pharmacy class of trade.

(2) AMP is calculated as a weighted average of prices for all the manufacturer's package sizes for each covered outpatient drug sold by the manufacturer during a rebate period. It is calculated as net sales divided by number of units sold, excluding goods or any other items given away unless contingent on any purchase requirements.

(3) The manufacturer must adjust the AMP for a rebate period if cumulative discounts, rebates, or other arrangements subsequently adjust the prices actually realized.

§ 447.505 Determination of best price.

(a) *Best price* means, with respect to a single source drug or innovator multiple source drug of a manufacturer (including any drug sold under an NDA approved under section 505(c) of the FFDCA), the lowest price available from the manufacturer during the rebate period to any entity in the United States in any pricing structure (including capitated payments), in the same quarter for which the AMP is computed. Best price shall be calculated to include all sales and associated discounts and other price concessions provided by the manufacturer to any entity unless the sale, discount, or other price concession is specifically excluded by statute or regulation or is provided to an entity specifically excluded by statute or regulation from the rebate calculation.

(b) For purposes of this section, *provider* means a hospital, HMO, including an MCO or entity that treats or provides coverage or services to individuals for illnesses or injuries or provides services or items in the provisions of health care.

(c) *Prices included in best price.* Except with respect to those prices identified in paragraph (d) of this section and § 447.505 of this subpart, best price for covered outpatient drugs, includes—

(1) Prices to wholesalers;

(2) Prices to any retailer, including PBM rebates, discounts or other price concessions that adjust prices either directly or indirectly on sales of drugs;

(3) Prices to providers (e.g., hospitals, HMOs/MCOs, physicians, nursing facilities, and home health agencies);

(4) Prices available to non-profit entities;

(5) Prices available to governmental entities within the United States;

(6) Prices of authorized generic drugs;

(7) Prices of sales directly to patients;

(8) Prices available to mail order pharmacies;

(9) Prices available to outpatient clinics;

(10) Prices to other manufacturers who act as wholesalers and do not repackage/relabel under the purchaser's NDC, including private labeling agreements;

(11) Prices to entities that repackage/relabel under the purchaser's NDC, including private labeling agreements, if that entity also is an HMO or other non-excluded entity; and

(12) Manufacturer coupons redeemed by any entity other than the consumer.

(d) *Prices excluded from best price.* Best price excludes:

(1) Any prices on or after October 1, 1992, charged to the IHS, the DVA, a State home receiving funds under 38 U.S.C. 1741, the DoD, the PHS, or a covered entity described in subsection (a)(5)(B) of the Act (including inpatient prices charged to hospitals described in section 340B(a)(4)(L) of the PHSA);

(2) Any prices charged under the FSS of the GSA;

(3) Any prices paid by an SPAP;

(4) Any depot prices (including Tricare) and single award contract prices, as defined by the Secretary, of any agency of the Federal Government;

(5) Any prices charged which are negotiated by a prescription drug plan under Part D of title XVIII, by any MA–PD plan under Part C of such title with respect to covered Part D drugs, or by a qualified retiree prescription drug plan (as defined in section 1860D–22(a)(2) of the Act) with respect to such drugs on behalf of individuals entitled to benefits under Part A or enrolled under Part B of Medicare;

(6) Rebates or supplemental rebates paid to Medicaid States agencies under section 1927 of the Act;

(7) Prices negotiated under a manufacturer's sponsored Drug Discount Card Program;

(8) Manufacturer coupons redeemed by a consumer;

(9) Goods provided free of charge under a manufacturers' patient assistance programs;

(10) Free goods, not contingent upon any purchase requirement;

(11) Nominal prices to certain entities as set forth in § 447.508 of this subpart; and

(12) Bona fide service fees.

