

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Part 447

[CMS-2238-FC]

RIN 0938-AO20

Medicaid Program; Prescription Drugs

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

ACTION: Final rule with comment period.

SUMMARY: This final rule with comment period will 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 HHS to promulgate a final regulation no later than July 1, 2007. In addition, we are adding to existing regulations certain established Medicaid rebate policies that are currently set forth in CMS guidance. This rule will bring together existing and new regulatory requirements in one, cohesive subpart.

Finally, this final rule with comment period allows for further public comment on the Average Manufacturer Price and Federal upper limit (FUL) outlier section of the rule.

DATES: *Effective Date:* These regulations are effective on October 1, 2007.

Comment date: To be assured consideration, comments must be received at one of the addresses provided below, no later than 5 p.m. on January 2, 2008.

ADDRESSES: In commenting, please refer to file code CMS-2238-FC. 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-FC, P.O. Box 8012, Baltimore, MD 21244-8012.

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-FC, Mail Stop C4-26-05, 7500 Security Boulevard, Baltimore, MD 21244-8012.

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 (AMP)).

Joseph Fine, (410) 786-2128 (for issues related to the determination of 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 FULs).

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 (RIA)).

SUPPLEMENTARY INFORMATION:

Submitting Comments: We welcome comments from the public on the AMP and FUL outlier provisions as 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-FC.

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 be also available for public inspection as they are received, generally beginning approximately three 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

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 the national 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 final rule implements sections 6001(a)-(d), 6002, and 6003 of the DRA, Pub. L. 109-171 (Feb. 8, 2006). It also codifies those parts of section 1927 of

the Act that pertain to requirements for drug manufacturers' calculation and reporting of AMP and best price, and it revises existing regulations that set upper payment limits for certain covered outpatient drugs. This final rule also implements 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 rule addresses other provisions of the Medicaid 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 rebate agreement (56 Fed. Reg. 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 final 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 FULs 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.

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 finalized 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, effective January 1, 2007, to permit States to use AMP to calculate payment rates.

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 were not addressed in the 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) of the Act 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.

C. Proposed Rule Published September 19, 1995

On September 19, 1995, CMS (then the Health Care Financing Administration) published a proposed rule in the **Federal Register** (60 FR 48442 (Sept. 19, 1995)). The purpose of the 1995 proposed rule 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 proposed rule 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 proposed rule 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 proposed rule are outside the scope of this final rule with comment period. This final rule with comment period 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 (§ 447.500)

We proposed that 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 the proposed rule, we also proposed to move the existing Medicaid drug provisions in the Federal regulations from subpart F to subpart I of 42 CFR part 447.

Definitions (§ 447.502)

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

We proposed to define “bona fide service fee” as 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.

We proposed to define “brand name drug” as a single source or innovator multiple source drug.

We proposed to define “bundled sale” as 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 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.

We proposed to define “Consumer Price Index—Urban (CPI-U)” as the same as it is defined 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.

We proposed to define “dispensing fee” 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 proposed to define 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 proposed 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 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 encouraged States to analyze the relationship between AMP and pharmacy acquisition costs to ensure that the Medicaid Program appropriately reimburses pharmacies for estimated acquisition costs.

We proposed to define “dispensing fee” 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.

We proposed to define “innovator multiple source drug” based on the definition in section 1927(k)(7)(A)(ii) of the Act. We also proposed using 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 (PLA), Establishment License Approval (ELA) or Antibiotic Drug Approval (ADA). 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.

We proposed to define “manufacturer” 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, we proposed that 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 proposed to remove the definition from that section and revise the definition to reflect the DRA amendments to section 1927 of the Act. We proposed to 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.

We proposed to define "national drug code (NDC)" 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 national rebate agreement, including reporting timeframes, manufacturer responsibilities, penalties, and confidentiality of pricing data. We proposed 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.

We proposed to define "nominal price" as it is in the national rebate agreement. We proposed 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). We proposed that 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 proposed to 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 PLA, ELA, or ADA.

We proposed to define the term single source drug as it is defined in the statute and the national rebate agreement.

Determination of Average Manufacturer Price (§ 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 NDC 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 (that is, 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 addressed these recommendations as we discussed provisions of the 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 (for example, 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 proposed excluding 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 (for example, 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. We proposed that 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 (for example, 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 proposed excluding 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 proposed including 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 proposed maintaining these prices in the definition. We noted 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 sought 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 recognized 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 considered 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 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 the 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 proposed 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 invited comments on whether this proposal is operationally feasible.

As discussed more fully below, we 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 acknowledged that manufacturers have a variety of arrangements with PBMs and thus invited comments on all aspects of our proposal as explained below.

The national 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 Manufacturer Release 28 and reiterated in Manufacturer 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 national 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 were 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 invited comments on this definition and whether AMP should be calculated to include all adjustments that affect net drug prices.

We acknowledged 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 proposed that these lower prices should be included in the AMP calculations. We requested 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 solicited 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 solicited 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 requested comments on any other issues that we should take into account in making our final decisions. These included, but were not 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 (for example, growth of "preferred" generic drugs); and possible impacts on reimbursement for brand name drugs under Medicaid. We were generally interested in comments on how and to what extent PBMs act as "wholesalers." We proposed 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 proposed to clarify and the proposed clarifications follow.

Retail Pharmacy Class of Trade: We proposed 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 (for example, retail, independent, chain and mail order pharmacies), except as otherwise specified by the statute or regulation (for example, 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 proposed 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; that is, 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 the proposed rule, we also proposed clarifying that prices to State Children's Health Insurance Program (SCHIP) Title XIX 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 the proposed rule, we proposed clarifying that the units associated with Medicaid sales should be included as part of the total units in the AMP calculation. We 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 proposed clarifying 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.

We also proposed to clarify how the prices of sales to SCHIP Title XXI 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 proposed clarifying 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 the proposed rule, we also proposed 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 proposed 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 proposed that any prices on or after October 1, 1992, to the Indian Health Service (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 PHS); any prices charged under the FSS of the General Services Administration (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 proposed 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 Rebate 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 proposed that all fees except fees paid for bona fide services should be included in AMP. We proposed 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 through 70251) that implemented the ASP provisions enacted in the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA). We did not propose to define fair market value. However, CMS invited 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 proposed that these sales and the rebates associated with these sales to patients through direct programs would be included in AMP. CMS invited 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 proposed 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 the proposed rule, we proposed to clarify how manufacturer coupons should be treated. The treatment of manufacturer coupons has been problematic for CMS as well as some manufacturers. We proposed 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 the proposed rule, we proposed to exclude coupons redeemed by the consumer directly to the manufacturer from the calculation of AMP. CMS invited comments from the public on the 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 proposed 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 proposed a new §447.504. In §447.504(a), we proposed a revised definition of AMP and clarified that AMP is determined without regard to customary prompt pay discounts extended to wholesalers. In §447.504(b), we proposed to define average unit price. In §447.504(c), we proposed to define customary prompt pay discount. In §447.504(d), we proposed to define net sales. In §447.504(e), we proposed to define retail pharmacy class of trade. In §447.504(f), we proposed to define wholesaler. In §447.504(g), we described in detail the sales, rebates, discounts, or other price concessions that must be included in AMP. In §447.504(h), we described the sales, rebates, discounts, or other price concessions that must be excluded from AMP. In §447.504(i), we provided 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 (§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;

- Must be determined on a unit basis without regard to special packaging, labeling or identifiers on the dosage form or product or package;
- 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 Medicare Modernization Act of 2003 (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 FDCA.

In the proposed rule we proposed 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 FDCA, 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 proposed 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 proposed 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 was reasonable to propose these provisions in the proposed rule, consistent with long-standing Medicaid Drug Rebate Program policy and the MMA with respect to best price as revised by the DRA.

We proposed 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 proposed 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 proposed 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.

We proposed 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 national 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 proposed to codify this policy in the proposed rule.

Customary Prompt Pay Discounts: The DRA revises the definition of AMP to exclude customary prompt pay discounts to wholesalers; however, it does not change the definition of best price to exclude customary prompt pay discounts. Therefore, we proposed 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 Manufacturer Release 28 and reiterated in Manufacturer 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 proposed 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, we proposed that these lower prices should be reflected in best price calculations. We acknowledged 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), we proposed that the PBM rebates, discounts, or chargebacks should be included in best price. We proposed to consider these rebates, discounts, or chargebacks in best price calculations. CMS invited public comment on the inclusion of certain PBM price concessions in the determination of best price. Also, we solicited 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 proposed 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 proposed 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 proposed to clarify and the proposed clarifications follow.

Administrative and Service Fees: We proposed 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 proposed 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 the proposed rule, we proposed 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 proposed 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 proposed that the prices listed

above be included for the purpose of calculating AMP, we proposed 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 the proposed rule, we proposed 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 (for example, retail pharmacy). We proposed 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 the proposed rule, we proposed to exclude coupons redeemed by the consumer directly to the manufacturer from the calculation of best price. CMS invited 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 proposed to exclude Medicaid rebates from best price. Likewise, we considered rebates paid under CMS-authorized separate (supplemental) Medicaid drug rebate agreements with States to meet this requirement and proposed 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 proposed a new § 447.505. In § 447.505(a), we provided a general definition of the term best price. In § 447.505(b), we proposed to define the sales and prices which must be included in best price. In § 447.505(c), we specified the price reductions and other pricing arrangements included in the calculation of best price.

Authorized Generic Drugs (§ 447.506)

In the proposed rule, we stated that 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 multiple source drug or brand manufacturer’s original NDA, but labeled with a different NDC than the innovator multiple source drug 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.

We proposed to implement section 6003 of the DRA by proposing 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 an NDA 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 proposed 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 proposed a broad definition of authorized generic drugs rather than a more narrow definition of such drugs. We proposed 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 welcomed comments on this issue.

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

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

In § 447.506(b), we proposed requiring 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 FDCA).

In § 447.506(c), we proposed requiring 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 FDCA 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 (§ 447.508)

Pursuant to the terms of the national rebate agreement, manufacturers excluded from their best price calculations outpatient drug prices below ten percent of the AMP. The national 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 proposed 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 proposed 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 (GPO) or other group purchasing arrangement. We did not believe it necessary to elaborate further on these entities. We proposed 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 proposed 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 chose 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 could 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 did not propose to do so in the proposed 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 considered crafting further guidance to address this issue. CMS invited 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, we proposed that 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 proposed a new § 447.508 in which we specified those entities to which a manufacturer of covered outpatient drugs may sell at nominal price and provided for the exclusion of such sales from best price.

Requirements for Manufacturers (§ 447.510)

On August 29, 2003, CMS finalized two of the provisions in the 1995 proposed rule 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 12 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 proposed 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 12 quarters from the quarter in which the data were due. We proposed 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 proposed 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 proposed this amendment so that the additional rebate would not increase due to changes in the definition of AMP. We proposed 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 proposed 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 were giving manufacturers this option because we were 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 (for example, 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, we proposed requiring manufacturers to report AMP and best price to CMS not

later than 30 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 did not believe that this reading is the better reading of the statute. 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 (URA) for single source and innovator multiple source drugs. While the DRA requires AMPs to 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 proposed 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 proposed requiring in § 447.510(d) that manufacturers must submit monthly AMP to CMS not later than 30 days after each month. We also proposed requiring manufacturers to report quarterly AMP, best price, and customary prompt pay discounts on a quarterly basis.

We proposed 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 recognized 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 proposed 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 were not certain that such rebates or other price concessions could be allocated with respect to monthly AMP calculations. We invited comments on allowing the use of 12-month rolling average estimates of all lagged price concessions 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 (that is, a rolling three-month AMP). While this methodology may minimize volatility in the data, we believed it would be fairly complex for manufacturers to operationalize. We encouraged 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 proposed to make the quarterly AMP publicly available. We noted 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 proposed to require that manufacturers report nominal price exception data to CMS on a quarterly basis. We further proposed 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 proposed to require that manufacturers certify the pricing reports they submit to CMS in accordance with § 447.510. We proposed 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 proposed 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 proposed to require manufacturers to use one uniform data transmission format to transmit and collect these data. We stated that CMS will issue operational instructions to provide additional guidance regarding the new electronic data submission requirements.

Aggregate Upper Limits of Payment (§ 447.512)

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

Upper Limits for Multiple Source Drugs (§ 447.514)

We proposed 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 proposed 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 (that is, manufacturers, wholesalers, repackagers, 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 (for example, Red Book, First DataBank, or Medi-Span). Then, using these pricing compendia, we select the lowest price (for example, the average wholesale price (AWP), wholesale acquisition cost (WAC), 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 proposed that the FUL will be established, as per section 1927(e)(4) of the Act, only using an “A” rated drug. However, we proposed to continue our current practice of applying the FUL to all drug formulations, including those drug versions not proven to be therapeutically equivalent, (for example, 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 proposed 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 proposed in § 447.514(a)(1)(ii) that a FUL will be set when at least two suppliers (for example, manufacturers, wholesalers, re-packagers, or re-labelers) list the drug in a nationally available pricing compendia (for example, 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 proposed 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 did not believe computing an AMP at the 11-digit NDC would be significantly more difficult than computing the AMP at the 9-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 proposed 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 believed it would offer minimal advantages. Furthermore, we expected 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 asked for comments on the alternative approach of using the 11-digit NDC to calculate the AMP. We invited comments on the merits of using both approaches in calculating the AMP for the FUL.

In computing the FUL, we proposed 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 seven 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 proposed that a FUL update of drugs, using the new methodology first be published when the revised AMPs are available and processed.

We proposed 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 proposed 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 proposed 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 proposed to use this percentage calculation as a benchmark to prevent an outlier price from determining the FUL, but invited 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 noted 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 welcomed suggestions about other means to address outliers and whether outliers should be addressed at all.

We proposed 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 invited comments from the public on all issues set forth in this subpart. We invited 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. We asked commenters to please submit data supporting their proposals when available. Upper Limits for Drugs Furnished as Part of Services (§ 447.516)

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

State Plan Requirements, Findings and Assurances (§ 447.518)

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

FFP: Conditions Relating to Physician-Administered Drugs (§ 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 referred 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 did not propose 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 proposed that the list 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 proposed, 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 believed 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 did not propose any criteria for reviewing these extension requests as we expected that most, if not all States would 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 expected that States would require physicians to submit all claims using NDC numbers, as using multiple billing systems would be burdensome for physicians and States. This would also advantage States because rebates would be collectible on all physician-administered drugs.

For States not currently billing manufacturers for rebates on single source drugs, we believed 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 proposed to 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 proposed requiring States to require providers to submit claims using NDC numbers. In § 447.520(c), we proposed allowing States that require additional time to comply with the requirements of this section to apply to the Secretary for an extension.

III. Analysis of and Responses to Public Comments

We received over 1,600 timely items of correspondence that addressed the issues in the proposed rule. We received comments from pharmacists and other health care providers, drug manufacturers, membership organizations, law firms, PBMs, consultants, State agencies, members of Congress, and individuals. A summary

of the major issues and our responses follow.

General Comments

We received many comments expressing general support for the provisions of the proposed rule. One commenter specifically indicated support for Federal efforts that are designed to positively affect the affordability of and access to prescription drugs and healthcare professionals. Other commenters indicated support for CMS' efforts to clarify the definitions of significant terms as well as the treatment of various types of sales and prices in manufacturer calculations.

Comment: Commenters asked CMS to explain how we will reconcile the national rebate agreement with this final rule, which substantially changes a number of the definitions and requirements of the agreement. One commenter asked CMS to specify that it will not incorporate into a revised national rebate agreement any definitions or requirements until such provisions have been subject to notice-and-comment rulemaking.

Response: The national rebate agreement provides that manufacturers should comply with the Medicaid rebate statute, any amendments to that statute, and regulations issued by the Secretary to implement the statute. We will consider revising the national rebate agreement in accordance with applicable Federal statutes and regulations.

Effective Date

Comment: Many commenters asked CMS to clarify that the provisions of this final rule will be applied prospectively. One commenter specifically asked for clarification of the effective date of the provision regarding the treatment of Medicaid sales in AMP. Another commenter expressed concern that CMS should have published the proposed rule by September 1, 2006 to provide adequate time for community pharmacies to prepare for the implementation of the changes in the Medicaid Program.

Response: In this final rule, we are bringing together existing and new regulatory requirements in one cohesive subpart. Unless otherwise indicated, these regulations are effective on October 1, 2007. However, this rule is not designed to delay the effective date with respect to statutory provisions, regulations or policies that are already in effect. Those existing requirements that remain unchanged in this final rule will continue in force. In addition, to the extent that this rule addresses

previous policies already established by the Agency, those policies will remain in effect. Further, the DRA provided specific effective dates for certain provisions as noted in the preamble to the proposed rule.

Comment: Many commenters asked us to consider delaying implementation of the final rule. Several commenters suggested that we delay the overall effective date of this final rule at least six months from the date of publication in order to provide manufacturers with necessary time to revise their systems and retrain personnel on the requirements of this final rule. One commenter noted that government pricing system vendors will need between six months to one year after the effective date of this final rule to code, implement and test the required computer changes.

Other commenters suggested a delay of four quarters for the entire rule. One commenter suggested we delay finalizing the rule until more detailed information regarding AMP and the established FUL is made available to the pharmacy industry; another commenter suggested a delay of 90 days after the release of the new FUL source file. Another commenter suggested a 180-day compliance period followed by a 90-day testing period, during which time the AMP may only be used for research and verification purposes only.

A few commenters specifically asked that we delay the implementation of the requirement that manufacturers submit a base date AMP. Another commenter noted that the practical implication of treating inpatient and outpatient hospital sales differently for AMP purposes would mean that hospital contracts for the purchase of prescription drugs would need to be renegotiated, which could necessitate a delay in the implementation of the AMP rule for six months to a year.

Response: The DRA provides specific timeframes for the implementation of many of the major provisions addressed in this final rule. Because the DRA was signed into law on February 8, 2006, we believe there was sufficient time for affected parties to prepare for the implementation of these provisions. In addition, CMS issued guidance to States and manufacturers in December, 2006 to address many of the details pertaining to the drug provisions in the DRA. Accordingly, we are not convinced that there is a compelling reason to delay implementation of the provisions of this final rule beyond the October 1, 2007, effective date.

Comment: One commenter recommended that CMS do more to educate Medicare participating

providers, particularly pharmacies, about the changes in reimbursement addressed in this final rule.

Response: We received hundreds of comments on the proposed rule from individual pharmacy providers and national pharmacy membership organizations. Therefore, we believe there is already a high level of awareness about how the provisions of this final rule will impact pharmacies. In addition, we recognize the vital role that States play in the State-Federal Medicaid partnership by establishing relationships with pharmacy providers. States process pharmacy claims, maintain participating provider lists, and provide a variety of information directly to pharmacies. Therefore, we continue to believe that States are in a better position to provide any education to pharmacies to the extent that States may opt to revise their payment rates.

Comment: One commenter noted that if we had published the proposed rule earlier, it would have been easier for all affected parties to meet the deadlines mandated in the DRA. The commenter asked that CMS extend the comment period for the proposed rule for an additional 60 days. One commenter expressed concern that our proposed rule did not contain enough discussion of the issue of bundled sales in § 447.502 to provide reasonable notice and an opportunity for comment. The commenter suggests that CMS provide some alternative mechanism or forum for manufacturers and other interested parties to have more substantial and more specific communication with CMS on this issue.

One commenter urged CMS to issue an interim final rule with comment period instead of this final rule. The commenter expressed confusion regarding the correct interpretation of a number of provisions in the proposed rule. The commenter believes that an interim final rule with comment period would foster even greater dialog between the pharmaceutical industry and CMS.

Response: We disagree with the commenters regarding the need for an additional comment period for the vast majority of issues addressed in this final rule. However, as discussed below in greater detail, we have decided to publish the AMP and FUL outlier provision as a final rule with an extended comment period. This will allow for further public comment after the clarified definition of AMP becomes effective and it will give CMS an opportunity to further revise this provision.

Definitions (§ 447.502)

Bundled Sale

Comment: One commenter supported the inclusion of bundled sales in the determination of AMP.

Response: We appreciate the support for this provision and have retained this requirement in the final rule.

Comment: One commenter said that the proposed definition of what constitutes a bundled agreement is confusing. For example, it could be assumed that any type of comprehensive, multi-product portfolio contract could fit within CMS' proposed new definition. The commenter does not believe that this is CMS' intent. The commenter asked us to provide examples of bundled discounts that meet the final definition.

Response: We appreciate the comment and are including an example to provide some additional clarity. This example is for illustrative purposes only as the complexity of the market place prevents us from describing every situation.

Bundled Sale Example

Products A and B are sold under a bundled arrangement and have a combined bundled discount equal to \$200,000 on total undiscounted sales of \$1 million. If Product A has undiscounted sales of \$600,000 and product B has undiscounted sales of \$400,000, the manufacturer would allocate 60 percent of the combined bundled discount to Product A when calculating AMP. Forty percent of the combined bundled discount would be allocated to Drug B. The effective unit price of each product would be calculated by subtracting the discount allocated to each drug product (\$600,000 – \$120,000 = \$480,000 for Product A; \$400,000 – \$80,000 = \$320,000 for Product B) and dividing the result by the number of units for each drug product in the bundled sale.

Comment: Several commenters requested that CMS explicitly clarify how bundled discounts that meet the definition should be allocated across products.

Response: We appreciate this comment and have clarified the regulation at § 447.502 to specify how to allocate a discount. We have clarified that where multiple drugs are discounted, the aggregate value of all the discounts in the bundled arrangement should be proportionately allocated across all the drugs in the bundle.

Comment: Several commenters said that CMS should not include sales of the same drug in the definition of bundled

sale. Another commenter requested that CMS confirm that the proposed “bundled sale” definition applies to sales of the same drug only where the manufacturer provides free or discounted goods contingent on a purchase requirement. The commenter stated that they can conceive of only one instance where sales of the same drug properly should be considered bundled—where the manufacturer provides a discount or free drugs if the purchaser agrees to buy a certain amount of the same drug; for example, “buy nine, get one free” or “buy nine, get the tenth at half price.” The commenter believes that such sales essentially represent volume discounts, and the discount properly should be apportioned across the drugs provided by the manufacturer in the bundled (or contingent) arrangement. The commenter stated that the Medicaid rebate statute mandates such a result, requiring “free goods that are contingent on any purchase requirement” and volume discounts to be included in best price.

Response: A contingent arrangement involving drugs with different NDC-9s constitutes a bundled arrangement. A contingent arrangement involving drugs that share the same NDC-9 may constitute a bundled sale or volume discount. For these types of arrangements, the aggregate value of all the discounts must be allocated proportionately to all drugs within the bundled or volume discount arrangement.

Comment: One commenter stated that CMS should define “drugs of different types” as those with different 9-digit NDC codes and clarify that it is the aggregate value of all the bundled discounts that must be allocated across the drugs in the bundle.

Response: We agree. The definition of bundled sale provides that drugs are considered to be the same drug when they share a 9-digit NDC and are considered to be drugs of different types when their 9-digit NDCs are not the same.

Comment: A few commenters said that the proposed definition differs significantly from the definition of bundled sales provided in the Medicaid rebate agreement and that it contains a number of vague and ambiguous terms.

Response: The clarification of the bundled sales definition in this final rule does not create a new definition or impose new obligations that did not already exist under the Rebate Agreement. It has always been our policy that AMP and best price must be adjusted to reflect discounts offered in bundled sale arrangements to those

entities included in the determination of AMP and best price.

Comment: Several commenters said that CMS does not provide any explanation for why it proposes to change the definition of bundled sale, describe the policy objectives the changes are intended to promote, or provide sufficient specificity to give adequate notice and opportunity to comment. Should CMS wish to pursue this new definition, the commenters requested that CMS provide additional information regarding the new definition and another opportunity for comment before the definition is finalized. In the interim, CMS should clarify that manufacturers may continue to rely on the definition included in the national rebate agreement.

Response: We believe that it is necessary to clarify the definition of a bundled sale because of questions we have received from manufacturers. Our policy objective is unchanged from that set forth in the rebate agreement inasmuch as manufacturers are required to report the effect of these and other arrangements that affect price on AMP and best price. The proposed rule was designed to clarify the definition in the rebate agreement and program guidance and to specify that AMP and best price must be adjusted to reflect discounts, rebates or other price concessions for all drugs in a bundled or contingent sale arrangement.

Comment: One commenter said that there are important implications that CMS should evaluate regarding the proposed new definition of "bundled sale" given that it differs significantly from that term's definition in the Medicaid Drug Rebate Agreement. The commenter believes that the new proposed definition would not improve the accuracy of rebate calculations. Since there is no compelling policy rationale for the new proposed definition and there is no demonstrated problem with the current definition, the proposed change does not appear necessary and serves no purpose.

Response: We believe that this clarification will enable manufacturers to better understand what constitutes a bundled sale and how discounts offered with bundled sales must be allocated when reporting the AMP and best prices for drugs in the bundle.

Comment: One commenter requested that CMS clarify how discounts should be allocated when a bundled sale arrangement includes both contingent and non-contingent discounts and rebates.

Response: We consider all contingent and non-contingent drugs to be within the bundled sale if any drug must be

purchased in order to get a discount on any drug in the bundle regardless of whether any drug is purchased at full price. Additionally, a bundled sale exists where the discounts available are greater than those which have been received had the drug products been purchased separately and apart from the bundled arrangement.

Comment: Several commenters recommended that CMS apply the bundled sale definition only in situations where a manufacturer cannot determine the price of a specific item and clarify how discounts involved in a bundled sale are to be allocated proportionately when such allocation is needed.

Response: We disagree. To assure the consistent application of this policy by all manufacturers, we believe that the definition, as clarified in this final rule at § 447.502, is needed to clearly and uniformly specify what constitutes a bundled sale and how discounts must be allocated across products in the bundle.

Comment: Another commenter expressed disappointment with the lack of meaningful detail in the proposed rule and noted that it essentially mirrors the bundling proposal CMS articulated last year for ASP in the 2007 Medicare Physician Fee Schedule Proposed Rule.

Response: We have provided further details on the application of this policy in this final rule. We believe a consistent methodology for addressing bundled sales in the Medicaid and Medicare Part B programs will reduce the burden and likelihood of errors for manufacturers calculating and reporting Medicaid rebate prices and ASP.

Comment: One commenter requested that CMS clarify that the new definition does not apply for periods prior to the effective date of this final rule.

Response: The provisions of this final rule do not create a new definition for bundled sales, but merely clarify the existing definition.

Comment: One commenter said that a figure for a prior period may be used as the basis of performance for the current period. For example, if the market share during the previous quarter was 20 percent, and an increase of 2 percent to 22 percent will gain the purchaser a discount of 5 percent, the commenter requested that CMS clarify whether the 5 percent discount should be reallocated to the sales in the prior quarter. The commenter asserts that the five percent discount need not be reallocated to the prior period.

Response: We have clarified in § 447.502 that the bundled sale applies to all drugs for all quarters including prior purchases used in the calculation

of the discount for the contingent and non-contingent drugs. The data used in the determination of bundled sales arrangement should reflect and apply to the month or quarter being used in the determination, for example, in a situation where a manufacturer must achieve a certain market share of the product in one quarter to achieve a discount in the second quarter, CMS would treat the contingent discount as a bundle. The quarter for the prior purchase and current purchase would be used in the determination of the bundled sale arrangement.

Comment: One commenter said that discounts for bundled sales should be used only if the bundled sales are available to a majority of retail pharmacies, and the manufacturer should not include bundled sales available to institutional long-term care or mail order pharmacies.

Response: We do not agree. AMP is based on the "average" price paid to a manufacturer by wholesalers. It does not take into account prices available to a certain percentage of pharmacies. As discussed previously, the calculation of AMP is based on the average price paid to the manufacturer by wholesalers for drugs distributed to the retail pharmacy class of trade. It is calculated to include the sale, as well as the discount, rebate, and other price concession associated with that sale, unless the discount, rebate, or other price concession is excluded by statute or regulation. Accordingly, in a bundled sale, the discount should be allocated to the drugs sold in the bundled sale arrangement, regardless of whether the discount is only available to certain retail pharmacies. We do not include institutional long-term care pharmacies in the retail pharmacy class of trade, while we do include mail order pharmacies.

Comment: One commenter suggested that the language should be clarified to remove room for interpretive error regarding the intent. The phrase "allocated proportionately to the dollar value of the units" should be slightly modified to state "allocated proportionately to the total dollar value of the units" and the word "should" in the last sentence should be amended to "shall."

Response: We agree and have revised the regulation text in § 447.502 to reflect the recommended changes.

Comment: One commenter stated that drugs placed on a formulary without a purchase requirement do not represent a discount on another product and should not be the basis for considering a sale to be bundled. The commenter further stated that the requirement that

the value of the discounts be proportionately allocated across all of the drugs in the bundle could open the door to manipulation of prices reported for bundled products. In addition, there is a large administrative burden for manufacturers to implement a system for aggregating and allocating discounts for bundled sales.

Response: We believe that the clarification of a bundled sale in this final rule at § 447.502 will ensure the accuracy of the AMP and best price calculation and reduce the opportunity for improper manipulation. A bundled sale exists where the rebate, discount, or price concession is “conditioned” upon additional purchase requirements. A bundled sale also exists where the discounts under the arrangement are greater than those which have been received had the drug products been purchased separately and apart from the bundled arrangement. The requirement to allocate discounts for bundled sales is not new for manufacturers that have been participating in the Medicaid drug rebate program. It has always been our policy that AMP and best price must be adjusted to reflect discounts offered as part of bundled sales. Therefore, we do not believe that this final rule places new obligations or additional administrative burdens on manufacturers.

Comment: A few commenters asked CMS to clarify that manufacturers may continue to rely on the definition of bundled sale in the national rebate agreement. Several commenters stated that the definition that is set forth in the national rebate agreement should be retained.

Response: The final regulation does not change the definition of bundled sales at § 447.502 but clarifies the existing definition.

Comment: A few commenters asked for additional guidance on how to treat a discount when its receipt is conditioned on utilization levels for multiple drug products.

Response: We have clarified in this final rule at § 447.502 that aggregate value of all discounts are to be allocated across all the products within the bundled arrangement.

Comment: One commenter stated that the concept of bundled sale does not seem to apply to market share arrangements and asked CMS to clarify what discounts on market based contracts are considered bundled sales for which discounts must be allocated.

Response: Discounts that are contingent on performance requirements, such as the achievement of market share may result in either a bundled arrangement or a volume

discount. In such an arrangement, the aggregate or total value of all the discounts must be allocated to all the drugs in the bundle. For example, if Drug A is discounted to a purchaser if the purchaser achieves a set market share of Drug B, Drugs A and B are part of a bundled arrangement. The total discount for Drug A and any discount on Drug B must be proportionately allocated to both drugs.

Comment: One commenter expressed concern that CMS broadens the definition of “bundled sale” in the proposed rule to potentially include routine multiple drug sales to entities such as wholesalers and GPOs. The commenter does not believe that CMS intended to require that manufacturers allocate on an item-by-item basis the discounts on the price of the drug product had it been sold separately. The commenter recommends that CMS should not broaden the definition of the term “bundled sale.”

Response: We disagree. A bundled sale occurs whenever a discount is given for the purchase of a group of drugs, contingent on the sale of another drug, a performance requirement such as market share arrangements or other purchases. Additionally, a bundled sale also exists where the discounts are greater than those which would have been received if the drugs were purchased separately and outside the bundled arrangement.

Comment: One commenter requested that CMS confirm the information provided in the Medicaid Drug Rebate Operational Training Guide that bundled sale arrangements are limited to arrangements that involve covered outpatient drugs.

Response: We have clarified in the regulation text at § 447.502 that a bundled sale arrangement involves an arrangement for the sale of covered outpatient drugs or some other purchase requirement.

Dispensing Fee

Comment: Some commenters asserted that the proposed definition of dispensing fee inferred a cost-based methodology not reflective of economies and competition in the marketplace. One commenter stated that the proposed definition of dispensing fee inadvertently infers that a pharmacy is entitled to a dispensing fee every time a covered outpatient drug is dispensed. The commenter goes on to say that such a definition does not assure efficient filling schedules for maintenance drugs, and encourages pharmacies to split prescribers' orders to receive more reimbursement, (for example, split a 30-day supply prescription into two 15-day

supplies) particularly in the nursing home setting. Several commenters said that the definition of dispensing fee should incorporate the true cost of a pharmacist's time spent and other real costs such as rent and utilities. One commenter agreed that the definition should be sufficiently broad to accommodate any future costs that pharmacies might incur in dispensing prescriptions to Medicaid beneficiaries, and supported the terminology “includes” and, “are not limited to” in the final definition. One commenter would add “professional” fees to the definition. One commenter notes that the proposed definition refers to “point of sale” which seems to preclude dispensing to Medicaid populations in nursing homes, home and community based settings, etc. A more appropriate replacement would be “point of service.” Several commenters stated that the CMS definition of dispensing fee specifies that pharmacy costs do not include “administrative cost incurred by the States in the operation of the covered outpatient drug benefit including systems costs for interfacing with pharmacies,” and that this disclaimer is unnecessary and confusing as it is obvious that States' costs are not those of pharmacy providers.

Response: We provided a definition in order to assist States in their evaluation of factors used in establishing a reasonable dispensing fee. We did not intend to mandate a specific formula or methodology which States must use when calculating those fees. Therefore, we believe that the definition of dispensing fee is generally sufficient to capture the activities involved with the dispensing of a drug. However, we concur with the commenter about the need to recognize different service settings. Therefore, in the final rule, we are revising the definition of dispensing fee by adding “or service” after “point of sale” in § 447.502. States may also require the prescriptions be filled in specified quantities or to have other measures in place in order to avoid paying additional dispensing fees and encourage efficient filling schedules.

Comment: Many commenters expressed concern that CMS did not propose that States be required to pay a minimum dispensing fee to ensure that pharmacies' operating costs are covered. A few commenters stated that CMS should require States to make a specific finding that their dispensing fee is adequate to cover the cost of dispensing prescriptions to the Medicaid population. Other commenters suggested that we include a comprehensive and accurate definition of dispensing fee in the final rule, issue

formal guidance to States, and require States to conduct annual surveys or studies on the pharmacy provider's cost to dispense a prescription. One commenter stated that the pharmacy dispensing fee should be increased based on the Federal Cost of Living Adjustment. One commenter stated that CMS should advise States if we intend that some profit to the pharmacy be included in the dispensing fee. One commenter believed that the proposed rule should remain silent on the criteria for calculating dispensing fees.

Response: We do not agree that CMS should establish or mandate specific criteria for States to use when setting their dispensing fees. We proposed to define the term dispensing fee in regulation to assist States in their evaluation of factors in establishing a reasonable dispensing fee to providers, and we continue to believe that we should not mandate a specific formula or methodology which the States must use to determine the dispensing fee. We believe that the flexibility provided States is sufficient to allow them to set reasonable dispensing fees. We have not separately identified profit as a component of the dispensing fee as we believe the components of the dispensing fee we have already identified include a reasonable profit. We also do not agree that we should remain silent on the criteria for calculating dispensing fees as we believe it is important that pharmacies be reasonably compensated for the services they provide in dispensing a prescription.

Comment: A few commenters said that allowing the States to determine their dispensing fees, without Federal guidelines or mandates, would permit States with financial problems the latitude to arbitrarily cut dispensing fees. Another commenter suggested that CMS expeditiously approve State plan amendments (SPAs) that would increase pharmacies' professional fees so that they are closer to the actual cost of dispensing and provide a reasonable return. The commenter also proposed that CMS disapprove SPAs that decrease reimbursement paid to pharmacies for the ingredient cost component unless they increase the dispensing fee. One commenter suggested that the language of the proposed regulation should be changed to clarify that States will retain the authority to set reimbursement rates and dispensing fees for single source drugs. Several commenters stated that it is inappropriate for CMS to require States to increase dispensing fees to compensate for decreased reimbursement. One commenter noted that a State decided to raise dispensing

fees for drugs reimbursed with FUL pricing, but admitted that until the State has experience with FUL prices, the State will not know if this dispensing fee compensates pharmacies appropriately.

Response: Dispensing fees must be approved as part of the Medicaid State plan. We encourage States to set reasonable dispensing fees to appropriately pay pharmacies for their costs. We will review State requests to change dispensing fees as to their reasonableness. States need to describe in their State plan the methodology they use to establish drug payment rates (which include dispensing fees) and demonstrate that their dispensing fees are reasonable. We will evaluate requests to change reimbursement for ingredient costs and dispensing fees separately but we encourage States to review their dispensing fees when they consider changes to reimbursement for ingredient costs.

Comment: Many commenters stated that dispensing fees must cover costs to safely and effectively dispense a prescription. Many commenters communicated the findings of surveys such as the Grant Thornton LLP National Study to Determine the Cost of Dispensing Prescriptions in Community Retail Pharmacies, prepared for the Coalition for Community Pharmacy Action (CCPA), published in January 2007, and accessible at <http://www.aphanet.org/AM/Template.cfm?Section=Home&CONTENTID=7641&TEMPLATE=/CM/ContentDisplay.cfm> that reported the average national cost to dispense a prescription to be \$10.50.

Response: We agree that States should set reasonable dispensing fees; however, we disagree that they should be required to use any specific methodology including the Grant Thornton study to do so. States may continue to use other sources to set dispensing fees, such as their own surveys. They may also look at dispensing fees paid to pharmacies by other payers or the amount of dispensing fees paid in neighboring States. CMS intends to permit States to retain the authority to set reasonable dispensing fees and exercise flexibility in setting their dispensing fees.

Comment: Several commenters pointed out that the Congressional Budget Office's (CBO) estimates of savings to the Medicaid Program based on the provisions of the DRA, assumed that States will raise dispensing fees to mitigate the effects of the revised payment limit on pharmacies.

Response: CMS will review any State plan amendments or revisions to drug payment rates, including any revisions to the dispensing fees, to assure

compliance with the applicable statutes and regulations.

Comment: Several commenters stated that CMS should specifically instruct States to establish higher reimbursement for specialty pharmacies, as Medicare Part B has done. Citing section 303(e)(1) of the MMA, which created a furnishing fee for certain blood clotting factors, some commenters felt that a separate furnishing fee should be established for Medicaid providers who dispense prescriptions that may require more time or resources for handling, storing, or delivery.

Response: We do not agree. CMS believes its proposal/provision provides a definition which is reasonable. While CMS appreciates the comment, the MMA provision is not applicable to Medicaid.

Comment: Some commenters stated that a formula for prescription drug reimbursement should include a dispensing and/or education fee as an actual part of the reimbursement. Another commenter stated that a percentage standard or a flat fee should be added to prescription reimbursement to achieve an adequate reimbursement to pharmacy providers.

Response: We disagree. The dispensing fee is determined separately from the cost of the drug ingredient and covers the cost of dispensing the drug as defined in this regulation. As discussed in the proposed rule, dispensing fees are related to the transfer or possession of the drug to the beneficiary. If dispensing fees were bundled with ingredient cost, it would be difficult for CMS or States to determine whether the dispensing fees, as discussed in this regulation, are reasonable.

Comment: Many commenters expressed concern that current dispensing fees, in light of the DRA provisions that change ingredient reimbursement for FUL drugs to a methodology based on AMP, will not cover the pharmacy provider's cost of dispensing medications to the Medicaid population and that, as a result, the dispensing fee should be increased for generic drugs. One commenter asserted that retail pharmacies that serve large numbers of Medicaid beneficiaries may be particularly hard hit. One commenter stated that the proposed rule suggested that the States examine the market realities and adjust their dispensing fee to compensate pharmacies, and while this was an important correction to the reimbursement system, it did not solve the underlying problem presented by an unreasonable system for calculating the FUL.

Response: We believe that States are in the best position to identify and

address what is a reasonable dispensing fee and we encourage them to evaluate and set such dispensing fees. Since the dispensing fee is meant to reflect the cost of dispensing a drug, it should not be affected by the determination of ingredient cost. As we have said elsewhere in this regulation, we believe the system for calculating the FUL will permit pharmacies to be reasonably compensated for drugs they dispense to Medicaid beneficiaries.

Estimated Acquisition Cost

Comment: One commenter suggested that CMS revise the definition of estimated acquisition cost (EAC) by adding at the end, "within the previous twelve months as provided to State Medicaid agencies by the Centers for Medicare & Medicaid Services." This would provide States with more specific guidance and a source from which to draw the information regarding the package size of drug most frequently purchased by providers.

Response: The DRA did not modify the definition of EAC and we have not made any modifications in this regulation. Additionally, States currently report all utilization information to CMS by package size; however, we do not sort by most frequently dispensed or utilized package size. This information is posted on our Web site at <http://www.cms.hhs.gov/MedicaidDrugRebateProgram/SDUD/list.asp>.

Innovator Multiple Source Drug

Comment: One commenter noted that our definition of innovator multiple source drug does not address the situation where, at the end of the life cycle of a particular drug product, the only covered outpatient drug remaining on the market in the U.S. happens to be a version of the product that was originally approved by the FDA under an abbreviated NDA (ANDA). The commenter also noted that we did not address products that came to market before 1962 and remain commercially available today. The commenter suggested that CMS revise the definition of innovator multiple source drugs to address these situations. Other commenters requested that we revise the definition of innovator multiple source drug to include those drugs approved under a biological license application (BLA).

Response: By statute, an innovator multiple source drug is a drug that was originally marketed under an original NDA approved by the FDA. We do not believe that it would be consistent with the statute to modify the definition to include drugs marketed under an

ANDA. To clarify the distinction between multiple source drugs approved under an ANDA and multiple source drugs approved under an NDA, we are adding a definition of noninnovator multiple source drug in this final rule. Noninnovator multiple source drugs are defined as multiple source drugs marketed under an ANDA or an abbreviated antibiotic drug application.

In response to the comments regarding drugs that entered the market prior to 1962, we believe these drugs are not classified as innovator multiple source drugs unless they are marketed under an NDA. Further, we recognize the need to classify drugs that entered the market prior to 1962 that are not marketed under an NDA. Therefore, we are further defining noninnovator multiple source drugs as drugs that entered the market prior to 1962 that were not originally marketed under an original NDA.

In response to comments regarding drugs approved under a BLA, we believe the statutory definition of covered outpatient drug in section 1927 of the Act is sufficient to address these concerns without further revision to the definition of innovator multiple source drug.