(e) *Further clarification of best price.* (1) Best price shall be net of cash discounts, free goods that are contingent on any purchase requirement, volume discounts, customary prompt pay discounts, chargebacks, returns, incentives, promotional fees, administrative fees, service fees (except bona fide service fees), distribution fees, and any other discounts or price reductions and rebates, other than rebates under section 1927 of the Act, which reduce the price available from the manufacturer.

(2) Best price must be determined on a unit basis without regard to special packaging, labeling or identifiers on the dosage form or product or package, and must not take into account prices that are nominal in amount as described in § 447.510 of this subpart.

(3) The manufacturer must adjust the best price for a rebate period if cumulative discounts, rebates, or other arrangements subsequently adjust the prices available from the manufacturer.

§ 447.506 Authorized generic drugs.

(a) *Authorized generic drug defined.* For the purposes of this subpart, authorized generic drug means any drug sold, licensed or marketed under an NDA approved by the FDA under section 505(c) of the FFDCA; and marketed, sold or distributed directly or indirectly under a different product code, labeler code, trade name, trade mark, or packaging (other than repackaging the listed drug for use in institutions) than the listed drug.

(b) *Inclusion of authorized generic drugs in AMP.* A manufacturer holding title to the original NDA of the authorized generic drug must include the direct and indirect sales of this drug in its AMP.

(c) *Inclusion of authorized generic drugs in best price.* A manufacturer holding title to the original NDA of an authorized generic drug approved under section 505(c) of the FFDCA must include the price of such drug in the computation of best price for the single source or innovator multiple source drug during the rebate period to any manufacturer, wholesaler, retailer, provider, HMO, non-profit entity, or governmental entity within the United States.

§ 447.508 Exclusion from best price of certain sales at a nominal price.

(a) *Exclusion from best price.* Sales of covered outpatient drugs by a manufacturer at nominal prices are excluded from best price when purchased by the following entities:

(1) A covered entity described in section 340B(a)(4) of the PHSA,

(2) An ICF/MR providing services as set forth in § 440.150 of this chapter; or

(3) A State-owned or operated nursing facility providing services as set forth in § 440.155 of this chapter.

(b) *Nonapplication.* This restriction shall not apply to sales by a manufacturer of covered outpatient drugs that are sold under a master agreement under 38 U.S.C. 8126.

§ 447.510 Requirements for manufacturers.

(a) *Quarterly reports.* A manufacturer must report product and pricing information for covered outpatient drugs to CMS not later than 30 days after the end of the rebate period. The quarterly pricing report must include:

(1) AMP, calculated in accordance with § 447.504 of this subpart;

(2) Best price, calculated in accordance with § 447.505 of this subpart;

(3) Customary prompt pay discounts, which shall be reported as an aggregate dollar amount which includes discounts paid to all purchasers in the rebate period; and

(4) Prices that fall within the nominal price exclusion, which shall be reported as an aggregate dollar amount and shall include all sales to the entities listed in § 447.508(a) of this subpart for the rebate period.

(b) *Timeframe for reporting revised AMP, best price, customary prompt pay discounts, or nominal prices.* A manufacturer must report to CMS revisions to AMP, best price, customary prompt pay discounts, or nominal prices for a period not to exceed 12 quarters from the quarter in which the data were due.

(c) *Base date AMP report.* (1) A manufacturer must report base date AMP to CMS for the first full calendar quarter following [publication date of the final rule].

(2) Any manufacturer's recalculation of the base date AMP must only reflect the revisions to AMP as provided for in § 447.504(e) of this subpart.

(d) *Monthly AMP.* (1) Monthly AMP means the AMP that is calculated on a monthly basis. A manufacturer must submit a monthly AMP to CMS not later than 30 days after the last day of each prior month.

(2) *Calculation of monthly AMP.* In calculating monthly AMP, a manufacturer may estimate the impact of its end-of-quarter discounts and allocate these discounts in the monthly AMPs reported to CMS throughout the rebate period. The monthly AMP should be calculated based on the methodology in § 447.504 of this subpart, except the period covered will be one month. Further, monthly AMP should be calculated based on the best data available to the manufacturer at the time of submission.