Manufacturer

Comment: One commenter recommended that the definition of manufacturer be narrowed such that entities that repackage drugs simply for distribution to retail pharmacies not be considered manufacturers. The commenter noted that these retail pharmacy service repackagers prepare "unit of use" quantities in a highly efficient manner, increasing the efficiencies of prescription dispensing for retail pharmacies, and they should not be responsible for signing rebate agreements with the Secretary of HHS or paying rebates to Medicaid.

Response: The statutory definition of manufacturer clearly includes such repackagers, so we are not excluding them from the definition of manufacturer in this final rule.

Comment: One commenter asked CMS to clarify the meaning of "legal title" in the definition of manufacturer. Specifically, if a product is sold from one manufacturer to another, are the manufacturers required to calculate data based on both labeler codes?

Response: Except as noted in the regulatory provisions pertaining to authorized generics, we would consider the manufacturer holding legal title to the drug to be the labeler whose NDC appears on the label at the time the drug

is dispensed. This is also the labeler responsible for paying rebates.

Comment: One commenter suggested that "manufacturer" should include an entity that does not possess legal title to the NDC but that markets a drug through a private labeling arrangement.

Response: This final rule incorporates the definition in the proposed rule with respect to drugs subject to private labeling arrangements, and provides that, with respect to drugs, the term "manufacturer" will also include the entity that does not possess legal title to the NDC.

Multiple Source Drug

Comment: One commenter suggested that CMS revise the definition of multiple source drug in two ways. First, the commenter asked us to consider the situation where, at the end of the life cycle of a particular drug product, the only covered outpatient drug remaining on the market in the U.S. happens to be a version of the drug that was originally approved by the FDA under an ANDA. Second, the commenter asked us to include products that came to market before 1962 and remain commercially available today.

Response: Multiple source drugs that are marketed under an ANDA are considered noninnovator multiple source drugs. We have added a definition of noninnovator multiple source drugs to this final rule, which we believe addresses this concern as well as the concern regarding products that came to market before 1962.

Comment: One commenter asked us to consider adding products approved under BLAs to the definition of multiple source drug.

Response: The definition of covered outpatient drug in section 1927 of the Act includes biological products, other than vaccines, that are licensed under section 351 of the PHS Act. Drugs that are approved under this statutory provision include products approved under BLAs.

Comment: A few commenters asked us to consider revising or creating separate definitions for multiple source drugs. One component of the definition should define this term with respect to the establishment of the FUL since the FUL will be applied on a particular date of service on a pharmacy claim, while the other component would address this term with respect to the payment of rebates. One of the commenters recommended maintaining the current definition of multiple source drug listed at 42 CFR § 447.301 with a note specifying that FULs are placed on multiple source drugs complying with

the requirements in §§ 447.512 and 447.514.

Response: We disagree with the commenters about the need to revise the definition of multiple source drugs in order to address the application of that term in the context of the FULs. The DRA amended the definition to require that two or more drug products be rated as therapeutically equivalent, pharmaceutically equivalent, or bioequivalent. The DRA also requires CMS to calculate a FUL for each drug that qualifies as a multiple source drug. We believe the regulatory provisions at § 447.514 are sufficient to address the application of the FULs to multiple source drugs.

Comment: One commenter supported the revised definition of multiple source drug, which requires only one other covered outpatient drug to be rated as therapeutically equivalent, pharmaceutically equivalent, and bioequivalent.

Response: We appreciate the support for this definition and agree because the FUL will apply to more drugs.

National Drug Code (NDC)

Comment: A few commenters asked for clarification of the relationship between the 10-digit NDC maintained by the FDA and the 11-digit NDC referenced in the proposed rule. One of these commenters suggested that we define NDC as “the segmented, 10-digit numerical code maintained by the FDA that indicates the labeler, product and package size, and that for commercial and technical reasons, must be converted to an unsegmented 11-digit number by inserting a place-holding zero.” The commenter also noted that the FDA recently published a proposed rule which contemplates changes to the NDC system maintained by the FDA and recommended that CMS consult with FDA prior to finalizing this rule so that, to the extent possible, the agencies can determine how best to harmonize the definition of NDC. Other commenters expressed support for our proposed definition of NDC, particularly as it pertains to 11-digits vs. 9-digits.

Response: We are retaining the use of the 11-digit NDC in the Medicaid Drug Rebate Program. Because we have used the 11-digit code since the start of the Medicaid Drug Rebate Program, we do not believe that it is necessary to clarify this further in the regulation. If the FDA makes changes to the NDC number, at some point in the future, we will determine the effect of this change on the program and respond accordingly.

Rebate Period

Comment: One commenter urged CMS to redefine the rebate period as a monthly period rather than a quarterly period. The commenter cited the new requirement that AMP be reported monthly as support for this change, in addition to the observation that Congress did not explicitly prohibit such a change in the provisions of the DRA.

Another commenter indicated support for maintaining a quarterly rebate period. The commenter noted that in addition to the lack of legislative intent to change the rebate period, establishing a different or more frequent time period would place unnecessary burdens on changing drug manufacturers’ government reporting systems without additional public benefit.

Response: We don’t see a need to redefine the rebate period at this time, so we are maintaining a quarterly rebate period.

Single Source Drug

Comment: A few commenters expressed concern with our definition of single source drug. The commenters noted that certain FDA regulations require biologic products to be approved under a BLA under section 351 of the PHS Act. The proposed definition of single source drug excludes these products. The commenters suggested we revise the definition to include these products as follows: “a covered outpatient drug that is produced or distributed under an original NDA or BLA approved by the FDA, including a drug product marketed by any cross-licensed producers or distributors operating under the NDA or BLA.”

Another commenter noted that our definition does not address the situation where, at the end of the life cycle of a particular drug product, the only covered outpatient drug remaining on the market in the U.S. happens to be a version of the product that was originally approved by the FDA under an ANDA. The commenter also noted that we did not address products that came to market before 1962 and remain commercially available today. The commenter suggested CMS revise the definition of single source drugs to address these situations.

Response: As noted above, we have added a definition of noninnovator multiple source drug to this final rule in order to clarify the distinction between drugs approved under an NDA and drugs approved under an ANDA. We concur with the commenters about the need to address products approved under a BLA in the definition of single

source drug, and have revised the definition in § 447.502 accordingly. However, we believe the statutory definition of covered outpatient drug in section 1927 of the Act is sufficient to address the remainder of these concerns without further revision to the definition of single source drug.

Terms Not Defined in the Proposed Rule

Comment: A few commenters recommended that CMS include in this final rule a definition of covered outpatient drug that addresses both over-the-counter (OTC) products and prescription drug products. The commenter also noted that the statutory definition of covered outpatient drug incorporates grandfathered products and drugs still undergoing the Drug Efficacy Study Implementation (DESI) review process.

Response: We believe the statutory definitions of covered outpatient drug and nonprescription drug in section 1927(k) of the Act, as well as the definition of noninnovator multiple source drug in this final rule, are sufficient to address the concerns raised by the commenters. We do not believe there would be an additional benefit to incorporating a definition of covered outpatient drug in this final rule.

Comment: One commenter asked us to define the term NDA. The commenter states that the term is not defined in the Medicaid Rebate statute, the national rebate agreement, or the FFDC. Another commenter asked us to define the term “original NDA.”

Response: The FDA has extensive information about the NDA process on its Web site at <http://www.fda.gov/cder/regulatory/applications/nda.htm>. We do not see the need to add a definition of NDA in this final rule. Further, the FDA does not make a distinction between an NDA and an original NDA; therefore, we view these terms as having the same meaning.

Comment: One commenter asked CMS to specify that the “United States” means the 50 States and the District of Columbia.

Response: It has been our longstanding policy to define States as the 50 States and the District of Columbia; this is the definition we adopted in the national rebate agreement. Therefore, we concur with the commenter and have added a definition of States as the 50 States and the District of Columbia.

Determination of AMP (§ 447.504)

Definition of Net Sales

Comment: Several commenters requested that CMS clarify that the term

“revenue” in the “net sales” definition refers only to sales dollars associated with a transaction and not revenue recognized for a transaction for financial accounting purposes. This interpretation is consistent with the position CMS already has taken in the context of ASP reporting. Another commenter believes that it is appropriate to define net sales as a measure of actual sales made regardless of the financial accounting treatment of the transaction.

Response: Net sales should be calculated as gross sales less cash discounts allowed and other price reductions (other than the rebates or price reductions excluded by the statute or regulations) which reduce the amount received by the manufacturer. We have defined AMP to center on the concept of a transaction, such that any given transaction includes both the “sale” and any discounts, rebates, or other price concessions associated with that sale. In certain instances, the statute or regulations specifically exclude from the calculation of AMP either certain portions of a transaction or entire transactions with certain entities. Absent such specific exclusions, we believe that manufacturers should calculate AMP by matching sales with their associated price concessions. In the absence of specific guidance, a manufacturer may make reasonable assumptions in its calculations, consistent with the general requirements and the intent of the Act, Federal regulations, and its customary business practices.

Comment: One commenter expressed support for the definition of net sales because it addresses quarterly gross sales revenue less discounts and price reductions which reduce the amount received by the manufacturer.

Response: We appreciate the support for this provision and have retained this requirement in this final rule at § 447.504(d).

Definition of Nursing Home Pharmacies

Comment: One commenter stated that CMS should unambiguously define nursing home pharmacies.

Response: We do not believe that it is necessary to define these entities in the final rule. We remind manufacturers that in the absence of specific guidance, they may make reasonable assumptions.

Definition of Repackagers/Relabelers

Comment: One commenter stated that CMS should unambiguously define repackager/relabelers.

Response: We have defined manufacturer to mean the entity that (except with respect to certain private

labeling arrangements) possesses legal title to the NDC for the covered outpatient drug. We do not believe that further definition is necessary at this time.

Private Labeling Arrangements

Comment: One commenter requested that CMS clarify whether sales under private labeling agreements are or are not included in AMP.

Response: We have clarified that sales to another manufacturer which acts as a wholesaler and does not repackage/relabel under the purchaser’s NDC including private labeling agreements are included in AMP.

Definition of Retail Pharmacy Class of Trade

Comment: Some commenters requested that CMS define the term “general public” used in the proposed definition of retail pharmacy class of trade.

Response: We appreciate the comment but do not believe that further definition is necessary at this time. We remind manufacturers that in the absence of specific guidance, they may make reasonable assumptions.

Comment: A commenter said that retail pharmacy class of trade is not universally defined. Variations may exist in the marketplace among manufacturers as to the class of trade to which PBMs and mail order pharmacies belong. One commenter requested that CMS reconsider the definition of retail pharmacy which will be used in the calculation of AMP. Several commenters requested that CMS define the retail pharmacy class of trade as defined in the Prescription Drug Marketing Act (PDMA) and FDA regulations.

Response: We have revised the definition of retail pharmacy class of trade in § 447.504(e) to mean any independent pharmacy, chain pharmacy, mail order pharmacy, or other outlet that purchases drugs from a manufacturer, wholesaler, distributor, or other licensed entity and subsequently sells or provides the drugs to the general public.

Comment: Several commenters noted that the proposed definition is different from the definition of “retail pharmacy” under Medicare Part D which defines retail pharmacy as a licensed pharmacy that is not a mail order pharmacy from which Part D enrollees can purchase a covered Part D drug. The commenters believe that adopting the Part D definition of retail pharmacy for retail pharmacy class of trade would result in an AMP that more accurately reflects the prices at which retail pharmacies

acquire prescription drugs and prevent confusion and burdensome administrative and recordkeeping requirements for drug manufacturers, health plans, wholesalers, and pharmacies that would result from use of inconsistent definitions.

Response: These statutory requirements applicable to the Medicaid drug rebate program are different from those applicable to Part D. We believe that the definition of retail pharmacy class of trade included in this rule at § 447.504(e) is defined for the purpose of the Medicaid Drug Rebate Program consistent with our interpretation of the applicable statutory requirements.

Comment: One commenter said that the inclusion of “other outlets” provides for a number of entities that are typically not considered retail pharmacies. For example, outpatient clinics are outlets that purchase drugs and provide these drugs to the general public; however, they are not retail pharmacies. The commenter further stated that it seems that the calculation of AMP would have to include these entities since they are not expressly excluded in subsequent paragraphs of the proposed rule.

Response: We believe that the inclusion of “other outlets” allows for the inclusion of sales for those entities, for example physician offices and outpatient clinics, that purchase drugs from the manufacturer and provide them to the general public.

Comment: A commenter stated that the definition of retail pharmacy class of trade should not use general and undefined descriptions such as “independent” or “mail order” pharmacy, or “other outlet.” The definition should be amended to mean any entity in the United States that is licensed as a pharmacy which provides drugs to the general public.

Response: We disagree. We believe that a narrow definition of retail pharmacy class of trade which would exclude independent and mail order pharmacies does not encompass the universe of entities which purchase drugs from manufacturers and provide them to the general public.

Wholesaler

Comment: Several commenters said that CMS should define the term “wholesaler” to mean any entity that purchases drugs from a manufacturer for purposes of resale. This would be consistent with the definition in the national rebate agreement. Another commenter said that “wholesaler” should be defined in a manner that better reflects current law and practice. The commenter proposed wholesaler to

mean any entity that is licensed in a State as a wholesaler distributor of pharmaceuticals to which the manufacturer sells, or arranges for the sale of, covered outpatient drugs, but that does not relabel or repackage the covered outpatient drug. Several commenters requested that CMS define the terms wholesaler, wholesale distribution and distributor be consistent with FDA regulation. The FFCA defines wholesale distributor as any person (other than the manufacturer or the initial importer) who distributes a device or drug from the original place of manufacture to the person who makes the final delivery or sale of the device or drug to the ultimate consumer or user. Under the PDMA regulations, wholesale distributor means any person engaged in the wholesale distribution of prescription drugs, including, but not limited to manufacturers, repackers, own-label distributors, private-label distributors, jobbers, brokers, warehouses, including manufacturers' and distributors' warehouses, chain drug warehouses, and wholesale drug warehouses, independent wholesale drug traders, and retail pharmacies that conduct wholesale distributions. Several commenters support warehousing pharmacy chains, warehousing mass merchant and supermarket pharmacy operations being treated as wholesalers.

Response: We believe that for this final rule to be consistent with current law as well as reflect recommendations made to us by the OIG and relevant comments, it is necessary to revise the definition of wholesaler. We have revised wholesaler at § 447.504(f) to mean any entity (including those entities in the retail pharmacy class of trade) to which the manufacturer sells the covered outpatient drug, but that does not relabel or repackage the covered outpatient drug.

Comment: Another commenter said that the only transactions that should be included in AMP are those prices that (1) are paid by wholesalers to manufacturers, and (2) apply to the purchase of prescription drugs by wholesalers from manufacturers for the wholesalers' redistribution to the retail pharmacy class of trade. The commenter believes that because Congress specifically exempted customary prompt pay discounts between the manufacturer and wholesalers from the definition of AMP, it is reasonable to conclude that they intended that only price concessions between manufacturers and wholesalers be included in AMP.

Response: We disagree. We have defined AMP in § 447.504(a) to be

consistent with the provisions of the DRA and section 1927 of the Act, and include cash discounts and all other price reductions. We have defined wholesaler at § 447.504(f) to mean any entity (including those entities in the retail pharmacy class of trade) to which the manufacturer sells the covered outpatient drugs, but that does not relabel or repackage the covered outpatient drug. The DRA amendment excluded customary prompt discounts "extended to wholesalers" but not other discounts or price reductions applicable to AMP.

Comment: One commenter stated that mail order purchases and discounts, Medicaid or SCHIP payments and discounts, or Medicare Part D payments and discounts should not be included in AMP because the discounts associated with these programs are not provided to entities which qualify as not wholesalers.

Response: We continue to believe that mail order pharmacies serve the general public and have included them in the retail pharmacy class of trade in this final rule at § 447.504(g)(9). We agree, in part with the comments on discounts, rebates or other price concessions from manufacturers to Medicaid, SCHIP, and Part D programs and have clarified at § 447.504(h)(23) that such discounts, rebates, or other price concessions when provided to third party payers such as a SCHIP program or an MA-PD are not included in the determination of AMP. We retained in the regulation text at § 447.504(g) that sales to wholesalers for drugs distributed to the retail pharmacy class of trade (including sales, which are provided to a SCHIP program or an MA-PDP) are included in AMP.

Comment: One commenter stated that it is not possible to determine AMP for direct sales to wholesalers where the wholesaler then sells to an entity that is unknown to the manufacturer. The manufacturer is not able to identify the purchaser or to assess whether the entity was in the retail pharmacy class of trade.

Response: We have modified this final rule at § 447.504(g)(1) to state that manufacturers should include sales to the wholesaler except where the subsequent sale of the drug to an excluded entity could be adequately documented.

Comment: One commenter said that many manufacturers rely on chargeback data to identify the retail pharmacy class of trade for AMP. The commenter requested that CMS confirm that to the extent that there is no chargeback associated with a sale and a manufacturer has no way of knowing

whether the end purchaser was "retail," those sales are excluded from AMP.

Response: We have modified this final rule at § 447.504(g)(1) to state that where the manufacturer can identify with adequate documentation that subsequent sales from the wholesaler are to an excluded entity, the manufacturer can exclude such sales from AMP.

Comment: A few commenters requested that CMS clarify that clearly identifiable indirect sales to excluded entities should be excluded from AMP (for example, sales identified through chargeback data). Similarly, they asked that we confirm that indirect sales to excluded entities, if not identifiable as such by the data available to a manufacturer, are not required to be "excluded."

Response: We have modified this final rule at § 447.504 to state that manufacturers should only exclude sales to the wholesaler where the subsequent sale of the drug to an excluded entity could be adequately documented.

Comment: One commenter noted that the proposed rule does not address whether sales to entities that relabel or repackage under the purchaser's NDC are included in AMP.

Response: We have defined manufacturer at § 447.502 to mean the entity that (except with respect to certain private labeling arrangements) possesses legal title to the NDC for the covered outpatient drug. Therefore, we decided in the final rule that sales to other manufacturers who repackage/relabel under the purchaser's NDC are excluded from AMP.

Comment: One commenter stated that they interpret the definition of wholesaler to mean it is exclusive of any entity that purchases a covered outpatient drug and repackages or relabels using the purchaser's own NDC. The commenter requests that CMS confirm or provide guidance on what is meant for an entity to relabel or repackage under § 447.504(f).

Response: We have clarified at § 447.504(f) that wholesaler means any entity (including those entities in the retail pharmacy class of trade) to which the manufacturer sells covered outpatient drugs, but that does not relabel or repackage the covered outpatient drug. Furthermore, we are requiring at § 447.504(g)(2) that sales to other manufacturers who act as wholesalers and do not repackage/relabel under the purchaser's NDC are included in AMP.

Comment: One commenter requested that CMS delete from the definition of wholesaler, the parenthetical

“(including a pharmacy, chain of pharmacies or PBM).”

Response: We have clarified the definition of wholesaler for these entities in the regulation text at § 447.504(f).

Customary Prompt Pay Discounts

Comment: One commenter asked that CMS confirm that a customary prompt pay discount is the discount “routinely offered by the manufacturer to an individual wholesaler at the time of payment,” and not a historical amount approximating the typical discount offered to all wholesalers.

Response: We agree and have clarified this issue in this final rule at § 447.504(c).

Comment: Several commenters said that customary prompt pay discounts extended to wholesalers should be included in the AMP calculation.

Response: We disagree. The statute requires that customary prompt pay discounts to wholesalers be excluded from AMP.

Comment: One commenter said that the word “routinely” should be deleted from the definition so that any customary prompt pay discounts the manufacturer passes on to the retail pharmacy class of trade are excluded from AMP. The commenter further believes that the definition is overly restrictive because manufacturers may have a standard customary prompt pay policy but may also occasionally offer other prompt pay discounts when a product is introduced or production is expanded to encourage wholesalers and retailers to stock a product without a proven demand. Additionally, manufacturers establish prompt pay standards that are intended to apply to the retail marketplace and expect the wholesaler to honor this policy. Another commenter said that CMS should clarify what is meant by “routinely offered” and specify the criteria that manufacturers should use to determine what is “routine.” In particular, CMS should address whether a customary prompt pay discount is considered routine if (1) it differs across customers; (2) it changes over the life cycle of the product; for example, the prompt pay discount offered at the introduction of the product differs from the prompt pay discount offered for the remainder of the product’s life cycle; and (3) it is different across products.

Response: CMS proposed a definition which we believe is consistent with customary business practice regarding a routine discount extended to all purchasers for payment within a set time period; for example, 30, 60, or 90 days and that would be flexible and

accommodate prompt pay policies for standard sales. Discounts that do not meet this standard which are used for other purposes (for example, marketing, sales, and promotional strategies, special package discounts, incentives, and performance based discounts) are not considered customary prompt pay discounts and should not be excluded from AMP.

Comment: One commenter said that, in restating the base date AMP, if prior data is not available, “customary prompt pay discounts” should be the discount that was typically offered by the manufacturer to wholesalers for prompt pay at the time of the price reporting submission related to such utilization, as reasonably determined by manufacturers. The commenter believes that any other reading would be arbitrary, impractical to implement, and inconsistent with congressional intent. The commenter requested that CMS confirm this interpretation.

Response: Manufacturers must have data on actual prompt pay discounts provided during the period for which the base date AMP applies in order to recompute their base date AMPs. Manufacturers should document how they calculated their base date AMPs and maintain supporting documentation.

Comment: One commenter said that prompt pay discounts, if included in AMP, will have a negative impact on the wholesaler drug distribution system, which needs that cash flow. The commenter further stated that the incentive for customary prompt pay discounts will be eliminated; therefore the impact will be negative to the economy of the industry. If wholesale distribution is negatively impacted, it will have direct consequences on drug availability at the patient level.

Response: The law requires that manufacturers exclude customary prompt pay discounts extended to wholesalers from AMP beginning in January 2007.

Comment: A few commenters agreed with the exclusion of customary prompt pay discounts from the AMP calculation.

Response: We appreciate the support for the provisions. This is a requirement of law and we have retained this requirement at § 447.504(h)(20) in the final rule.

Comment: Several commenters stated that many people in the industry have historically referred to “prompt pay discounts” as “cash discounts;” therefore, to avoid confusion, CMS should clarify the term “cash discounts.” Another commenter requested that the final rule should

further clarify “cash discounts” to exclude any discount off of the purchase price of a drug routinely offered by the manufacturer to a wholesaler for prompt payment of purchased drugs within a specified time from when the payment is due. Another commenter requested that CMS add a parenthetical phrase reading “(except customary prompt pay discounts extended to wholesalers)” after the term “cash discount” in § 447.504(d) and (i).

Response: We agree and have clarified what we mean by cash discounts in the regulation at § 447.504(d). We have also changed §§ 447.504(d) and (i) to add “except customary prompt pay discounts” after “cash discounts.”

Comment: One commenter requested that CMS refrain from defining “cash discounts” in a manner that is inconsistent with the definition of customary prompt pay discounts in the proposed rule. Clarity and consistency of pricing terms is essential for the accurate submission of AMP data.

Response: We agree and have clarified cash discounts in this final rule at § 447.504(d).

Comment: One commenter said that customary prompt pay cash discounts extended by wholesalers to pharmacies should be omitted from AMP. Cash discounts are provided to some retail pharmacies based on financing terms negotiated between the wholesaler and the pharmacy. These are not performance-based discounts. Not all pharmacies, especially independent pharmacies, have the distribution capabilities or the cash flow to take advantage of these terms.

Response: The statute defines AMP as the average price paid to the manufacturer by wholesalers for covered outpatient drugs distributed to the retail pharmacy class of trade, without regard to customary prompt pay discounts extended to wholesalers. Therefore, neither prices nor discounts to those prices offered by wholesalers to pharmacies affect AMP.

Comment: A few commenters agreed with the definition of customary prompt pay discount, but requested that CMS confirm that manufacturers may make reasonable assumptions in applying this definition to their AMP calculations and in the reporting of such discounts each quarter. One commenter expressed hope that CMS will take note of the significant administrative burdens associated with tracking customary prompt pay discounts on an individual basis.

Response: As with other pricing calculations, in the absence of specific guidance, manufacturers may make reasonable assumptions consistent with

the statute, Federal regulations, and customary business practices. We believe that manufacturers should maintain documentation to support the customary prompt pay discounts reported to CMS. However, manufacturers may not assume an across the board percentage for customary prompt pay discounts. We recognize that reporting the amount of customary prompt pay discounts is a new requirement but that it is required by law.

Comment: A commenter requested that CMS clarify that “prompt” is defined by the manufacturer regardless of the length of time in which the purchaser can receive the discount.

Response: The length of time in which the purchaser can receive the discount should be consistent across purchasers for that manufacturer as well as consistent with customary business practice.

Comment: A commenter requested that CMS clarify that, in accordance with current industry practice, it is appropriate for manufacturers to calculate customary prompt pay discounts by applying the available prompt pay discount percentage (for example, two percent) to total direct sales.

Response: We do not agree. Manufacturers must report the actual amount of customary pay discounts provided for the period.

Comment: One commenter requested that CMS clarify that “any discount” means a discount regardless of the amount that is conditioned on the timing of payment.

Response: We disagree. “Any discount” should be the discount off of the purchase price of a drug provided when payment is made within a specified time that is consistent with customary business practices.

Comment: One commenter requested that we clarify the term “routine” to apply only to those discounts that are provided to entities that satisfy manufacturer defined, objective criteria.

Response: We agree and have clarified in § 447.504(c) that the discount should be consistent with customary business practice.

Comment: One commenter requested that CMS clarify the term “prompt pay.”

Response: The term “prompt pay” refers to a discount provided consistent with industry customary business practices for payment within a specific timeframe.

Comment: One commenter requested that CMS clarify whether prompt pay discounts paid to pharmacies and PBMs are eligible for exclusion from AMP based on the definition of wholesaler.

Response: As specified in statute, only prompt pay discounts to wholesalers, as defined in this final rule in at § 447.504(c) are to be excluded from AMP.

Comment: Several commenters support the definition of customary prompt pay discount.

Response: We appreciate the support for this definition.

Comment: One commenter requested that CMS exclude customary prompt pay discounts from the calculation of ASP.

Response: These issues are not addressed in the proposed rule and are outside the scope of this rulemaking document. Therefore, we have not considered these comments as we consider revisions to the final rule.

Comment: One commenter stated that the exclusion of customary prompt pay discounts from AMP will effectively increase the AMP, resulting in incremental increases to the rebates for drugs to States and the Federal Government.

Response: CMS does not have data sufficient to predict how AMP will change to the exclusion of customary prompt pay discounts or other changes in this rule.

Comment: One commenter agreed that CMS should not specify payment amounts or time terms in the definition. Although some manufacturers may ask CMS to further define the various aspects of customary prompt pay discounts, the commenter encouraged CMS to maintain the proposed definition in this final rule because this approach allows manufacturers and wholesalers the necessary flexibility to negotiate payment terms, including customary prompt pay discounts based on their particular situations and the commercial conditions at the time of the particular transaction. Additionally, this flexibility promotes competition in the healthcare distribution business, which ultimately will lower distribution costs.

Response: We appreciate the support but note that customary prompt pay discounts must be routinely offered in order to be excluded from AMP.

Determination of AMP

Comment: One commenter stated that the law clearly limits prices included in AMP to be prices paid by wholesalers, including discounts received by wholesalers. However, CMS proposed to require that manufacturers include prices that are not paid by wholesalers, such as to PBMs, as well as discounts on drugs that are not received by wholesalers. The commenter believes that the proposal is inconsistent with both congressional intent and CMS’

longstanding interpretation of the statute.

Response: We have clarified in this final rule in § 447.504 that AMP should 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. We have also clarified that rebates, discounts, or other price concessions to PBMs should not be included in AMP because we believe they do not adjust the price actually realized. We believe that this final rule provides a definition of AMP and wholesaler consistent with the provisions of the DRA and section 1927 of the Act.

Comment: One commenter stated that they know that an imprecise definition of AMP, especially if publicly posted, will be misleading to State Medicaid Directors and others who will use this as a reference point for setting pharmacy reimbursement.

Response: We have clarified the definition of AMP in § 447.504(a) to be consistent with the current law. We intend to clarify in guidance that posted AMPs are not designed to reflect prices paid by specific pharmacies.

Comment: Another commenter said that CMS proposes to include in AMP all sales to wholesalers except for those sales that can be identified with “adequate documentation” as being subsequently sold to any excluded entity. The commenter requested CMS to specify what constitutes adequate documentation. In the absence of further guidance, the commenter presumes that manufacturers may make reasonable assumptions in determining whether they have satisfied the adequate documentation requirement. However, the commenter requests that CMS provide an opportunity for manufacturers to comment on any further guidance prior to issuing a final rule.

Response: We have clarified that adequate documentation includes, but is not limited to, chargeback data or data for which an outside auditor, certified public accounting firm, CMS, the OIG, or another authorized government agency could reconstruct the transaction. Manufacturers may continue to make reasonable assumptions that are consistent with this final rule, statute, and general business practices. We do not specifically request comments on guidance issued to implement the rebate

program but we intend to respond to comments received before and after such guidance.

Comment: One commenter suggested that CMS reconsider whether all of the sales enumerated under § 447.504(g) are appropriately “included” in AMP based on the definition of “wholesaler.”

Response: We appreciate the comment and have revised the regulation text in § 447.504 to reflect revisions based upon comments received on this issue.

Comment: Several commenters requested that CMS provide a clear definition of AMP. Other commenters said that it must be defined fairly and equitably. Another commenter also said that the current definition of AMP is ambiguous and has never been adequately defined by CMS. One commenter said that AMP cannot be clearly defined as the industry does not have a true standard definition.

Response: We believe that this final rule provides a clear and adequate definition of AMP consistent with the provisions of the DRA and helps resolve ambiguities and confusion that may have existed with the pre-DRA definition.

Comment: One commenter said that they did not support the current definition of AMP.

Response: We have revised the regulation text at § 447.504 to reflect revisions based upon comments received.

Comment: One commenter said that this final rule should be consistent with established Medicaid rebate policies, definitions and terms set forth in current CMS guidance, such as program releases and the national rebate agreement.

Response: We have clarified previous policies as well as incorporated changes mandated by the DRA. This final rule is consistent with current law and it reflects recommendations made to us by the OIG and relevant comments.

Comment: One commenter requested clarification regarding whether the definition of AMP is being changed. The commenter requested clarification regarding whether AMP is the price received by the manufacturer, the price recognized by the manufacturer, or the price paid by the retail pharmacy class of trade.

Response: We have clarified at § 447.504(a) that the AMP is the average price received by the manufacturer for the drugs in the United States from wholesalers for drugs distributed to the retail pharmacy class of trade, without regard to customary prompt pay discounts extended to wholesalers, and inclusive of sales and associated

discounts, which reduce the amount received by the manufacturer (unless the sale or discount is excluded by the statute or regulation). We have clarified the definition in the regulation.

Comment: One commenter requested that CMS clarify the phrase “prices which are actually available” used in the proposed rule. Available prices should not be used to define AMP. If a price is offered and not taken, it is irrelevant to prices received by manufacturers or prices paid by retail pharmacies.

Response: Actual sales must occur in the period in order for a particular price to be reflected in AMP.

Comment: One commenter requested that AMP be defined as, “with respect to a covered outpatient drug of a manufacturer (including those sold under an NDA approved under section 505(c) of the FDCA) for a calendar month, 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.” The commenter requested that AMP be defined to include only sales to chain and independent pharmacies, and discounts to retail pharmacies, but only to the extent that such discounts reduce the actual price paid by retail pharmacies.

Response: We disagree. In light of our understanding of the statute and DRA amendments, we have decided to include in the AMP and retail pharmacy class of trade, sales to chain, independents, and mail order pharmacies, as well as discounts to such entities to the extent that they reduce the amount received by the manufacturer and are not otherwise excluded by statute and regulation.

Comment: One commenter requested that CMS clarify the meaning of the term, “associated with,” referenced in § 447.504(g)(10) in the proposed rule.

Response: The term, “associated with” means with respect to the AMP calculation, that manufacturers should include all sales and associated rebates, discounts, or other price concessions which relate to the sale, unless those sales, rebates, or other price concessions are excluded by statute or regulation.

Comment: One commenter requested that CMS exclude from AMP price adjustments that do not affect the actual price provided by the manufacturer and that are not received by retail community pharmacies.

Response: As noted previously, we have defined AMP to include 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. Absent such specific exclusions, we believe that manufacturers should calculate AMP by matching sales with their associated price concessions.

Comment: Many commenters asked that CMS issue a clear definition of AMP that covers community, independent and chain pharmacy acquisition costs. This definition should be issued as soon as possible, before AMP takes effect.

Response: We have defined AMP consistent with our understanding of the current law. Because AMP is based on the average price received by the manufacturer for the drug, it does not necessarily reflect a pharmacy’s acquisition cost for the drug.

Comment: One commenter commended CMS for articulating the rationale behind our proposals regarding the determination of AMP. For example, in the definition of “retail pharmacy class of trade,” CMS articulated an assessment based on whether or not sales are available to the general public. The commenter appreciated this effort to describe the history and development of the Agency’s thinking. However, the commenter was concerned that the test, as articulated, lacks sufficient clarity. The commenter believed that the proposed rule represents an important and necessary step forward in standardizing AMP calculations. However, the commenter urged CMS to significantly refine its guidance.

Response: We believe that this final rule provides a clearer, accurate and precise definition of AMP to allow manufacturers to accurately calculate AMPs. We expect to continue to issue further guidance and answer specific questions to the extent necessary to provide additional clarity. Furthermore, this final rule period allows for additional public comment on AMP.

Comment: One commenter said that the proposed definition of AMP is unfair to retail pharmacies because it includes sales to PPOs, HMOs, and outpatient clinics, all of which receive bid prices from drug companies. To be fair, the cost should be derived from the prices paid by retail pharmacies. Many commenters said that if AMP is to accurately serve as both the basis for rebates and payment, CMS must define AMP to reflect the actual acquisition cost with respect to prices paid for

drugs by retail pharmacies, excluding all rebates and price concessions not available to retail pharmacy.

Response: As we noted previously, the statute defines AMP, in part, as the average price received by the manufacturer for drugs distributed to the retail pharmacy class of trade. Accordingly, AMP does not necessarily reflect the pharmacy's acquisition cost. We note that when the AMP is used in the calculation of FULs, the calculation includes a markup of 250 percent and excludes certain outlier prices, as described elsewhere in this regulation. The DRA does not require the States to otherwise base their payments on AMPs. To the extent that they do so, we would expect them to look at appropriate mark-ups and any other relevant factors to ensure access. Such changes in payment would also require the submission and CMS approval of a State plan amendment.

Comment: One commenter agreed with CMS' interpretation of congressional intent that both direct and indirect pharmacy sales be included in AMP. The commenter requested that CMS incorporate direct retail pharmacy sales in AMP without adopting a strained, overly-broad definition of wholesaler. It should be sufficient to include a provision in the final rule expressly stating that net sales to retail pharmacies are to be included when AMP is calculated, but CMS could avoid all ambiguity about the requirement to include direct pharmacy sales in AMP by adding the parenthetical, "(direct and indirect)" after the word "sales" at the beginning of proposed § 447.504(g)(5).

Response: We appreciate the comment and believe that we have defined AMP to be consistent with the provisions of the DRA and section 1927 of the Act, and include sales, rebates, and price concessions provided by the manufacturer for drugs distributed to the retail pharmacy class of trade. In addition the definition of wholesaler has been revised.

Comment: One commenter said that the new determination of AMP will cause many pharmacies to consider disenrolling from Medicaid pharmacy programs. Commenters said that the current definition of AMP will cause their retail pharmacy to lose money with each prescription that is filled. A few commenters stated that AMP must be defined as it relates to the retail pharmacy class of trade. Retail pharmacy must be able to purchase these drugs at a price that is less than the reimbursement it is to receive, including the cost of electronic transmission to the PBM, labeling,

container, counseling time, delivery costs, and packaging. Another commenter stated that the formula must be tweaked to provide a true cost.

Response: We disagree. As we have noted elsewhere in this regulation, the AMPs will be used to establish FULs, which is calculated based, in part, on 250 percent of the AMP. To the extent States decide to use AMPs for reimbursement that decision will be subject to our review and approval through a State plan amendment approval process. We believe that this final regulation provides an adequate opportunity for States to set adequate reimbursement rates for drugs subject to the upper limits. We also believe that States that opt to use AMP as a basis for their pharmacy reimbursements will also use other resources available to them to determine fair and reasonable reimbursement to ensure continued access to pharmacy services for Medicaid patients. We also note that we encourage States to reevaluate their dispensing fees to ensure that they are reasonable and cover the costs to dispense drugs identified in this final rule.

Comment: A few commenters said that a new definition for AMP is needed, which should be Average Retail Price (ARP).

Response: Current law requires that AMP be computed based, in part, on the average price received by manufacturers and submitted by manufacturers and it provides no authority for us to define AMP as an average retail price.

Comment: A few commenters stated that the field is skewed against independent pharmacies. If CMS proceeds with AMP, then there needs to be a different AMP for different classes of trade. Some commenters stated further that mail order, retail, hospital, and long-term care pharmacies all purchase drugs at different costs and the same AMP should not be used for every class of trade. One commenter said that the formula is taking into account all of the rebates and special pricing afforded to the "closed door" specialties such as nursing homes, mail order houses, and hospitals. It has already been shown that the actual reimbursement proposed will be far less than what retail pharmacies can purchase the product for.

Response: We disagree. We know of no evidence at this point that the payments, which would be set as a result of the revised FULs or publication of AMPs would be any less than pharmacy acquisition prices especially given that neither the FUL methodology nor AMP data has been established or available prior to publication of this

rule. Current law provides no authority for a different AMP for different types of entities. However, we believe that the publication of AMP will provide the Federal and State Governments with more transparency with respect to the average price received by manufacturers for prescription drugs, and provide a basis on which to set payments rates. We further believe that, in light of the methodology for calculating the FULs, the AMPs will be fully adequate for computing the upper limits and that States will make their own best decisions, subject to the State plan amendment process, with respect to how to use AMP as a factor in provider payment.

Comment: One commenter said that it will be harder for community pharmacies to compete with the retail giants as their prescription volume is much lower and it will be harder to recover their expenses. Community pharmacies will not necessarily receive the discounts that the larger retail pharmacies receive when purchasing generic drugs.

Response: We believe that any payment revisions that states may establish as a result of these provisions will not prevent community pharmacies from competing with other pharmacies. CMS has calculated the FULs without regard to any outlier AMPs and will review any state plan amendment submission as a result of those FULs to ensure sufficient access. We further note that States maintain the authority to vary payment rates by rural area as well as by the type of the provider.

Comment: Several commenters said that the proposed rule would unduly reduce AMP.

Response: We appreciate the comment and have revised AMP at § 447.504 to address similar concerns.

Comment: One commenter said that it is clear from the proposed rule discussion that CMS has struggled to balance AMP-based rebate collection and AMP-based reimbursement through the inclusion of non-pharmacy entities. Should CMS believe it important to maintain these entities in AMP for the purposes of reducing manufacturer rebates, then an alternative would be to have monthly and quarterly rebates calculated differently. Monthly and quarterly AMPs would afford CMS the opportunity to use the monthly AMP to establish the FUL in a way that would provide a more accurate reflection of traditional retail pharmacy purchasing (that is, only including licensed pharmacies and excluding other entities such as PBMs) and maintain the CMS decision to reduce manufacturer rebate liabilities by the inclusion of the various

non-pharmacy entities in the quarterly AMP reporting. Another commenter said that the best method of resolving any conflict between the two functions of AMP (paying rebates and payment) is to examine the basic purposes of the statutes and craft the definition and use of AMP to better fit those purposes. The commenter did not believe the proposed rule dealt with these purposes adequately.

Response: We do not agree. There is only one definition of AMP, as revised by the DRA, that is applied for both rebate and FUL purposes. By using only one definition, these AMPs become much more transparent and provide information regarding the average price received by manufacturer from wholesalers for drugs distributed to the retail pharmacy class of trade. We believe that the definition of AMP as clarified in this final rule at § 447.504(a) accurately reflects the dual purposes of AMP.

Comment: One commenter stated that the approach that CMS used in the determination of AMP is overly broad, in that past policy reflects a different focus on the use of AMP and the agency's interpretation of the marketplace does not provide adequate consideration of the obvious inconsistencies that occur when FULs based on AMPs are defined in the proposed rule as approximations for estimated acquisition cost (EAC). The transactions included in AMP should be based on a more narrow view of what is meant by the retail pharmacy class of trade, but should also consider more significantly the link between FULs and EAC.

Response: We agree that although AMP was defined in the rebate agreement, the list of sales included in the AMP calculation was not well established when the DRA was enacted. While we have reviewed the OIG's recommendations and those of commenters, and incorporated changes where we thought appropriate, we believe that we have crafted a definition of AMP that reflects the requirements of the law and serves as a basis for both rebates and the FULs program.

Comment: A few commenters said that without clear and concise guidance from CMS regarding how AMP is to be calculated, including what classes of trade are eligible and which classes of trade are not eligible, for inclusion in the AMP calculation manufacturers who compete in the same therapeutic area could have differing methodologies resulting in unfair physician reimbursement calculations. CMS needs to provide clear guidance on the calculation of AMP in order to maintain

a fair and level playing field for physician reimbursement.

Response: We believe that we have developed requirements in this final regulation that are clear and concise and that can provide a basis for consistent calculations and fair reimbursement rates.

Comment: One commenter stated that AMP would be valid for determining transactions between a manufacturer and the next step down the trade chain (for example, a drug wholesaler) but using AMP is not valid to compute the price of the drug at the point a community pharmacist is dispensing it to his or her patients.

Response: The statute provides that manufacturers calculate Medicaid rebates and CMS calculates the FULs based in part, on AMP. In accordance with the statute, we have defined AMP as the average price received by the manufacturer from wholesalers for drugs distributed to the retail pharmacy class of trade, excluding customary prompt pay discounts extended to wholesalers and including certain sales and associated discounts. As stated elsewhere in this final rule, we have not only applied the 250 percent markup to the lowest price therapeutically equivalent drug, we have implemented other policies to assure that the resulting FULs, in the aggregate, are reasonably established to reflect the pharmacy acquisition cost of drugs subject to the FULs, while protecting the taxpayer against excessive costs.

Comment: A commenter recommended that the playing field on drug pricing be leveled by making the discounts extended to PBMs, mail order pharmacies, and government contracts available to retail pharmacies and allow a reasonable profit structure as any business deserves.

Response: These issues were not addressed in the proposed rule; therefore, we can not consider these comments as we consider revisions to be included in the final rule.

Comment: One commenter stated that the definition of AMP must be operational and feasible for manufacturers. Manufacturers are frequently not aware of the subsequent sales of their drug products after the first sale. Manufacturers do not have information about sales to hospitals, other wholesalers, mail order pharmacies, and PBMs.

Response: We have modified the requirements in § 447.504(h) with respect to AMP calculations to exclude certain sales to hospitals and PBMs. The requirement of AMP specifies that where sales to excluded entities are

documented, they should be excluded from AMP.

Comment: One commenter said that AMP should be calculated based on the average price, not the lowest price.

Response: We agree. The AMP, as amended by the DRA, represents the average unit price, not the lowest price, received by the manufacturer for the drug in the United States from wholesalers for drugs distributed to the retail pharmacy class of trade, without regard to customary prompt pay discounts extended to wholesalers as noted previously, AMP should be calculated to include sales and associated discounts and other price concessions provided by a 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), which reduce the amount received by the manufacturer.

Comment: One commenter said that an appropriate calculation of AMP depends on an accurate definition of retail pharmacy class of trade, accurate identification of manufacturers' prices paid by wholesalers for drugs distributed to retail pharmacies, and an appropriate definition of wholesaler. The commenter stated that CMS' proposed definition has problems in all three areas.

Response: In response to comments, we have clarified the definition of retail pharmacy class of trade at § 447.504(e), wholesalers at § 447.504(f), and the list of sales included in the determination of AMP at § 447.504(g).

Comment: One commenter said that AMP is as ambiguous as AWP or ASP in that it can be interpreted many ways and does not consider business overhead requirements of drug wholesalers and distributors.

Response: We do not agree. ASP and AMP are defined in the statute and Medicare regulations. However, AWP is a term that is not further defined in the regulation and has been found to frequently overstate the actual cost of drugs.

Comment: One commenter stated that AMP should have full transparency. Another commenter said that the AMP calculation should be solidified and that a more transparent method should be developed.

Response: We have clarified at § 447.504(i)(2) and § 447.510(d)(2) how manufacturers should calculate and report AMP on both a quarterly and monthly basis, and we expect to post AMP data for public review on our Web site. Although the manufacturers' documentation for these calculations will not be made available to the general

public, they are subject to Federal Government verification.

Comment: Many commenters stated that all rebates and price concessions are appropriately included in best price but should not be included in AMP. Another commenter said that CMS should exclude from AMP those sales that are exempt from best price under section 1927(c)(1)(C)(i) of the Act. The commenter asserts that including sales to SPAPs and Part D Plans that are exempt from best price in AMP will artificially lower AMP as a reimbursement benchmark by including discounts in AMP to which pharmacists do not have access.

Response: We have revised this final rule in § 447.504(h)(23) to exclude rebates and other price concessions provided to SPAPs and Part D plans. It is our understanding that such rebates and price concessions do not adjust the prices actually realized. We have continued in § 447.504(g)(15) to include sales with respect to such programs and plans to the extent that they occur through the retail pharmacy class of trade.

Comment: One commenter asked whether CMS' intent is to continue to allow manufacturers to treat an entity as either included or excluded in the retail pharmacy class of trade based on its function, provided that the manufacturer can provide sound rationale.

Response: In the final rule we have defined that AMP be calculated to include sales and associated discounts and other price concessions provided by the manufacturer to wholesalers 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. Sales and associated price concessions should be included in AMP to the extent they concern sales at the retail pharmacy class of trade and are not otherwise exclude.

Comment: One commenter stated that any entity that does not directly purchase drugs from the wholesaler should be excluded from AMP.

Response: We have revised wholesaler in § 447.504(g) to mean any entity (including those entities in the retail pharmacy class of trade) to which the manufacturer sells the covered outpatient drugs, but that does not relabel or repackage the covered outpatient drug.

Comment: A commenter stated that CMS will need to be exceedingly clear in the guidance that it provides to manufacturers in calculating AMP to

ensure that manufacturers are able to determine the sales and associated price concessions that should not be included in AMP and to ensure consistency in AMP calculations across all manufacturers.

Response: We have clarified in the regulation text at § 447.504(g) those sales and associated price concessions included in AMP.

Comment: A commenter stated that §§ 447.504(a), (g) and (i) indicate types of discounts and price concessions that manufacturers should deduct from the calculation of the AMP. By including these discounts and concessions, the proposed rule incorrectly based AMP, not on the amounts paid by wholesalers—the predominant supply source for retail pharmacies—but instead includes amounts that manufacturers have contracted to pay other entities. While these discounts, rebates, chargebacks and other forms of price concessions may reduce the amount received by the manufacturer for drugs, they are not realized by retail pharmacies and do not reduce prices paid by retail pharmacies.

Response: Our definition of AMP is consistent with our understanding of the section 1927(k)(1), as amended by the DRA. While we understand that some commenters do not agree with that definition because it does not represent the exact amount at which pharmacies purchase drugs, we believe that our definition is consistent with the statute. As we explain elsewhere in this final rule, the statute requires the use of AMPs in the FUL calculation with a sufficient markup of the AMP and we have included other exclusions in the FUL calculation to assure that these FULs prices in the aggregate are sufficient to cover pharmacists' costs.

Comment: One commenter said that § 447.504(a) through (i) proposed revisions to various definitions and directions to manufacturers related to AMP calculation. The validity of CMS' consideration for inclusion or exclusion of factors in determining AMP is essential for obtaining data that accurately reflects drug pricing. The commenter recommended that CMS adopt clear and specific policies to ensure consistency in the calculation of AMPs across all manufacturers.

Response: We appreciate this comment and believe we have done so.

Comment: One commenter said that the proposed definition, coupled with the broad definition of wholesaler, is intended to capture transactions with entities that do not pay manufacturers a price established by the manufacturer directly or through distributors. When combined with the proposed inclusions

and exclusions from AMP, this definition creates confusion.

Response: We appreciate the comment. As discussed previously, we have revised the definition of AMP in § 447.504(g) to clarify which sales and associated price concessions must be included.

Comment: One commenter said that the proposed rule provided manufacturers a significant amount of latitude and discretion with respect to the final AMP calculation. It is likely that there will be widespread differences in interpretation with respect to those elements that should be included or excluded from AMP. One example of this confusion relates to the treatment of a "bona fide service fee." It remains unclear as to the comparative standard that will be used to establish the determination of "fair market value." The commenter requests that additional clarity be provided to eliminate variation in manufacturer's AMP calculation.

Response: We believe that this final rule provides a clearer, accurate and precise definition of AMP, eliminating much of the confusion and assumptions regarding the entities included and excluded in AMP. For example, we have introduced the concept of bona fide service fees and provided further instructions on how they are to be determined. We expect that manufacturers participating in the Medicaid Drug Rebate Program will be in a much better position to understand our requirements and to determine their AMP calculations consistent with this final regulation. In the absence of specific guidance, manufacturers may make reasonable assumptions consistent with the statute, regulations and general business practices.

Nursing Homes

Comment: Many commenters said that nursing home pharmacies should not be included in AMP because they are not traditional retail pharmacies. Several commenters stated that rebates and discounts to nursing homes are not available to retail pharmacies. Other commenters said that nursing homes sales should be outside the retail pharmacy class of trade as these sales are not accessible to the public. A few commenters supported excluding nursing home pharmacies from the definition of retail pharmacy class of trade and noted that long-term care pharmacies are not retail pharmacies for Part D.

Response: We appreciate the support for this policy and have decided to finalize our proposal to exclude nursing facility pharmacies from the retail

pharmacy class of trade, and, therefore AMP, in this final rule at § 447.504(h)(6).

Comment: One commenter requested that CMS clarify whether contract pharmacies that dispense drugs to nursing home and long-term care residents also should be excluded from the calculation of AMP.

Response: We have clarified in the regulation text at § 447.504(h)(6) that sales to contract pharmacies that dispense drugs through nursing homes and long-term care facilities and other entities such as assisted living facilities which do not serve the general public are excluded from AMP. Since we believe a manufacturer would not know which drugs are dispensed to a nursing facility through an outside contract pharmacy, we have not excluded these sales from AMP unless that manufacturer has reasonable documentation that the drugs were subsequently sold to an excluded entity.

Comment: One commenter stated that to remove nursing home sales from AMP would be inconsistent with CMS guidance issued to date and would be a substantive policy change. The commenter requested that long-term care sales continue to be included in AMP because these transactions are a significant portion of the market for many drugs and the exclusion of those transactions from AMP would yield inaccurate and misleading AMPs. Changing the current policy would require substantial changes in systems, policies, procedures, and data links that would more than offset the benefit from simplifying the AMP calculations. A few commenters encouraged CMS to continue its long-standing policy of including these sales in the calculation of AMP.

Response: We have decided to retain the proposed exclusion at § 447.504(h)(6) in this final rule because we believe that nursing home sales are not in the retail pharmacy class of trade because the general public cannot obtain drugs through this source.

Comment: One commenter said that CMS has not clearly identified those entities that would be considered long-term care (or nursing home) pharmacies. The commenter encouraged CMS to clearly define the attributes of entities that qualify as long-term care pharmacies to avoid disparate treatment by manufacturers as they exclude prices to long-term care pharmacies. In particular, the commenter believed that it is not clear whether the following would be considered a long-term pharmacy: long-term care pharmacies owned by a hospital, infusion centers, and rehabilitation centers. The

commenter further recommended that CMS establish a list of long-term care pharmacies similar to the list of eligible 340B covered entities provided by the Office of Pharmacy Affairs in HRSA.

Response: We consider a long-term care pharmacy to be a pharmacy that provides drugs to nursing home patients. Infusion centers and rehabilitation centers that serve patients outside a nursing home would not be included. We do not believe it is administratively feasible for CMS to maintain a list of the entities that fall into this category.

Comment: A commenter asserted that it is often operationally infeasible for manufacturers to identify those sales that are made to a particular type of entity such as a long-term care pharmacy, as opposed to another type of entity that might not satisfy the definition of a long-term care pharmacy. Manufacturer sales data are captured at the contract level, but any included or excluded class of trade customer could purchase products from any wholesaler source contract. Thus, manufacturers have no way of determining whether final sales are made to customers excluded from AMP. Given this inherent difficulty with calculating AMP, it is imperative that CMS provide mechanisms by which manufacturers can calculate AMP as consistently as possible.

Response: The final rule in § 447.504(h)(6) clearly indicates that nursing home sales are excluded from AMP and allows manufacturers to use standards of reasonable documentation to identify such sales.

Hospice and Other Home Health Care Pharmacies

Comment: One commenter suggested that sales to hospice pharmacies should be treated the same as sales to long-term care pharmacies and excluded from AMP and best price.

Response: Hospice pharmacies are outside of the regular retail marketplace, as drugs from these pharmacies are not available to the general public. Therefore, we have clarified in the regulation text at § 447.504(h)(7) that sales to hospices (outpatient and inpatient) are excluded from AMP.

Comment: Several commenters requested that CMS specify in the final rule whether home health care providers meet the retail pharmacy class of trade definition. One commenter asked CMS to clarify whether prices paid by home health care agencies for drugs delivered to home bound patients are included in AMP. Several commenters requested that CMS clarify that home health care providers are

included in the retail pharmacy class of trade because such entities provide pharmacy to the general public.

Response: We have clarified in this final rule at § 447.504(g)(12) that sales to home health care providers are included in the retail pharmacy class of trade and AMP unless such drugs are dispensed through nursing facilities. We believe that, unlike nursing facilities, home health care providers operate to provide drugs to the general public.

Physician Offices and Other Provider Settings

Comment: Many commenters requested that CMS specify in the final rule whether sales to physicians are in the retail pharmacy class of trade. Several commenters requested guidance regarding the treatment of the physician class of trade (direct and indirect sales) since it was not addressed in the proposed rule.

Response: We have clarified in the regulation text at § 447.504(g)(13) that sales to physicians fall into the definition of retail pharmacy class of trade and are included in AMP. The definition of retail pharmacy class of trade includes any pharmacy or other outlet that purchases, or arranges for the purchase of, drugs from a manufacturer, wholesaler, or distributor and subsequently sells or provides the drugs to the general public. We believe that, to the extent that the physician is operating to provide drugs to the general public, they should be included within the definition of retail pharmacy class of trade and AMP.

Comment: One commenter sought clarification concerning whether sales to surgical centers, ambulatory care centers, prisons, and mental health centers are in the retail pharmacy class of trade. Unlike walk-in pharmacies, these providers generally provide drugs incident to providing medical services to persons who are their private patients, although some physician practices sell self-administered products to patients who take the products home.

Response: We appreciate this comment and have clarified in the regulation text at § 447.504(h)(9) that sales to prisons are excluded from AMP. We have further clarified at § 447.504(g)(8) that sales to surgical centers, ambulatory care centers, and mental health centers are included in AMP to the extent that such facilities provide drugs to the general public unless such drugs are provided through a nursing facility pharmacy.

Hospital Pharmacy Sales

Comment: Several commenters stated that hospital prices should be excluded

from AMP because hospital pharmacies receive generous price breaks from wholesalers and manufacturers that are not available to retail pharmacies. Many commenters believe that CMS should exclude all hospital pharmacy sales from AMP because the vast majority of sales are for inpatient use and hospitals do not generally track whether a drug is provided to an individual receiving inpatient services or outpatient services. Another commenter stated that it would be administratively difficult for manufacturers to include sales to walk-in pharmacies located in hospitals because most hospitals buy drugs for inpatient and outpatient use through wholesalers or distributors under agreements negotiated by GPOs. The commenter further suggested that manufacturers be permitted to assume hospital purchases are for their inpatient inventory and exclude them from AMP unless sales to hospital outpatient pharmacies are identifiable. One commenter said that drugs provided through hospital outpatient departments are not available to the general public and should be excluded as they are not in the retail pharmacy class of trade. Another commenter stated that hospital outpatient departments receive drugs at lower prices than retail pharmacies which would result in a lower AMP and unfairly lower reimbursement to retail pharmacies.

Response: We agree that manufacturers often do not know what drugs sold to hospitals are used in the hospital outpatient pharmacies or other hospital facilities, such as clinics. In such an event, we believe that manufacturers should exclude hospital sales from AMP. We have provided in this final rule at § 447.504(g)(3) that drugs sold to hospitals for use in an outpatient pharmacy are included in AMP, except where the manufacturer cannot identify and document hospital sales for outpatient use.

Comment: One commenter stated that it is unclear if pharmacies in physician clinics that dispense prescriptions in such clinics are included in the retail pharmacy class of trade.

Response: We consider physician clinics, to the extent that they provide drugs to the general public, to be in the retail pharmacy class of trade and drugs sold to these clinics should be included in AMP.

Comment: One commenter asked if an outpatient clinic includes hospital surgical centers, ambulatory care centers and outpatient departments in which a patient is admitted to the hospital and released the same day.

Response: The term outpatient clinic was intended to capture all outpatient facilities including hospital surgical centers, ambulatory care centers and outpatient departments because such facilities provide drugs that are available to the general public. We have revised the regulation text in § 447.504(g)(8) to expand the term "outpatient clinic" to "outpatient facilities; for example, outpatient clinic."

Comment: One commenter requested that CMS define outpatient clinic. The commenter assumed that federally qualified health centers, independent diagnostic facilities, and the like are outpatient clinics.

Response: We have revised the term outpatient clinic in § 447.504(g)(8) to mean "outpatient facilities; for example, outpatient clinic" in the regulation text.

Comment: One commenter indicated that it is unclear if the term outpatient clinic was intended to include physician offices. If not, the proposed rule is silent on the handling of sales to physicians in AMP.

Response: The term outpatient clinic was not intended to cover direct physician sales. We have clarified in the final regulation text at § 447.504(g)(13) that the retail pharmacy class of trade may include physicians to the extent that they provide drugs to the general public.

Comment: One commenter requested that CMS clarify that the term "outpatient clinic" is not intended to mean hospital outpatient departments since a different sub-paragraph in 42 CFR § 447.504(g) addresses sales to hospitals outpatient pharmacies. Manufacturers may find it difficult to distinguish between hospital-affiliated freestanding outpatient clinics and true hospital-based outpatient departments.

Response: We have clarified in the regulation text at § 447.504(g)(8) that outpatient clinics and facilities, which are not hospital-affiliated entities, are included in AMP. We have further clarified in the regulation text at § 447.504(g)(3) that sales to hospitals, for use by an outpatient pharmacy for a hospital outpatient department, clinic or affiliated entity are included in AMP, except when a manufacturer does not have information to distinguish these sales from sales used for inpatients.

Mail Order Pharmacies

Comment: Many commenters said that though mail order pharmacies have a tendency to decrease AMP, they should be included in AMP because they are licensed pharmacies and provide drugs to the general public. Some commenters support CMS'

decision to maintain its existing policy to include sales and price concessions to mail order pharmacies in the AMP calculation. One commenter agreed that mail order should be included in AMP on the basis that it is simply another form of how drugs enter into the retail pharmacy class of trade.

Response: We appreciate the support for this provision and have retained this requirement in this final rule at § 447.504(g)(9).

Comment: One commenter said that mail order pharmacy rebates, chargebacks, and other price concessions should not be included in AMP.

Response: We do not agree. After consideration of all comments received, we continue to believe that mail order pharmacies are part of the retail pharmacy class of trade inasmuch as they are accessible and dispense prescriptions to the general public. The rebate agreement which provides for the inclusions of rebates, discounts, and price concessions associated with drugs provided to the retail pharmacy class of trade be included in AMP. We further believe that we are correct to include mail order pharmacies in AMP, since Congress did not seek to change the policy regarding the inclusion of mail order pharmacy sales and associated price concessions in AMP with the recent DRA (except with respect to customary prompt pay discounts extended to wholesalers). Accordingly, CMS has not changed the policy in this final rule.

Comment: Several commenters said that any closed-door mail order pharmacy, in that it sells only to facilities or plans with which a contractual relationship exists, should be excluded.

Response: As previously discussed, we believe that all sales to mail order pharmacies are within the retail pharmacy marketplace and drugs from these pharmacies are available to the general public. We have clarified in the final regulation at § 447.504(e) the definition of retail pharmacy class of trade.

Comment: Several commenters said that any mail order pharmacy whose rebate and discount arrangements are not available to other pharmacies in the retail pharmacy class of trade should be excluded.

Response: We disagree. The rebate agreement which provides that rebates, discounts, and price concessions associated with drugs provided to the retail pharmacy class of trade be included in AMP. It does not precondition this on whether other

entities within the retail pharmacy class of trade can get these same discounts.

Comment: One commenter expressed the concern that the inclusion of mail order discounts and rebates in the AMP calculation will impact access for a drug when used for the purposes of the FUL process. Several commenters said that to include mail order pharmacies in AMP will skew the price to a lower price at which retail outlets will never be able to purchase medications. Another commenter noted that although mail order pharmacies serve consumers on a retail level their dispensing rate per day is many hundreds of times larger than a community-based retail pharmacy, allowing them to buy at a lower cost that is not available to a community-based retail pharmacy. Another commenter stated that the inclusion of mail order pharmacies will lower reimbursement to the community pharmacies below their cost. Several commenters stated that drug acquisition costs available to mail order pharmacies may not be available to smaller retail pharmacies and that inclusion of mail order pharmacies will serve to drive down pharmacy ingredient costs even further below average acquisition cost. One commenter said that it is self-evident to those in the industry that independent pharmacies do not purchase pharmaceuticals at the same cost as mail order pharmacies or chain pharmacies. This is driven by the inability to collectively negotiate with manufacturers and to purchase pharmaceuticals without acquiring the product from a wholesaler or distributor that requires significant additional margins for the distribution of those items from the manufacturers to independent pharmacies. They further noted that the differentials of mail order and chain pharmacies to other pharmacies acquisition cost are very significant. Many commenters said that the proposed rule is flawed by allowing manufacturers to include mail order in AMP on the basis that AMP will not reflect the price paid by traditional retail pharmacies or community pharmacies. A few commenters said that the idea of an AMP is acceptable, but only if hospital and mail order pharmacy pricing is excluded from AMP as mail order and hospital pharmacies receive generous price breaks from wholesalers and manufacturers alike, and thus their AMP should be calculated separately from other traditional retail pharmacies. One commenter further said that mail order pharmacies do not create a level playing field with community pharmacies. Mail order pharmacies have

tremendous advantages over community retail pharmacies due to their preferential treatment by pharmaceutical manufacturers. Their special discounts and pricing are not available to the public. Therefore, adding their pricing into the equation will cause an artificially low AMP to be reported. Another commenter stated that community pharmacies are at a loss compared to hospital/clinic organizations, PBMs, and mail order pharmacies because these pharmacies have access to rebates and price concessions that may not be available to community pharmacy.

Response: We disagree. Mail order and other pharmacies are included in the definition retail pharmacy class of trade given that they provide drugs to the general public. Furthermore, the calculation of AMP is based, in part, on the average price received by manufacturers. Some drug prices in AMP will be lower than the average but they will be combined with other sales prices that are higher. The FULs, in turn, are calculated based on the lowest priced drug inflated by 250 percent. In addition, we have taken other measures as described in this regulation to assure that drugs used in the FUL calculation will be available at the FULs price.

Comment: One commenter said that while the proposed rule makes a strong case for the inclusion of prices of sales to mail order pharmacies, it remains extremely vague on operational issues. Because the inclusion of these prices will have a significant impact on the AMP, the operational detail is extremely important.

Response: We are unable to respond to this comment as the commenter did not include enough specific information regarding operational issues to enable us to do so. Prices of sales to mail order pharmacies are currently included in AMP; therefore, we do not believe that the finalization of this provision will present or create new operational issues for manufacturers.

Comment: Many commenters said that mail order pharmacies should be excluded from AMP because mail order pharmacy sales are not traditional retail pharmacies and are a restricted vehicle for the delivery of prescriptions which is not publicly accessible to all patients. They do not provide the expected and needed services a retail pharmacy provides nor do they provide identical medications. Another commenter noted that a traditional retail pharmacy almost without exception pays the highest price. Mail order pharmacies are structurally similar to pharmacies that service nursing homes, which have been excluded in the proposed rule from the

retail pharmacy class of trade. They should be considered separate entities.

Response: We disagree. We continue to believe that mail order pharmacies are a segment of the retail pharmacy class of trade and should remain in AMP. We note that in the OIG's 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 in the GAO report, "Medicaid Drug Rebate Program—Inadequate Oversight Raises Concerns about Rebates Paid to States," (GAO-05-102), February 2005, retail pharmacy class of trade was defined to mean 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. We do believe that there are not sufficient similarities between long-term care pharmacies and mail order pharmacies especially given that drugs of long-term care pharmacies are only available to residents of those institutions.

Comment: One commenter said that removing mail order pharmacies from the retail pharmacy class of trade creates consistency in the regulation and conforms the definition to market reality.

Response: We disagree. We have consistently applied the definition of retail pharmacy class of trade to mean that segment of the market accessible to the general public. Given that mail order pharmacies are a segment of the retail marketplace, we continue to believe that their inclusion reflects market reality.

Comment: One commenter stated that mail order pharmacies are owned by PBMs and PBMs are not wholesale distributors; therefore, there is no method for distributing this lower cost to the retail sector. Another commenter said that should CMS decide to include mail order pharmacies in its definition of "retail pharmacy class of trade" then PBMs acting as wholesalers and or mail order pharmacies would by default need to have their purchase discounts included in the calculation of AMP.

Response: As discussed previously, we have decided to exclude PBM rebates, discounts and other price concessions from the determination of AMP, except for purchases through PBM mail order pharmacies. We understand that PBMs do not generally take possession of pharmaceutical products. Only in their role as mail order pharmacies do PBMs participate directly in the purchase or delivery of prescriptions drugs. However, we

continue to include sales to mail order pharmacies operated by PBMs. We believe that the sale to a mail order pharmacy, regardless of whether such a pharmacy is owned by a PBM, meets the definition of a sale to the retail pharmacy class of trade given that the drugs provided by such pharmacies are generally available to the general public.

Comment: One commenter said that mail order sales should not be included in the calculation of AMP because they are treated by the pharmaceutical manufacturers as a different class of trade.

Response: We disagree. The definition of retail pharmacy class of trade for the purposes of the drug rebate program is governed by the standards in this rule, not by how a manufacturer treats a sale.

Comment: A few commenters stated that mail order pharmacies will have an unfair competitive advantage over retail pharmacy if the final rule permits the inclusion in AMP.

Response: We do not believe the inclusion of mail order pharmacies in AMP in this final rule will significantly affect the competitive advantage one segment of the market has over the other. As we previously noted, the FULs price, which is calculated as an aggregate upper limit based on 250 percent of the AMP, should allow adequate payment to any pharmacy. We believe that States will consider the interests of all pharmacies in the State in setting other pharmacy payment rates and note that such rates will require approval of a State plan amendment.

Comment: One commenter suggests that if mail order pharmacy pricing is not excluded, then it should at least be used only with a diminished weight in the actual equation used to calculate AMP.

Response: We disagree. The legislation does not support a different methodology for mail order pharmacies or any other segment of the retail pharmacy class of trade when calculating AMP.

Comment: One commenter said that including mail order pricing in the determination of AMP is wrong and instead there should be a retail AMP and a mail order AMP.

Response: The current law does not provide for separate AMP calculations.

Comment: One commenter questioned why mail order pharmacies pay less for drugs. The commenter stated that community pharmacy should have the same rebates and pricing to save money.

Response: Such issues regarding the purchase prices of different entities are not covered by this final rule.

Comment: A few commenters stated that if mail order price concessions are

included in AMP, the resulting base date AMP will be artificially low.

Response: As elsewhere described in this final rule, we are allowing manufacturers to revise their base date AMPs for the first four calendar quarters following publication of this final rule.

Comment: AMP needs to be defined so that the community pharmacist can continue to serve Medicaid patients.

Response: We believe that this final regulation permits states to provide for adequate reimbursement for FUL drugs subject to the FULs.

Comment: One commenter said that CMS should take into consideration how price concessions are earned by mail order pharmacies. Mail order pharmacies are able to provide manufacturers with increased market share via the use of formularies and incentives, such as copayments. In return for increased market share and profits, manufacturers offer monies and incentives not available to purchasers other than mail order for Medicaid prescriptions. Medicaid requires manufacturers to pay rebates/incentives directly to States. Manufacturers expressly exclude Medicaid prescriptions from incentive programs offered to mail order. The calculation of AMP should exclude discounts or incentives that are not available for Medicaid prescriptions.

Response: We appreciate the comment; however, the methods for earning such price concessions by mail order pharmacies are outside of the scope of the proposed rule. The calculation of AMP is not based on incentives offered to one segment of the market or whether these incentives are offered for Medicaid prescriptions.

Comment: Several commenters stated that because mail order pharmacies do not generally service the Medicaid population, they should not be included in the definition of retail pharmacy class of trade.

Response: We disagree. The definition of retail pharmacy class of trade is not dependent on whether or not Medicaid beneficiaries obtain their services from the pharmacy.

Comment: One commenter said that the inherent variable nature of AMP coupled with the fact that CMS proposed to include the prices paid to mail order pharmacies in the calculation of AMP will not provide for a viable benchmark for the cost of drugs that will allow States to control prescription drugs cost while providing pharmaceutical care for the Medicaid population.

Response: We disagree. We believe that the AMPs will be fully adequate for computing FULs and that States will

make their best decisions on the application of these AMPs to the providers in their States.

Comment: One commenter said that providing mail order pharmacy services in rural areas will not suffice because of the inability to do what is required to obtain medicines.

Response: In this final rule, we are addressing the issue of what prices are included in AMP; we are not addressing this issue at this time.

Comment: One commenter said that if mail order pharmacies are in the same class of trade as retail pharmacies, then it is not clear why the MMA, which established Medicare Part D, created separate distinctions for retail pharmacy, nursing home pharmacy and mail order pharmacy. Another commenter stated that CMS specifically excluded mail order pharmacies from the definition of retail pharmacy in the rule implementing the Medicare Part D Program. Therefore, excluding mail order pharmacies from AMP would be consistent with CMS' current Part D definition of retail pharmacy.

Response: The statutory provisions applicable to Medicare Part D and the Medicaid Drug Rebate Program are significantly different. We continue to believe that mail order pharmacies are a segment of the retail pharmacy class of trade accessible to the general public and should remain in AMP.

Comment: One commenter said that the only reason offered by CMS in the proposed rule for including mail order pharmacies in AMP is that the removal would be inconsistent with past policy (71 FR 77178). The commenter further states that this does not apply to the DRA AMP.

Response: We disagree. Our reasons for including mail order pharmacies are clearly enunciated in this final rule and as noted, we do so based on more than consistency with previous policy. We continue to believe that mail order pharmacies are a segment of the retail pharmacy class of trade accessible to the general public and should remain in AMP. The DRA required that we clarify the definition of AMP, but did not mandate a manner in which we do so.

Comment: One commenter stated that if mail order should be included in the definition of retail pharmacy class of trade, a significant additional percentage increase to the FUL or significantly higher dispensing fee should be provided to those entities that provide the more desirable mode of delivery of products and services, such as community pharmacies.

Response: We disagree. The law provides that the FUL should be calculated based on a 250 percent of the

AMP for the lowest price drug. The determination of dispensing fees is left up to each State, with CMS' approval through a State plan amendment. We also disagree that mail order pharmacies do not offer a desirable mode of delivery.

Specialty Pharmacies and Direct Patient Sales

Comment: One commenter stated that direct sales to patients are usually for specialty drugs provided through a direct distribution arrangement and should be excluded from AMP. Several commenters believed that specialty pharmacies should not be included in the definition of retail pharmacy class of trade and therefore, excluded from AMP, because they limit their services to a defined population and do not dispense to the general public. Another commenter requested that CMS provide specific guidance regarding the treatment of discounts and rebates to specialty pharmacies when calculating AMP. Several commenters stated that traditional pharmacies do not have access to the prices provided to specialty pharmacies.

Response: We believe that drugs supplied through specialty pharmacies are within the regular retail marketplace. The fact that the pharmacies serve a client population characterized by specific medical conditions does not mean that their drugs are not sold to the general public, nor does it take them out of the retail pharmacy class of trade. Therefore, we have clarified in the regulation text at § 447.504(g)(11) that sales, rebates, discounts, or other price concessions to specialty pharmacies are included in AMP.

Comment: Several commenters said that sales to specialty pharmacies should be included in AMP.

Response: We appreciate the commenters' support for this provision and have retained this requirement at § 447.504(g)(11) in this final rule.

Comment: One commenter requested that CMS confirm that payments for specialty pharmacy services that satisfy the definition of a bona fide service fee should be excluded from the calculation of AMP.

Response: We concur. Payments for specialty pharmacy services that satisfy the definition of bona fide service fees should be excluded from the determination of AMP.

Comment: A few commenters said that home infusion pharmacies do not clearly fit the definition of retail pharmacy class of trade for the purpose of this regulation because they do not sell or provide drugs to the general

public. Unlike retail pharmacies, infusion pharmacies treat only a specialized class of patients who rely on these pharmacies for services that support their therapy regimen as a substitute for hospitalization. In other contexts, infusion pharmacies have been excluded from the retail pharmacy class of trade. For instance, CMS excluded infusion pharmacies from this classification for purposes of Health Insurance Portability and Accountability Act (HIPAA) standards when it established the National Council for Prescription Drugs Program (NCPDP) claim format for retail pharmacy claims. Infusion pharmacies also are distinguished from retail pharmacies under HCPCS. HCPCS provides approximately 80 "S" codes for home infusion therapy services that may not be used by retail pharmacies for their drug claims. It is not clear if payment based on AMP would appropriately reimburse home infusion pharmacies for the drugs that they provide.

Response: We believe that even though home infusion therapy pharmacies serve a defined population based on medical condition and are classified differently for the purpose of reimbursement; the drugs from these pharmacies are sold in the retail marketplace and are available to the general public. In accordance with the statute, the AMPs could be used to establish FULs. States may decide to use AMPs for reimbursements subject to our review and approval of a State plan amendment. We further believe that this final regulation provides states with sufficient flexibility to establish adequate reimbursement rates for FULs drugs. Therefore, we have clarified in the regulation text that sales to home infusion therapy pharmacies are included in AMP.

Retail Pharmacy Class of Trade

Comment: One commenter said that the proposed definition of retail pharmacy class of trade does not allow for adequate analysis of the costs related to operating such pharmacy. What normally qualifies as a retail pharmacy is an independently owned grocery, or chain pharmacy locations. Mail service and hospital outpatient pharmacies do not incur the same costs as retail pharmacies. These practice sites are able to purchase drugs at a lower cost than retail pharmacies. Any definition of pharmacy that is used in calculating costs must adequately differentiate between various practice settings so that the reimbursement can properly cover the true cost associated with each setting.

Response: The AMP is the average price received by the manufacturer for the drugs in the United States from wholesalers for drugs distributed to the retail pharmacy class of trade excluding certain customary prompt pay discounts and including certain price concessions, as defined in the regulation. We have defined AMP consistent with our understanding of current law. Since AMP is based on the price received by the manufacturer for the drug, it does not necessarily reflect a particular pharmacy's acquisition cost of a drug.

Comment: One commenter asked whether all community retail entities buy drugs at the same price; if not, what are the differences in purchased drugs for all the retail outlets (HMOs, mail order pharmacies, hospital pharmacies, Federal agency pharmacies, chain pharmacies and independent retail pharmacies). If there is a significant difference, is CMS discriminating against some retail outlets? One commenter said that the definition should reflect the prices at which traditional retail pharmacies purchase medications. Another commenter said that in order to be included in the definition of retail pharmacy class of trade, the prices used should be prices available to community pharmacy and the prescriptions should be publicly accessible.

Response: As we have previously noted, AMP is based on the average price received by the manufacturer for the drug; it does not necessarily reflect the pharmacy's acquisition cost.

Comment: Several commenters agreed that the entities included in the retail pharmacy class of trade must provide public access. Another commenter said that retail pharmacy class of trade describes outlets that dispense drugs to the general public.

Response: We agree.

Comment: One commenter stated that entities should be included in the definition of retail pharmacy class of trade on the basis that they do not conduct a manufacturer-wholesaler transaction. Also, hospitals and nursing homes do not distribute drugs to the general public and should not be included in retail pharmacy class of trade. Only traditional retail pharmacies (chains and independents) should be included. The retail pharmacy class of trade should be defined as those pharmacies that provide face-to-face service to patients, offer timely delivery, can provide 24/7 availability and response to patient needs, and are available to patients in the event of a disaster.

Response: We do not agree that the retail pharmacy class of trade is limited

to those entities proposed by the commenter. As stated in response to prior comments, we define retail pharmacy class of trade more broadly to include, for example, direct sales to physicians and outpatient hospital sales, to the extent that they provide drugs to the general public.

Comment: Many commenters stated that the retail pharmacy class of trade should include any independent pharmacy, independent pharmacy franchise, independent chains, independent compounding pharmacy, and traditional chain pharmacy—including each traditional chain pharmacy location, mass merchant pharmacy and supermarket pharmacy.

Response: We agree, but note that we do not believe this list of pharmacies to be inclusive of all entities in the retail pharmacy class of trade.

Comment: Another commenter said that the proposed definition of retail pharmacy class of trade includes entities such as mail-service pharmacies, hospital outpatient pharmacies, and outpatient clinics that may have access to rebates and price concessions that are not accessible to community pharmacies. One commenter further said that these entities fall clearly outside of the statutory definition of AMP. Some commenters said that if AMP is to represent the price of drugs bound to the retail pharmacy class of trade then it should include and exclude components (including discounts, rebates, and other price concessions) according to their impact on the acquisition price actually paid by the retail pharmacy class of trade.

Response: We disagree. We believe the statute requires that rebates, discounts, and price concessions associated with drugs to the retail pharmacy class of trade be included in AMP. The definition does not precondition the inclusion of such discounts or other price concessions on whether other entities within the retail pharmacy class of trade can access these same discounts. We believe there are variety of circumstances in which an entity within the retail pharmacy class of trade might receive a rebate or discount not available to other entities in that class.

Comment: One commenter said that manufacturers should be instructed to exclude from AMP sales to entities that do not meet the definition of the retail pharmacy class of trade.

Response: We have clarified at § 447.504(g)–(h) which sales are included and excluded in this final regulation.

Comment: A few commenters said that independent pharmacy owners should have a level playing field. It is not fair to include rebates and discounts to PBMs, insurance companies and government agencies and exclude rebates to independent business owners. One commenter said that only if complete access to all discounts offered at every level, mail order, government, HMO and PPOs are offered to any willing buyer will this system be fair.

Response: We disagree. The rebate agreement provides for the inclusion of rebates, discounts, and price concessions associated with drugs provided to the retail pharmacy class of trade in AMP. It does not condition the inclusion of such price concessions on whether other entities within the retail pharmacy class of trade can receive these same discounts. We agree with the comments concerning the PBMs and certain government purchasers, and have decided to exclude certain Federal and state sales, and PBM rebates, discounts, or other price concessions from the determination of AMP, except for purchases through PBM mail order pharmacies. As noted previously, we believe there may be circumstances in which an entity within the retail pharmacy class of trade might receive a rebate or discount not available to other entities in that class of trade.

Comment: One commenter stated that there is no basis in the statute or in the congressional discussion surrounding the legislation to include sales to mail order pharmacies and rebates, discounts, or other price concessions associated with sales of drugs provided to the retail pharmacy class of trade in AMP. Had Congress wanted to do so, it would have expressly provided for these items to be included in AMP, as it had done in establishing the ASP-based reimbursement system for Medicare Part B drugs.

Response: We do not agree. After consideration of all comments received, we continue to believe that mail order pharmacies are part of the retail pharmacy class of trade in as much as they dispense prescriptions to the general public. The rebate agreement has consistently provided for the inclusion of rebates, discounts, and price concessions associated with drugs provided to the retail pharmacy class of trade be included in AMP. We see no reason to change that policy in this rule.

Comment: One commenter requested that CMS clarify what it means to sell or provide covered drugs to the general public.

Response: We believe that the term sell or provide covered drugs to the general public as discussed previously

in the OIG reports is consistent with our definition of the retail pharmacy class of trade. As discussed previously, we have defined retail pharmacy class of trade to include the sector of the drug marketplace, similar to the marketplace for other goods and services, which dispenses drugs to the general public and which include all price concessions related to such goods and services.

Treatment of Medicaid Sales

Comment: One commenter stated that price concessions associated with the sales to Medicaid should be included in AMP but Medicaid rebates should be excluded because no portion of these rebates is shared with the retail pharmacy community. One commenter agreed that prices paid by Medicaid programs should be included in AMP.

Response: We appreciate the support for this provision and have clarified in the regulation text at § 447.504(h)(23) that discounts and other price concessions to third party payers, including Medicaid, are excluded from AMP.

Comment: One commenter stated that if CMS requires Medicaid sales and units to be included in AMP, then CMS should require that the applicable Medicaid rebates are included in AMP. Requiring the inclusion of Medicaid units in AMP without including the applicable Medicaid rebates will skew the AMP calculation and make the resulting AMP inaccurate.

Response: We disagree. We do not believe that including Medicaid sales and units without the respective rebate in AMP results in an inaccurate AMP. AMP is calculated by dividing net sales by total number of units sold, less free goods. This has been CMS' policy since the inception of the Medicaid Drug Rebate Program. While AMP and best price include discounts or other price concessions, we do not believe that Medicaid rebates should be subtracted from sales. As a practical matter, we do not know how this could be done with accuracy because manufacturers often do not know which of their sales are dispensed to Medicaid beneficiaries.

Comment: Many commenters stated that Medicaid sales should not be included in AMP, similar to other Federal payers.

Response: We disagree. Medicaid sales are included in AMP, as are the sales in other Federal programs (except for those excluded as identified in the regulation), because Medicaid sales are part of the chain of sales to retail pharmacies. Therefore, we believe that it is appropriate to include Medicaid sales in AMP. Furthermore, manufacturers often do not know which

of their sales are dispensed to Medicaid beneficiaries, making it impossible to remove these sales from AMP.

Comment: One commenter stated that AMP should reflect rebates paid by manufacturers to third party payers such as Medicaid which are unavailable to retail pharmacies.

Response: AMP generally reflects rebates provided by the manufacturer for drugs distributed to the retail pharmacy class of trade. However, the rebate agreement specifically state that rebates paid to States under the Medicaid Drug Rebate Program are excluded from AMP calculations. We see no reason to change that policy in this rule.

Comment: One commenter requested that CMS explain what sales and associated rebates are paid under the Medicaid Program other than those paid under section 1927 of the Act.

Response: Rebates paid to State Medicaid Agencies for covered outpatient drugs dispensed to Medicaid beneficiaries, including CMS-authorized State supplemental rebates, are excluded from AMP.

Comment: One commenter requested that CMS clarify what we mean in the proposed by the statement, "Therefore, we would clarify that rebates paid to the States under the Medicaid Drug Rebate Program should be excluded from AMP calculations but that the price concessions associated with the sales of drugs in the retail pharmacy class of trade which are provided to Medicaid patients should be included" (71 FR 77180).

Response: This statement was intended to clarify how price concessions provided to wholesalers for drugs for which Medicaid is the payer differ from Medicaid rebates paid directly by manufacturers to Medicaid agencies. It would be virtually impossible for a manufacturer to separate these price concessions out from its AMP calculation because Medicaid does not purchase drugs directly, but reimburses pharmacies for drugs. Rebates, however, are paid based on state utilization data by manufacturers to States. These are clearly identifiable and are not taken into account in the calculation of AMP.

Comment: One commenter requested that CMS clarify how rebates paid to State Medicaid agencies under either the national rebate agreement or a CMS-authorized supplemental rebate agreement are treated in the calculation of AMP. The commenter asked whether manufacturers are expected to perform some level of diligence to trace Medicaid sales to the retail pharmacy class of trade.

Response: Rebates paid to State Medicaid Agencies under either the national rebate agreement or CMS-authorized State supplemental rebate agreements are excluded from AMP.