(3) *Prohibition against reporting revised monthly AMP.* In calculating monthly AMP, a manufacturer should not report a revised monthly AMP later than 30 days after each month, except in exceptional circumstances authorized by the Secretary.

(e) *Certification of pricing reports.* Each report submitted under paragraphs (a) through (d) of this section must be certified by one of the following:

(1) The manufacturer's Chief Executive Officer (CEO);

(2) The manufacturer's Chief Financial Officer (CFO); or

(3) An individual who has delegated authority to sign for, and who reports directly to, the manufacturer's CEO or CFO.

(f) *Recordkeeping requirements.* (1) A manufacturer must retain records (written or electronic) for 10 years from the date the manufacturer reports data to CMS for that rebate period. The records must include these data and any other materials from which the calculations of the AMP, the best price, customary prompt pay discounts, and nominal prices are derived, including a record of any assumptions made in the calculations. The 10-year time frame applies to a manufacturer's quarterly and monthly submissions of pricing data, as well as any revised quarterly pricing data subsequently submitted to CMS.

(2) A manufacturer must retain records beyond the 10-year period if both of the following circumstances exist:

(i) The records are the subject of an audit or of a government investigation related to pricing data that are used in AMP, best price, customary prompt pay discounts, or nominal prices of which the manufacturer is aware.

(ii) The audit findings or investigation related to the AMP, best price, customary prompt pay discounts, or nominal price have not been resolved.

(g) *Data reporting format.* All product and pricing data, whether submitted on a quarterly or monthly basis, must be submitted to CMS in an electronic format.

§ 447.512 Drugs: Aggregate upper limits of payment.

(a) *Multiple source drugs.* Except for brand name drugs that are certified in accordance with paragraph (c) of this section, the agency payment for multiple source drugs must not exceed, in the aggregate, the amount that would result from the application of the specific limits established in accordance with § 447.514 of this subpart. If a specific limit has not been established under § 447.514 of this subpart, then the rule for ''other drugs'' set forth in paragraph (b) applies.

(b) *Other drugs.* The agency payments for brand name drugs certified in accordance with paragraph (c) of this section and drugs other than multiple source drugs for which a specific limit has been established under § 447.514 of this subpart must not exceed, in the aggregate, payment levels that the agency has determined by applying the lower of the—

(1) Estimated acquisition costs plus reasonable dispensing fees established by the agency; or

(2) Providers' usual and customary charges to the general public.

(c) *Certification of brand name drugs.* (1) The upper limit for payment for multiple source drugs for which a specific limit has been established under § 447.514 of this subpart does not apply if a physician certifies in his or her own handwriting that a specific brand is medically necessary for a particular recipient.

(2) The agency must decide what certification form and procedure are used.

(3) A checkoff box on a form is not acceptable but a notation like ''brand necessary'' is allowable.

(4) The agency may allow providers to keep the certification forms if the forms will be available for inspection by the agency or HHS.

§ 447.514 Upper limits for multiple source drugs.

(a) *Establishment and issuance of a listing.*

(1) CMS will establish and issue listings that identify and set upper limits for multiple source drugs that meet the following requirements:

(i) The FDA has rated two or more drug products as therapeutically and pharmaceutically equivalent in their most current edition of ''Approved Drug Products with Therapeutic Equivalence Evaluations'' (including supplements or in successor publications), regardless of whether all such formulations are rated as such and only such formulations shall be used when determining any such upper limit.

(ii) At least two suppliers list the drug, which has met the criteria in paragraph (a)(1)(i) of this section, based on all listings contained in current editions (or updates) of published compendia of cost information for drugs available for sale nationally.

(2) CMS publishes the list of multiple source drugs for which upper limits have been established and any revisions to the list in Medicaid program issuances.