Comment: Several commenters stated that including Medicaid data in AMP is "bootstrapping" the AMP calculation and does not recognize that Medicaid pricing is heavily regulated by the State and Federal Government. The commenters believed that the inclusion of Medicaid data would have an artificial impact on market prices, and that Medicaid should be excluded from the AMP calculation. Other commenters stated that including Medicaid sales data would likely create a circular loop, negating the validity of AMP.

Response: We disagree. The AMP is not intended to represent the prices paid by retail pharmacies for medications; rather, it 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. We do not believe that the inclusion of Medicaid sales will have an impact on market prices because they are subsumed in the total sales from manufacturers to wholesalers.

Treatment of Supplemental Rebates

Comment: One commenter stated that supplemental rebates paid to the Medicaid agency are not disclosed, never shared with pharmacy vendors and may be significant in their negative impact on those vendors participating in the Medicaid Program.

Response: Medicaid supplemental rebates paid to the Medicaid agency are not included in AMP. We see no reason why supplemental rebates paid to the State that do not impact the payment rate to pharmacies would affect their participation in the Medicaid Program.

Comment: A few commenters stated that because community pharmacies do not receive State supplemental rebates, the rebates should be excluded from AMP. Another commenter requested that CMS clarify that any supplemental rebates manufacturers pay to State Medicaid programs are to be considered "other price concessions" for the purposes of this section; thus, these rebates should be included in AMP calculations.

Response: Supplemental rebates paid under a CMS-authorized State supplemental rebate agreement are excluded from AMP and not considered as "other price concessions" for the purposes of this section. We have clarified in the regulation text at § 447.504(h)(24) that such supplemental drug rebates are excluded from AMP.

Comment: One commenter requested that CMS 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.

Response: Rebates paid to States under the Medicaid Drug Rebate Program are excluded from AMP, but the units and price concessions associated with the sales of drugs in the retail pharmacy class of trade, regardless of whether such drugs are provided to Medicaid patients, are included.

Comment: A commenter requested that CMS clarify whether supplemental state rebates (for example, those associated with a preferred drug list) are included as well.

Response: All supplemental rebates paid under a CMS-authorized State supplemental rebate agreement are excluded from AMP regardless of whether the agreement is associated with a preferred drug list.

Treatment of Medicare Part D Sales

Comment: Several commenters expressed support for CMS' treatment of Medicare Part D.

Response: We appreciate the support for this provision and have clarified in the regulation text at § 447.504(h)(23) that associated discounts, rebates, or other price concessions to third party payers such as a PDP or an MA-PD are not included in the calculation of AMP on the basis that such price concessions are essentially third party discounts and not discounts which adjust the price actually realized at the retail pharmacy. We retained in the regulation text that the sales of drugs in the retail pharmacy class of trade which are provided to a PDP or an MA-PD are included in AMP.

Comment: Several commenters stated that sales and rebates to a Medicare Part D PDP and an MA-PD should not be included in AMP. One commenter recommended that CMS exclude price concessions under Medicare Part D, as these price discounts are PBM discounts of those PBMs that administer the Part D Program. One commenter further stated that the rebates paid by the manufacturer to a PDP or an MA-PD are not considered by wholesalers when determining the purchase price to a retail community pharmacy and should not be included in any calculation to reimburse the pharmacy. A few commenters stated that Medicare Part D rebates are similar to Medicaid rebates, which are excluded from AMP, and that Medicare Part D rebates should be treated similarly. One commenter

requested that CMS confirm and provide guidance regarding whether rebates paid to Medicare Part D are excluded from AMP. Another commenter stated that including the prices of sales and rebates through a PDP, MA-PD, or a qualified retiree prescription drug plan would result in a windfall to manufacturers and an additional burden for retail pharmacies. The commenter stated that while prices charged to Part D plans cannot create a new best price for the Medicaid Program, including Part D prices that are lower than typical commercial prices in AMP calculations could further reduce the reported AMPs below the actual cost to retail pharmacies.

Response: We have clarified in the regulation text at § 447.504(h)(23) that associated discounts, rebates, or other price concessions to third party payers such as to a PDP or an MA-PD are not included in AMP. Such price concessions are essentially third party discounts and not discounts which adjust the price actually realized. We retained in the regulation text that the sale of the drugs reimbursed by these programs and units associated with the sales of drugs in the retail pharmacy class of trade which are reimbursed by a PDP or an MA-PD should remain in AMP. We do not believe that this will be a burden for retail pharmacy because the manufacturer would not necessarily know the ultimate destination or whether the discount or price concession to the third party payer is passed on to the retail pharmacy class of trade such that it would result in an adjustment of the price actually realized.

Comment: One commenter requested that CMS clarify whether a manufacturer discount provided to a PBM in connection with Part D mail order business should be included in AMP.

Response: We have clarified in the final rule at § 447.504(g)(6) that sales and discounts to mail order pharmacies operated by PBMs are included in AMP.

Comment: One commenter requested that CMS clarify the treatment of qualified retiree prescription drug plans for purposes of AMP.

Response: We have clarified in the regulation text at § 447.504(h)(23) that associated discounts, rebates, or other price concessions paid to third party payers such as rebates paid by the manufacturer to a qualified retiree prescription drug plan under section 1860D-22(a)(2) of the Act are not included in AMP. Such price concessions are essentially third party discounts and not discounts which adjust the price actually realized. We

retained in the regulation text that the sale of the drugs reimbursed by these programs and units associated with the sales of drugs in the retail pharmacy class of trade which are reimbursed by a qualified retiree prescription drug plan under section 1860D-22(a)(2) of the Act should remain included in AMP.

Comment: One commenter stated that the proposed rule excludes from AMP rebates to Medicaid, the DoD, the IHS, and the DVA because prices to these entities are not available to the retail pharmacy class of trade. Rebates offered to SCHIP, Medicare Part D Plans, and SPAPs are also not available to the retail pharmacy class of trade but are required to be included in AMP. The commenter asserted that assumptions in the proposed rule regarding these programs are definitely flawed and should be revisited.

Response: We revised the regulation text at § 447.504(h)(23) to state that associated discounts, rebates, or other price concessions to third party payers such as a PDP, MA-PD, SCHIP, or an SPAP are not included in the calculation of AMP. Such price concessions are essentially third party discounts and not discounts which adjust the price actually realized.

Comment: One commenter stated that including Part D in AMP may change manufacturer discounting behavior for Part D.

Response: We do not believe that a change in manufacturer discounting behavior is likely, as the manufacturer would not necessarily know the ultimate destination when initially sold. Furthermore, as discussed previously, we have revised the regulation to exclude discounts, rebates, or other price concessions to third party payers, such as a PDP or MA-PD. Such price concessions are essentially third party discounts and not discounts which adjust the price actually realized.

Comment: A few commenters said that the proposed rule directs manufacturers to consider sales and associated price concession extended to Part D. However, manufacturers do not have access to this information until they receive quarterly invoices from the States. CMS should include in the final rule instructions for addressing lagged data.

Response: We appreciate these comments and have clarified in the regulation text at § 447.504(h)(23) that associated discounts, rebates, or other price concessions paid to third party payers such as rebates paid by the manufacturer to a qualified retiree prescription drug plan under section 1860D-22(a)(2) of the Act are not

included in AMP. As discussed previously, such price concessions are essentially third party discounts and not discounts which adjust the price actually realized.

Comment: One commenter said that CMS should recognize in the final rule the operational challenges manufacturers face in collecting data. Based on those challenges, the commenter urged CMS to allow manufacturers to make and rely upon appropriate reasonable assumptions when including Part D sales in AMP.

Response: We recognized the operational challenges manufacturers face in collecting data and have clarified in the final regulation text the submission of lagged price concessions and the use of manufacturer assumptions.

SPAP Price Concessions

Comment: Many commenters suggested that CMS exclude manufacturer rebates to SPAPs from AMP calculations as it does with Medicaid rebates. Another commenter expressed appreciation for CMS' specific guidance regarding the treatment of discounts/rebates to SPAPs, but disagreed with including discounts/rebates to SPAPs in AMP. This commenter argued that SPAPs are government-run programs, and discounts offered to them are often statutorily driven (sometimes tied to Medicaid rebates) or otherwise not determined by market factors. Another commenter stated that SPAPs are similar to the Medicaid Program in that SPAPs represent third-party government payers; therefore, rebates for these programs should be treated the same as Medicaid rebates. One commenter stated that the proposal to include all SPAP sales and rebates in AMP to the extent that these sales are made to the retail pharmacy class of trade conflicts with Manufacturer Release 68, which states that only SPAPs that meet specified criteria are excluded from AMP. Another commenter requested that CMS clarify that all SPAP sales and rebates are included regardless of the administrative structure of the SPAP. Other commenters supported the inclusion of SPAP sales and rebates in AMP.

Response: We recognize that SPAPs are typically third-party governmental payers that do not directly purchase drugs from manufacturers. After considering the comments received, we agree that SPAP sales, as well as sales to PDPs and MA-PDs under the Medicare Part D Program should be treated in the same manner as Medicaid sales. That is, sales of drugs that are

paid by these programs to pharmacies are included in AMP, but we have revised our policy and provide in this final rule at § 447.504(h)(23) that associated discounts, rebates, or other price concessions to the extent that they do not adjust prices at the retail pharmacy class of trade are excluded from AMP. As discussed previously, we believe that such price concessions are essentially third party discounts and not discounts which adjust the price actually realized. Other State payments for drugs, such as State employee benefit programs or medical programs for inmates or patients of State prisons or hospitals, do not meet the criteria of an SPAP. We also agree with the commenter regarding Manufacturer Release 68 and have clarified that SPAP sales should be included in AMP and SPAP discounts should be excluded. Therefore, all SPAP sales will be treated the same for AMP, regardless of whether they meet the criteria in Manufacturer Release 68.

Comment: Several commenters stated that community pharmacies do not receive State-only and SPAP prices and rebates; therefore, these should be excluded from AMP. One commenter believed it is inconsistent with the legislative intent of the DRA for CMS to include sales reimbursed by SPAPs for non-Medicare Part D covered prescriptions in the calculation of the AMP because no Federal money is involved, making it outside CMS' purview in determining what to include in AMP. One commenter stated that the inclusion of SPAPs seems inconsistent with legislative intent.

Response: CMS believes that SPAP sales should be included in AMP given our understanding of the statute. We also find that SPAP sales, like Medicaid and Medicare Part D sales, are part of the broader chain of sales from manufacturers to wholesalers or pharmacies that are indistinguishable from other market sales. We believe that SPAP sales are within the scope of AMP because AMP is intended to capture sales to the retail pharmacy class of trade.

Comment: One commenter requested that CMS post on its Web site a complete and accurate list of qualified SPAPs which is updated on a frequent and regular basis.

Response: We appreciate this comment and will continue to post a current list of SPAPs designated as exempt from best price on the CMS Web site at <http://www.cms.hhs.gov/MedicaidDrugRebateProgram/Downloads/SPAPBestPriceList.pdf>.

Comment: Another commenter asked that CMS treat SPAP sales consistently

for AMP and best price purposes and exclude them from both. AMP should reflect prices in the commercial marketplace and including prices set by statute in the AMP calculation undermines this purpose. Likewise, excluding prices from best price encourages manufacturers to provide concessions that do not reflect commercial considerations, as is the case with SPAPs, where prices or rebates are generally the result of State law rather than market negotiations.

Response: We disagree. While the statute specifically excludes SPAPs from the determination of best price, CMS believes that SPAP sales should be included in AMP because they are subsumed in the overall chain of sales from the manufacturers through wholesalers to the pharmacies in the retail pharmacy class of trade.

Comment: One commenter asked CMS to provide guidance regarding how SPAP sales and rebates should be included. Specifically, the commenter asked CMS to specify what ratio of sales manufacturers should apply to SPAP rebates, since the data available to manufacturers do not indicate the particular sales to which the rebates apply.

Response: We have clarified in the regulation text at § 447.504(h)(23) that associated discounts, rebates, or other price concessions paid to third party payers such as rebates paid by the manufacturer to a SPAP are not included in AMP. Such price concessions are essentially third party discounts and not discounts which adjust the price actually realized.

Comment: One commenter noted that the proposed rule directs manufacturers to consider sales and associated price concession extended to SPAPs. However, manufacturers do not have access to this information until they receive quarterly invoices from the states. CMS should include in the final rule instructions for addressing lagged data.

Response: We have in § 447.504(h)(23) excluded the associated discounts, rebates, or other price concessions provided by the manufacturer to SPAPs from AMP in this final rule.

Comment: One commenter requested that CMS define SPAP.

Response: We have decided not to define SPAP in this regulation at this time. The current guidance for the definition of SPAP has been set forth in Manufacturer Release 68.

Comment: One commenter requested that we share with SPAPs the quarterly unit rebate amount (URA) on the basis

that the data is already being furnished to State Medicaid Agencies.

Response: The URAs for brand name drugs are based on best price, which we consider confidential. The URAs for generic drugs are 11 percent of AMP, which will be posted on our Web site.

Treatment of SCHIP

Comment: One commenter noted that the proposed rule directs manufacturers to consider sales and associated price concession extended to SCHIP.

However, manufacturers do not have access to this information until they receive quarterly invoices from the States. CMS should include in the final rule instructions for addressing lagged price concessions.

Response: We have modified the regulation text regarding the submission of lagged price concessions to allow manufacturers to submit such information.

Comment: One commenter asked that we clarify the meaning of the term "associated with sales of drugs provided to the retail pharmacy class of trade" in regard to Part D, SCHIP, and SPAP.

Response: We have clarified in the regulation text at § 447.504(h)(23) that associated discounts, rebates, or other price concessions paid to third party payers such as rebates paid by the manufacturer to Medicare Part D, SCHIP, and SPAP are not included in AMP. However, we continue to believe that the respective sales are included in AMP to the extent that such sales have occurred through the retail pharmacy class of trade. However, the associated discounts, rebates, or other price concessions for these sales are not included in AMP because we understand such price concessions are essentially third party discounts and not discounts which adjust the price actually realized.

Comment: One commenter stated that SCHIP should be excluded from AMP and another commenter expressed support for the inclusion of SCHIP.

Response: We agree that the treatment of SCHIP sales is determined by the entities that are actually in the sales chain for drugs for SCHIP beneficiaries. We recognize that SCHIP sales are similar to Medicaid sales and should be treated as such. Therefore, we have clarified in the regulation text at § 447.504(h)(23) that the associated discounts, rebates, or other price concessions for these sales are not included in AMP. We understand that such price concessions are essentially third party discounts and not discounts which adjust the price actually realized. We retained in the regulation text at § 447.504(g)(15) that the sale and units

associated with the sales of drugs in the retail pharmacy class of trade which are provided to SCHIP are included in AMP.

Prices to Other Federal Programs

Comment: One commenter endorsed CMS' position to exclude from AMP the prices provided to government programs on the basis that such purchases are outside the retail pharmacy class of trade. Other commenters stated that community pharmacies do not receive FSS/depot prices and should be excluded from AMP.

Response: We appreciate the support for this provision and have retained this requirement at § 447.504(h) in the final rule.

Comment: Several commenters stated that CMS rightly excluded from AMP, manufacturer rebates paid to the DoD under TRICARE. One commenter requested that the classification of the retail TRICARE pharmacies as a depot should be avoided until the issue between manufacturers and the DVA has been resolved. Several commenters requested that CMS provide clarification regarding which TRICARE prices, if any, are considered depot prices and are excludable. Several commenters requested that CMS provide clarification in the treatment of TRICARE utilization when the manufacturer has not paid rebates on the utilization and does not receive utilization data.

Response: We appreciate the comment regarding the litigation concerning TRICARE and DVA program. See *The Coalition for Common Sense in Government Procurement v. Secretary of Veteran Affairs*, 464 F.3d 1306 (Fed. Cir. 2006). However, we recognize that TRICARE, like the Medicaid Program, is a third-party governmental payer that does not directly purchase drugs from manufacturers. After considering the comments received, we agree that TRICARE sales, as well as sales to SPAPS, PDPs and MA-PDs under the Medicare Part D Program should be treated in the same manner as Medicaid sales to the extent that such sale has occurred through the retail pharmacy class of trade. That is, sales of drugs to pharmacies that are reimbursed by these programs are included in AMP, but we have revised our policy and provide in this final rule at § 447.504(h)(23) that associated discounts, rebates, or other price concessions to these programs are excluded from AMP.

Comment: One commenter requested that CMS clarify whether the exclusion for depot prices applies both to mandatory rebates and voluntary rebates paid to the DoD. Additionally, if voluntary rebates paid to DoD are to be

excluded from AMP, the final rule must specify whether the units are to be left in the calculation, as with Medicaid rebates, or, if the units are to be excluded, the value at which the excluded units should be removed from the AMP calculation.

Response: We have clarified in this final regulation at § 447.504(g)(15) that sales of drugs to pharmacies that are reimbursed by TRICARE are included in AMP, but we have revised our policy and provide in this final rule at § 447.504(h)(23) that associated discounts, rebates, or other price concessions, whether mandatory or voluntary, are excluded from AMP.

Comment: One commenter requested that CMS clarify whether payment of rebates by a manufacturer on TRICARE utilization is a prerequisite for concluding that such utilization is a depot sale.

Response: We have clarified in the final regulation at § 447.504(h)(23) that associated discounts, rebates, or other price concessions to TRICARE are excluded from AMP.

Comment: Several commenters stated that CMS rightly excluded manufacturer rebates paid to the DVA and the DoD from AMP.

Response: We appreciate the support for this provision and have retained this requirement at § 447.504(h)(1) in the final rule.

HMOs and MCOs

Comment: A few commenters stated that it is unclear whether the HMO/MCO exclusion from AMP applies only to purchases by MCOs that have their own facilities, or whether it also excludes transactions of health plans that reimburse network providers. The commenters further stated that only transactions with clearly identifiable HMOs and health plans should be treated as excluded from AMP. Many commenters asked that CMS clarify that HMOs that simply reimburse enrollees for their drug purchases at retail pharmacies (without themselves purchasing or taking possession of the drugs) are included in the calculation of AMP.

Response: We recognize that many HMOs that act as third party payers, like SPAPs and PBMs, do not generally take possession of pharmaceutical products. Sales of these drugs flow through the regular retail chain of sales and are not distinguishable to manufacturers. Accordingly, similar to a third party payer, when an HMO does not purchase or take possession of drugs, we consider those sales to be within the retail sales chain and not the HMOs. Because as with other third party payers, the

discounts, rebates, or price concessions are not available to the wholesaler, we have clarified that the associated rebates, discounts, or other price concessions are not included in AMP. We retained in the regulation text at § 447.504(h)(23) that the sales of the drug reimbursed by the HMO/MCO should remain in AMP, but sales directly to the HMO/MCO should be excluded. However, when drugs are dispensed by HMOs, including managed care organizations, those drugs are not subject to the requirements of the Medicaid drugs rebate program.

Comment: One commenter noted that in some places in the proposed rule CMS uses the terms MCO and HMO interchangeably, but in others, it refers to "health maintenance organizations (HMOs), including managed care organizations (MCOs)." The commenter noted that MCO is usually an umbrella term for a number of different entities, one of which is an HMO. The commenter requested that CMS clarify the definition of MCO for purposes of the final rule. Another commenter stated that neither HMO nor MCO is defined in the proposed rule.

Response: We acknowledge that the terminology used for these entities varies. Our intent is that sales to HMOs and MCOs that purchase and take possession of drugs are excluded from AMP. We have clarified in § 447.504(h)(23) that the associated rebates, discounts, or other price concessions for an HMO does not purchase or take possession of drugs are not included in AMP. We retained in the regulation text at § 447.504(g)(15) that the sales of the drug reimbursed by the HMO/MCO should remain in AMP.

Comment: One commenter requested that CMS clarify whether HMO-operated pharmacies that provide drugs only to their enrollees are excluded from AMP. The commenter noted that these pharmacies do not serve the general public in the way that other retail pharmacies do.

Response: HMO-operated pharmacies that purchase drugs and provide these drugs only to their enrollees are excluded from AMP. We have clarified in the regulation text at § 447.504(h)(5) that direct sales to HMO-operated pharmacies are excluded from AMP.

Comment: One commenter asked that we clarify whether the reference to HMOs and MCOs are limited to so-called "staff model" HMOs and MCOs that purchases pharmaceuticals for dispensing to their members, or whether they include so-called "IPA-model" HMOs and MCOs that arrange for pharmacy discounts but do not actually purchase drugs.

Response: As explained above, direct sales to HMOs that purchase and take possession of drugs, such as many staff model HMOs, would be excluded from AMP.

Comment: One commenter was pleased that CMS included MCOs in its definition of HMOs, which the statute specifically excludes in section 1927 of the Act. Another commenter expressed support for the treatment of HMOs/MCOs.

Response: As discussed in the preceding responses, we distinguish between HMOs and MCOs that purchase and take possession of drugs, which are excluded from AMP, from those that reimburse for drugs through retail pharmacies, which are included in AMP.

Comment: One commenter requested that CMS exclude direct and identifiable indirect sales to HMOs that operate their own pharmacy.

Response: As noted in the preceding responses, these sales are excluded from AMP.

Administrative and Service Fees

Comment: Several commenters agreed with CMS that “bona fide service fees” should not be taken into account for the purpose of AMP. These commenters noted that this is consistent with Congress’s intent and consistent with the treatment of bona fide services fees for the calculation of ASP for Medicare Part B.

Response: We appreciate the support for this provision and have retained this provision at § 447.504(h)(19) in the final regulation.

ASP

Comment: Many commenters requested that CMS explicitly adopt all guidance related to the definition of bona fide service fee contained in the preamble to the 2007 Physician Fee Schedule (PFS) final rule published on December 1, 2006 (71 FR 69624). Another commenter supported the same approach for AMP in Medicaid. CMS defined these fees as “expenses that generally would have been paid for by the manufacturer at the same rate had these services been performed by other or similarly situated entities.” CMS should continue to permit manufacturers, depending on the circumstances and the nature of the services involved, to calculate the fair market value for a set of itemized bona fide services, rather than for each service individually. Moreover, as the method for determining fair market value may vary based on the terms of the contract at issue, CMS should refrain from requiring manufacturers to

follow a particular method for evaluating whether a fee equals fair market value. The commenter further said that the bona fide service fee definition requires these fees to “not be passed on, in whole or in part, to a client or customer of an entity.” The commenter urged CMS to replicate its interpretation of this clause in the ASP context for AMP. Another commenter stated that CMS should clarify that the explanations applicable to the definition of bona fide service fees when manufacturers are calculating ASP also apply when they are determining AMP and best price because many manufacturers do not make products subject to ASP reporting and may not be familiar with the discussion of service fees in the preamble to the 2007 PFS final rule. The commenter requested CMS to expressly reference the discussion of bona fide service fees in the preamble to the 2007 PFS final rule, as well as make clear that CMS is adopting the principles and positions applicable to bona fide service fees outlined in the 2007 PFS final rule in the ASP context for purposes of AMP and best price.

Response: We agree. In light of the many comments received, we are adopting the 2007 final ASP reporting rule’s (71 FR 69668, December 1, 2006) interpretation of the definition of bona fide service fees and how manufacturers may apply the definition for the purposes of AMP and best price. We appreciate these comments and have further clarified in § 447.502 that bona fide service fees mean fees for an expense that would have been paid by the manufacturer at the same rate had these services been performed by the manufacturer or another entity.

Comment: One commenter believes CMS should apply the definition of bona fide service fees to the term “distribution services” on the basis that the ASP final rule has clearly articulated a standard for exclusion. Furthermore, incorporating the term “distribution services” into the definition of AMP does not reflect the fact that many core distribution services—such as packaging, shipping and handling—may meet the test of bona fide service fee and should be excluded from AMP.

Response: We appreciate this comment and have clarified at § 447.504(h) that distribution services which meet the definition of bona fide services fees are excluded from AMP.

Comment: Several commenters expressed support for the exclusion of legitimate service fees from AMP, since by definition, these fees are paid for services, not the drug. However, the exclusion only recognizes one of the

two standard methods by which manufacturers have paid service fees and recommended that CMS create an additional explicit exclusion for administrative fee arrangements that meet the OIG safe harbor under the anti-kickback statute.

Response: We believe that it is outside the scope of our authority to propose exclusions regarding the OIG safe harbor under the anti-kickback statute since only the IG of the U.S. Department of Health and Human Services has been authorized to issue advisory opinions related to health care fraud and abuse under section 1128D(b) of the Act.

Comment: Several commenters recommended that CMS eliminate the condition that the services would be required “in the absence of the service arrangement” or otherwise clarify that fees paid for bona fide administrative services related to the administration of a rebate contract will qualify as “bona fide service fees” as long as they are: (i) for legitimate services, (ii) for services that the manufacturer would otherwise have to perform or have others perform for it, and (iii) represent fair market value.

Response: We disagree. We do not believe that for the purposes of the Medicaid drug rebate program, administrative services related to the administration of a rebate contract would qualify as bona fide service fees because these fees are not associated with the efficient distribution of drugs or our interpretation of the bona fide service fee guidance.

Comment: A commenter further said that bona fide service fees should explicitly include all fees paid by manufacturers to non-terminal retail providers.

Response: We disagree. We believe that the definition and additional guidance clearly defines what constitutes a bona fide service fee and distinguishes these fees from other fees that may reduce the price of a drug.

Comment: One commenter strongly supports CMS’ proposed definition of bona fide services and believes that the decision to adopt the same definition of these fees for both ASP and AMP will enhance uniformity in reporting across the Medicare and Medicaid Programs. However, the commenter encourages CMS to confirm several points by replicating portions of the narrative of the PFS final rule and (1) deleting the specific reference to “distribution fees” in the definition of AMP, (2) confirm that the terms “bona fide,” “itemized,” and “actually performed on behalf of the manufacturer or otherwise performed” include “any reasonably necessary or useful services of value to

the manufacturer that are associated with the efficient distribution of drugs.” CMS should reiterate that AMP will incorporate the ASP definition’s reference to services that are performed “on behalf of” a manufacturer as including both those services that a manufacturer possesses the capacity to perform and those that only another entity can perform.

Response: We appreciate the support for this provision and have incorporated the final ASP reporting rule’s interpretation of the definition of bona fide service fees at § 447.502 and how manufacturers may apply the definition for the purposes of AMP in its entirety.

Group Purchasing Organizations

Comment: Many commenters requested that CMS specify that administrative fees paid to GPOs be specifically excluded from AMP. A few commenters requested that CMS clarify an issue in the preamble to the final ASP rule regarding whether fees paid to GPOs would come within the definition of bona fide service fees. The commenters stated that these fees should receive the same treatment as other administrative and service fees for the purpose of AMP and best price. Also, CMS should clarify in the final rule that such arrangements do not constitute price concessions or discounts to purchasers and should require the manufacturer to ascertain if the fee is passed on. One commenter requested that CMS clarify that fees paid to GPOs are excluded and revise the definition of bona fide service fee to read, “For purposes of 42 CFR § 447.504(h) and 447.505(e), fees paid by a manufacturer to a bona fide group purchasing organization, as defined at 42 CFR § 100.952(j)(2), will not constitute a price concession by the manufacturer unless the fees (or any portion thereof) are passed on to the group purchasing organization’s members or customers as part of an agreement between the manufacturer and the GPO.”

Response: We have clarified in § 447.504(h)(19) that to the extent that fees, including service fees, distribution fees, and administrative fees and other fees to GPOs meet the definition of “bona fide service fee,” such fees are excluded from the calculation of AMP and are not considered price concessions. If the manufacturer has an agreement with the GPO that any of these monies are passed on to the group purchasing organization’s members or customers, they would not be excluded as a bona fide service fee. We believe there must be no evidence or arrangement that the fee is passed on to

the member pharmacy, client or customer of any entity included in the calculation of AMP in order for the manufacturer to exclude these fees from the determination of AMP.

Comment: Several commenters said that unlike the “safe harbor” regulations, the proposed rule should not differentiate between administrative fees paid to entities, such as GPOs and PBMs, and fees for other services, such as distribution and inventory management. The commenter further supported the exclusion of both types of fees from AMP, if they satisfy the criteria for itemized bona fide services performed on behalf of a manufacturer for fair market value not passed through to a customer or client of the recipient, regardless of whether it takes title to the drugs, because such fees are necessary business expenditures. However, the commenters urge CMS to allow categorical exclusion of administrative fees of three percent or less if they fall within the GPO administrative fee safe harbor, including its limitation with ownership of members. Such a categorical exclusion would be consistent with the purpose of the statutory exemption and safe harbor, which encourage group purchasing arrangements, and alleviate the necessity to evaluate each GPO agreement to determine if it is fair market value for bona fide services received by the manufacturer.

Response: We appreciate these comments and have clarified at § 447.504(h)(19) that to the extent that fees to GPOs meet the definition of “bona fide service fee,” they are excluded from the calculation of AMP. We believe that to propose a categorical exclusion of administrative fees of 3 percent or less if they fall within the GPO safe harbor provisions would be inconsistent with our guidance regarding an actual determination of the amount of bona fide service fees.

Comment: One commenter requested that CMS clarify that the guidance provided in the preamble to the final rule on the ASP calculation is equally applicable in the Medicaid context, except with regard to those circumstances in which a GPO is passing on fees to members.

Response: As we have previously stated, we have incorporated the policy in the ASP rule into this final regulation in § 447.502.

Comment: One commenter further requested that CMS clarify that GPO fees do not affect AMP calculations when the GPO negotiates prices for member hospitals for drugs used in the inpatient setting, since the underlying

sales to hospitals would be excluded from AMP in this circumstance.

Response: We agree that these fees should be excluded to the extent that the sales are not recognized as outpatient hospital sales as elsewhere discussed in this final rule.

Comment: One commenter expressed support for the comment provided by an entity within the industry which suggested that fees to GPOs should not be treated as price concessions “unless the fees (or any portion thereof) are passed on to the group purchasing organization’s members or customers as part of an agreement between the manufacturer and GPO.”

Response: We have incorporated the 2007 final ASP reporting rule’s interpretation of the definition of bona fide service fees at § 447.502 and how manufacturers may apply these definitions for purposes of AMP. We believe that it is necessary to retain consistency regarding bona fide service fees and clarify that to the extent that fees to GPOs meet the definition of “bona fide service fees” the fees are excluded from the calculation of AMP.

Comment: One commenter stated that the proposed rule treats fees, discounts and other concessions offered to purchasers of drugs the same as payments made to third parties like PBMs and GPOs that do not purchase or take possession of drugs (and for GPOs, do not even pay for drugs). The commenter requested that CMS limit the provision to price reductions and other payments that flow to purchasers, and expressly exclude payments that flow to third parties not involved in the purchase transactions. The commenter recommended that CMS clarify this to state that all fees that manufacturers pay to customers or third parties meeting the definition of a bona fide service fee are excluded from the calculation of AMP. The commenter contended that the provision clouds the issue of proper handling of bona fide service fees and appears to create distinctions between administrative fees, service fees and distribution fees that do not always exist.

Response: We appreciate this comment and have clarified at § 447.502 that to the extent that fees to any entity included in the retail pharmacy class of trade meet the definition of bona fide fees, they are excluded from the calculation.

Comment: One commenter recommended that CMS remove the bona fide service fees provision because this term is not well defined and is open for interpretation, abuse, and fraud. The commenter believed that if this term reduces AMP, it should be eliminated.

Response: We disagree. We believe that the excluding bona fide service fee results in an appropriate measure of AMP. We also believe that it provides the appropriate safeguard against potential fraud and abuse. The Federal Government, however, will continue to monitor these calculations to assure they are not done improperly.

Comment: One commenter said that the final rule should provide an overview of the types of payments that are bona fide service fees but not identify an exclusive list. This would allow for manufacturers and contracting entities to make future interpretations based on the practices of the marketplace. The commenter did not see the need for future guidance or rulemaking to add to this list and believes that doing so may reduce the level of innovation and impede the delivery of new products to patients. Other commenters requested that CMS provide more guidance as to what constitutes a bona fide service fee, as well as provide additional parameters and/or specific examples to assist manufacturers in making this determination. Another commenter supported excluding bona fide service fees from AMP, especially when those fees are not passed through to the product's ultimate purchaser, but did not support any attempt to list specific bona fide service fees in the final regulation. The commenter further noted that the preamble should provide examples of types of bona fide service fee payments that would be acceptable for exclusion from the AMP calculation at this time.

Response: We believe that the definition defines what constitutes a bona fide service fee. Providing a list of types of bona fide service fee payments could limit the scope of what constitutes a bona fide service and, because of the complexities of the marketplace, raises further questions as to why some examples were included and some excluded from that list.

Other Fees

Comment: Commenters requested that CMS provide guidance regarding the treatment of payments from manufacturers for performing certain patient care programs, such as patient education and compliance and persistency programs. These payments should be omitted from the AMP calculation because they do not reflect prices paid by wholesalers for drug products or reduce the retail pharmacy's cost of purchasing the drugs.

Response: We are providing no further policy on these arrangements in

this final rule and will continue to review such arrangements individually.

Fair Market Value

Comment: One commenter disagrees with the adoption of Medicare Part B's definition of fair market value. The commenter said that AMP should not exclude bona fide service fees set at the fair market value because Part B drugs cannot be purchased by the pharmacy community at the prices set using ASP. The commenter further stated that excluding bona fide service fees from AMP would transform chain pharmacy stores into variety stores and independent pharmacies would cease to exist. Access to prescription drugs would be unavailable and hospital emergency rooms would become understaffed clinics.

Response: We disagree. We do not believe that allowing manufacturers to exclude bona fide service fees that represent the fair market value of the service will have any impact on the operations of chain and independent pharmacies.

Comment: One commenter stated that to be truly fair and appropriate, the definition of fair market value of drugs must be in some way related to the purchasing power of the pharmacy involved. If all pharmacies are to be included in the calculation, then it must be the cost at which the least powerful purchaser can obtain the product. Alternatively the markets could be separated in a fair manner and the average acquisition cost for each market could be considered to be the fair market value of that particular segment.

Response: We believe that the commenter misunderstood the context of fair market value as it relates to a manufacturer's payment of bona fide service fees. We do not believe that allowing manufacturers to determine the fair market value of drug distribution services as it relates to bona fide service fees impacts the average acquisition cost.

Comment: One commenter supported the exclusion of bona fide service fees from AMP but stated that an unnecessarily narrow reading of what constitutes "fair market value" remuneration for legitimate services performed on behalf of a manufacturer may disrupt normal and legitimate business transactions between PBMs and manufacturers.

Response: Elsewhere in this final rule, we have excluded rebates, discounts and price concessions provided to PBMs from the determination AMP, except for purchases through PBM mail order pharmacies eliminating an effect on these transactions between

manufacturers and PBMs. We have not further defined "fair market value" so that manufacturers have the flexibility to determine fair market value consistent with industry accepted methods. This is consistent with our adoption of the discussion in the 2007 final ASP reporting rule (see 71 FR 69668, December 1, 2006).

Comment: One commenter recommended that CMS not provide that a fee must not be passed on in order for it to be considered a bona fide service fee. If the fee is for a legitimate service performed for the manufacturer, it should not matter if it is passed on. Moreover, the administrative burden for manufacturers to gather confidential information from PBMs and others in the drug channel would be significant and may cause manufacturers to forgo any service arrangements.

Response: We disagree. We believe that a fee which is passed on is not a bona fide service fee but rather a price concession. Price concessions reduce the price realized by the manufacturer for drugs distributed to the retail pharmacy class of trade. We understand that manufacturers may face administrative burdens regarding the collection of data to determine whether a fee is passed on and have incorporated the discussion in the 2007 final ASP reporting rule (see 71 FR 69669, December 1, 2006). Finally, elsewhere in this final rule, we have excluded rebates, discounts and price concession to PBMs so there is no longer the administrative burden associated with PBM adjustments.

Comment: One commenter asked that CMS allow manufacturers discretion in selecting methodologies for determining fair market value and in identifying the types of services that can qualify as bona fide services.

Response: We have not further defined "fair market value" so that manufacturers have the flexibility to determine fair market value consistent with generally recognized standards. This is consistent with our adoption of the discussion in the 2006 final ASP reporting rule (see 71 FR 69668, December 1, 2006).

Comment: One commenter requested that CMS amend the definition of bona fide service fee to reflect that a fee paid by a manufacturer to a group purchasing organization, as that term is defined in 42 CFR § 1001.952(j), represents "fair market value" if the fee results from arms-length, bona fide bargaining between the manufacturer and the GPO.

Response: We believe that the proposed definition and additional guidance incorporated from the final ASP reporting rule clarifies that fees,

including service fees, administrative fees and other fees paid to GPOs are not considered price concessions to the extent that they satisfy the definition of a bona fide service fee.

Comment: A commenter said that CMS should amend the definition of "bona fide service fee" to allow that a payment need not represent fair market value in order to qualify as a bona fide services fee.

Response: We do not agree. As previously discussed, we have not further defined "fair market value" so that manufacturers have the flexibility to determine fair market value consistent with generally recognized standards. This is consistent with our adoption of the discussion in the 2006 final ASP reporting rule (see 71 FR 69668, December 1, 2006).

Comment: Other commenters stated that CMS should allow a manufacturer to exclude from AMP any payment to any entity other than a purchaser, where this payment is not passed on in whole or in part by the entity to a purchaser of the manufacturer's drugs as a price concession by the manufacturer.

Response: We disagree. We believe that the proposed definition and additional guidance incorporated from the final ASP reporting rule clearly define what constitutes a bona fide service fee to an entity included in the retail pharmacy class of trade, which is excluded from AMP.

Comment: One commenter requested that CMS clarify whether a service fee determined not to be "bona fide," should be prorated to include only that portion related to sales included in AMP.

Response: A manufacturer's AMP should include administrative fees, service fees (except bona fide service fees) and distribution fees for those entities and units of drugs included in the determination of AMP.

Comment: One commenter agreed that certain service fees should be included in the calculation of AMP on the basis that some wholesalers charge inventory service or stocking fees to certain manufacturer for carrying their products. Fees such as inventory service or stocking fees should not be considered bona fide service fees as they do not fall under the proposed definition and effectively result in a discount that should be considered when calculating AMP. The commenter further expressed concern that inventory service or stocking fees charged to manufactures by wholesalers are not imposed uniformly and agreed that these should be excluded from AMP to ensure consistency between manufacturers.

Response: We believe that the definition and additional guidance clearly defines what constitutes a bona fide service fee and distinguishes these fees from other fees that may reduce the price of a drug.

Retail Impact

Comment: One commenter said that community pharmacies do not receive administrative service agreements from wholesalers and should be excluded from AMP. Another commenter stated that administrative fees and service fees paid to wholesalers, PBMs or HMOs should not be excluded from the calculation of AMP because these fees are not available to the retail pharmacy of trade. The commenter further stated that the fees are kept by the above entities and have no effect on invoice pricing to the retail pharmacy. If CMS feels that these fees are more than nominal, then this should be addressed in the future through further legislation.

Response: We disagree. A manufacturer's AMP should include administrative fees, service fees (except bona fide service fees) and distribution fees for those entities and units of drugs included in the determination of AMP.

Direct Patient Sales

Comment: One commenter supported the inclusion of direct patient sales in AMP on the basis that when drugs are provided to patients through distributors, the distributor is acting as a wholesaler and the transaction is a sale to the retail pharmacy class of trade.

Response: We appreciate the support for this provision and have retained this requirement in the final rule at § 447.504(g)(7). However, as discussed below, we did not intend to include patient assistance programs.

Comment: A few commenters stated that CMS should reconsider the rationale used to include direct sales to patients in AMP because the statute does not contemplate those patients within the classes of purchasers used to determine AMP. One commenter said that sales directly to patients should be excluded from AMP. Several commenters said that sales and rebates associated with direct sales programs should not be included in AMP for pharmacy reimbursement. Many commenters said that the retail pharmacy class of trade does not have access to direct to patient sales and that they should not be included in AMP. One commenter requested that CMS explain how drugs distributed directly to patients fall within the definition of drugs distributed to the retail pharmacy class of trade when patients do not

resell or provide drugs to the general public. A few commenters said that there is no support for CMS to expand "wholesaler" and "retail pharmacy class of trade" to include direct-to-patient sales by a manufacturer. CMS has not provided an analysis as to why it believes patients are within the retail pharmacy class of trade.

Response: We appreciate the comment and have clarified that where the distributor is acting as a wholesaler, such sales should be included in AMP. We believe such sales are usually for specialty drugs through a direct distribution arrangement, where the manufacturer may retain ownership of the drug and pay either an administrative or service fee to a third party for functions such as the storage, delivery and billing of the drug. In this case, where the distributor is acting as a wholesaler, such sales should be included in AMP.

Comment: A few commenters said that direct-to-patient programs are an efficient, cost-effective means to provide much needed therapies. Federal policy should encourage such programs rather than discourage their development and use. However, requiring manufacturers to include such sales in AMP many have an unintended effect of discouraging manufacturers from implementing such programs. The commenter urged CMS to revise its proposed rule so that direct sales to patients are excluded from AMP. Another commenter said that including these sales and, presumably, discounts, in the AMP calculation may potentially serve as a disincentive for manufacturers to offer patient assistance programs or other subsidies to patients. If the intent of the AMP calculation is to determine the net price paid by wholesalers for drugs to the retail pharmacy class of trade, including sales and discounts directly to patients may improperly lower AMP.

Response: The inclusion of direct patient sales in AMP is not intended to discourage manufacturers from implementing these programs. However, we believe that the inclusion of such direct patient sales in AMP (where the distributor is acting as a wholesaler) is consistent with our understanding of the statute and our definition of wholesaler. The policy with respect to patient assistance programs is addressed elsewhere in this final rule.

Comment: One commenter said that the inclusion of direct patient sales in AMP is inconsistent with CMS' position on patient coupons, which are excluded from AMP.

Response: We disagree. Direct patient sales (where the distributor is acting as

a wholesaler) are like other sales included in AMP where the manufacturer sells a drug to a wholesaler/distributor which then sells/transfers the drug to a pharmacy or dispenses the drug itself. Our policy is based on our understanding of the transaction and on the pharmacy or wholesaler not being involved in the patient coupon transaction given that there is no adjustment of price at the wholesaler or pharmacy level.

Comment: One commenter requested that CMS clarify whether products which are sold directly to patients through company stores that sell only to the company's employees are included in AMP.

Response: We are unable to respond to this comment as the commenter did not include enough specific information to enable us to do so. However, we have defined retail pharmacy class of trade at § 447.504(e) to mean any independent pharmacy, chain pharmacy, mail order pharmacy or other outlet that purchase drugs from a manufacturer, wholesaler, distributor, or other licensed entity and subsequently sells or provides the drugs to the general public. We will continue to respond to such questions via the website or informal guidance when additional information can be obtained.

Comment: One commenter requested that CMS clarify the meaning of "direct sales" as it used in the calculation of AMP.

Response: As we understand this term, it means sales for which the manufacturer exerts control over the distribution of the drug through either an exclusive wholesaler/distributor or pharmacy. While this is the general definition we used to respond to these comments, we note that the underlying basis for our policy on these sales' inclusion in AMP is based on our broader policy concerning the type of sales that are included in our definition of the retail pharmacy class of trade.

Returned Goods

Comment: Some commenters expressed support for CMS' proposal to exclude returned goods from the calculation of AMP pursuant to manufacturer policies that are not designed to manipulate or artificially inflate or deflate AMP. The commenters believed that manufacturers should be able to design their return policies and exclude such returns from AMP, provided the policies do not represent a covert means of manipulating AMP. As they understood it, CMS' proposal permits manufacturers the operational freedom to define and accept returned goods, while eliminating administrative burdens, preserving the integrity of the

Medicaid drug rebate program, and harmonizing the AMP calculation with that of ASP. Thus, they asked that CMS finalize its proposed rule on returned goods.

Response: We appreciate this support and have retained this requirement in the final rule at § 447.504(h)(21).

Comment: Several commenters requested that CMS clarify the standards for determining when a return is made in good faith. The commenters asked whether a manufacturer may assume that goods are returned in good faith if a manufacturer has no evidence to the contrary. Alternatively, they requested that CMS delete the "good faith" requirement as this requirement addresses the intentions of those returning the drugs and not the manufacturer.

Response: We intend that "good faith" must be demonstrated on the part of the manufacturer, not the returning entity. We believe that returns made in good faith should be made in accordance with pre-existing manufacturer policies that comply with customary acceptable business practices; and applicable laws and regulations.

Comment: One commenter stated that these negotiated return goods policies should take into consideration the unique burdens which retail pharmacies must absorb in order to efficiently return expired pharmaceutical products to manufacturers. By mandating that only returns made pursuant to manufacturers' policies be excluded from AMP, CMS could be voiding these negotiated return goods policies (which were negotiated in good faith between manufacturers and retailers) and are forcing retailers to accept manufacturers' policies and their inherent deficiencies. The commenter asserted that such action ignores that retailers absorb considerable cost through replacement value of returns, inventory carry cost, reverse logistic costs, and administrative expense. In order to remedy this inequity, the commenter believes that goods returned in good faith pursuant to a commercial agreement, written or otherwise, between a manufacturer and a purchaser of its product, including wholesalers and pharmacies, should also be excluded from AMP. The commenter further recommended that CMS adopt a policy regarding returned goods that define them as the result of a commercial agreement, written or otherwise, between a manufacturer and a purchaser of its product, including wholesalers and pharmacies, which are designed to reimburse pharmacies for

the replacement cost of products returned in good faith.

Response: The returned goods policy in this regulation pertains to when payments for these goods are to be excluded from AMP. It should not affect negotiated agreements between pharmacies and manufacturers regarding returned goods. While the proposed rule did not address the treatment of replacement products, in the final rule at § 447.504(h)(21), we clarify that replacement products should not be included in AMP.

Comment: One commenter said that the language regarding handling returned goods in "good faith" leaves too much opportunity for interpretation by various manufacturers. The commenter stated that CMS should clearly state whether or not returned goods are to be included in pricing calculations rather than providing a method for some manufacturers to pick and choose when they will exclude returns.

Response: We do not agree that we should provide a standard definition at this time. As previously stated, we believe that returns made in "good faith" should be made in accordance with manufacturer policies that comply with customary business practices; and applicable laws and regulations.

Comment: The commenter recommended that we eliminate the reference to "manufacturers' policies" as it is unfair and could result in additional changes by manufacturers in their policies that would compromise community retail pharmacy.

Response: We disagree. Historically, manufacturers have had the flexibility to determine whether returns were to be credited to the quarter of sales or quarter of receipt. This has caused difficulty for some manufacturers when returns have substantially reduced AMP in a quarter or resulted in a negative AMP. In light of these concerns, we proposed to exclude returned goods from the calculation of AMP. The intent of this revision is not to cause or encourage manufacturers to change their current policies regarding returns. On the contrary, 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 eliminates artificially low, zero or negative AMPs that may result from these adjustments.

Comment: One commenter expressed support for the proposal to exclude returned goods from AMP. The commenter further requested that CMS clarify that manufacturers may exclude

returned goods based on the good faith of the manufacturer in accepting the return, because manufacturers do not have a basis to determine the good faith of the returning purchaser.

Response: We intend that the “good faith” be shown on the part of the manufacturer, not the pharmacy returning the goods. In order to exclude returned goods from the AMP calculation, the manufacturer must exercise good faith, in accordance with the manufacturer's return policy.

Comment: One commenter requested that CMS clarify that goods that are returned in accordance with the manufacturer's written return policies will be deemed to have been made in good faith.

Response: We agree to the extent it meets the criteria specified in this final rule.

Comment: One commenter said that a manufacturer's payment to a pharmacy or wholesaler for expired or recalled merchandise as well as fees associated with those services should be excluded from the manufacturer's AMP calculation of the basis that the level of credit provided is not enough to cover the replacement values, the cost of carrying the product to expiration, the cost of returning the product and the administrative cost associated with tracking the return.

Response: We would consider these payments acceptable provided that this payment is in lieu of a credit for the returned good and meet the other criteria in this final rule for such returns.

Comment: One commenter requested that CMS clarify that products destroyed by purchasers (and thus, not returned to the manufacturer) should be excluded from AMP.

Response: We agree. Products that are destroyed with no replacement product issued can be treated as a return.

Comment: One commenter recommended that recalls be treated the same as returned goods and excluded from AMP and urged CMS to clarify the treatment for AMP calculation of any return fees or reasonable recall fees paid by manufacturers.

Response: We agree to the extent that these recalls meet the other criteria in this final rule.

Comment: One commenter requested that CMS clarify whether a manufacturer may treat all chargeback reversals as returns if data is not available to the manufacturer to indicate otherwise.

Response: Only returns within the criteria in this final rule are to be excluded from AMP.

Comment: One commenter expressed concern regarding the exclusion of returned goods because of the effect that excluding these goods may have on AMP. The commenter believed that a significant increase or decrease in the AMP as a result of a returned good could lead to inaccuracies in FULs and potential future payment methodologies based on AMP to be used by third party programs.

Response: We disagree. We believe that the exclusion of returns will stabilize AMP and allow the manufacturer to calculate and report an AMP that is reflective of its pricing to the retail pharmacy class of trade in the reporting period. It eliminates artificially low, zero or negative AMPs that may result from these adjustments.

Manufacturer Coupons

Comment: One commenter stated that the final rule should clarify that manufacturer coupons redeemed by consumers, either directly to the manufacturer or at point of sale through pharmacies, are excluded from AMP as long as manufacturer payments to pharmacies are limited to administrative fees, charged at fair market rates, to compensate the pharmacies for their services; and, the prices paid by such pharmacies for the drugs are not affected by the coupon. Several commenters stated that if CMS decides that coupons redeemed by entities other than the consumer are to be included in AMP, additional guidance would be needed regarding the valuation of such transactions in AMP (for example, at wholesale acquisition cost (WAC), retail cost, or some other method). Another commenter requested that CMS clarify that coupons should not be included in AMP if, the benefit provided to the patient was set by the manufacturer without any negotiation between the manufacturer and a third party; the entire amount of the benefit was made available to an individual patient, without any opportunity for the retail pharmacy or other third party (such as an insurer or PBM) to reduce that benefit or take a portion of it for its own purposes; and the pharmacy collected no additional payment, other than the benefit amount, from the drug discount program. Coupons redeemed directly by patients with the manufacturer should be treated the same as coupons redeemed through other parties. The commenter proposed that CMS adopt as a definition of manufacturer coupon any certificate provided to a consumer that provides by its terms that the consumer is entitled to a discount on his or her purchase of drugs, either at the point-of-purchase, through a reduction equal to

the face value of the coupon up to the amount the consumer is required to pay the entity that dispense the drugs, or subsequent to the purchase, through receipt of a cash reimbursement from the manufacturer (or a vendor under contract to the manufacturer to administer the coupon program) where the reimbursement amount is equal to the lesser of the amount the consumer paid to the dispensing entity or the face value of the coupon. The commenter further requested that CMS clarify that manufacturers should exclude from AMP any fee paid to an entity other than a consumer that redeems a manufacturer coupon where the fee satisfies the definition of “bona fide service fee” adopted by the final rule.

Response: In light of the comments received, we believe that manufacturer coupons redeemed by any entity other than the consumer where full value of the coupon is passed on to the consumer, and the pharmacy does not receive any price concessions, should be excluded from AMP. We also agree with the comment regarding the need to clarify criteria regarding coupons and are codifying our prior guidance in this final rule with respect to manufacturer coupons at § 447.504(g)(15) to state that manufacturer coupons redeemed by any entity other than the consumer are excluded from AMP as long as the following provisions are met:

1. The manufacturer coupon is not contingent upon any purchase requirement to individuals.

2. The manufacturer establishes a benefit amount of the coupon to be given to individual patients, without any negotiation between the manufacturer and any other third party (such as an insurer or PBM) as to that amount.

3. The entire amount of the free product or coupon amount is made available to the individual patient, without any opportunity for the retail pharmacy or any third party (such as an insurer or PBM), to reduce the benefit amount, or take a portion of it, for its own purposes.

4. The pharmacy collects no additional payment, other than the benefit amount and a bona fide service fee, from the coupon.

Comment: Many commenters requested that CMS clarify that it does not matter who or which type of entity provides the benefit to the patient. Another commenter requested that CMS make clear that manufacturer coupons redeemed by a consumer, whether directly or indirectly to the manufacturer should be excluded from AMP. One commenter stated that in instances where a third party vendor is

used by the manufacturer to administer a coupon program on its behalf, that the coupon be considered redeemed directly to the manufacturer by the consumer. One commenter requested that CMS affirm that, when the only party receiving an economic benefit from the program is the patient, the value of the coupon will not be included in AMP. The commenter further requested that CMS confirm that the delegation of the operations of a coupon program to a fulfillment house or other agent does not by itself cause the coupon to be included in AMP. One commenter requested that CMS abandon its focus on redemption mechanics, as that focus will yield arbitrary results on the basis that the coupons would require disparate treatment for transactions that are indistinguishable in their substance.

Response: We appreciate these comments and have provided in the final regulation at § 447.504(h)(15) that manufacturer coupons redeemed by any entity other than the consumer which meet the previously discussed criteria may be excluded from AMP.

Comment: One commenter said that although coupon and voucher programs may appear similar, they are different in purpose and function. The commenter was concerned that “vouchers” may also be included in potential interpretations of the term coupon, whether or not this was CMS’ intent. The commenter used the term, coupons as certificates provided to patients that entitle them to discounts on their prescription drug purchases, either at the point of sale (through a reduction in the amount that consumer is required to pay the dispensing pharmacy) or subsequent to the purchase (by sending the coupon to the manufacturer or a clearinghouse with proof of purchase to receive a cash reimbursement from the manufacturer). In either case, the amount of the discount provides a dollar for dollar reduction in the amount paid out of pocket by the patient. In point-of-sale coupons, the dispensing pharmacy receives reimbursement for the discount passed on to the patient plus a small handling fee for administering the transaction. Vouchers are certificates provided to patient that entitle the patient to receive a specified number of units of a drug free of charge. The vouchers function similarly to product samples. The pharmacy dispenses the drug free-of-charge to the patient and is then reimbursed by the vendor according to a formula negotiated between the vendor and the pharmacy, plus a dispensing fee. The vendor bills the manufacturer for this reimbursement

expense, plus a bona fide service fee. The commenter further stated that CMS should require manufacturers to exclude from AMP any manufacturer coupon redeemed by a consumer either directly to the manufacturer or to a vendor under contract to the manufacturer to administer the coupon program; or alternately, any manufacturer coupon redeemed by an entity other than a consumer (after being presented by the consumer and honored by such entity) either directly to the manufacturer or to a vendor under contract to the manufacturer to administer the coupon program. If CMS does decide to treat manufacturer vouchers separately from, or as part of, manufacturer coupons, CMS should define manufacturer voucher to mean any certificate provided to a consumer that provides by its terms that the consumer is entitled to a specified number of units of a drug free of charge, without any co-payment from the consumer, or reimbursement to the entity that dispenses the drug from any insurance program of which the consumer may be a beneficiary. Furthermore, the commenter requested that CMS instruct manufacturers to exclude from their AMP: (i) any manufacturer voucher redeemed by a consumer either directly to the manufacturer or to a vendor under contract to the manufacturer to administer the voucher program; and (ii) any manufacturer voucher redeemed by an entity other than a consumer (after being presented by the consumer and honored by such entity) either directly to the manufacturer or to a vendor under contract to the manufacturer to administer the program; and specify that manufacturers should also exclude from AMP: (i) the reimbursement amount paid for any manufacturer vouchers; and (ii) any fees paid to an entity other than a consumer that redeems a manufacturer voucher where the fee satisfies the definition of “bona fide services fee.” If CMS does not adopt the approach to treating coupon and voucher programs, clear guidance from CMS as to how manufacturers should account for the value of point-of-sale coupons and vouchers in the calculation of AMP is needed, including specific mathematical examples as to how the value of such coupon and voucher should be accounted for in AMP.

Response: We believe that vouchers for free sample products should be excluded from AMP in instances that the, voucher is not contingent on other purchase requirements and is redeemed by any entity other than the consumer, where the full value of the coupon is passed on to the consumer and the

pharmacy does not receive any price concessions, it should be excluded from AMP. We have amended the final rule at § 447.504(h)(16) to incorporate these comments.

Comment: One commenter said that no distinction should be made between manufacturer coupons and other manufacturer-sponsored point-of-sale discounts.

Response: This policy only applies to manufacturer coupons and vouchers, as discussed in the previous response.

Comment: A commenter said that CMS should provide further guidance concerning what arrangements it considers to constitute “coupons directly redeemable to the manufacturer.” It is unclear whether CMS intends for the term “coupon” only to cover coupon arrangements in their traditional sense or whether the term also is intended to cover other types of consumer subsidies. Another commenter requested that CMS provide an explanation of what arrangements CMS considers to be patient coupons and guidance regarding how such arrangements should be incorporated in AMP.

Response: We have clarified in the final regulation at § 447.504(h)(15) the criteria that must be met for manufacturer coupons redeemed by the consumer to be excluded from AMP.

Comment: One commenter requested that CMS explain how coupons other than those redeemed by the manufacturer are to be accounted for in those calculations. The commenter further stated that the proposed rule does not account for a variety of coupon arrangements that exist.

Response: We have clarified in the final regulation at § 447.504(h)(15) that manufacturer coupons redeemed by the consumer that meet the criteria in this final rule are excluded from AMP.

Comment: One commenter asked if patient assistance continue to be excluded from AMP. Another commenter requested that CMS provide guidance regarding how a manufacturer may properly structure a patient assistance program utilizing coupons.

Response: In light of the comments received, we believe that patient assistance programs which extend free products to consumers without purchase contingencies and which do not provide any price concessions to the pharmacy, should be excluded from AMP. We are codifying guidance in this final rule at § 447.504(h)(12) to clarify that patient assistance programs should be excluded from AMP as long as the following criteria are met.

1. The program is focused on extending free products not contingent

upon any purchase requirement or extending financial assistance to low-income individuals and families, as determined by CMS.

2. Each manufacturer establishes an amount of the subsidy to be given to individual patients, without any negotiation between the manufacturer and any other third party (such as an insurer or PBM) as to that amount.

3. The entire amount of the free product or subsidy is made available to the individual patient, without any opportunity for the retail pharmacy or any third party (such as an insurer or PBM), to reduce that subsidy, or take a portion of it, for its own purposes.

4. The pharmacy collects no additional payment, other than the benefit amount and a bona fide service fee, from the patient assistance program.

Comment: One commenter said that CMS should provide in the final rule that any type of consumer program, be it a patient assistance, coupon, or debit card program, be exempted from AMP, and so as long as such program does not affect the price paid by the pharmacist to acquire the product. The commenter further said that CMS should clarify that programs should be excluded from AMP to the extent that the full amount of the discount goes to the consumer and does not affect the price realized by the pharmacist, or any end user other than a patient.

Response: We have clarified in the final regulation at § 447.504(h) the types of programs; for example, patient assistance programs and manufacturer coupons that provide free goods which are not contingent upon future purchases to patients, that should be excluded from AMP.

Comment: Many commenters said that coupons redeemed by pharmacists, just as those redeemed directly by manufacturers, should be excluded from AMP. In such cases the pharmacist is merely a pass-through entity as the pharmacist does not realize any monetary gain. Another commenter noted that patient coupons do not have an impact on prices for entities included in AMP and any requirement to include such arrangements in those calculations could impact the continued viability of the patient access programs. Other commenters stated that CMS should clarify that patient coupons transactions should not be included in AMP.

Another commenter said that CMS incorrectly assumed that all indirect redemption arrangements necessarily affect the price realized by the redeeming pharmacy and that CMS should revise its proposed policy on manufacturer coupons to make clear that only arrangements that affect the

price realized must be included in AMP. To count these coupons in AMP would distort those price figures and create a disincentive for manufacturers to continue offering these valuable programs. Several commenters said that manufacturer coupons should be excluded from AMP because these are not sales to traditional pharmacies.

Response: We appreciate these comments and have clarified in § 447.504(h)(15) that manufacturer coupons redeemed by any entity other than the consumer which meet the previously discussed criteria are excluded from AMP.

Comment: A few commenters requested that CMS clarify the definition of "coupon." A commenter further asked if CMS intended the term to refer only to paper coupons or to include patient assistance discount cards and other media provided to consumers.

Response: We have not specified that coupons must be printed on paper so as not to limit these in the future. We have clarified in the final regulation the treatment of other patient assistance programs.

Comment: One commenter urged CMS to expand the patient assistance program exception to cover those programs as a category, regardless of whether they provide goods free of charge or at limited cost to patients.

Response: We appreciate this comment and have clarified in § 447.504(h)(12) that patient assistance programs which met the previously discussed criteria are excluded from AMP.

Comment: One commenter said that CMS should exclude all patient transactions; for example, direct patient sales, patient coupons, and patient assistance programs from AMP on the basis that patients are not part of the retail pharmacy class of trade.

Response: We appreciate this comment and have clarified the treatment of these transactions in this final rule at § 447.504.

Copayment Assistance Programs

Comment: One commenter requested that CMS clarify the treatment of copayment assistance coupons.

Response: We have clarified that copayment assistance programs are another form of patient assistance programs and should receive similar treatment provided they otherwise qualify for exclusion from AMP under this final rule at § 447.504(h)(12).

Drug Discount Card Programs

Comment: Some commenters stated that if the manufacturer drug discount

program exclusion from best price is retained in the final rule, then the final rule should also provide a similar exclusion from AMP. The commenter further stated that a drug discount card program involving the pass-through of a manufacturer discount of 100 percent to the consumer and does not affect the price received by the manufacturer for drugs distributed to the retail pharmacy class of trade.

Response: We have clarified at § 447.504(h)(17) that manufacturer-sponsored discount card programs which meet the previously discussed criteria for patient assistance programs are excluded from AMP.

Other Entities

Comment: A few commenters requested that CMS provide clarification regarding the treatment of dialysis centers, surgical centers, ambulatory care centers, and mental health centers. Unlike walk-in pharmacies, these providers generally provide drugs incident to providing medical services to persons who are their private patients, although some physician practices sell self-administered products to patients who take the products home.

Response: Sales to outpatient facilities such as dialysis centers, surgical centers, ambulatory care centers and mental health centers that are not hospital-affiliated entities are included in AMP. We have clarified at § 447.504(g)(8) in the regulation text the treatment of outpatient facilities.

Comment: A few commenters requested that CMS clarify whether sales to prisons are included in AMP.

Response: We have clarified at § 447.504(h)(9) in the regulation text that sales to prisons are not included in AMP.

Comment: One commenter stated that examples of non-retail entities should be included in final rule; that is sold to other manufacturers, academic medical centers and physician investigators for research purposes.

Response: We have provided clarification at § 447.504(g)-(h) regarding which sales are included and excluded in this final regulation.

Comment: One commenter requested that CMS clarify whether sales to veterinary offices are within the definition of retail pharmacy class of trade. In the commenter's view, veterinary offices are not licensed to provide drugs to people and thus could not provide them to the general public.

Response: We have clarified in the regulation text at § 447.504(h)(8) that sales to veterinarians are excluded from AMP.

Comment: One commenter requested that CMS clarify whether State, county, and municipal entities are excluded from the retail pharmacy class of trade.

Response: We have clarified in the regulation text at § 447.504(h)(11) that sales to State, county, and municipal entities are excluded from the retail pharmacy class of trade and, therefore, are excluded from AMP.

Comment: One commenter requested that CMS explicitly state that the retail pharmacy class of trade does not include physician-administered drugs. The preamble to the proposed rule did not address whether to include prices to physicians in the retail pharmacy class of trade. In the same way that CMS excluded sales to long-term care pharmacies from the AMP calculation because they typically are closed operations that serve only residents of a specific long-term care facility, a physician's office is not a retail location open to the general public.

Response: In light of the definition of wholesaler set forth in the rule, physician-administered drugs are included in AMP because physicians operate to provide such drugs to the general public. Specifically, the sales to physicians for these drugs are included in AMP as well.

Comment: One commenter requested that CMS provide clarification regarding the treatment of sales to facilities that may operate both a closed-door long-term care pharmacy (excluded from AMP in the proposed rule) and a retail pharmacy (included in AMP). For such a facility, it is impossible for the manufacturer to identify which units were sold through the long-term care pharmacy and which units were sold through the retail pharmacy, since their orders do not distinguish between the two.

Response: Where a manufacturer does not have adequate documentation to substantiate whether these drugs are dispensed to a long-term care facility or to the general population, the manufacturer should include all of these sales in AMP.

Comment: One commenter requested that CMS specify that closed-wall pharmacies which do not sell to the general public are not included in the retail pharmacy class of trade.

Response: We are not familiar with the term "closed-wall pharmacy," but we have clarified the definition of retail pharmacy class of trade. If a pharmacy meets this definition, sales to it would be including in AMP.

Comment: A commenter asked that CMS provide guidance regarding price concessions offered by generic companies. The commenter

recommended that CMS specify that all discounts, rebates, payments and fees (other than bona fide service fees) provided to entities in the retail pharmacy class of trade or related sales flowing through the retail pharmacy class of trade be included in the calculation of AMP. This would include off-invoice discounts, rebates, and payments of preferred product positioning, payments for the number of products carried or preferred, floor stock adjustments, new store credits, "meet the competition" price adjustments, and the like.

Response: We have clarified at § 447.504(g) those sales that are included in AMP in this final rule. We do not agree that price concessions offered by generic manufacturers are to be included in AMP if they do not relate to the sale of the drug and do not otherwise meet the criteria in this final rule.

Discounts and Rebates

Comment: One commenter said that rebates, kickbacks, allowances, discounts and all other schemes should be declared illegal or not counted in AMP.

Response: Issues regarding health care fraud and abuse are not addressed in the proposed rule. Concerns regarding health care fraud and abuse should be addressed to the IG of the U.S. Department of Health and Human Services.

Comment: One commenter said that the calculation of AMP for the purpose of establishing FULs should exclude discounts or incentives that are not available for Medicaid prescriptions.

Response: We disagree. Under the law, AMP has the same definition for purposes of rebates and the FULs program.

Comment: One commenter stated that it is inappropriate to include cash discounts and price reductions in AMP.

Response: The rebate agreement provides that AMP includes cash discounts and price concessions which reduce the price amount received by the manufacturer with respect to drugs distributed to the retail pharmacy class of trade.

Comment: One commenter said that discounts included in the retail pharmacy class of trade should reflect only those prices that are provided to wholesalers for drugs distributed to retail pharmacies.

Response: AMP includes cash discounts, free goods that are contingent on any purchase requirement, volume discounts, chargebacks, incentives, administrative fees, service fees, distribution fees (except bona fide

service fees), other 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.

Free Goods

Comment: Several commenters stated that non-contingent free goods should be excluded from AMP because community pharmacies do not receive them. Exclusion of free goods from the AMP calculation effectively penalizes the manufacturer for engaging in this type of marketing by not lowering the AMP which bases the Federal rebate on a higher value and by not reducing the difference between AMP and best price. However, another commenter supported the exclusion of free goods from the calculation of AMP.

Response: When a free good is non-contingent on any other purchase requirement, there is no sale of this drug and it is appropriately excluded from AMP. We have retained in the final rule at § 447.504(h)(18) the requirement that free goods not contingent upon any purchase requirement are excluded from AMP.

Comment: One commenter asked CMS to make clear in the final rule that a free goods coupon that is redeemed through a pharmacy that either used consigned product or its own product but receives replacement product, plus a bona fide service fee, is excluded from AMP. A few commenters said that CMS should clarify that coupons for free drugs, such as starter prescriptions, that are not contingent on the purchase of the same or any other drugs, should be excluded from AMP.

Response: As previously discussed, we believe that vouchers for free samples should be excluded from AMP in instances that the pharmacy receives a replacement product or collects no payment greater than the cost of the sample and a bona fide service fee. We have amended the final rule at § 447.504(h)(21) to incorporate these comments.

Nominal Price

Comment: One commenter stated that nominal prices are not available to the retail pharmacy class of trade and should be excluded from AMP.

Response: In order to be included in AMP, nominal prices must be available to the retail pharmacy class of trade. As we explain elsewhere in this final rule, we consider the retail pharmacy class of trade to encompass more than walk-in pharmacies.

Future Clarification of AMP Calculation

Comment: One commenter said that CMS should commit to updating the Medicaid regulations and/or guidance on a regular basis so that manufacturers have clear guidance with regard to the treatment of new and evolving classes of trade within the retail channel. Such regular updating will prevent a recurrence of the situation where ambiguity of the AMP definition leads to different practices across manufacturers.

Response: We appreciate this comment. We believe that the final rule clarifies the determination of AMP. We are unable to commit to a schedule for the issuance of Medicaid regulations at this time. We expect to continue to issue subregulatory guidance regarding these regulations and other policy clarification, as appropriate, in a timely manner. In addition, given some of the revisions, we have decided that this final rule with comment period should allow for further public comment on AMP.

Comment: One commenter believed that any future clarifications by CMS should be prospectively effective, providing manufacturers with a reasonable period of time to implement necessary changes in order to ensure accuracy.

Response: We appreciate this comment and will address this concern when we issue the subregulatory guidance.

Comment: One commenter expressed concern that other new classes of trade which receive prices not available to community pharmacy should not be included in AMP.

Response: We disagree. New classes of trade which provide sales to the general public are by definition included in the retail pharmacy class of trade and AMP.

Comment: One commenter expressed the concern that some areas of clarification will likely reflect policy choices, as opposed to being technical clarifications. For those more substantive areas, a regulatory, due process method of proposing and receiving comments on proposed rulemaking should be used. Another commenter requested that CMS reconsider the strategy to address future clarifications of AMP and to publish a proposed rule for public comment.

Response: We appreciate this comment. We believe that the final rule clarifies the determination of AMP, thereby eliminating ambiguity, confusion and need for additional clarification. However, we do not believe that rulemaking is the most

appropriate or efficient mechanism to provide interpretations or additional guidance as may be necessary.

Other Issues

Comment: One commenter stated that CMS should provide more explanation for “reasonable assumptions” manufacturers are to use when data are insufficient or not available to calculate prices.

Response: We believe that reasonable assumptions are those made by manufacturers consistent with Medicaid drug rebate statute, regulation, and general business practice.

Comment: One commenter said that should CMS provide clarification regarding whether FFP is available for drugs included in a package with a non-drug item and if so, how is pricing to be reported.

Response: These issues are not addressed in the proposed rule and are outside the scope of this rulemaking document. Therefore, we cannot consider these comments as we consider revisions to the final rule.

Comment: One commenter recommended that a formal appeals and adjudication process is needed at CMS to provide a forum in which retailers can bring forth concerns regarding the method by which AMP is calculated, as well as which products are included in the determination of AMP.

Response: We appreciate this comment. The proposed rule was designed to provide the public with an opportunity to provide meaningful comments; however, retailers and manufacturers have the option of raising additional concerns directly to CMS to the extent necessary. Retailers can also raise concerns to the states as may be necessary.

Comment: One commenter said that CMS should specify a timeframe for review of manufacturer methodology change requests so that manufacturers can resolve their financial liability for past quarters.

Response: We cannot specify a timeframe; however, in the absence of guidance, manufacturers may make reasonable assumptions consistent with the statute, regulations, and reasonable business practices.

Comment: One commenter said that CMS should avoid including in the calculation of AMP data that is not readily available to manufacturers, or that would significantly increase the number of calculations and assumptions to be made.

Response: The provision of the DRA does not provide for the exclusion of AMP data that is not readily available to manufacturers. To the extent that we

were able to do so within the law, we have considered the impact this calculation will have on manufacturers. We believe that this final rule provides a clear, precise and adequate definition of AMP consistent with the provisions of the DRA and helps resolve ambiguities and confusion associated with the pre-DRA definition.

Comment: One commenter suggested that CMS consider implementing a tolerance level for quarterly AMP variation, within which an AMP restatement (positive or negative) would not be permitted. This would reduce the burden on States, CMS and manufacturers to comply with the requirement that a manufacturer must adjust the AMP if cumulative discounts, rebates, or other arrangements subsequently adjust the prices actually realized.

Response: We disagree. The calculation of AMP is based on actual sales data, and the AMP must be revised when errors or omissions are found, consistent with the regulations.

Comment: A few commenters requested that CMS define the terms “include” and “exclude” with respect to the dollars and units components of the AMP calculation. The proposed rule is not clear as to how to treat such terms for purposes of performing the AMP calculation. The commenter requested that CMS include a sample AMP calculation and a chart indicating each of the various entities that may affect the AMP and best price calculation whether sales, discounts, and/or units are deducted from the gross (for example, factor dollar and unit numbers) for purposes of AMP. The commenter suggested that the list of excluded entities should have an identifier such as a Drug Enforcement Administration (DEA) number or Health Industry Number and updated as frequently as AMP reports are filed.

Response: We have provided clarification in § 447.504(g)–(h) regarding which sales are included and excluded in this final regulation. We have not provided a sample calculation or chart of included AMP and best price sales here but will consider doing so in subregulatory guidance, depending on whether we get more specific questions.

Comment: One commenter cautioned CMS to carefully weigh the OIG’s recommendation against the Agency’s own significant expertise in the area. Because the OIG lacked a working understanding of the history of many of these issues, the commenter feared that its recommendation could lead to the inconsistent treatment of important issues related to the program.

Response: The DRA required the OIG to review how AMP is determined and recommend changes to the Secretary of the Department of Health and Human Services by June 1, 2006. It also required CMS to consider the IG's recommendations and promulgate a regulation that clarifies the requirements for and the manner in which AMP is determined no later than July 1, 2007. We have evaluated the OIG's recommendations and have incorporated them where we believe they are appropriate.

Comment: One commenter requested that CMS confirm and provide guidance regarding whether rebates paid to Medicaid as a secondary payer under this title and the national rebate agreement on outpatient drugs are excluded from AMP.

Response: Rebates paid under this title are excluded from AMP, including those rebates paid for Medicare claims where Medicaid is the secondary payer.

PBMs

Comment: Many commenters requested that PBM rebates, discounts, or other price concessions be excluded from the calculation of AMP because PBMs receive discounts, rebates, or other price concessions that are not available to community retail pharmacies. Commenters stated that the fact that these discounts, rebates, or other price concessions are not paid to community retail pharmacies clearly indicates that they should not be included in a cost-based benchmark that may become the determining factor associated with reimbursement for community retail pharmacies. The commenters contended that PBMs are not included within the retail pharmacy class of trade. They argued that, in light of the rationale used by CMS to exclude nursing facility sales from the definition of retail pharmacy class of trade, CMS should similarly exclude PBM sales, discounts, rebates, and other price concessions.

Other commenters stated that excluding PBM pharmacies from the definition of retail pharmacy class of trade offers numerous benefits, including reduced recordkeeping requirements, reduced risk of price fluctuations, and limiting the need for additional regulatory burdens. In addition, commenters argued that PBMs do not dispense to the public, and that patients have to belong to a specific health plan in order to access drugs through a particular PBM.

Consequently, commenters stated that PBM rebates, discounts, or other price concessions are not typically available to the public. Commenters argued that

for PBMs to purchase prescription drugs from a manufacturer or wholesaler, or to dispense drugs to the public, PBMs generally need to be licensed as pharmacies under the applicable State's law. Commenters stated that they were not aware of any State that licenses PBMs as pharmacies to purchase, receive, or dispense drugs to the public.

Response: We have decided to exclude PBM rebates, discounts, or other price concessions from the determination of AMP, except for purchases through PBM mail order pharmacies in § 447.504(h)(22). We believe this is consistent with previous guidance issued in manufacturer releases and to the extent that PBM discount rebates and price concessions did not meet these criteria, the impact on the calculation of AMP is likely to be minor.

Furthermore, we understand that PBMs do not generally take possession of pharmaceutical products. Only in their role as mail order pharmacies do PBMs participate directly in the purchase or delivery of prescription drugs. Accordingly, except with respect to such mail order activities, we have decided that PBM sales and associated rebates, discounts, or other price concessions fall outside of our definition of AMP.

Comment: Many commenters requested that PBM rebates, discounts, or other price concessions be excluded from the calculation of AMP because they believe that PBMs are not wholesalers; therefore, transactions with them should not fall within the definition of AMP. The commenters argued that the proposed definition is contrary to how the term wholesaler is defined in the national rebate agreement and that Manufacturer Releases 28 and 29 support that PBMs do not meet the definition of a wholesaler in that they do not purchase, or take delivery of drugs or redistribute drugs to retail and institutional pharmacies. Commenters indicated that they were not aware of any PBM arrangements currently in existence where PBMs are acting as wholesalers, as they do not buy pharmaceuticals directly from the manufacturers and resell them to pharmacies, which then dispense to the public. Commenters suggested that we define the term wholesaler to be consistent with its traditional meaning and the definition in the national rebate agreement to mean any entity that purchases drugs from a manufacturer for purposes of resale.

Response: We agree with the commenters that many of the sales to PBMs do not flow through wholesalers so the discounts received by PBMs

generally do not affect the price actually realized. The distribution functions typically performed by wholesalers are different from the functions performed by PBMs. Furthermore, because rebates, discounts, or other price concessions obtained by PBMs are not passed on to the retail pharmacy class of trade, including PBMs in the definition of wholesalers would permit the inclusion of price concessions to which community retail pharmacies do not have access. Therefore, in § 447.504(g), we are not classifying PBMs as wholesalers.

Comment: Some commenters requested that PBM rebates, discounts, or other price concessions (except for mail order sales) be excluded from the calculation of AMP because to include them in the calculation of AMP could increase drug costs for Medicare Part D and lower Medicaid rebate payments.

Response: As discussed elsewhere in this regulation, we have decided to exclude PBM rebates, discounts, or other price concessions from the determination of AMP, except for purchases through PBM mail order pharmacies in § 447.504(h)(22).

Comment: Some commenters stated that reporting PBM rebates, discounts, or price concessions can cause operational difficulties and competitive concerns. The degree to which manufacturer rebates are passed through or shared with PBM clients is privately held, competitively sensitive information that can differ from contract to contract. Drug manufacturers are not privy to this information and would need to review thousands of rebate arrangements to require PBMs to share this information.

Response: We agree with the commenters that the administrative burden for manufacturers to gather confidential information from PBMs and others in the drug chain regarding rebates, discounts, or other price concessions is significant. Therefore, as discussed above and in § 447.504(h)(22), we have decided to exclude PBM rebates, discounts, or other price concessions from the determination of AMP, except for purchases through PBM mail order pharmacies.

Comment: One commenter stated that CMS should clarify that there is no automatic requirement that manufacturers affirmatively obtain information concerning transactions between downstream entities. The commenter believes that such a requirement would create serious administrative difficulties. Manufacturers have no authority to require recipients of these payments to disclose to the manufacturers whether

they have shared the payment with their customers or clients, and there is no guarantee that payment recipients would agree to such disclosure.

Response: As discussed previously, we have decided to exclude PBM rebates, discounts, or other price concessions from the calculation of AMP, except for purchases by PBM mail order pharmacies in § 447.504(h)(22). Therefore, manufacturers do not have to collect rebate data with respect to such transactions between such downstream entities.

Comment: Many commenters raised other concerns about PBMs, such as that there is a need for PBM transparency, that PBMs should be regulated, that PBMs continue to impose non-negotiable contracts on independent pharmacies, or that PBMs are making too much profit.

Response: These issues are not addressed in the proposed rule and are outside the scope of this rulemaking document. Therefore, we cannot consider these comments as we consider revisions to this final rule.

Comment: Some commenters stated that the proposed rule included confusing language about how to treat price concessions to PBMs in the AMP calculation. The commenters requested that CMS clarify that the AMP calculation includes all PBM rebates, discounts, or other price concessions in the AMP calculations. The commenters believed that such a requirement would be administratively less burdensome to implement and would not affect the overall value of manufacturer AMP calculations. While manufacturers can track price concessions provided to PBMs, the commenters stated that it is neither realistic nor appropriate for them to track which price concessions PBMs pass through to the retail pharmacy class of trade. To include all PBM rebates, discounts, or other price concessions would also help promote greater uniformity in AMP calculations and preclude the possibility of confusion regarding the treatment of PBM price concessions. Conversely, requiring additional granularity in allocating PBM rebates could require manufacturers to make significant modifications to existing systems and could result in inaccurate and inconsistent AMP calculations. Commenters also stated that if CMS include discounts for products that flow through the retail pharmacy class of trade in AMP, CMS also should include rebates paid directly to health plans by manufacturers, unless the health plan is a staff model HMO.

Response: As discussed previously, we have decided to exclude PBM

rebates, discounts, or other price concessions from the calculation of AMP, except for purchases through PBM mail order pharmacies in § 447.504(h)(22). We believe this will alleviate some of the administrative burden associated with the calculation of AMP and result in more accurate and consistent AMPs across manufacturers.

Comment: While some commenters supported CMS' proposal to include PBM rebates and discounts in the AMP calculation, they and other commenters stated that there would be operational difficulties if manufacturers were required to segregate price concessions provided on mail order utilization from that provided on other PBM utilization as such detail is not available from the PBMs to quantify these two figures. The commenters stated that it is often impractical, if not impossible, for a manufacturer to obtain precise retail and non-retail analysis on a PBM's non-mail order sales. The commenters also stated that some PBMs may provide data that may allow some manufacturers to segregate their non-mail order sales data into retail and non-retail sales under some circumstances. However, the commenters argued this is not always the case. The commenters contended that many PBMs are unwilling or unable to provide this data to manufacturers and that some PBMs do not compile such data. Due to the lack of PBM data, commenters argued that manufacturers should be able to make reasonable assumptions with respect to PBM sales and discounts.

Response: We have decided to exclude PBM rebates, discounts, or other price concessions from the determination of AMP except for purchases through PBM mail order pharmacies in § 447.504(h)(22). Therefore, manufacturers will not need to obtain retail and non-retail analysis with respect to PBM non-mail order sales.

Comment: Some commenters supported the inclusion of PBM rebates, discounts, or other price concessions in the determination of AMP. However, the commenters stated that CMS needs to clarify what factors are included and excluded in PBM price concessions and be more direct and specific as to what types of PBM rebates and discounts should be included in AMP. If CMS fails to define the term PBM for the purpose of AMP calculations, manufacturers would include sales from any entity that a manufacturer considers to be a PBM, including sales to MCOs, which are specifically excluded from AMP under the national rebate agreement. The commenters believed that CMS needs to clearly define the attributes of entities

qualifying as PBMs for purposes of including price concessions from such entities and/or establish a list of excluded entities. This would allow manufacturers to use uniform criteria to distinguish between PBMs and non-PBMs for purposes of incorporating rebates and fees into AMP calculations. The commenters argued that if CMS fails to set forth guidance regarding PBMs, manufacturers would continue to treat PBM price concessions disparately, resulting in inconsistent AMP calculations across manufacturers.

Response: We have decided to exclude PBM rebates, discounts, or other price concessions from the determination of AMP, except for purchases through PBM mail order pharmacies in § 447.504(h)(22). Therefore, we do not need to define the attributes of entities qualifying as PBMs for purposes of including price concessions from such entities and/or establish a list of excluded entities.

Comment: One commenter agreed that PBM discounts should be included in the calculation of AMP since most Americans, including dual eligible beneficiaries enrolled in the Medicare prescription drug program, benefit from these discounts.

Response: We appreciate the comment, but we have decided to exclude PBM discounts from AMP calculations, except in certain situations where the PBM is operating a mail order pharmacy. The issue regarding the benefits associated with PBM arrangements is outside the scope of this rulemaking document.

Comment: One commenter supported the inclusion of Medicare Part D PDPs and PBM rebates, discounts, or other price concessions for drugs provided to the retail pharmacy class of trade for the purpose of determining AMP. However, the commenter asked that CMS clarify the treatment of sales associated with PBMs and how these differ from payments to PDPs. The commenter believes that PDPs are functioning as PBMs for Medicare Part D beneficiaries. Another commenter also argued that it seems inconsistent that prices to PDPs, which are PBMs, be excluded from best price calculations but included in AMP calculations.

Response: We appreciate the comment and have decided to exclude PBM rebates, discounts, or other price concessions from the calculation of AMP, except for purchases through PBM mail order pharmacies in § 447.504(h)(22).

Comment: A few commenters agreed that the exclusion of PBM rebates, discounts, or other price concessions would cause AMP to be higher than it

would be if these discounts were included. However, the commenters disagreed with the characterization of this higher amount as artificial inflation. Instead, the commenters believed that the exclusion of these amounts results in a more accurate reflection of AMP, and that their inclusion artificially depresses AMP because PBMs are not wholesalers nor are PBM rebates reflected in the prices paid by community retail pharmacies.