(b) *Specific upper limits.* The agency's payments for multiple source drugs identified and listed periodically by CMS in Medicaid program issuances must not exceed, in the aggregate, payment levels determined by applying for each drug entity a reasonable dispensing fee established by the State agency plus an amount established by CMS that is equal to 250 percent of the average manufacturer price (as computed without regard to customary prompt pay discounts extended to wholesalers) for the least costly therapeutic equivalent.

(c) *Ensuring a drug is for sale nationally.* To assure that a drug is for sale nationally, CMS will consider the following additional criteria:

(1) The AMP of a terminated NDC will not be used to set the Federal upper limit (FUL) beginning with the first day of the month after the actual termination date reported by the manufacturer to CMS.

(2) Except as set forth in paragraph (c)(3) of this section, in establishing the FUL, the AMP of the lowest priced therapeutically and pharmaceutically equivalent drug that is not less than 30 percent of the next highest AMP will be used to establish the FUL.

(3) When the FUL group includes only the innovator single source drug and the first new generic or authorized generic drug enters the market, the criteria in paragraph (c)(2) of this section will not apply.

§ 447.516 Upper limits for drugs furnished as part of services.

The upper limits for payment for prescribed drugs in this subpart also apply to payment for drugs provided as part of skilled nursing facility services and intermediate care facility services and under prepaid capitation arrangements.

§ 447.518 State plan requirements, findings and assurances.

(a) *State plan.* The State plan must describe comprehensively the agency's payment methodology for prescription drugs.

(b) *Findings and assurances.* Upon proposing significant State plan changes in payments for prescription drugs, and at least annually for multiple source drugs and triennially for all other drugs, the agency must make the following findings and assurances:

(1) *Findings.* The agency must make the following separate and distinct findings:

(i) In the aggregate, its Medicaid expenditures for multiple source drugs, identified and listed in accordance with § 447.514(a) of this subpart, are in accordance with the upper limits specified in § 447.514(b) of this subpart; and

(ii) In the aggregate, its Medicaid expenditures for all other drugs are in accordance with § 447.512 of this subpart.

(2) *Assurances.* The agency must make assurances satisfactory to CMS that the requirements set forth in §§ 447.512 and 447.514 of this subpart concerning upper limits and in paragraph (b)(1) of this section concerning agency findings are met.

(c) *Recordkeeping.* The agency must maintain and make available to CMS, upon request, data, mathematical or statistical computations, comparisons, and any other pertinent records to support its findings and assurances.

§ 447.520 FFP: Conditions relating to physician-administered drugs.

(a) No FFP is available for physician-administered drugs for which a State has not required the submission of claims using codes that identify the drugs sufficiently for the State to bill a manufacturer for rebates.

(1) As of January 1, 2006, a State must require providers to submit claims for single source, physician-administered drugs using Healthcare Common Procedure Coding System codes or NDC numbers in order to secure rebates.

(2) As of January 1, 2008, a State must require providers to submit claims for the 20 multiple source physician-administered drugs identified by the

Secretary as having the highest dollar value under in the Medicaid program using NDC numbers in order to secure rebates.

(b) As of January 1, 2007, a State must require providers to submit claims for physician-administered single source drugs and the 20 multiple source drugs identified by the Secretary using NDC numbers.

(c) A State that requires additional time to comply with the requirements of this section may apply to the Secretary for an extension.

(Catalog of Federal Domestic Assistance Program No. 93.778, Medical Assistance Program)
(Catalog of Federal Domestic Assistance Program No. 93.773, Medicare—Hospital Insurance; and Program No. 93.774, Medicare—Supplementary Medical Insurance Program.)

Dated: August 10, 2006.

Mark B. McClellan,

Administrator, Centers for Medicare & Medicaid Services.

Approved: October 16, 2006.

Michael O. Leavitt,

Secretary.

[FR Doc. 06–9792 Filed 12–15–06; 4:51 pm]

BILLING CODE 4120–01–P