Response: As discussed previously, we agree with the commenters that excluding PBM rebates, discounts, or other price concessions would result in a more accurate reflection of AMP. Therefore, in § 447.504(h)(22) we have excluded them from the determination of AMP in this final rule, except for purchases through PBM mail order pharmacies.

Comment: Some commenters argued that because CMS excluded manufacturer rebates paid to State Medicaid programs, to the DoD under TRICARE, and to the DVA from the AMP calculation, CMS should also exclude rebates paid to PBMs from the AMP calculation. The commenters reasoned that these rebates are not available to the retail pharmacy class of trade, and none of the funds are ever received by community retail pharmacies. They also argued that the retail pharmacy class of trade does not have access to these direct-to-patient sale prices and thus these transactions should also be excluded from the AMP calculation.

Response: We agree that these PBM rebates, discounts, or other price concessions are not generally available to the retail pharmacy class of trade and should be excluded from AMP. We have excluded them from the determination of AMP in this final rule in § 447.504(h)(22), except for purchases through PBM mail order pharmacies.

Comment: Some commenters said best price was included as a factor in the rebate calculation so that States receive a rebate that more closely matches pricing in the marketplace. Manufacturers must pay States the greater of a percentage of AMP or the difference between AMP and best price. In this context, the commenters suggested that best price is the most appropriate place to include PBM rebates, discounts, or other price concessions as well as direct-to-patient sales and manufacturer coupons.

Response: We appreciate the commenters' suggestion to include PBM rebates, discounts, or other price concessions in best price; however, we have decided to exclude PBM rebates, discounts, or other price concessions

from the determination of AMP in § 447.504(h)(22) and best price in § 447.505(d)(13), except for purchases through PBM mail order pharmacies.

Comment: A few commenters stated that rebates and discounts offered to PBMs typically are based on relationships between the PBM and HMO or Medicaid MCO. Given that CMS proposed to exclude rebates and discounts to HMOs and Medicaid MCOs from the calculation of AMP, the commenter believed that rebates and discounts to their associated PBMs should be excluded as well.

Response: As discussed previously, we have decided to exclude PBM rebates, discounts, or other price concessions from the determination of AMP, except for purchases through PBM mail order pharmacies in § 447.504(h)(22).

Reimbursement Based on AMP

We received numerous comments regarding the option for State Medicaid Agencies to use AMP as a benchmark to calculate pharmacy payment rates, as discussed below:

Comment: Many commenters opposed the proposal to permit States to use AMP as a benchmark for pharmacy reimbursement because the commenters believed that AMP is not representative of pharmacy providers' acquisition costs and does not consider the markup applied within the distribution chain between the manufacturer and the purchasing pharmacy. Other commenters expressed concern that the proposal to permit States to use AMP to calculate pharmacy payment rates would result in a decrease in reimbursement to retail pharmacies. Many commenters stated that using AMP for reimbursement targets independent pharmacies because AMP does not adequately address the costs incurred by independent pharmacies. These commenters predicted that the proposal will result in decreased pharmacy reimbursement and decreased profits on the dispensing of generic medications and may drive independent pharmacies out of business. Many commenters estimated that retail pharmacy profit margins are less than ten percent of gross sales and pharmacists will be unable to dispense drugs to Medicaid patients if reimbursement rates are set by using the proposed definition of AMP. One commenter said that the proposed AMP-based reimbursement is unfair to retail pharmacies as their profit margins are being set by insurers when other entities, such as manufacturers and wholesalers, are able to set their prices and determine their profit margins.

Another commenter opposed using AMP as a benchmark for Medicaid reimbursement stating that pharmacies save money for State Medicaid agencies, have provided many hours of free counseling services to Medicaid patients, spent uncompensated hours resolving Medicare Part D issues and deserve actual acquisition costs for dispensed medications.

Response: The DRA does not require States to use AMP as a benchmark to calculate pharmacy payment rates. To the extent that States opt to use AMP in their payment methodologies, they will be required to submit SPAs. We will review the amendments to ensure that proposed payment methodologies are consistent with State plan requirements, and will allow for fair and reasonable payments to providers for drugs to protect beneficiaries' access to quality pharmacy services.

Comment: Several commenters requested that CMS clarify how AMP will be balanced to benefit all entities within the pharmaceutical industry and the retail pharmacy class of trade since lower AMPs will benefit manufacturers in lower rebate payments to States and higher AMPs will allow pharmacies to receive increased reimbursement rates but may not reflect all market pricing.

Response: As discussed elsewhere in this rule, we have decided to exclude rebates, discounts and price concessions to PBMs (except those to PBMs' mail order pharmacies) while maintaining our position that prices to mail order pharmacies should be included in the determination of AMP. We believe that we have carefully considered the impact that our decisions made in this final rule will have on AMP and all of the entities that may be affected by it.

Comment: A few commenters stated that there is a conflict in using AMP as a baseline for reimbursement and an index for rebates that manufacturers pay to States.

Response: The law does not require that AMP be used for reimbursement. Rather, the law provides that AMP be used as a basis for the calculation of rebates and the FULs (based on 250 percent of the relevant AMP) and that States may also use AMP data when determining pharmacy reimbursement.

Comment: One commenter stated that a publicly reported, widely available AMP that includes all supply chain discounts will lead to higher prices for the entire pharmaceutical market, as the AMP will become the benchmark below which manufacturers will not lower their prices. In addition, an AMP that includes all supply chain discounts will reduce competition, particularly in the generic market, as manufacturers make

the decision to stop the production of certain products. The commenter believed that these factors together will raise pharmaceutical prices.

Response: The DRA provides for the public release of AMP data. We have no reason to believe the market will not adjust to the availability of this information.

Comment: A few commenters stated that AWP better reflects true costs to independent retail pharmacies as it has allowed payment to exceed the estimated acquisition costs of generic drugs, compensating pharmacies for counseling services and medical advice offered to Medicaid patients. Another commenter suggested that AWP would be a better benchmark for reimbursement than AMP because it is a publicly available list price and it is easily accessible. One commenter stated that the proposal to allow States to use AMP as a benchmark for pharmacy reimbursement eliminates pharmacists' ability to cover their costs as opposed to using AWP as a benchmark, in that pharmacies benefit from the difference between the actual cost of the drug and AWP. One commenter stated that AMP may offer a closer estimate of ingredient cost than AWP but recommended that CMS consider both the cost of the drug and the cost of dispensing in the final rule as dispensing fees in most States are far below the actual cost pharmacies incur to dispense prescriptions. One commenter expressed concern that not only will pharmacy reimbursement for generic drugs be reduced but that the President's Fiscal Year 2008 budget proposes to further reduce reimbursement to pharmacists to 150 percent of AMP and urged CMS to oppose any further cuts to pharmacy reimbursement.

Response: We do not believe that AWP reflects acquisition cost. In the OIG report, "Determining Average Manufacturer Prices for Prescription Drugs Under the Deficit Reduction Act of 2005" (A-06-06-0063), it was noted that Medicaid pharmacy reimbursement based on AWP often exceeds pharmacies' actual acquisition costs. GAO also stated in its report, "Medicaid Outpatient Prescription Drugs: Estimated 2007 Federal Upper Limits for Reimbursement Compared With Retail Pharmacy Acquisition Costs" (GAO-07-239R), that the AMP-based FUL is preferable to an AWP-based FUL as long as States ensure adequate pharmacy reimbursement. As discussed previously, we believe that States who opt to use AMP, as opposed to AWP, to determine pharmacy payment rates will ensure that such payment rates have greater transparency, as consistent with

the DRA amendments. Elsewhere in this regulation, we have encouraged States to examine their dispensing fees to determine whether they reasonably cover the cost of dispensing the drug.

Comment: Several commenters stated that using AMP to set reimbursement is flawed and would not be an appropriate indicator of community pharmacy costs because it does not include wholesaler costs to pharmacies. One commenter stated that the proposal requires manufacturers to calculate AMP using prices that are inaccessible to community retail pharmacies and will result in skewed calculations and misinterpretation that could negatively affect provider reimbursement. Another commenter noted the importance of accurately incorporating the acquisition costs of providers and suppliers in the AMP calculation if AMP is to be used as a benchmark for pharmacy reimbursement.

Response: There is no requirement that States use AMPs to set payment rates for pharmacy providers. The DRA amended section 1927 of the Act to require that CMS use AMP, as opposed to AWP, in the FUL calculation. States may continue to use methodologies that they believe will accurately reflect pharmacy acquisition costs. We believe that we have made States aware in our discussions of AMP in this rule of what AMP represents and that States will use this as a factor when determining a reasonable reimbursement methodology for pharmacy providers.

Comment: One commenter suggested that CMS consider a definition of AMP that differentiates between various practice settings so that reimbursement will adequately address true costs associated with each setting. Another commenter recommended that CMS consider using one AMP such as the monthly AMP for the calculation of the FUL (and a benchmark for reimbursement) and the quarterly AMP for use as the basis for Medicaid rebates.

Response: We disagree that AMP should be calculated separately for each entity within the retail pharmacy class of trade or that monthly and quarterly AMPs should be defined and used differently. The law makes no distinction in AMP by entity or use.

Comment: A few commenters suggested that setting reimbursement rates based on AMP is complicated and would result in States reimbursing pharmacy providers below the acquisition costs of generic drugs. For this reason, the commenters requested that CMS not implement this portion of the proposed rule. A few commenters expressed concern that AMP is not a true indicator of market prices because

business transactions may cause periodic changes in AMP from month-to-month. Therefore, the AMP may fluctuate depending on the timing of the original sale and transactions that occur after the original sale that could span across multiple periods.

Response: The DRA amended the statute to require that, effective January 1, 2007, the Secretary calculate FULs based on 250 percent of the AMP (as computed without regard to customary prompt pay discounts extended to wholesalers). The statute also provides that, by July 1, 2007, the Secretary promulgate a regulation clarifying the requirements for AMP calculations. AMPs are based on the average prices paid to manufacturers, net of discounts and price concessions, and will be more useful than prices reported to drug pricing compendia that have been shown to often have no relationship to market prices.

Comment: One commenter expressed concern that drug rebates and other complicated payment arrangements account for high costs for prescription drugs. The commenter cited a report by the McKinsey Global Institute, "Accounting for The Cost of Healthcare in the United States (January 2007)," that found that although Americans use fewer drugs per capita, they pay about 70 percent more for prescription drugs than citizens of peer nations. This commenter recommended that CMS bring greater transparency and accuracy by exposing hidden rebates and discounts and determining the true cost of prescription drugs to enable more purchasers to obtain lower prices for drugs.

Response: The law only provides for making AMPs publicly available. However, we believe that the public availability of monthly and quarterly AMPs will bring greater transparency and accuracy to manufacturer pricing.

Comment: Several commenters recommended alternatives to States' use of AMP as a benchmark for reimbursement. One commenter recommended that AMP not be used to set pharmacy reimbursement rates and recommended that CMS instruct States to use actual net acquisition costs, allowing for a reasonable profit and dispensing fee. One commenter recommended that CMS urge States to consider the markup applied within the distribution chain between the manufacturer and the purchasing pharmacy when setting pharmacy payment rates. A few commenters recommended that CMS consider a reimbursement formula that pays pharmacies actual acquisition costs for drugs plus a fair retail markup and

incorporates a dispensing fee and an education fee to compensate pharmacists for Drug Utilization Review services, including checking for interactions with medicine and food and educating patients regarding their medications. One commenter suggested that CMS refocus efforts to save Medicaid dollars on brand name drugs by mandating an additional rebate on brand name drugs and stated that this would result in far greater savings for the Medicaid Program than reducing payment for generic drugs. One commenter recommended that CMS require States to include a minimum profit margin for low-cost generic drugs in their reimbursement methodologies for independent pharmacies that at least covers the cost of dispensing that drug. Several commenters expressed concern that the proposal that States use AMP as a benchmark for reimbursement does not address dispensing fees and suggests that the lack of guidance allows States to continue to underpay pharmacists for dispensing-related services. One commenter recommended that CMS consider an alternate proposal that would cap the cost of medications from the pharmaceutical companies, charge all pharmacies the same price without preferential treatment or pricing for one type of pharmacy over another, and set all Medicaid dispensing fees at the same rate for all pharmacies based on the Grant Thornton LLP National Study to Determine the Cost of Dispensing Prescriptions in Community Retail Pharmacies, prepared for the CCPA, published in January 2007, and accessible at <http://www.aphanet.org/AM/Template.cfm?Section=Home&CONTENTID=7641&TEMPLATE=/CM/ContentDisplay.cfm>. Another commenter recommended that CMS require reimbursement to be based on the WAC plus a professional fee of \$10 for brands and \$15 for generics to more accurately account for pharmacy acquisition costs and ensure that pharmacy providers are reimbursed fairly. One commenter recommended that CMS set a standard reimbursement methodology for pharmacy providers based on AWP or the average price per unit that a pharmacy pays for a drug. Another commenter recommended that CMS offer guidance to the States to establish a meaningful percentage differential to be applied to all FULs (AMPs) for all small pharmacies that meet the definition of "small business" as defined by the Small Business Administration (SBA). Other commenters stated that pharmacy provider acquisition costs surveys should be used to estimate pharmacy

acquisition costs. Another commenter recommended that CMS instruct States to use the monthly Retail Price Survey (RPS) data as a benchmark for pharmacy reimbursement as this data represents the weighted average reimbursement received by independent community pharmacies for each drug. One commenter requested that CMS define the pharmacy reimbursement methodology for States and set the dispensing fee in a manner that adequately compensates independent retail pharmacies, as independent pharmacies will not be offered drug products from their suppliers at AMP or near the AMP. One commenter agreed with CMS that States should be allowed to use AMPs as a benchmark for pharmacy reimbursement and suggested that CMS conduct studies to identify manufacturers whose products consistently have atypically large spreads between AMP and AWP or WAC. The commenter suggested that States may then implement alternative payment rates on products distributed by these manufacturers, thus preventing revenue enhancing schemes and retaining the usefulness of their current reimbursement techniques. Another commenter stated that AMP should be considered by States as the minimum allowable reimbursement.

Response: We do not agree with these proposals that CMS should establish dispensing fees or reimbursement methodologies as the States are in a better position to determine such payment amounts. The statute does not give CMS the authority to assess higher rebates on certain brand name drugs or to regulate the price charged by manufacturers for drugs.

Comment: One commenter noted that State MAC lists currently are significantly lower than the FUL for some products and that AMP-based reimbursement will not adequately cover pharmacy operating costs. The commenter suggested that CMS complete a study to evaluate whether States are currently reimbursing providers below 250 percent of AMP.

Response: Since the FULs methodology is established in the DRA, we see no benefit at this time in completing a study to determine whether States are already paying less than this amount. We note that States continue to be able to establish their own MACs as well as adjust the individual prices of drugs provided they do not exceed the FULs in the aggregate.

Comment: One commenter recommended that CMS review the price disparity between retail pharmacy class of trade and mail order pharmacies.

Response: We appreciate the comment; however, as our definition of AMP is based on what we have defined as the retail pharmacy class of trade, we believe it is unnecessary for CMS to conduct the recommended review. As previously discussed in this final rule, we have decided that the retail pharmacy class of trade includes mail order pharmacies. We believe that, as with traditional pharmacies, mail order drugs are available to the general public.

Comment: One commenter recommended that CMS offer grants to the States to (1) develop separate, differentiated payment to pharmacies for clinical services provided to Medicaid beneficiaries beyond OBRA 90 mandates and (2) develop differential payments based on quality measures and implementation of patient safety measures. Other commenters requested that CMS encourage the use of incentives to support efforts of pharmacists to improve patient outcomes through patient education and medication compliance instead of reducing costs to States by decreasing reimbursement to pharmacies.

Response: While we appreciate these comments, they are beyond the scope of this final rule.

Comment: A few commenters expressed concern that AMP may serve as a benchmark for reimbursement by other third party payers. Other commenters stated that although the rule proposes that States may use AMP as a benchmark for reimbursement of generic drugs, it will also have implications for the reimbursement of single source products.

Response: The use of AMPs by other payers is beyond the scope of this rule.

Comment: One commenter requested that CMS use its authority to review and approve SPAs to prevent States from modifying pharmacy reimbursement methodologies before the final rule has been implemented and the new AMP data has been assessed.

Response: We do not agree. While we will review SPAs to ensure compliance with the dictates of section 1902(a) of the Act, we do not have the authority to prevent States from submitting SPAs to modify pharmacy reimbursement methodologies before this final rule has been implemented and the new AMP data assessed.

Comment: A few commenters recommended that CMS instruct States to provide appropriate reimbursement for clinical services provided by specialty pharmacies, including long-term care pharmacies and other pharmacies that specialize in unit dose packaging as these services help ensure the effectiveness of patients' treatment

regimens, are not provided in the retail pharmacy setting and ultimately reduce costs to the Medicaid Program. One commenter requested that CMS consider the financial impact of the proposed AMP-based reimbursement methodology on specialty pharmacies as the average cost to dispense prescriptions in the specialty pharmacies is ten times greater than that of traditional retail pharmacies. Some commenters expressed concern that pharmacies' cost of serving mentally ill Medicaid patients, particularly those whose drugs require pharmacies to provide special packaging, would not be covered by the FULs, resulting in many special needs patients being institutionalized at Medicaid's expense.

Response: States may differentiate dispensing fees for specialty pharmacies and other classes of providers to ensure appropriate reimbursement.

Comment: One commenter stated that the proposal to permit States to use AMP as a benchmark for pharmacy reimbursement does not address a separate furnishing fee for anti-hemophilic clotting factors as set forth in section 303(e)(1) of the MMA. The commenter has requested that CMS consider a separate furnishing fee, a separate payment added into the payment rates, to allow Medicaid patients who are affected by bleeding disorders to maintain access to care and access to anti-hemophilic clotting factor medications.

Response: Medicaid already has other service categories that can be used to appropriately reimburse providers for these other services. States are also able to establish a dispensing fee that is appropriate for the dispensing of anti-hemophilic clotting factor medications.

Comment: One commenter expressed concern that CMS will not consider expert advice from pharmacists, pharmacy organizations and Congress regarding the proposal that States may use AMP as a basis for reimbursement.

Response: We have considered and appreciate the advice that we received from all interested parties including the comments received on the proposed rule.

Comment: Another commenter recommended that CMS require the use of therapeutic alternatives when an alternate product in the same class has a generic available in order to control the use of expensive brand name medications and save Medicaid dollars.

Response: Since many States already require generic substitution and have other measures in effect to encourage the dispensing of generic drugs, we do not agree that there needs to be a further CMS requirement here.

Determination of Best Price (§ 447.505)

Comment: One commenter asked that if a manufacturer offers a price that is lower than any actual price paid, is best price set on the lowest price paid or the lowest price available.

Response: The best price is the price from the manufacturer which is calculated to include all applicable sales and discounts; it is the price actually realized. Best price includes prices available to any purchaser, inclusive of cash discounts, free goods contingent on any purchase requirement, volume discounts, and rebates (other than rebates under section 1927 of the Act).

Comment: One commenter stated that the proposed rule defines best price as “* * * the lowest price available from the manufacturer during the rebate period to any entity in the United States * * *.” However, the national rebate agreement defines best price as “* * * the lowest price at which the manufacturer sells the covered outpatient drug to any purchaser in the United States * * *.” The commenter asked if CMS intends to materially change the definition of best price by using “entity” rather than “purchaser.” If CMS is not changing the definition, the commenter asked that we use the language from the national rebate agreement in the final rule.

Response: We used the term “entity” in the proposed rule because this is the term used in the DRA. We are retaining this term in the final rule. We do not intend any material change, except that given the DRA amendments, the term entity may include sales to other manufacturers.

Comment: One commenter questioned if all SPAPs are excluded from the determination of best price in the proposed rule or only SPAPs that qualify under the criteria set out in Manufacturer Release 68.

Response: SPAPs should continue to meet the qualifications in program guidance, which is currently set out in Manufacturer Release 68, which can be found on the CMS Web site at http://www.cms.hhs.gov/MedicaidDrugRebateProgram/03_DrugMfrReleases.asp. A list of designated Medicaid SPAPs can be found on the CMS Web site at <http://www.cms.hhs.gov/MedicaidDrugRebateProgram/Downloads/SPAPBestPriceList.pdf>.

Price concessions to SPAPs that do not meet these standards would not be exempt from best price. We have added language to this final rule to clarify this point.

Comment: One commenter stated that SPAPs are generally third-party payers

and do not typically purchase drugs directly. The commenter recommended that the exclusion from best price be expanded to include price concessions received by SPAPs including rebates.

Response: We agree. SPAPs operate their programs similar to PBMs whose rebates, discounts, or other price concessions have been excluded from AMP and best price. These PBM rebates, discounts or price concessions are not available to the retail pharmacy class of trade and, therefore, are not passed on to community pharmacies. SPAPs, as with PBMs, are treated by pharmaceutical manufacturers as a different class of trade and are not accessible to the public. Therefore, in accordance with section 1927(c)(1)(C)(i) of the Act, we are excluding rebates obtained from designated SPAPs from manufacturers from the best price.

Comment: One commenter noted that in § 447.505(b) of the proposed rule, CMS defined providers as “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”. In § 447.505(c)(3), CMS noted that “prices to providers (for example, hospitals, HMOs/MCOs, physicians, nursing facilities, and home health agencies)” are included in best price. The commenter asked if it is the intent of CMS to define home health providers as retail providers or non-retail providers.

Response: We consider home health providers to be retail providers. Home health agencies (as well as hospices, hospitals, and skilled nursing facilities) are providers for purposes of Medicare (see section 1861(u) of the Act). Accordingly, we have decided, in light of section 1927(c)(1)(C) of the Act, that CMS should include sales to home health agencies within best price.

Comment: One commenter expressed concern with the exemption from best price of payments made by PDPs and MA-PDs to manufacturers. With the advent of the Medicare Part D program, there are substantial sales attributable to PDPs and MA-PDs. If included in best price, the commenter believed these sales arrangements would result in more accurate pricing information and enhance the Medicaid Drug Rebate Program.

Response: Section 1927(c)(1)(C)(i)(VI) of the Act provides that prices negotiated by a PDP under Part D and an MA-PD under Part C, both of Title XVIII of the Act, are excluded from best price.

Comment: Several commenters agreed with the statement in the preamble to the proposed rule that 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.

Response: We agree and have retained this policy in the final rule.

Comment: One commenter recommended that CMS publish a proposed rule for public comment when significant changes related to best price are being considered rather than issue program releases and post clarifications on the CMS Web site as proposed in the rule. Another commenter noted that clarifications to the definition of AMP should be made through formal notice and comment rather than through program releases and Web site postings.

Response: We agree that substantive changes in policy should be made through the rulemaking process. We note, however, that policy established through regulation may need to be clarified to explain how it applies in specific situations or to new situations in the marketplace. CMS will continue to issue subregulatory guidance when we find this to be necessary or appropriate.

Comment: Several commenters disagreed with limiting the exemption from best price for manufacturer coupons to those redeemed by the consumer with the manufacturer. The commenters believe that coupons redeemed by a pharmacy or other third party should also be exempt from best price when the pharmacy or other party passes through the full value of the coupon to the consumer and does not receive any price concession on acquisition cost from the manufacturer other than the coupon amount and the handling fee.

Response: We concur. We are exempting coupons redeemed through a pharmacy from best price as long as the exact value of the coupon is paid to the pharmacy from the manufacturer or its agent, the full value of the coupon is passed on to the consumer, and the pharmacy does not receive any price concessions.

Comment: One commenter requested that CMS reaffirm that multi-manufacturer patient assistance programs continue to be exempt from the best price determination.

Response: We agree, and as discussed previously with respect to AMP, we have decided to codify our existing policy in this rule. Accordingly, patient assistance programs are exempt from the best price determination under 1927(c)(1)(C) of the Act as long as the following provisions are met:

1. The program is focused on extending financial assistance to low-income individuals and families, as determined by CMS, who are not otherwise eligible for Medicare and do not have public or private prescription drug coverage.

2. Each manufacturer establishes an amount of the subsidy to be given to individual patients, without any negotiation between the manufacturer and any other third party (such as an insurer or PBM) as to that amount.

3. The entire amount of the subsidy is made available to the individual patient, without any opportunity for the retail pharmacy or any third party (such as an insurer or PBM), to reduce that subsidy, or take a portion of it, for its own purposes.

4. The pharmacy collects no additional payment, other than the benefit amount, from the patient assistance program.

Comment: Several commenters stated that to include PBM rebates in best price poses significant operational issues because manufacturers often do not know the amount a PBM receives as rebates for retail mail order and non-mail order sales. The commenters suggested that the final rule should allow manufacturers to use reasonable assumptions to estimate PBM rebates. This would be similar to Medicare Part B ASP reporting requirements (71 FR 69623 and 69676, Dec. 1, 2006).

Response: We recognize the commenters' concerns and have decided that, except in those situations where PBM rebates are designed to provide price concessions, discounts, or rebates, or to adjust prices recognized by providers or retailers, PBM rebates should not be included in best price calculations.

Comment: Several commenters stated that some industry analysts appeared to misread the proposed rule to suggest that manufacturers may be obligated to add concessions paid to PBMs to the concessions paid to customers of the PBMs in calculating best price. This would effectively call for the combining of two separate prices, one offered to a PBM and the other to a customer of a PBM. The commenter stated that the statute is quite clear in defining best price as the lowest price to "any wholesaler, retailer, provider, health maintenance organization, non-profit entity, or government entity * * *." The commenters argued that if Congress had intended anything other than a customer-by-customer analysis of separate prices, the statute would have combined each customer with the word "and" instead of the disjunctive "or." The commenters requested that CMS

reaffirm that best price is the lowest price available from the manufacturers reflecting concessions provided by the manufacturers.

Response: We do not agree with the commenters. Although we have deleted the requirement that manufacturers include PBM rebates and discounts and other price concessions in best price, there are instances where some PBM rebates and discounts may be designed to adjust prices at the retail or provider level. Best price is designed to reflect the lowest price available from the manufacturer to any purchaser, inclusive of rebates, discounts, or price concessions that adjust the price realized. Where PBM rebates, discounts, or price concessions do not operate to adjust prices, they should not be included in the best price calculation.

Comment: Several commenters suggested that PBM rebates should be included in the best price calculation but not in the calculation of AMP because including these prices would reduce the FUL to an amount below available market price. The commenter stated that this would undermine the FUL and shrink rebates paid to States.

Response: We appreciate the recommendation of the commenters. We believe that, as a general matter, PBM rebates, discounts, and price concessions obtained from manufacturers (except for PBM mail order purchases) should be excluded from both best price and AMP. We have concluded that we should not consider PBMs as falling within the retail pharmacy class of trade as they are not directly involved in the supply chain of pharmaceuticals. PBMs are treated by the pharmaceutical manufacturers as a different class of trade and the public does not necessarily have access to drugs supplied through PBMs. Therefore, we do not believe that it is appropriate to include PBM rebates, discounts, and prices in either AMP or best price, except for mail order purchases.

Comment: One commenter requested that PBM price concessions should not be used in the best price calculation because they are not shared with pharmacies.

Response: We have excluded PBM price concessions except for mail order purchases where rebates or price concessions are designed to adjust prices at the retail or provider level.

Comment: One commenter disagreed with the proposed rule that prices of sales directly to patients should be included in best price because direct-to-patient sales are not specified in the statute. Rather, the commenter believed that the statutory definition is intended

to capture prices to commercial entities, and that CMS' interpretation goes beyond, and is inconsistent with, the plain language of the statute.

Response: The statute clearly specifies at sections 1927(c)(i)(I)–(VI) of the Act those sales, including, for example, sales provided to patients through the endorsed discount card program, that are excluded from best price. As we discussed previously, we believe that sales directly to patients are included, except as specifically excluded by statute, as this is an alternate channel for sales that normally flow through included entities.

Comment: One commenter requested that discounts negotiated on behalf of retirees enrolled in retiree prescription plans which are excluded from best price be extended to their dependents. The commenter stated that rebate agreements for retirees for qualified retiree prescription drug utilization apply the same price structure to all of the individuals covered by the plan and do not distinguish between utilization by retirees and of their dependents.

Response: We proposed to exempt from best price any prices charged which are negotiated by a qualified retiree prescription drug plan under section 1860D–22(a)(2) of the Act. To the extent the prices are negotiated by a qualified retiree prescription drug plan under section 1860D–22(a), they are exempt from best price.

Comment: Several commenters requested that CMS not include customary prompt pay discounts in the determination of best price to the extent that such discounts are excluded from AMP. They stated that Congress recognized that discounts serve an important role in providing a revenue stream for distributors to ensure the safe and effective distribution of drugs to patients.

Response: We do not agree. Congress did not exclude customary prompt pay discounts from the determination of best price. Therefore, customary prompt pay discounts remain included in the determination of best price.

Comment: One commenter requested that when best price is determined, customary prompt pay discounts extended to wholesalers should not be aggregated with price concessions available to an end-customer under a contract administered through a wholesaler chargeback arrangement, regardless of whether the manufacturer negotiated the contract directly with the end-customer or with a third party.

Response: We do not agree. As we have previously stated, there is no basis to exclude these discounts. Both the customary prompt pay discounts and

other price concessions available to the end-customer are to be included in the determination of best price.

Comment: One commenter requested that the regulation not define fair market value for administrative and service fees that are excluded from best price. The commenter suggested that CMS mirror Medicare's position on ASP which permits manufacturers to determine the most appropriate industry-accepted method to determine fair market value of the drug distribution services they receive.

Response: We concur that manufacturers should be permitted to determine the fair market value of drug distribution services using industry-accepted methods and have not defined these terms in this final rule.

Comment: One commenter requested that further guidance be given on when GPOs should be excluded from best price. The commenter suggested that fees to GPOs should not be treated as price concessions unless the fees (or any portion thereof) are passed on to the GPO's members or customers.

Response: GPOs may function as negotiators for price concessions on behalf of member pharmacies with GPOs receiving service fees for their services or they may function as a distributor to their member pharmacies of price concessions from manufacturers after volume sales benchmarks have been attained. If the service fees paid to GPOs are bona fide service fees, and there is no evidence or arrangement that the fee is passed on to the member pharmacy, client or customer of any entity, the manufacturer can exclude the fees from the determination of best price.

Comment: One commenter stated that in 2004, the DoD restructured its pharmaceutical benefit plan TRICARE and placed the pharmacy benefit under contract with PBMs. DoD determined, and CMS agreed, that the TRICARE transactions, known as TRICARE Retail Pharmacy Program or TRRx, amounted to depot sales that qualified for Federal ceiling prices (FCP). Manufacturers paid rebates, called refunds on TRRx utilization, and those rebates were calculated in a manner intended to provide DoD with FCP for that utilization. In Manufacturer Release 69, CMS directed that both TRRx sales and refunds be excluded from AMP and best price because they qualified as depot sales. In September 2006, the Federal Circuit Court of Appeals raised significant concerns with the TRRx drug program holding that DoD could not require manufacturers to pay refunds without issuing a regulation through formal notice and comment rulemaking

(464 F.3d 1306 (Fed. Cir. 2006)). It is our understanding that DoD has ceased the TRRx program and is refunding any rebates previously paid. The commenter requested that any voluntary price concessions provided to DoD by manufacturers on direct purchases, sales to TRICARE mail order pharmacy, or through rebates on TRICARE be exempt from best price even though the prices are not obtained from depot purchasing.

Response: We recognize the Federal Circuit Court of Appeals remanded the DVA's Dear Manufacturer Letter (October 24, 2004) for substantive rulemaking. However, to the extent section 1927(c)(1)(C)(i)(I) of the Act includes the DoD as an exclusion from best price, TRRx prices are excluded from best price.

Comment: One commenter requested that if the final rule changes the AMP NDC reporting from 9 digits to 11 digits, CMS should also require that best price be reported for each package size. This would allow for more consistent, transparent, and accurate calculations between AMP and best price.

Response: This final rule maintains that AMP reporting remain at nine digits.

Authorized Generic Drugs (§ 447.506)

Summary of Comments

The DRA requires drug manufacturers to include drugs sold under an NDA approved under section 505(c) of the FDCA in their AMPs and best prices.

In the proposed rule, we would require the manufacturer holding title to the NDA of the authorized generic drug to include the direct and indirect sales of this drug in its AMP and to include in the computation of best price the price of the innovator multiple source drug as well as the single source drug.

We received numerous and detailed comments concerning these proposed requirements that led us to agree with commenters that these requirements would be unduly burdensome on manufacturers, call into question the veracity of manufacturer pricing information reported to CMS, and potentially violate anti-trust statutes because they would require manufacturers to share pricing information and engage in anti-competitive practices.

In the final rule, we limit the application of the requirement to the sale of an authorized generic product from the primary manufacturer; that is, the manufacturer that holds the NDA, to the secondary manufacturer; that is, the manufacturer that markets and sells the authorized generic drug. This eliminates the need for manufacturers to share

information on sales to other entities and potential competitors. We believe that the sale price of the drug from the primary to the secondary manufacturer will generally be lower than the lowest price paid for the authorized generic drug by subsequent purchasers. We have further supported this by stating that all price concessions, discounts and fees other than bona fide service fees must be reflected in the primary manufacturer's calculations of best price. This will prevent the primary manufacturer from circumventing its rebate liability, impact the rebate owed by the primary manufacturer, and result in the savings contemplated by the provision.

At this time, we do not require that subsequent sales of an authorized generic product by the secondary manufacturer be included in the AMP calculation of the primary manufacturer. We note that this is consistent with our reading of the DRA in that, unlike the best price amendment, the DRA did not amend the definition of AMP, which continues to require that AMP be calculated with respect to the covered outpatient drug of a manufacturer based on the price paid to the manufacturer "by wholesalers for drugs distributed to the retail pharmacy class of trade." The DRA did not amend the AMP definition to include prices paid to the manufacturer by other manufacturers. Furthermore, in light of the comments we have received with respect to the proposed rule, we believe that to require the primary manufacturer to include sales of the secondary manufacturer within its calculation would be problematic from an administrative accounting and anti-trust perspective. We also note that to include the sales of the authorized generic drug in the AMP of the primary manufacturer's drug could lower the AMP and rebate liability, and present additional concerns with respect to the FUL calculation, contrary to our reading of the provision.

In light of the comments received and our concerns given the statutory amendment, at this time we have decided not to include authorized generic products marketed by the secondary manufacturer in the AMP calculation. We will continue to review this issue, but we believe this interpretation best implements the DRA amendments.

General Comments

Comment: One commenter expressed general support for the authorized generic provisions in the proposed rule.

Response: We appreciate the support the commenter expressed.

Definition of Authorized Generic

Comment: One commenter urged CMS to clarify that the term "authorized generic" is limited to those products for which the title passes to an authorized generic entity.

Response: We disagree. We do not interpret the DRA amendment as necessarily limiting the application of this provision to drugs for which the secondary manufacturer holds title.

Comment: One commenter suggested that CMS exclude from the definition of "authorized generic," drugs that are repackaged for use in institutions. The commenter requested that CMS clarify that private label arrangements involving distinct packaging due to variations in package size from the branded product do not constitute "authorized generics" where the private label product is used in an institution. Another commenter recommended that CMS preserve its current policy of exempting manufacturers who repackage products (for sale) from reporting best price. The commenter recommended that CMS classify the secondary manufacturer of authorized generic products as a repackager.

Response: The definition of authorized generic drugs excludes drugs that have been repackaged for use in institutions. Thus, any sales of the repackaged drug by the repackager would not be included in the primary manufacturer's rebate calculation if it were simply repackaged in an institutional package size with the primary manufacturer's NDC; however, the sale to the institution would be included in the primary manufacturer's best price.

AMP and Best Price Reporting Requirements

Comment: Many commenters expressed concern regarding the proposed policy to require the price or sales of the authorized generic drug to be included in the AMP and the best price of the branded drug. Many commenters requested further guidance to clarify how the price or sales of authorized generic products should be gathered, shared and incorporated into the AMP and best price of the branded drug. One commenter stated that the proposed rule did not address whether the primary manufacturer must incorporate raw sales data into the brand drug calculations in order to derive a blended AMP and best price or whether the primary manufacturer can rely on the secondary manufacturer to provide the authorized generic AMP-eligible units and dollars to derive the AMP. Several commenters

recommended that CMS allow the primary manufacturer to calculate a blended AMP and determine the best price based on the pricing data provided by the secondary manufacturer. One commenter suggested two methods for blending authorized generic sales data with the sales data of the primary manufacturer. Several commenters suggested that CMS require the primary manufacturer to obtain from the secondary manufacturer either the AMP and best price or underlying authorized generic sales data. The primary manufacturer would then combine its own sales data with the sales data provided by the secondary manufacturer to calculate the AMP and determine the best price for the brand drug. One commenter asked for guidance regarding a method for calculating a weighted AMP value for authorized generic drugs. Several commenters recommended that CMS require manufacturers to use a weighted average to calculate the AMP for authorized generic drugs.

Response: This final rule provides the requirements for manufacturers to use in calculating the AMP for covered outpatient drugs. Specific calculation methods are left up to the manufacturer consistent with this rule.

In light of the comments, we have decided to reconsider our proposal that primary manufacturers include the authorized generic product pricing data of a secondary manufacturer in their best price and AMP calculations. At this time, we have revised the authorized generics provision to require the primary manufacturer to include in best price the authorized generic sales from the primary manufacturer to a secondary manufacturer or subsidiary of the brand company.

At this time, based on concerns raised by the commenters, primary manufacturers would not be required to incorporate the sales of the authorized generic in the AMP of the brand drug. The primary manufacturer and the secondary manufacturer would be responsible for separately calculating their own AMP. The method for determining the AMP, as described elsewhere in this final rule, is the same for all covered outpatient drugs, including authorized generics.

Comment: A few commenters expressed concern that a blended AMP and best price would distort the AMP and the best price of authorized generic drugs which in turn may cause pharmacies to receive substantially lower reimbursements for such drugs. One commenter stated that a blended AMP for the brand drug may be lower than a pharmacy's acquisition cost for the product. A few commenters stated

that while CMS may allow the primary manufacturer to pay its rebate based on a blended AMP, it is not fair to use this blended AMP to potentially underpay pharmacies for dispensing the brand drug when prescribed by a physician. One commenter stated that this final rule would result in new AMP-based calculations that would apply to more medications, thereby compounding concerns regarding decreased reimbursement to pharmacies for authorized generic products. The commenter further stated that the broadened definition of authorized generic could create a disincentive for generic utilization, thereby increasing costs to the Medicaid Program. A few commenters suggested that separate AMPs should be posted on CMS' website for the brand drug and the authorized generic drug.

Response: We agree with these comments. The primary manufacturer should not include within its AMP calculation any pricing data concerning the sale by the secondary manufacturer regarding the authorized generic product.

Comment: A few commenters requested further clarification on how to handle incomplete or inaccurate data reported by the secondary manufacturer. In addition, commenters wanted to know what should be done when information is not received from the secondary manufacturer in a timely manner. One commenter recommended that CMS allow the use of the prior month's data to calculate the blended AMP to ensure compliance with reporting deadlines. Many commenters requested that CMS confirm that the primary manufacturer may rely on the AMP and sales data provided by the secondary manufacturer without having to review the underlying data and methodologies for accuracy. Several commenters also requested that the primary manufacturer not be held responsible for certifying (in accordance with the certification requirements set forth in this rule) the accuracy and completeness of the AMP and best price data provided by the secondary manufacturer. Another commenter requested that CMS allow the primary manufacturer to incorporate the AMP and best price of the authorized generic product into the AMP and the best price of the brand drug.

Response: We appreciate the comments and have revised the authorized generics provision to require the primary manufacturer to include in best price the authorized generic sales from the primary manufacturer to a secondary manufacturer or subsidiary of the primary manufacturer. As discussed

previously, based on the comments received, we have decided that the primary manufacturer should not incorporate the sales of authorized generic products by the secondary manufacturer in the AMP of the brand drug. At this time, we have decided that the primary manufacturer and the secondary manufacturer would separately calculate their own AMP.

Comment: One commenter requested that CMS clarify whether the sales by the primary manufacturer of an authorized generic to a secondary manufacturer should be included in the primary manufacturer's AMP and best price. The commenter indicated that inclusion of such manufacturer-to-manufacturer sales in the AMP would result in double-counting in AMP of every authorized generic unit; once when the unit is sold by the primary manufacturer to the secondary manufacturer, and again when the unit is sold by the secondary manufacturer to its customers, thereby resulting in a distortion of the AMP. A few commenters urged CMS to clarify that manufacturer-to-manufacturer sales are non-retail sales and, therefore, excluded from AMP. Another commenter stated that including inter-company transfer prices in the AMP for every unit of a drug would deflate the market price and skew the AMP to an inappropriately low level. The commenter suggested that the final rule clarify that inter-company transfer prices will be excluded from AMP or best price regardless of the circumstances surrounding the transfer of product within the same corporate company, even if the product is provided at a lower price from one member of the company to another member of the company. Another commenter recommended that CMS define the term "any entity" in the best price definition to exclude the sales price of authorized generics from the primary manufacturer to the secondary manufacturer so that this sales price would not set the best price. The commenter further explained that failure to exclude the sale price from the primary manufacturer to the secondary manufacturer would result in increased costs that will shift to payors and consumers because both the primary manufacturer and the secondary manufacturer will raise their prices in order to recoup reduced profit margins resulting from an inaccurate best price.

Response: We appreciate the comments but have not revised our definition of "any entity" as we believe, in light of the DRA amendments, that any sales of covered outpatient drugs between manufacturers must be included in the best price. The DRA

amended the definition of best price, in part, to specifically provide that the best price should be inclusive of the lowest price available from the primary manufacturer to "any manufacturer." In accordance with the best price provisions in section 1927(c)(1)(C)(i) of the Act, we believe that all price discounts, except for bona fide service fees, should be included in the best price of the brand drug unless the discount is specifically excluded by statute or regulation. Therefore, the primary manufacturer will be required to include in the best price of its drug any price concession provided by the manufacturer to any entity (including the secondary manufacturer) that reduces the price of the authorized generic drug sold by the primary manufacturer and actually realized by the primary manufacturer, unless the price concession is specifically excluded by statute or regulation or falls within the definition of a bona fide service fee.

Comment: Several commenters expressed concern that our proposed policy would require the primary manufacturer and the secondary manufacturer to share confidential pricing information that may result in anti-trust violations. Commenters strongly urged CMS to consult with the FTC before implementing the new reporting requirements outlined in the DRA. One commenter recommended that CMS consider eliminating or delaying implementation of the authorized generic reporting requirements until a later date.

Response: We appreciate the comments and have revised the authorized generics provision to require the primary manufacturer, that is, is the NDA holder, to include its sales of the authorized generic to the secondary manufacturer in best price. We have revised the best price provision to provide, at this time, that best price should only include authorized generic sales from the primary manufacturer to a secondary manufacturer or subsidiary of the primary manufacturer and shall be the lowest price at which the primary manufacturer sells the drug.

At this time, we believe this revision will avoid any anti-trust concerns that could potentially arise as a result of pricing data being exchanged between manufacturers. In light of the DRA amendments, we are not eliminating or delaying the implementation of this provision but we will continue to consider this issue as we receive AMP and best price data.

Comment: Several commenters requested that CMS require the primary manufacturer and the secondary

manufacturer to separately report and calculate the AMP and determine the best price for their own products, using only the sales data based on the products' NDCs, and include in each of their own AMP reports the number of units sold during the rebate period. Other commenters recommended that CMS allow the primary manufacturer and secondary manufacturer to submit separate pricing data regarding their own sales so that CMS may calculate the AMP and best price.

Response: We have revised the provision to no longer require the primary manufacturer to include authorized generic sales of the secondary manufacturer in the AMP. The best price shall include authorized generic sales from the primary manufacturer to a secondary manufacturer or to a subsidiary of the primary manufacturer and shall be the lowest price at which the drug is sold by the primary manufacturer.

Comment: A few commenters expressed concern that there are a number of transactions that may not have been intended to fall within the scope of the authorized generic provision. Several commenters requested that CMS clarify that inter-company transactions between the primary manufacturer and the secondary manufacturer will not be included in the primary manufacturer's pricing calculations. Several commenters recommended that inter-company transactions such as transfer price, royalties and/or license payments made by the secondary manufacturer to the primary manufacturer should not be included in pricing calculations. A few commenters indicated support of CMS' decision not to require manufacturers to include the transfer price of the authorized generic drug in best price. One commenter requested that CMS clarify how manufacturers should account for transfer prices when the product is sold from the primary manufacturer to the secondary manufacturer. Other commenters were concerned that transfer fees, licensing fees and manufacturer contracting fees would be inappropriately included in the best price and AMP for authorized generic sales. Several commenters stated that such fees should not be taken into account in the authorized generic provision and only the sales of the authorized generic products in the marketplace should be considered. One commenter requested that CMS clarify that the term "price" used in § 447.506(c) would be considered to be either (1) the adjusted transfer price after the value of all profit-sharing, royalties, license fees and other

adjustments to the contracted transfer price have been added; or (2) the lowest price at which the secondary manufacturer sells the authorized generic in the marketplace. The commenter stated that either clarification of the term "price" would help ensure a true and accurate reflection of the best price of the authorized generic in the marketplace. The commenter indicated that the sales of the authorized generic drugs by the secondary manufacturer to its own customers should be included in the best price, not the primary manufacturer's sales price to the secondary manufacturer. Several commenters requested that the transfer price at which the primary manufacturer sells the drug to the secondary manufacturer not be taken into account or included in the best price or the AMP. One commenter stated that the transfer price should not be included in the best price even if this price would otherwise be the lowest price at which the drug is sold. The commenter stated that transfer prices involve complex royalty or profit-sharing arrangements that would be difficult for the primary manufacturer to incorporate into its best price and difficult for CMS to evaluate. Another commenter recommended that CMS require manufacturers to include the transfer price from the primary manufacturer to the secondary manufacturer in the best price.

Response: We believe that transfer prices and all fees paid by the secondary manufacturer to the primary manufacturer for the authorized generic product, other than bona fide service fees or other discounts excluded by statute or regulation, are price discounts which should be included in the best price of the primary manufacturer. The inclusion of such price reductions or fees ensures that the amount recognized by the primary manufacturer for the authorized generic product reflects all discounts and price concessions that are meant to be included in the best price. Therefore, we have revised the authorized generic provision to include in the best price of the brand drug, transfer prices and other fees paid for authorized generics by the secondary manufacturer to the primary manufacturer, unless such prices or fees are excluded by statute or regulation or fall within the definition of a bona fide service fee as defined in § 447.505 of this final rule.

Comment: One commenter requested that CMS confirm that the best price for authorized generic products is the lowest price charged for the drug by the primary manufacturer in a best price-

eligible sale. In addition, the best price for the secondary manufacturer is the lowest price charged for the drug by the secondary manufacturer in a best price-eligible sale. Another commenter requested that CMS allow the primary manufacturer to obtain from the secondary manufacturer the best price for the authorized generic and compare the secondary manufacturer's best price to its own best price and then submit the lowest price of the two drugs.

Response: In this final rule, we state that the best price includes authorized generic sales from the primary manufacturer or subsidiary of the primary manufacturer, and the best price is the lowest price at which that product is sold.

Comment: One commenter recommended that CMS clarify that the proposed authorized generic provisions do not apply to situations in which a product is sold to a secondary manufacturer for purposes of incorporating the product into a "kit" consisting of multiple products.

Response: The authorized generic provisions apply to the transaction between the primary and secondary manufacturers. Therefore, the price for any authorized generic product sold for the purpose of incorporating the product into a kit consisting of multiple products must be included in the best price of the primary manufacturer.

Comment: One commenter stated that the authorized generic provisions negatively impact manufacturers and penalize them for entering into authorized generic arrangements. The commenter stated that CMS has prematurely taken a negative position on authorized generics before receiving results from an FTC study that is currently analyzing the impact of authorized generics in the marketplace. The commenter further indicated that it would be premature and unwise of CMS to adopt any policy that would impose a penalty on the authorized generic industry before conclusions of the FTC study are in hand.

Response: We appreciate the comments, but the statute does not condition this policy on the results of the FTC study or its findings. The policy concerning authorized generics is intended to implement our understanding of the provisions of the DRA. The purpose of the authorized generic provisions is to ensure that prices for such drugs are accounted for in prices reported by manufacturers participating in the Medicaid Drug Rebate Program.

Comment: One commenter recommended that CMS treat authorized

generic drugs as noninnovator multiple source drugs unless the manufacturer has licensed the drug to another labeler and has no control over pricing, marketing or distribution.

Response: We disagree. Authorized generic drugs are single source or innovator multiple source drugs. In accordance with our understanding of the statute, drugs sold, marketed or distributed under an NDA must be treated as single source or innovator multiple source drugs for purposes of the Medicaid Drug Rebate Program.

Comment: Several commenters requested further guidance regarding the inclusion of authorized generics in the AMP and best price when the drug is being sold by the primary manufacturer and a secondary manufacturer at the same time. The commenter suggested that all sales of the authorized generic product should be considered when calculating the AMP and best price and requested that CMS provide guidance in order to confirm this interpretation. Another commenter requested that CMS clarify in the final rule that the authorized generic provision applies to sales of the brand drug under a new labeler code. A few commenters asked if the authorized generic provision would apply to situations where the primary manufacturer has completely sold the drug to another manufacturer (including all rights to sell the authorized generic drug). Other commenters asked how sales should be treated when the primary manufacturer is no longer manufacturing the authorized generic product but is selling off existing inventory. One commenter requested that CMS confirm its interpretation that the licensed drug would meet the definition of a single source drug because the primary manufacturer is not a source of the drug. Another commenter recommended that the primary manufacturer not be required to take into account authorized generic sales after the date the primary manufacturer stops marketing the brand product.

Response: The manufacturer that holds the title to the labeler code and whose NDC appears on the product when a Medicaid prescription is dispensed is responsible for reporting pricing and paying rebates. We have revised this final rule to state that the primary manufacturer will no longer be required to include the sales of authorized generics by the secondary company in the AMP or best price of the brand drug. Each manufacturer will be responsible for determining the AMP or best price for its own products consistent with the methodology described elsewhere in this rule. If the

primary manufacturer no longer sells the brand drug and the secondary manufacturer buys an authorized generic version of the drug and changes the NDC, the primary manufacturer is responsible for paying rebates on its drugs still in the supply chain and must supply a termination date equal to the shelf life of the last lot/stock sold under the previous NDC. It must also supply pricing data for four quarters beyond the shelf life of the drug. The secondary manufacturer would be responsible for supplying pricing data starting with the quarter the authorized generic is for sale under its own NDC.

Comment: A few commenters requested clarification regarding whether the secondary manufacturer or licensee should include the combined sales of two separate NDCs in its price reporting data where the licensee is selling both the brand and authorized generic version of the licensed innovator multiple source drug, or should the licensee continue to report data for two separate NDCs as is currently done under existing policy.

Response: If the secondary company markets two drugs that have the same nine-digit NDC numbers, the pricing data with respect to both products should be used in AMP and best price calculations.

Comment: One commenter recommended that CMS redefine the rebate period following the initial launch of an authorized generic by dividing the first quarter in which the authorized generic is launched into two separate rebate periods: (1) One period prior to the launch of the authorized generic; and (2) one period starting at the date of the launch. The commenter indicated that this change would allow the manufacturer to apply an AMP and weighted best price for the first quarter of the authorized generic entry. The commenter also mentioned a second option that would allow manufacturers to report, for the first quarter of the authorized generic entry, an AMP and weighted best price based on the number of days the authorized generic is available in the quarter. Additionally, the commenter suggested a third option, in which the incorporation of the authorized generic would begin with the first full quarter the authorized generic is available. Another commenter recommended that for authorized generic agreements effective during the middle of a quarter, CMS should not begin to apply the blending of AMP data until the following quarter. One commenter recommended that CMS require the brand manufacturer to incorporate authorized generic products into pricing calculations the first full

quarter after the authorized generic product is launched. The commenter suggested CMS clarify that authorized generic products will not be taken into account in monthly AMP calculations until the first month of the first full quarter following the launch of the authorized generic.

Response: We are not redefining the rebate period or adjusting the monthly and quarterly reporting requirements as they are currently defined under the law and this regulation. Like other manufacturer programs that start in the middle of a quarter or a month, the appropriate authorized generic sales must be reported for whatever part of the reporting period they occur.

Comment: Several commenters indicated that there are several operational issues that may prevent the primary manufacturer from incorporating authorized generic AMP and best price data from the secondary manufacturer within the required 30-day timeframe. A few commenters stated that it would be infeasible for the primary manufacturer to calculate the AMP and best price for the brand drug within 30 days if the primary manufacturer is unable to rely on the information provided by the secondary manufacturer. In addition, a few commenters stated that the primary manufacturer would not have access to the proprietary data and records of the secondary manufacturer, who may be a competitor, and there may be intersystem incompatibility between the reporting systems of the primary manufacturer and the secondary manufacturer. Another commenter suggested that allowing the primary manufacturer to calculate a weighted AMP and determine the best price based on sales data provided by the secondary manufacturer would allow primary manufacturers to avoid the administrative burden and complexity of incorporating raw sales data of authorized generic products into the pricing calculations of the brand drug. Another commenter recommended that CMS allow the manufacturers to use aggregate data at the 11-digit NDC level (supplied by the secondary manufacturer to the primary manufacturer) to minimize operational and legal issues. Another commenter requested that CMS allow manufacturers flexibility in reporting in order to minimize operational issues.

Response: We have revised this final rule to no longer require the primary manufacturer to include the sales of the secondary manufacturer or subsidiary in the AMP. The primary manufacturer will be required to include in best price its sales to the secondary manufacturer

or subsidiary of the primary manufacturer and the best price shall be the lowest price at which the drug is sold.

Comment: One commenter expressed support for CMS' assertion that the secondary manufacturer would continue to calculate AMP and best price and pay rebates for the authorized generic drug based on its own NDC according to its own utilization of the drug, as is done under current policy.

Response: We appreciate the support this commenter expressed.

Comment: One commenter recommended that CMS clarify that for store brand versions of the brand drug, the primary manufacturer must include in its AMP and best price the sales of such authorized generics to the secondary manufacturer, not sales to consumers by the secondary manufacturer. The commenter indicated that the sales of store brand products to retailers are commercial prices and are not subject to transfer pricing or other similar profit-sharing arrangements. The commenter mentioned that in many cases the primary manufacturer labels the store brand products under the retailer's labeler code, thereby making the retailer a secondary manufacturer of those drugs. The commenter stated that unlike secondary manufacturers of prescription authorized generic products, a secondary manufacturer of an OTC authorized generic sells the authorized generic directly to consumers and typically does not participate in the Medicaid Drug Rebate Program. The commenter stated that the most appropriate sales data to include in the branded product's AMP and best price calculations would be the primary manufacturer's sales transactions with the retailer. The commenter further suggested that in calculating the blended AMP and best price figures for authorized generics sales, the primary manufacturer should incorporate the direct and indirect sales to secondary manufacturers of the store brand authorized generic. The commenter requested that CMS confirm that the primary manufacturer may comply with the authorized generics provisions by including its sales of the authorized generic to the secondary manufacturer when the primary manufacturer calculates the blended AMP and best price figures for the brand product.

Response: The primary manufacturer would be responsible for including prices to the secondary manufacturer, but further sales from the secondary manufacturer to the consumer would not be included.

Exclusion From Best Price of Certain Sales at a Nominal Price (§ 447.508)

Comment: Several commenters did not agree with the statement in the preamble that using the nominal price exception as a marketing tool was not within the spirit and letter of the law and requested CMS to issue further guidance through the formal rulemaking process. Another commenter requested that until such guidance is forthcoming, manufacturers should be permitted to continue to exclude nominal price sales from best price.

Response: CMS does not believe that further guidance is needed on this subject. We believe, in light of the DRA amendments, that the final regulation is clear concerning what sales at nominal price may be excluded from best price.

Comment: Numerous commenters expressed concern that the proposed rule explicitly declined to exercise the Secretary's statutory discretion to identify additional safety net providers that could receive nominal pricing on drugs that would be excluded from best price. They stated that CMS' failure to define a fourth category to include other charitable health care providers is contrary to congressional intent, ill-advised and unfair to providers that are the mainstay of the nation's health care safety net. Many of these commenters suggested that a fourth category of safety net providers include non-profit entities that serve the uninsured and underinsured, regardless of their ability to pay and for whom a majority of their patients have income at less than 200 percent of the Federal Poverty Level (FPL). Many commenters disagreed with the limited entities that qualify to purchase drugs under the proposed nominal price exclusion. These commenters suggested that other safety net providers who offer low-cost oral contraceptive drugs to their low-income, uninsured or underinsured patients should continue to be eligible for nominal pricing exceptions. Commenters requested that nominal pricing exceptions should continue to be extended to such reproductive health care centers, including college and university health centers, which have traditionally purchased contraceptive drugs from manufacturers at nominal prices. Commenters contended that the impact of the rule is significant because it would require the reproductive health care centers to close their doors or to charge the patients who are unable to pay and, therefore, eliminate access to oral contraceptives. These patients would be at risk for unplanned pregnancies and increased reliance on abortion.

Response: The statute allows the Secretary to determine other entities to which sales of drugs at a nominal price would be excluded from best price. However, the statute does not mandate that the Secretary do so. This final rule exercises the Secretary's authority to choose not to expand that list of entities. We believe the entities listed in the statute to be sufficiently inclusive. In addition, commenters indicated that many manufacturers routinely used the nominal price exclusion for other than charitable purposes. Furthermore, manufacturers who have chosen to make drugs available to indigent patients often do so through patient assistance programs, which are excluded from best price (as discussed previously in this rule), and not through nominal pricing.

Comment: One commenter stated that sales of contraceptive drugs at a nominal price are not contingent on market share agreements or the purchase of other products, which were the concerns that prompted Congress to restrict the nominal price exemption. A few commenters stated that nominal pricing predated Medicaid best price and rebates and that keeping family planning providers as entities that can receive nominal prices would not suddenly have an adverse effect on the Medicaid Drug Rebate Program. Another commenter stated that family planning is a cost-effective public health strategy that saves money by preventing other, more costly health problems. In addition, several commenters noted that although family planning clinics that receive funding under Title X of the PHS Act and are funding covered entities under the PHS Drug Pricing Program, their 340B status is not permanent and could be lost due to funding deficits. Other commenters remarked that 340B clinics that rely on subsidies from non-340B clinics within the same organization to finance their operation may not be able to continue to keep their doors open because the non-340B clinics will no longer have access to excess funds when they can no longer purchase contraceptives at nominal prices. Numerous commenters wrote indicating that non-Title X family planning clinics are often the sole source of primary health care for uninsured or underinsured women and provide vital reproductive health care services including birth control drugs and supplies at deeply discounted prices, well-woman exams, screenings for breast and cervical cancer, and treatment for sexually transmitted diseases, diabetes, hypertension, and anemia. Many of these commenters also

noted that the ability of these providers to continue to provide quality health care at low or no cost rests on their ability to purchase contraceptives at nominal price. Other commenters noted that because Title X funding has not increased since 1977, newer clinics have not received Title X funding. Another commenter stated that where two non-profit entities perform the same function for similar populations and one is a 340B covered entity and the other is not, it is reasonable to believe that the Congress intended both to have access to the same discounted pricing structure.

Response: CMS recognizes the important role that family planning clinics play in providing for the basic health care needs of a vulnerable patient population. However, we do not agree that the broad categories of populations served by the clinics suggested by the commenters, which include student health centers, constitute a vulnerable population. It would also be difficult for us to distinguish between agencies; for example, agencies with non-profit status under the Internal Revenue Code that are truly serving a public interest from others that may not be doing so. Such an expansion would be far in excess of the current definition in the 340B Program. Therefore, we do not believe that there is sufficient reason to include these entities in the nominal price exclusion.

Comment: A few commenters noted that Congress established the nominal price exclusion to protect discounts offered to charitable organizations and clinics. One commenter noted that surveys conducted by the Senate Committee on Finance in 2004 and 2005 found that not-for-profit, acute care, teaching and other hospitals appeared to be the primary recipients of nominal prices. This commenter, along with others, urged CMS to define safety net provider as non-profit organizations, comprised of an outpatient clinic or several clinics, which offer health care to patients regardless of their ability to pay, and for whom the majority of their patients have income at less than 200 percent of the FPL.

Response: In its 2004 and 2005 surveys, the Senate Committee on Finance found that while hospitals appeared to be the primary recipients of nominal pricing, most manufacturers' policies did not reflect the use of the nominal price exception for charitable purposes. (This discussion can be found at <http://www.cms.hhs.gov/eRulemaking/ECCMSR/list.asp>; docket ID CMS-2238-P; paper comment number 33.)

Manufacturers did not differentiate between for-profit and non-profit entities when offering nominal pricing, and manufacturers' agreements frequently included market share requirements. Additionally, the surveys found that the use of the nominal price exception has declined since 2003.

Comment: A few commenters noted that their purchase price for a month's supply of oral contraceptives has increased more than tenfold. Other commenters reported that manufacturers are discontinuing nominal prices for oral contraceptives. Numerous commenters expressed concern that prices will increase for these patients, many of whom are on fixed incomes and unable to absorb additional expense to purchase these medications. Another commenter asked if a mechanism will be provided for non-Medicaid patients to continue to receive deeply discounted drugs if existing philanthropic programs no longer qualify for the best price nominal price exclusion.

Response: As previously stated, we believe that there are already programs in place by which manufacturers can continue to make available drugs to the indigent and underinsured without raising best price concerns for drug manufacturers.

Comment: One commenter expressed disappointment that we did not list community health providers that receive funding under Title V of the PHS Act as 340B covered entities because they serve the same populations as family planning clinics. They stated that by this oversight, the government would incur increased costs for maternity care and providing welfare. Additionally, the commenter noted that local health departments were considering no longer providing family planning services, which would have a tremendous impact on underserved populations and that this may pave the way for civil rights action.

Response: CMS does not determine what entities qualify for the 340B Program. In this final rule, as discussed above, we have decided not to expand the entities which can have nominal price sales excluded from best price for purposes of the Medicaid Drug Rebate Program.

Comment: One commenter requested that CMS clarify the scope of the best price exemption specifically to allow the best price exemption for nominally priced drugs to a 340B hospital to extend to drugs purchased for inpatient use and by other components of a large health system of which a 340B participating hospital is a part. Other commenters said that the loss of

nominal pricing contracts in the non-340B parts of their hospitals would be devastating to the amount of service they could continue to provide.

Response: Section 1927(c)(1)(C)(i)(I) of the Act exempts inpatient prices charged to 340B hospitals from best price, so we believe that there is no need to address these prices in the context of the nominal price exemption. Section 1927(c)(1)(D)(i)(I) of the Act provides that nominal prices to 340B covered entities are exempt from best price; the statute does not extend the exemption to any part of a broader organization of which the 340B covered entity is a part. The Secretary has not chosen to expand the list of which entities qualify for the nominal price exclusion to include facilities not identified in the statute.

Comment: One commenter noted that a study of manufacturers' policies and practices with respect to nominal price practices indicated that the nominal price exclusion was used primarily as a competitive marketing tool and not used for charitable purposes as intended by Congress.

Response: We appreciate this comment and believe that this was a key factor in the legislation to restrict the types of entities eligible for the nominal price exclusion from best price.

Comment: One commenter requested that CMS provide a list of qualified safety net providers eligible for the best price exemption. Another commenter suggested that CMS maintain a current list of entities that qualify as ICFs/MR or State-owned or operated nursing facilities, similar to the CMS list of qualified SPAPs under Medicare Part D. Yet another commenter requested CMS to develop and publish procedures to be used to identify additional safety net providers. Yet another commenter recommended that safety net providers be required to complete a self-certification process. Another commenter stated that they appreciated the clear guidance given by CMS in delineating the covered entities eligible for the nominal pricing exemption.

Response: The Secretary has chosen not to designate a fourth category of safety net providers; therefore, the argument for a certification process is unnecessary, as is the need to establish and publish procedures for the identification of additional safety net providers. The Health Resources and Services Administration (HRSA) administers the 340B Program and we rely on that agency to identify providers in the 340B Program. Furthermore, ICFs/MR and State-owned or operated nursing facilities fall under State jurisdiction and we expect the State

Medicaid Agencies to identify these for manufacturers.

Comment: A few commenters requested that we add language in the preamble or in the regulation text of the final rule to state that the Secretary intends to retain his discretionary authority to add to the list of safety net provider entities for which sales at nominal prices are excluded from best price should CMS choose not to exercise the authority at this time. Several comments urged CMS not to relinquish the authority to establish nominal price exemptions for additional classes of providers.

Response: In accordance with the reasons stated above, the Secretary has chosen not to exercise his authority at this time. The Secretary retains the authority to propose expansion of this list for any appropriate safety net providers at a future time through the notice and comment process.

Comment: One commenter agreed with the proposed rule directing manufacturers to exclude nominal sales from the AMP calculation stating it would be unfair to allow deeply discounted prices offered only to safety net providers and not available in commercial transactions to put downward pressure on AMPs and depress Medicaid reimbursement to retail pharmacies.

Response: We agree that nominal price sales that are excluded from best price should not be included in AMP and we have retained that provision in the final rule.

Comment: One commenter asked whether the AMP used in determining a nominal price for purposes of the best price exclusion should be the combined AMP for the brand manufacturer who also has sold or licensed an authorized generic.

Response: Brand manufacturers who also have sold or licensed rights to an authorized generic should compute the AMP for the brand drugs according to the requirement in § 447.506.

Comment: A few commenters believed that nominally priced products should be excluded from best price calculations because those prices are not representative of the acquisition costs available to retail pharmacies. Several commenters stated that nominal prices are not available to the retail pharmacy class of trade and should therefore be excluded from any calculations.

Response: CMS concurs with the commenter that nominal priced sales to certain specified entities such as 340B entities, ICFs/MR and State-owned or operated nursing facilities are to be excluded from best price calculations. For purposes of this exclusion, nominal

price is defined as less than ten percent of AMP in the same quarter for which the AMP is computed.

Requirements for Manufacturers (§ 447.510)

Electronic Data Submission

Comment: A few commenters expressed support for CMS' proposal to require manufacturers to submit all product and pricing data in an electronic format.

Response: We appreciate the support for this provision and have retained this requirement in the final rule.

Data Reported to CMS

Comment: One commenter asked CMS to revise the regulation text at § 447.510(a) to clarify that manufacturers are responsible to ensure that they report to CMS only those products/NDCs that are truly covered outpatient drugs. The commenter also asked CMS to coordinate with the FDA or other Federal agencies to ensure that the products manufacturers report to CMS actually are covered outpatient drugs. Finally, if any products are subsequently determined to not be covered outpatient drugs, the commenter asked that CMS clarify that States are not to be held accountable for any expenditures or rebates collected for the products in the interim.

Response: CMS already coordinates with the FDA to ensure that drugs covered by the Medicaid Program meet the statutory definition of covered outpatient drugs.

Comment: A few commenters expressed support for our position that AMP should be reported on a monthly basis and AMP, best price, and customary prompt pay discounts should be reported on a quarterly basis. Another commenter urged us to eliminate the monthly AMP reporting requirement.

Response: We continue to believe that in accordance with the DRA, AMP should be reported monthly, while AMP, best price, and customary prompt pay discounts should be reported quarterly.

Comment: Several commenters suggested that AMP must be reported weekly in order to accurately realize market costs and reimburse retail pharmacy accordingly. One commenter noted that the monthly reporting system would be inadequate and unfair, if not illegal. Some commenters noted that pricing changes daily; therefore, monthly reporting will cause too long of a delay in updated AMP prices. Another commenter noted that with manufacturers supplying CMS the

pricing data 30 days after the month closes, the published pricing data will be at least 60 days behind the marketplace pricing. One commenter asked CMS to revise the AMP reporting period to a timeframe that is available in the private sector.

Response: The DRA requires manufacturers to report AMP monthly to CMS. While we acknowledge that prices change in the marketplace more frequently than monthly, we are implementing the monthly AMP reporting requirement in this final rule. We note that States are not required to base their Medicaid pharmacy reimbursement on AMP. AMP will be one of many prices that States can look at when setting their pharmacy reimbursement rates. Furthermore, we note that the FULs will be calculated based on 250 percent of the AMP, in accordance with the statute, which should allow for some market fluctuations.

Comment: A few commenters noted that the lag time between the timeframe covered by monthly AMP and when the AMPs are available may result in inaccurate AMPs due to the reporting delay. The commenters urged CMS to address this timing issue directly and in detail before we encourage States and others to use it as a reimbursement benchmark. One way to do this would be to compare AMPs to WACs, and only publish those AMPs that approximate the WAC for a brand name drug. Another commenter suggested that CMS issue new FULs within seven to ten days of receiving monthly AMP data.

Response: We share the commenters' interest in making sure that AMPs reported to CMS and released to the public are as accurate as possible. Also, we note that States have been notified of the limitations of the AMP data. We appreciate such concerns and have decided to establish a timeframe sufficient for initial implementation of the new FUL prices. CMS has posted a timeline for implementation of the FUL on its Web site (<http://www.cms.hhs.gov/DeficitReductionAct/Downloads/AMPFULTentativeTimeline.pdf>).

Comment: A few commenters noted that the record layout for the quarterly pricing report that CMS issued in December 2006 did not include a field for customary prompt pay discounts. The commenters asked for clarification as to how customary prompt pay discounts should be reported.

Response: We will issue a revised record layout to manufacturers to include customary prompt pay discounts in accordance with this final rule.

Comment: A few commenters asked for operational guidance on reporting customary prompt pay discounts to CMS. Specifically, should manufacturers recognize discounts given at the time of sale of the product to the customer? Also, should manufacturers report customary prompt pay discounts at the 9-digit NDC, 11-digit NDC, or at the labeler code level? Should the information be provided in whole dollars, units, or by percentage? Would reporting an accrued amount by NDC suffice? One commenter noted that the statement in the proposed rule, that these discounts should be reported at an aggregate level, including discounts paid to all purchasers in the rebate period is too vague to know what level of detail is required. The commenter asked CMS to include additional specification in this final rule.

Other commenters noted that it is difficult for a manufacturer to quantify the discounts taken by a purchaser, or deducted from payments made during the rebate period, as doing so requires the manufacturer to reconcile the deductions relating to customary prompt pay discounts and deductions taken for other reasons, such as shortages in the amount of product shipped. Even if the manufacturer could quantify such deductions, that amount would relate to the invoices paid rather than the sales made in the rebate period. In contrast, the commenters believed that manufacturers can readily quantify the customary prompt pay discounts offered during a rebate period, and ask that CMS clarify the reporting requirement accordingly.

Response: We want this reporting requirement to be as simple as possible. Therefore, manufacturers may report customary prompt pay discounts offered during a rebate period aggregated with respect to all purchasers. All of the pricing information reported to CMS, including customary prompt pay discounts, should be reported at the nine-digit NDC level. We also clarified in § 447.510(a)(3) that manufacturers should report customary prompt pay discounts provided to all wholesalers in the rebate period. We will clarify this requirement further when we issue a revised record layout after publication of this final rule.

Comment: One commenter asked for guidance on whether manufacturers should combine customary prompt pay discounts for authorized generics with customary prompt pay discounts for the brand name drug. Similarly, should nominal prices for authorized generics be combined with nominal prices for brand name drugs? The commenter

believed there is no purpose to report a combined figure for these values.

Response: We agree with the commenter. A primary manufacturer should not include customary prompt pay discounts or nominal prices for authorized generic drugs marketed by another manufacturer when reporting these data to CMS.

Comment: One commenter asked for clarification about what format will be used to report nominal sales. Another commenter asked for clarification as to whether nominal price reporting should be at the gross or net level, with a preference for reporting at the net level. The commenter also asked CMS to provide an example of how nominal price data should be reported.

Response: In the proposed rule, we stated that nominal prices shall be reported as an aggregate dollar amount and shall include all sales to the entities listed in § 447.508(a) of this subpart. The dollar value of all sales should be aggregated for each drug at the 9-digit NDC level. We will issue further instructions and a revised record layout to clarify the format manufacturers should use to report nominal prices after the publication of this final rule.

Comment: One commenter asked CMS to clarify that quarterly AMP submissions should be based on quarterly sales, not the aggregate or average of the three monthly AMPs submitted during the same quarterly period. Other commenters urged CMS to allow manufacturers to calculate their quarterly AMPs based on the weighted average of monthly AMPs in the quarter and to clarify that manufacturers that select this option would not be required to restate their quarterly AMP, other than to correct an error. The commenters believed this approach would minimize discrepancies between monthly and quarterly AMP and would be administratively simple for manufacturers and CMS to administer.

Response: We concur with the commenters who suggested we define quarterly AMP as the weighted average of monthly AMPs. Accordingly, we have revised the regulation text at § 447.504(i)(2) to require manufacturers to calculate quarterly AMP as the weighted average of monthly AMPs in the quarter. We agree that this approach will minimize discrepancies between monthly and quarterly AMPs. However, because we do not agree that this will eliminate the need for manufacturers to correct their quarterly AMPs, we have retained in the final rule the requirement that manufacturers report revisions to quarterly AMPs for up to 12 quarters from the quarter in which the data were due. Furthermore,

manufacturers should restate their quarterly AMPs if there are subsequent restatements of the monthly AMPs on which the quarterly AMPs are based.

In addition, we are revising the regulation text at § 447.510(d)(2) to clarify that monthly AMP should be calculated as the weighted average of prices for all the manufacturer's package sizes for each covered outpatient drug sold by the manufacturer during a month. 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.

Comment: One commenter expressed concern with the provision in the regulation that allows manufacturers to revise their quarterly AMPs for up to twelve quarters from the quarter in which the data were due. The commenter recommended that CMS address the ability of a payer to recoup erroneous payments or the ability of a provider to claim shortages based on incorrect AMPs in this final rule.

Response: We intend to use monthly AMPs in the calculation of the FULs. Although manufacturers will be allowed to restate their monthly AMPs, we do not anticipate that there will be any retroactive adjustments to the FULs because we will calculate the FULs based on the current monthly AMPs and we do not intend to recalculate the FULs if the monthly AMPs are subsequently revised by manufacturers.

However, we note that States may need to revise payments to the extent they base their reimbursement methodologies on AMPs that are subsequently revised by manufacturers.

Comment: One commenter asked for guidance on monthly reporting of AMP when a product is discontinued. Another commenter asked CMS to clarify that a manufacturer's reporting obligation for monthly AMP ceases with the product's termination date, beginning with the first monthly report after the expiration date of the last lot sold. Also, States should not be able to set reimbursement rates based on expired AMPs as they do not reflect the acquisition price of a product that is currently available for purchase by the retail pharmacy class of trade.

Response: Manufacturers should continue to report monthly AMP for twelve months past the product's termination date. The purpose of reporting a terminated product is that a product may be billed by the pharmacy for up to a year past the date the drug was dispensed. We have clarified this requirement in the final rule at § 447.510(d)(5).

In regard to the issue of State payment rates, we will continue to review SPAs to ensure that payment complies with section 1902(a)(30) of the Act.

Comment: A few commenters suggested that CMS implement a process that would trigger an alert if there is a severe shift in AMP from one reporting period to another. The commenters suggested that the OIG be alerted of all AMP price shifts and the OIG would research and then recommend an updated AMP figure to CMS. Such a trigger mechanism would limit the effects of price posting lag, mitigate potential market manipulation, mitigate a possible disincentive to fill generics by the retail pharmacies, limit incorrect public data, and provide CMS with the most up-to-date calculation of AMP. One commenter noted that there is even greater concern regarding the heightened risks of error and inconsistency among manufacturers because AMP is potentially a reimbursement metric that will be calculated and reported on a monthly basis. Other commenters urged CMS to implement systems checks and measures to hold manufacturers accountable for the quality of the data they provide, including reporting or not reporting accurate data. The commenters requested that CMS include representation from State Medicaid Agencies in developing this system of checks and accountability measures.

One commenter suggested that CMS compare the NDCs reported by manufacturers with the NDCs listed on databases maintained by First DataBank and Medispan in order to help assure that all NDCs and their AMPs are reported to CMS.

Response: We are not implementing a trigger mechanism at this time; we will use the monthly AMPs that are submitted by manufacturers to calculate the FULs, and we will post the monthly and quarterly AMPs on our Web site. In regard to the NDCs reported by manufacturers, we will address these ongoing operational issues at a later time.

Comment: One commenter suggested that CMS allow First DataBank, the pricing source used by most States, to have access to the AMP data electronically. This would centralize administrative tasks and allow efficient and cost-effective integration of AMPs into State data warehouses. The commenter also suggested that the AMP files include specific data elements to streamline importing AMPs into State databases. Those data elements are the 11-digit NDC, brand name, strength, dose form, metric billing unit (for example, each, milliliter, or gram),

termination date, metric unit AMP, AMP begin date, AMP end date, and file reporting date.

Response: The monthly and quarterly AMPs will be on our Web site, so we do not see a need to provide them separately to First DataBank. In regard to the specific data elements, we expect to address these concerns in operational guidance after this final rule is published.

Comment: A few commenters noted that CMS' Drug Data Reporting System (DDR) requires that the employee posting submissions to provide his or her Social Security number (SSN). The commenters recommended that access to the DDR be revised to include the corporation's tax ID number (TIN) or SSN associated with the corporation instead of the individual's SSN. One of the commenters urged CMS to destroy records of employee SSNs once a company has been enrolled under its TIN and notify the technical contacts of the destruction.

Response: This issue is not addressed in the proposed rule; therefore, we cannot consider this comment as we consider revisions to be included in the final rule. We intend to address this issue in the future in guidance or regulations, as appropriate.

Comment: One commenter suggested that CMS revise the DDR system to allow manufacturers to submit a text document along with their AMP and best price reports.

Response: We are not revising the DDR system to permit manufacturers to submit a text document at this time. The DDR system was specifically designed to streamline the collection of product and pricing data from manufacturers. We believe that any alterations to the system at this time may hamper its functionality. Manufacturers that wish to submit documentation regarding their AMP and best price reports may do so outside the DDR system.

Comment: One commenter asked for guidance on how manufacturers may report pricing corrections on the record layout.

Response: We will clarify how manufacturers should report pricing corrections in future operational instructions.

Comment: A few commenters asked for guidance on how to handle zero or negative monthly AMPs. The commenters noted that for quarterly reports, CMS has instructed manufacturers to use the last quarter's positive value when the current quarter is a zero or negative value.

Response: Manufacturers should report the most recent positive AMP value. This is consistent with our past

policy and we believe it best represents the AMP for each drug. This will assure that manufacturers pay a rebate and will prevent offsets due to a negative AMP.

Comment: A few commenters asked whether product reports must be filed monthly.

Response: As set forth in the national rebate agreement, initial product information must be submitted within 30 days after the first month in which the drug is marketed in order for the program to identify the relevant drug products covered by the program. Initial product data must be submitted once before any prices can be reported.

Comment: One commenter suggested that we require manufacturers to report AMP and best price information using NCPDP standard units, and that CMS report the FUL using the same.

Response: NCPDP standard units are based on package pricing. The AMP and best price information that manufacturers report is based on unit pricing, without regard to package size; therefore, we do not see a basis for using the NCPDP units given the Medicaid statute reporting requirements.

Monthly AMP

Comment: Several commenters focused on the issue of revising monthly AMPs. A few commenters agreed with the position we stated in the proposed rule, that manufacturers should not be permitted to revise their monthly AMPs. Otherwise, the commenters noted that the revised monthly AMPs could be used as a basis for reducing reimbursements already paid for the drugs. Another commenter urged CMS to allow manufacturers to revise their monthly AMPs for up to twelve quarters after initially submitted, as is currently allowed for quarterly AMP data. One commenter noted that a prohibition on restatements of monthly AMPs could have financial consequences for manufacturers, pharmacies, physicians and outpatient hospital departments.

Other commenters expressed concern with allowing manufacturers to revise their monthly AMPs for up to 30 days after each month. The commenters urged CMS to enforce the prohibition against adjusting monthly AMP beyond the 30-day period.

Response: After consideration of these comments, we have decided to allow manufacturers to revise their monthly AMPs for a period not to exceed 36 months from the month in which the data were due and have revised the regulation at § 447.510(d)(3). We reached this decision in part because we want to minimize the disparities between monthly and quarterly AMPs. If a manufacturer discovers an error one

year after the AMP is reported, we want the correction to be reflected in the monthly and quarterly AMPs.

We also recognize that because we are using monthly AMP in the calculation of the FULs, it would be impractical and burdensome for States and pharmacies if we revised the FULs based on revised monthly AMPs for up to three years. Furthermore, we note in § 447.510(d)(2) that manufacturers are required to submit monthly AMPs based on the best data available and to certify the accuracy of those submissions. As a result, we do not expect that we will need to revise the FULs. We will consider revisiting this issue if monthly AMP submissions become problematic.

Comment: One commenter noted that in our December 15, 2006 guidance to manufacturers, CMS stated that “adjustments, such as those resulting from sales data, received after the reporting period ends, should be reflected in the next monthly AMP submission.” The commenter noted that the addition of data attributable to a previous month’s transactions into a later month’s AMP could artificially inflate or deflate the later month’s AMP.

Response: Our intent in the December 2006 release was to advise manufacturers that they should submit a revised monthly AMP in the next monthly AMP submission if they receive sales data after the reporting period ends. In this final rule, as noted above, we are permitting manufacturers to make revisions to monthly AMP for up to 36 months after the month in which the data were due. Therefore, data attributable to a previous month’s transactions should not result in the artificial inflation or deflation of a later month’s AMP. We further believe this concern will be addressed by requiring manufacturers to estimate their lagged price concessions, as discussed in detail below.

Comment: One commenter asked whether it is acceptable for manufacturers to run monthly reports of sales and discounts to be included in the AMP calculations based on the “post” date of chargebacks, which indicates when a chargeback has been “paid.”

Response: We will continue to allow manufacturers the flexibility to count chargebacks based on their GAAPs, provided they use one methodology uniformly.

Comment: One commenter asked what procedure CMS will put in place if a manufacturer believes the monthly AMP on CMS’ Web site is incorrect.

Response: We will establish a procedure to address this and will issue

operational guidance after publication of this final rule.

Comment: One commenter suggested that CMS address the requirements for monthly AMPs under Determination of AMP, § 447.504, rather than addressing monthly AMP under Requirements for Manufacturers, § 447.510.

Response: We appreciate this comment but have decided to address the requirements for monthly AMP under § 447.510.

Comment: One commenter recommended that we include the 11-digit NDC on the monthly AMP file that we distribute to States.

Response: The 11-digit NDC will be included on the monthly file distributed to States.

Comment: One commenter asked CMS to consider defining monthly and quarterly AMPs differently. Another commenter agreed with CMS’ proposal that monthly AMP be defined the same as quarterly AMP, except the monthly AMP would represent data for one calendar month.

Response: For reasons noted in the preamble to the proposed rule, we continue to believe that monthly and quarterly AMPs should be defined the same.

Lagged Price Concessions

In the proposed rule, we proposed allowing manufacturers to rely on estimates regarding the impact of their end-of-quarter rebates or other price concessions for purposes of calculating monthly AMP. We suggested a 12-month rolling average of all lagged price concessions for purposes of calculating monthly and quarterly AMPs and requested comments on the appropriate methodology for calculating monthly AMP.

Comment: Many commenters favored allowing manufacturers the flexibility to estimate lagged price concessions for monthly and quarterly AMPs. Many of these commenters expressed a preference for using a 12-month rolling average. Several commenters pointed out that a 12-month smoothing methodology for AMP would mirror the smoothing methodology CMS established for ASP; therefore, it would be easier for manufacturers to implement, would reduce the risk of errors, and would minimize the volatility in the data. One commenter noted that a 12-month rolling average is an auditable approach, but there are other, more credible approaches that would result in potentially more accurate AMPs (but the commenter did not elaborate on what those approaches are). Another commenter urged CMS to mandate that all manufacturers use a

rolling 12-month average for reporting monthly AMP, but require actual discounts to be used in reporting the quarterly best price. Some commenters suggested manufacturers should be allowed to employ a variety of smoothing methodologies to calculate accurate quarterly and monthly AMPs, while one suggested that manufacturers be allowed to choose a preferred method, provided that the method is used consistently. One commenter asked that manufacturers be given the option to estimate lagged price concessions for quarterly AMP through a smoothing methodology or an estimation method based on accruals and sales experience. One commenter asked us to clarify that manufacturers can estimate all lagged rebates or concessions regardless of whether they are quarterly or on a different period. Other commenters asked us to specify whether manufacturers should calculate the 12-month rolling average using the date the rebate is earned versus the date the rebate is paid.

Commenters suggested a modification of the 12-month rolling percentage methodology. They suggested requiring manufacturers to look to the four full calendar quarters before the reporting period to calculate the rolling 12-month percentage, which could then be applied to all three monthly AMPs and the quarterly AMP. As an alternative, chargebacks and rebates could be singled out for lagged treatment on a routine basis. In addition, the commenters urged CMS to provide examples showing how the methodology should be applied in both the monthly and the quarterly context, taking into account the proper treatment of the various types of bundled sales.

Other commenters recommended that manufacturers be permitted to use a four-quarter rolling average of rebates to sales, and apply that percentage to monthly sales. The commenters believe that using a four-quarter rolling average for smoothing is more operationally feasible than a 12-month rolling average because rebates and other price concessions are typically invoiced by customers and paid by the manufacturer on a quarterly basis. The commenters also asked that CMS allow manufacturers to estimate excluded sales for the month using a four-quarter rolling average based on gross sales units divided by excludable AMP units.

One commenter noted that end-of-year rebates or chargebacks should be excluded from the AMP calculation in order to avoid significant 12 to 18-month revisions to AMP data. Such revisions would render AMP data unusable for reimbursement purposes.

An alternative would be to require manufacturers to estimate their end-of-year settlements at minimum discount levels.

Response: We have decided to require manufacturers to use a 12-month rolling average to estimate the value of lagged price concessions in their calculation of monthly and quarterly AMPs and have added this requirement to the regulation at § 447.510(d)(2). We believe this methodology will ensure the greatest stability and accuracy for AMP data.

Comment: One commenter noted that if CMS changes its position with regard to the treatment of Medicaid units and rebates to Federal programs such as Medicare Part D, that CMS should consider allowing discretionary smoothing of those units and removal of a corresponding value from gross sales dollars.

Response: We are not changing our position with regard to the treatment of Medicaid units and rebates to Federal programs such as Medicare Part D.

Comment: One commenter asked CMS to clarify what we consider to be "lagged price concessions." Another commenter urged us to only allow manufacturers to estimate the value of price concessions between manufacturers and true wholesalers.

Response: We consider lagged price concessions to be any discounts or rebates that are realized after the sale of the drug, except for customary prompt pay discounts. Lagged price concessions are not limited to discounts or rebates offered to wholesalers. Accordingly, we have added a definition of lagged price concessions to the regulation text at § 447.502.

Comment: A few commenters asked CMS to clarify whether the current month should be included in the 12-month rolling average.

Response: Manufacturers should include the current month in calculating the 12-month rolling average they use to determine the value of lagged price concessions.

Comment: One commenter asked that manufacturers who estimate lagged price concessions be exempt from the requirement to report revised quarterly AMPs in § 447.510(b).

Response: The purpose of requiring manufacturers to report revised quarterly AMPs in § 447.510(b) is to ensure the Medicaid rebate amounts are as accurate as possible. In this final rule, we are requiring manufacturers to estimate the value of lagged price concessions using a 12-month rolling average; however, we do not expect this requirement will eliminate the need for manufacturers to correct their quarterly AMP calculations for other reasons,

such as errors in the initial AMP calculation. Therefore, we are not creating a broad exemption from this requirement. Instead, we have clarified in this final rule at § 447.510(b)(2) that manufacturers should report revised AMPs except when the revision would be solely as a result of data pertaining to lagged price concessions.

Comment: One commenter asked that smoothing not be required for the first partial year of sales for new products because the base date AMP can be skewed by non-recurring post-launch start-up payments.

Response: We disagree with the commenter's suggestion about estimating lagged price concessions during the first partial year of sales for new products. We believe such an exception would run counter to the intent of the DRA, which is to provide for increased transparency in AMP pricing.

Comment: One commenter expressed concern that in light of the increasing vertical integration of the pharmacy market, manufacturers could use the monthly and quarterly "dual reporting" timeframes to manipulate AMP, thereby manipulating the market. This concern stems from the ability of manufacturers to restate their quarterly AMPs for twelve quarters from the quarter in which the data were due, as well as the ability of manufacturers to estimate their end-of-quarter discounts and allocate these discounts in the monthly AMPs reported to CMS throughout the rebate period. The commenter was also concerned that this situation could lead to a loss of price transparency.

Response: We disagree with the commenter that the possibility exists for a lack of price transparency. Beginning with the data for January 2007, we interpret the law to provide for posting of monthly and quarterly AMPs on our Web site, which allows full transparency for monthly and quarterly AMPs. The intent behind the decision to require manufacturers to estimate their end-of-quarter discounts was to minimize volatility in the monthly AMP data, which is used to set the FUL and which States may consider in setting their pharmacy reimbursement rates. Without this requirement, we anticipate there would be significant volatility in the data from month to month, thereby eroding its usefulness.

The provision requiring manufacturers to restate their quarterly AMPs for a period not to exceed twelve quarters from when the data were due became effective on October 1, 2003. Prior to that time, the national rebate agreement did not provide a specific period for recalculations. As noted in

the final rule with comment period published on August 29, 2003 (68 FR 51912) we believe this provision helps streamline the administration of the Medicaid Drug Rebate Program.

Pricing Lag

Comment: A few commenters expressed concern with the lag time between when manufacturers calculate and report their monthly AMPs to CMS and when those AMPs are made public. They noted that the process could result in data being up to 90 days old and asked CMS to provide guidance to States and other users of AMP on the proper method to address any issues resulting from this lag time. One commenter noted that this problem highlights the challenges CMS faces in implementing AMP's new dual purpose of serving as a measure for quarterly Medicaid rebates and potentially as a reimbursement benchmark. Another commenter speculated that the lag time would likely result in brand name drug prices being higher than AMP, with the result that pharmacies will be underpaid if they are reimbursed based on AMP.

Response: While we will make every reasonable effort to publish this data as soon as possible after we receive it, we are aware that the monthly AMP data we make available to the public will likely be 45–60 days old, given the timeframes in the reporting requirements. While we will make these limitations known to the States and other parties, it will generally be up to them to determine how to best use this data.

Base Date AMP

Comment: Many commenters expressed support for allowing, but not requiring manufacturers to recalculate their base date AMPs. Noting the difficulty in performing a calculation using data that may be more than ten years old, several of these commenters further suggested that CMS permit manufacturers to estimate their recalculated base date AMPs by relying on reasonable assumptions, extrapolation or other accepted methods of estimation where partial data are available. One commenter suggested that CMS allow manufacturers to use a ratio derived from a comparison to the current AMP and the AMP calculated in accordance with this final rule. Another commenter asked CMS to allow manufacturers to use an alternate methodology to restate base date AMP when the original source data or systems are not available, such as a decrease of two percent. Several commenters urged CMS to clarify that

manufacturers have discretion to recalculate their base date AMPs on a product-by-product basis.

Response: Our intent in permitting manufacturers to report a revised base date AMP is to allow all manufacturers the opportunity to recalculate their base date AMPs in accordance with the definition of AMP in this final rule. We want this requirement to be minimally burdensome to manufacturers. Therefore, we have added a provision to the regulation at § 447.510(c)(2)(ii) to allow manufacturers to choose to recalculate their base date AMPs on a product-by-product basis. As with other pricing calculations, in the absence of specific guidance, manufacturers may make reasonable assumptions consistent with the statute, Federal regulations, and customary business practices. However, because the base date AMPs will be used to determine all future rebate calculations, we are not permitting manufacturers to rely solely on estimates or reasonable assumptions for calculating a revised base date AMP. Manufacturers must use actual data to calculate revised base date AMPs. We have clarified this requirement in the regulation text at § 447.510(c)(iii).

Comment: A few commenters noted that the preamble and regulation text appear to permit recalculation of base date AMP only in accordance with § 447.504(e), the provision defining retail pharmacy class of trade. The commenters asked CMS to clarify that manufacturers are permitted to recalculate base date AMP in light of all of the revisions and clarifications to the definition of AMP.

Response: We have clarified the regulatory text at § 447.510(c)(2)(i) such that a manufacturer's recalculation of the base date AMP should only reflect the revisions to AMP as provided for in § 447.504 of this subpart, rather than the provisions of § 447.504(e) of this subpart.

Comment: A few commenters requested that CMS consider a longer implementation timeframe for resetting base date AMP than two quarters following release of the final rule. One commenter suggested that CMS establish a date certain within which manufacturers must submit revised base date AMPs, but require that all manufacturers who choose to recalculate must refile their AMPs as of the effective date of the final rule. The commenter noted that given the importance of the base date AMP in determining a manufacturer's rebate liability, any recalculation should be undertaken in a manner that allows adequate time for thorough review and analysis. Another commenter

specifically recommended that CMS allow manufacturers to restate their base date AMPs during the first four quarters after the publication of this final rule. One commenter suggested that revised base date AMPs can be reported during the third full calendar quarter following the publication of the final rule.

Response: We concur with the commenters about importance of an accurate base date AMP in the calculation of the Medicaid rebate amount. Therefore, in light of the comments we received, we will permit manufacturers to submit a revised base date AMP within the first four calendar quarters following publication of this final rule at § 447.510(c)(1). We expect that this extended timeframe will allow manufacturers to perform the necessary research and analysis regarding the decision to revise their base date AMPs in accordance with the definition of AMP in § 447.504.

Comment: One commenter asked CMS to explain how the revised base date AMP would be used for purposes of calculation of the Medicaid rebate amount.

Response: The revised base date AMP will be incorporated in the formula that CMS uses to calculate the Medicaid rebate on a prospective basis, beginning with the quarter in which the revised base date AMP is submitted. It will not be used to revise the rebate for prior periods.

Comment: Commenters asked CMS to allow manufacturers to restate base date AMPs back to January 1, 2007 to account for the impact caused by the implementation of the customary prompt pay discount and authorized generic provisions of the DRA that became effective on that date.

Response: In this final rule, we are permitting manufacturers to restate their base date AMPs in accordance with all of the clarifications to the determination of AMP. We believe it would be impractical to allow base date AMPs to be restated twice because, in accordance with the effective date of this rule, the restated base date AMPs will be used on a prospective basis. We don't see the administrative practicality of delaying restatements of base date AMP longer than four quarters after this final rule is published.

Comment: A few commenters asked CMS to clarify which quarter's AMP should be submitted for the base date AMP requirement.

Response: Manufacturers should submit the AMP for the same calendar quarter that is currently used as the base date AMP for each of its active NDCs.

Comment: One commenter asked for clarification as to how base date AMP is

to be reported. The commenter noted that the record layout CMS issued in December 2006 for the quarterly report does not include a field for base date AMP.

Response: We will issue a revised record layout to manufacturers and will clarify how base date AMP is to be submitted after publication of this final rule.

Certification Requirement

Comment: Commenters noted several difficulties with complying with the requirement that the CEO or the CFO certify the pricing reports submitted to CMS. First, it may be difficult to obtain signatures from senior executives on a routine basis, and they may not be the best individuals to attest to the accuracy of the reporting to CMS. Further, these titles do not fit into the organizational structure of every manufacturer. One commenter suggested that CMS clarify that certification can be done by an individual with authority and accountability equivalent to an individual holding such a title. Another commenter suggested that the certification could be done by an individual who reports indirectly to the CEO or CFO. One commenter suggested that the individual designated as being responsible for reporting of pricing information be the one accountable for certification purposes. Commenters suggested that a quarterly certification could be applied to the quarterly and monthly data submissions; otherwise, the timeliness of the monthly data submissions would be compromised. Another commenter asked CMS to clarify whether an electronic signature or an e-mail will suffice in complying with this requirement.

Response: We recognize that manufacturers anticipate that it will be challenging to obtain signatures from a CEO or CFO on a monthly basis for purposes of complying with the certification requirements. We also recognize that those titles may not apply to the management structure of every company. Therefore, we are revising the regulation at § 447.510(e) to specify that the certification may be made by the CEO, the CFO, or an individual with another title who has authority equivalent to one of those positions. In addition, the certification may be made by an individual with the authority directly delegated to perform the certification on behalf of that individual.

In light of the fact that we are requiring manufacturers to submit data to CMS in an electronic format, we will provide that the certification be made electronically. In addition, the

certification must be made with every data submission to CMS, regardless of whether submission is for monthly data or quarterly data. We will issue further operational guidance on the mechanism manufacturers must use to certify their data after publication of this final rule.

Comment: A few commenters noted that the certification language for AMP should not be identical to the certification language for ASP. The commenters specifically recommended that the certification language for AMP include a knowledge qualifier until the AMP calculation standards are no longer in a state of flux. One commenter suggested that the certification language should be expressly qualified and should read as follows, "To the best of my knowledge and belief, the reported average manufacturer prices and best prices were calculated accurately and all information and statements made in this submission are true, complete, and current." Another commenter asked CMS to clarify the certification requirements.

Response: We appreciate the commenters' suggestions regarding the certification language. As noted above, we will issue further guidance or regulation, as may be necessary, on the certification requirements after publication of this final rule.

Comment: One commenter noted serious reservations regarding the certification of data from other manufacturers or data submitted based on the company's best estimates regarding price concessions that may be redeemed in any given month. The commenter also asked for further elaboration as to how the certification requirements would be enforced.

Response: As of the effective date of this rule, we will not accept data from a manufacturer unless the certification requirement has been met. As discussed above, we are not requiring brand manufacturers to report sales by generic manufacturers for authorized generic drugs. We believe this decision will alleviate concerns regarding certification of data from other manufacturers.

Recordkeeping

Comment: One commenter asked CMS to clarify what customary prompt pay information is needed for retention under the recordkeeping requirements.

Response: These recordkeeping requirements are the same as for the rest of the manufacturer's data for computing the amount of the Medicaid drug rebate. As we noted in the proposed regulations text at § 447.510(f)(1), a manufacturer must retain the customary prompt pay data

and any other materials from which the customary prompt pay information is derived, including a record of any assumptions made in the calculations.

Comment: One commenter suggested that CMS reduce the recordkeeping timeframe from ten years to seven years.

Response: CMS finalized the ten-year recordkeeping requirement for manufacturers in a final rule published on November 26, 2004 (69 FR 68815). In that rule, we provided a thorough rationale for requiring manufacturers to retain their pricing data for a period of ten years. We have not received information to support a lesser period; therefore, we are retaining the ten-year recordkeeping requirement at § 447.510(f).

Recalculations

Comment: One commenter asked CMS to specify whether manufacturers need to obtain CMS' approval of methodology changes where those changes are being made to comply with provisions of this final rule. Other commenters asked CMS to describe in this final rule the circumstances in which we would either expect or permit manufacturers to recalculate their AMPs. In particular, one commenter asked for guidance regarding whether, in light of the need to maximize stability in reimbursement metrics, restatements remain an appropriate means for correcting subsequently discovered AMP calculation errors. Another commenter suggested that the timeframe for restatements be shortened from twelve quarters to four quarters. One commenter asked CMS to permit, but not require manufacturers to restate their quarterly AMPs when actual data become available.

Response: Manufacturers do not need to obtain CMS' approval of methodology changes where those changes are being made to comply with provisions of this final rule. In regard to all other AMP restatements, manufacturers should submit their written requests to CMS and wait for CMS' response before submitting revised AMPs for retrospective restatements. For prospective restatements, manufacturers should submit their written requests to CMS, but they are not required to wait for CMS' approval to submit revised AMPs. We note that requirements regarding timeframes for recalculations at §§ 447.510(b) and (d)(3) apply to all restatements. Manufacturers should restate their quarterly AMPs if there are subsequent restatements of the monthly AMPs on which the quarterly AMPs are based.

We disagree with the suggestion that the timeframe for restatements be

shortened from twelve quarters to four quarters. Quarterly data can be revised for up to twelve quarters after the quarter in which the data were due. Similarly, monthly AMP can be revised for up to 36 months after the month in which the data were due.

Drugs: Aggregate Upper Limits of Payment (§ 447.512)

Comment: One commenter asked that CMS clarify proposed § 447.512 to allow a physician to certify through electronic means that a brand is medically necessary. Another commenter stated that CMS should reconsider the requirement that a physician must certify in his or her own handwriting that a drug is medically necessary in order to indicate that a specific brand drug is to be dispensed to a patient, as this is inconsistent with State and Federal efforts to transition to e-prescribing and other health information technology innovations.

Response: We appreciate these comments and have revised the final regulation at § 447.512(c)(1) to permit certification by an electronic alternative approved by the Secretary. CMS intends to address electronic certification in future program guidance or regulations, as appropriate.

Upper Limits for Multiple Source Drugs (§ 447.514)

Comment: Several commenters support the agency's goal of paying appropriately for generic drugs. One commenter raised concerns regarding the pre-DRA FUL system including infrequent adjustments to the FULs, which did not necessarily reflect market trends.

Response: We agree. Numerous OIG reports found that the published prices used to set FUL amounts often greatly exceeded prices available in the marketplace. As noted in those reports, the pre-DRA FUL amounts often greatly exceeded pharmacy acquisition costs, and thus, could have unnecessarily increased costs to the State and Federal Governments.

Implementation of FULs

Comment: Another commenter stated that CMS should suspend implementation of the FULs until States are able to adopt the changes necessary to ensure that pharmacies are properly compensated for providing generic drugs; that is, until States have evaluated their dispensing fees.

Response: We disagree. The DRA changed the formula used to establish the FUL. Effective January 1, 2007, the DRA required CMS to calculate the FUL at 250 percent of the AMP (computed

without regard to customary prompt pay discounts extended to wholesalers) for the least costly therapeutic equivalent drug. The States have been advised that they should evaluate the reasonableness of their dispensing fees in light of the changes in payment methodology for multiple source drugs under the DRA.

Comment: One commenter proposed that the effective date of the new FUL should be 90 days after release of the new source file to provide time for CMS to issue guidance to States regarding the source of the revised FULs, including the file parameters, in order to allow advance programming to take place. Another commenter said that at least a 60-day timeframe should be allowed for the implementation of FULs.

Response: We appreciate such concerns and have decided to establish a timeframe sufficient for initial implementation of the new FUL prices. CMS has posted a timeline for implementation of the FUL on its Web site (<http://www.cms.hhs.gov/DeficitReductionAct/Downloads/AMPFULTentativeTimeline.pdf>).

Comment: One commenter requested CMS to release its best estimate of FULs based on AMPs in order to analyze their impact. One commenter also requested an extension of the formal comment period to the proposed rule to analyze the data.

Response: We appreciate the comment. CMS has stated that the new FULs would not be issued until the AMPs for 2007, which reflect the exclusion of customary prompt pay discounts and authorized generic drugs, are available and processed. CMS is required by the DRA to publish a regulation by July 1, 2007. Given this deadline, we do not feel that an extension or complete reopening of the formal comment period is appropriate.

Comment: One commenter stated that the FULs published data should be in a format that allows importing data into Excel. One commenter also stated that all unique and identifiable data elements should be included on the file; that is, name, strength, dosage, billing unit, FUL implementation date, NDC, and AMP file reporting date used to establish the FUL.

Response: CMS will publicly post the FUL data in a format similar to the current Web site posting of FUL reimbursement prices. We expect that further specifications will be provided in future program instructions.

Comment: One commenter stated that the final rule should state our schedule of FULs updates.

Response: CMS expects to publish the updated FULs reimbursement prices on a monthly basis consistent with our

understanding of congressional intent to keep FUL reimbursement in line with market pricing trends.

Comment: One commenter stated that the FUL data on the CMS website should indicate the effective date. Another commenter stated that the identity of the manufacturer whose product is used to set the FUL should be made public to provide a checks-and-balance system whereby the pharmacy community could supply feedback on the availability of the drug product.

Response: CMS expects to publish the AMP data when it finds them sufficiently complete and accurate. The AMP data will have corresponding NDCs; thus, specific drug product prices, as well as the manufacturer, will be available to the public and transparent. CMS expects that the FULs will be established monthly for all groups and will be in effect until the next monthly update.

Comment: A commenter questioned whether CMS will calculate and disseminate the FUL list, or if the individual States will be responsible for calculating the FUL based on the published AMP data. The commenter proposes that CMS post the FUL.

Response: We agree. We will calculate the FUL based on the criteria established in the final rule, and post the FULs on our website.

Comment: One commenter expressed concern that it will be difficult for CMS to establish an accurate FUL if all AMPs are not submitted monthly on a timely basis by manufacturers.

Response: Manufacturers are required to submit monthly AMP data to CMS not later than 30 days after the last day of the month. Manufacturers must comply with this reporting requirement to continue participation in the Medicaid Drug Rebate Program and avoid potential penalties, as set forth in section 1927(b)(3)(C) of the Act. CMS will monitor compliance rates from manufacturers and initiate action or make referrals to the OIG, as may be necessary, for non-compliance of data submission.

Comment: One commenter expressed concern that updating the FUL on a monthly basis could increase administrative burden on States and make planning of inventory levels for pharmacies difficult.

Response: Timely updating of FULs is necessary in order that States and the Federal Government receive the cost savings benefits of market changes. This regulation encourages pharmacy providers to buy the lowest priced generic available in the market, as may be appropriate, to ensure to bill for drugs at or below the FUL price.

Comment: Another commenter supported the provision in law that CMS determine whether a drug product should have a FUL within seven days after receiving notification from the RPS contractor to assure the FULs are updated in a timely manner.

Response: We agree. CMS is required to determine if a drug is eligible for a FUL within seven days of notification by the RPS contractor. CMS intends to make additions to the FUL list in a timely manner to achieve cost savings for States and the Federal Government.

Comment: Several commenters stated that additions or changes to the FUL should be disseminated to the larger pharmacy community for their input on availability and pricing before releasing as final.

Response: We disagree. The 250 percent markup of the lowest priced drug with respect to the FUL calculation, and our outlier policy which assures that two drugs are available at or below the FUL price should assure the availability of those drugs at or below the FUL price for the pharmacists.

Comment: Several commenters stated that CMS should provide a timely appeals mechanism, to allow providers and States an opportunity to seek removal or modification of a FUL which is not consistent with changing market conditions. One commenter said that severe price shifts and significant issues associated with pricing lags could be effectively addressed by a redetermination process similar to the exceptions and appeals process under Medicare Part D, including a toll-free number which would be monitored by CMS. The commenter further suggested that the OIG or other Federal agency could review appeals and recommend an updated AMP figure to CMS. Another commenter stated that changes to the FUL list should be allowed on a State-by-State basis to reflect availability. One commenter stated that CMS should be vigilant in monitoring the marketplace for signs of negative effects of using AMP as a basis for FULs, and be prepared to alert Congress of the negative effects and recommend any changes to ameliorate them.

Response: We believe that basing reimbursement on actual sales data such as AMP will help capture transparent pricing data to assure that the Federal Government and State Medicaid programs are paying appropriately for generic drugs. We do not agree that an appeal or redetermination process is necessary or would be useful because AMPs will be updated on a monthly basis to reflect changes in prices. We also note that the 250 percent markup

of the lowest priced NDC used to compute the FUL, and the outlier policy established in this regulation, will help to ensure that two or more drugs can be purchased at or below the FUL. To address the need for a State variation in the FUL, we note that States may pay above the FUL for an individual drug, given that the FUL is designed as an "aggregate" limit.

Comment: Many commenters urged that the implementation of the new FULs based on the DRA provisions be permanently suspended because the new generic reimbursement methodology of 250 percent of AMP will be below acquisition cost. One commenter who analyzed AMP and drug acquisition cost data said that the proposed FULs poorly estimate pharmacy acquisition costs.

Response: We disagree. The DRA requires that, effective January 1, 2007, CMS calculate the FUL at 250 percent of the AMP (computed without regard to customary prompt pay discounts extended to wholesalers) for the least costly therapeutic equivalent drug. The 250 percent markup of the lowest priced drug, along with our outlier policy will assure the availability of drugs at or below the FUL price for pharmacies.

Comment: One commenter stated that a pharmacy's acquisition cost may exceed the FUL reimbursement for a particular drug because wholesalers sell to independents under contractual agreements which are not readily transferable, and independent retail pharmacies are not able to "cherry pick" between wholesalers on a product-by-product basis.

Response: We believe that the FULs will be sufficient to allow all pharmacies to purchase drugs at or below the FUL price. If a State finds it necessary to pay a higher price than the FUL price, it can do so as long as it remains within the aggregate limit.

Comment: Several commenters stated that AMP was never meant to be a reimbursement metric.

Response: The law requires the FULs to be based on AMP and permits States to use AMP in their reimbursement methodologies. We believe that basing reimbursement, in part, on AMPs will help capture transparent pricing data to assure that the Federal Government and State Medicaid programs are paying appropriately for generic drugs.

Comment: Many commenters stated that AMP and the resulting FUL will not only impact Medicaid Programs, but will substantially impact the entire private market. Therefore, it is imperative that the FUL represent actual acquisition costs. Another commenter stated that the impact of using AMP for

reimbursement cannot be gauged at this time.

Response: The law provides that AMPs be publicly available. Therefore, they may have an impact on reimbursement from other payers. AMP will be based, in part, on the average price paid to manufacturers by wholesalers for drugs distributed to the retail pharmacy class of trade. The 250 percent markup of the lowest priced drug should assure the availability of those drugs at or below the FUL price for the pharmacies.

Comment: One commenter stated that pharmacies will seek further price reductions from manufacturers to maintain their margins and that this will further reduce AMPs and FULs, creating a downward cycle that will continue to lower profits for pharmacies.

Response: CMS appreciates the comment but has no reason or evidence to believe the use of AMP data would lead to price reductions or a downward cycle of prices.

Comment: One commenter stated that the FUL amount should be the minimum reimbursement amount that the States can reimburse pharmacies for a multiple source drug. The State maximum allowable cost (MAC) programs should be discouraged with the implementation of the AMP-based FULs, which will better reflect acquisition cost to pharmacies.

Response: We disagree. The DRA clearly mandates that the FUL amount be the upper limit for payment. States retain the authority to implement a MAC program to limit reimbursement amounts for certain drugs. Individual States retain the authority to determine the types of drugs that are included in their MAC programs and the method by which the MAC for a drug is calculated.

Methodology of FUL

Comment: Many comments were submitted pertaining to the new calculation/methodology for establishing a FUL for multiple source drugs. Some commenters recommended using an AMP "average" instead of the lowest AMP to establish a FUL.

Response: The DRA provides, effective January 1, 2007, that the upper limit for multiple source drugs 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. Therefore, we do not believe that the statute allows for an AMP average to be used to set the FUL amount.

Comment: One commenter requested that CMS clarify how an aggregate payment system can be implemented

prospectively given the uncertainty of utilization for multiple source drugs subject to a FUL.

Response: States have flexibility with respect to implementation. For example, they can look at the previous years' claims data to estimate their aggregate caps.

Comment: Many commenters expressed concern that the new FULs methodology will create a disincentive to dispense generic drugs. One commenter stated that the proposed rule does not affect brand name drugs that have the greatest budgetary impact on State Medicaid programs.

Response: The commenter is correct that the FULs apply to multiple source drugs. However, we do not believe that this will lead to a decrease in the dispensing of generic drugs. States will continue to require the use of generic drugs when appropriate. We also believe that drug pricing transparency will lead to more equitable and appropriate reimbursement for prescription drugs as States gain greater knowledge about the actual market price of prescription drugs. Because AMPs for all covered outpatient drugs will be available to States, they will have more information to use in setting appropriate prices for brand name drugs as well as generic drugs.

Disincentive To Market or Dispense Generic Medications

Comment: Other commenters stated that manufacturers may choose to not introduce new generics to the market and wholesalers may not buy generic products because pharmacies will prefer to dispense brand name drugs.

Response: We do not agree that these changes with respect to the calculation of the FUL will so dramatically change market dynamics.

Net Payments to States

Comment: A few commenters said that FULs should be compared to net payments after rebates, since that will allow the State to take advantage of higher rebates on brand name drugs.

Response: We disagree. In accordance with provisions of the DRA which amend section 1927(e) of the Act, the FUL is based on 250 percent of the AMP. Thus, we have based the FULs on AMP, as opposed to any payments by States net of rebates.

Comment: Several commenters stated that it is not uncommon for a State to designate a multiple source brand name drug as preferred when the supplemental rebate offered by a manufacturer results in the brand name drug being less expensive than the A-rated generic equivalent. The new FULs

will require States to reanalyze these arrangements, and possibly require States to cancel or amend supplemental rebate contracts with manufacturers.

Response: In accordance with the DRA amendments, States' payments for multiple source drugs must not exceed, in the aggregate, the FULs. States may need to consider how this may affect their preferred drug lists.

Nine-Digit Versus Eleven-Digit NDC

Comment: Some commenters supported using the 9-digit NDC weighted AMP to calculate the FUL and noted that this method is sufficient because per-unit pricing differences between package sizes are not generally significant. Other commenters expressed concern that significant system changes would be required to move to the 11-digit NDC method.

Response: We agree that the AMP should continue to be weighted at the 9-digit NDC level, and retain this requirement in the final rule. CMS has used the weighted 9-digit AMP since the start of the rebate program and there is nothing in the statute or legislative history to indicate that the Congress meant for this to change when AMP is used for FULs.

Comment: With the changes in the DRA to compute the FUL based on AMP, some commenters questioned if the weighted AMP, calculated at the 9-digit NDC level (as currently reported for the Medicaid Drug Rebate calculation) will result in adequate reimbursement levels that will be in line with market-based acquisition costs and preferred that we set FULs using the 11-digit NDC.

Response: We believe that using a weighted AMP will result in adequate reimbursement and have retained this in the final rule.

Comment: One commenter stated that the use of the 9-digit weighted AMP to calculate the FUL will be problematic when the weighted average is controlled by high volume sales of larger-sized packages with a lower unit cost.

Response: We disagree. We believe a weighted average will adequately reflect all package sizes.

Comment: Some commenters stated that using the 11-digit AMP to set the FUL would allow the FUL to be based on individual package sizes, or would allow a FUL to be established on the most commonly used package size. Other commenters stated that using the 11-digit AMP would reflect the difference in the popularity of a drug in different areas of the country, or the package size that is most economical for a pharmacy provider to purchase. Several commenters said that AMP

prices should be based on the most commonly prescribed package sizes as the current FULs are calculated.

Response: We disagree. Using an 11-digit level NDC specific to a package size to calculate the AMP may allow manufacturers to avoid best price implications for certain products by manipulating sales. The use of the 11-digit level NDC to calculate AMP would also have an effect on rebates paid by manufacturers which we believe is inconsistent with the statute.

Comment: Commenters expressed concern that AMPs calculated and reported at the 9-digit NDC level, would adversely affect 340B covered entities, whose ceiling prices are based on AMP, because of a lack of transparency and efficiency in setting prices.

Response: We continue to believe that in accordance with the statute, AMPs should be uniform across package sizes.

Comment: Several commenters stated that the 11-digit NDC should be used to calculate the AMP, as this aligns with State Medicaid Agencies' drug payments that are based on package size.

Response: We continue to believe that in accordance with the statute, AMPs should be uniform across package sizes.

Manufacturer-Submitted Utilization

Comment: One commenter stated that manufacturers should submit drug utilization numbers so that FULs can be based on the most commonly prescribed package size. Also, the commenter suggested that CMS could calculate the 9-digit weighted AMP from this information for rebate purposes, and this information could also be used to identify outliers by noting supply numbers. One commenter suggested that CMS require manufacturers to submit information on their net units shipped for each product so CMS can determine if a product is widely available, bearing in mind that such information is confidential. The commenter noted that this requirement would mirror the requirement for ASP reporting. The commenter also suggested that CMS consider additional factors when setting FULs, such as whether the product is available from several wholesalers. The net unit information could also be used for weighting, as required for the rebate calculation process.

Response: We disagree. While CMS appreciates the comment, it does not believe that such information is necessary in light of the DRA amendments.

Therapeutic Equivalency

Comment: One commenter stated that the inclusion of B-rated multiple source

drugs in the FUL reimbursement means that CMS is sanctioning the practice of dispensing generic drugs which are not therapeutically equivalent. This commenter further stated that if CMS chooses to include B-rated drugs, then it must indemnify retail pharmacies from all adverse patient reactions and/or negative outcomes. One commenter states that some Medicaid Programs will only reimburse A-rated equivalent drugs.

Response: We disagree. We believe that in light of the provisions of section 1927(e) of the Act, as amended, it is appropriate to continue to apply the FUL to B-rated drugs. To do otherwise may encourage pharmacies to substitute B-rated drugs to avoid the FUL. Based on section 1927(e)(4) of the Act, while the FUL would apply to a B-rated drug, the FUL will only be set based on the AMP of formulations that are therapeutically and pharmaceutically equivalent.

Number of Suppliers

Comment: Several commenters expressed concern that the FUL criteria should be revised to require an adequate number of suppliers, or that drug supplies should be nationally available. One commenter stated that CMS should develop a method to survey manufacturers to determine if the products included in the calculation of the AMP are actually widely available in the marketplace. A reasonable threshold for marketplace penetration should be defined and applied to ensure that products are available nationally and in consistent supply. One commenter pointed out that smaller generic manufacturers seek to capture market share when entering the market by discounting their prices by 20–30 percent, but do not have product inventories sufficient to serve the entire Medicaid population. One commenter stated that repackagers of drugs may often have limited availability, yet the prices of such drugs could be used to set a FUL. One commenter suggested that three suppliers of "A" rated products should be necessary to establish a FUL. One commenter stated that the FUL should not be applied until there are two or three different suppliers in the market, because establishing a FUL with just an innovator multiple source drug and an authorized generic by a subsidiary of the company may not show much price difference between the two. One commenter stated that a drug should not be considered to be available unless it is available from the top five wholesalers in each CMS region. Another commenter said that CMS should include a provision for a

product-specific exemption or adjustment by State or region when products are unavailable in those markets at the FUL price. Another commenter agreed that revision of criteria to establish a FUL for ingredient groups with two therapeutically equivalent drugs was a positive step.

Response: We proposed to revise the methodology we use to establish FULs for multiple source drugs based on the provisions of the DRA. Specifically, sections 6001(a)(3) and (4) of the DRA changed the definition of multiple source drug established in 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 amended section 1927(e)(4) of the Act to require that a FUL be established for each multiple source drug for which the FDA has rated two or more products therapeutically and pharmaceutically equivalent. We do not agree, in light of these DRA revisions, with the comment that CMS should survey manufacturers regarding availability or make product-specific exemptions when products are not available at the FUL price. We believe that our policy of applying the FUL in the aggregate, not using terminated products when setting FULs, and adopting an outlier policy on the use of AMPs to set FULs addresses the commenters' concerns.

Listing in National Compendia

Comment: One commenter raised concerns with the upper limit methodology set forth in § 447.514(a)(1)(ii) and specifically questioned if CMS would consider a drug to be available for sale nationally, and thus consider it eligible to set the FUL, if the drug otherwise meeting the criteria in § 447.514(a)(1)(i) is not listed in a current edition or update of published compendia of cost information.

Response: In this final rule, CMS is revising the text language in § 447.514(a)(1)(ii) by deleting "based on all listings contained in current editions (or updates) of published compendia of cost information for drugs available for sale nationally," because in light of the DRA amendments CMS will not be using the published compendia of cost information, (for example, *Red Book*, *First DataBank*, or *Medi-Span*) to establish and set the FUL. CMS will be

using AMPs submitted by manufacturers to establish the FUL.

National Availability

Comment: One commenter stated that CMS should consider revising § 447.514(b) to read, "for the least costly therapeutic equivalent available for sale nationally" to ensure that AMPs used to set the FUL are available nationally and will yield sufficient FUL prices.

Response: We disagree. We believe that the FUL will be calculated to ensure that a drug is available nationally at or below the FUL price. The FUL will be calculated based on a 250 percent markup of AMP, will be applied in the aggregate, will not be set using terminated products, and will incorporate an outlier policy on the use of AMPs. We believe these considerations address the commenter's concern.

Outlier AMPs

Comment: Many commenters submitted recommendations pertaining to the FUL outlier policy, under which one or more of the lowest AMPs for an ingredient group would be passed over when setting the FUL in order to avoid a FUL reimbursement below the cost at which the drug is nationally available. Commenters agreed with CMS that an outlier policy should be implemented, but differed on the metrics that should be used. Several commenters proposed that we set the FUL on the lowest AMP that is not less than 80 percent of the next highest AMP. Another commenter stated that we should set the FUL on the lowest AMP that is not less than 60 percent of the next highest AMP. Another commenter stated that, to reduce the potential for volatility in the AMP-based reimbursement system, we should exclude outliers that are more than 10 percent below the next highest AMP, looking at each AMP available in the ingredient group. Another commenter stated that AMPs no more than 20 percent less than the next highest AMP should be excluded. Another commenter proposed that CMS should establish a different outlier policy for immunosuppressive multiple source drugs due to the critical access need for these drugs by transplant recipients, under which the FUL would be based on the lowest AMP that is not less than 70 percent of the next-highest AMP in the multiple source drug group. Another commenter stated that the rationale behind the 30 percent outlier rule proposed by CMS is not readily apparent, because verifiable data was not supplied in the proposed rule. One commenter suggested that the 30 percent outlier rule was appropriate, but

wanted CMS to remove all outlier AMPs that are less than 30 percent of the next highest AMP, and use the industry-wide weighted average AMP to establish the FUL.

Several commenters agreed with CMS' proposal to set the FUL based on the lowest AMP that is not less than 30 percent of the next highest AMP. One commenter stated that CMS should use a statistical calculation of a standard deviation for each group of therapeutically equivalent drugs. Any manufacturer's AMP falling below one standard deviation would be removed as an outlier. The AMP would then be based upon the lowest value within one standard deviation. Another commenter suggested that AMPs falling at or below the 25th percentile of drug prices within the ingredient group should be excluded from establishing the FUL. Several commenters stated that the FUL should be calculated using the AMP of the lowest priced drug that is not less than 50 percent of the next highest AMP. In other words, look at the lowest AMP, and then the next lowest AMP, and so on, rejecting AMPs until an AMP is at least 50 percent of the next highest AMP.

Other commenters suggested that manufacturers should report AMPs at the 11-digit NDC level with their respective unit volume. These commenters state that the final rule should include a FUL outlier methodology that examines AMPs on a cumulative market share basis, starting with the lowest AMP, then the next lowest and so on, rejecting AMPs until a cumulative market share of 50 percent has been reached.

Response: We appreciate the many suggestions for how we could determine outlier AMPs. We have expanded our outlier policy in the final rule by excluding the lowest AMP if it is less than 40 percent of the next highest AMP in § 447.514(c)(2). 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 60 percent below the second lowest AMP. In those cases, the second lowest AMP will be used in the FUL calculation. By setting this as our outlier exclusion policy, we ensure that at least two drugs are available at or below the FUL price. Also, further analysis of the manufacturer-submitted AMP data revealed that we could exclude more outlier prices by using the 40 percent standard. We have also decided to publish § 447.514(c)(2) as a final rule with comment period. This will allow for further public comment after the clarified definition of AMP becomes

effective and States would then have an opportunity to analyze AMPs, as revised by the DRA, and FULs. It will also give CMS an opportunity to receive further comments based on a broader analysis of the data. CMS will accept comments on the outlier (and as discussed previously on the AMP) policy for a period of 180 days from the date of publication of this final rule in the **Federal Register**.

Comment: Several commenters strongly recommended that, in lieu of an outlier, CMS should set FULs based on the weighted average AMP of the therapeutically equivalent products available in the market. One commenter stated that this would avoid regional pricing that may not be widely available for a specific product, "fire sale" pricing on short-dated products, and prices that are not sustainable over a consistent period of time.

Response: We disagree. The DRA provides, effective January 1, 2007, that the upper limit for multiple source drugs 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.

Comment: One commenter stated that if the calculated FUL exceeds the AWP of the innovator multiple source drug, or exceeds the innovator multiple source drug's AMP by 25 percent or more, CMS should not publish a FUL for that ingredient group.

Response: We do not agree that a FUL should not be set if it exceeds the AWP for the innovator multiple source drug. There is no basis, given the statutory amendments, to calculate a FUL using an AWP standard. We agree that States may not find a FUL useful if it exceeds the AMP of the innovator multiple source drug by 25 percent; however, we do not believe we should make an exception in this instance. The FUL is designed to be an aggregate upper limit, not necessarily a payment rate for drugs.

Terminated Drugs

Comment: Some commenters submitted comments regarding the use of a terminated drug to set the FUL. One commenter expressed concern that the proposed rule does not take into account that an AMP may be from a terminated product. One commenter stated that CMS should provide notification of terminated NDCs associated with the establishment of FULs, so that State Medicaid agencies do not continue to reimburse for a terminated drug. One commenter stated that CMS should clarify the meaning of "terminated."

Response: The proposed rule would exclude terminated NDCs from consideration when setting a FUL beginning with the first day of the month after the actual termination date reported by the manufacturer to CMS. We are retaining this provision in the final rule. A FUL reimbursement applies to all drugs within an ingredient group, including drugs that are being terminated by the manufacturer, but still being produced by a manufacturer. However, a terminated NDC would not be used to set the FUL. We continue to define a terminated drug according to the reason the product is being discontinued. If it is being pulled from the shelf immediately due to a health or safety reason, whether it is by FDA or labeler directive, the termination date is the date removed. If, however, it is being replaced by an improved version, or discontinued, the termination date is the shelf life of the last batch sold.

Upper Limits for Drugs Furnished as Part of Services (§ 447.516)

Comment: One commenter pointed out that while the FUL will be revised monthly, managed care capitation arrangements are negotiated for longer periods of time, making it difficult for State Medicaid Agencies to comply with frequent FUL changes when setting capitation rates. Another commenter stated that the final rule should be amended to exclude FULs from capitation arrangements to address this concern.

Response: States will need to consider possible fluctuations in FULs when negotiating future MCO contracts and modify current contracts, if necessary, to address any revisions needed to capitation rates as a result of monthly FUL changes. Also, to note the FULs are designed to be aggregate upper limits, and do not represent individual payments for drugs. In accordance with § 447.516, the upper limits for payment for prescribed drugs also apply to payment for drugs provided under prepaid capitation arrangements. CMS has not changed this requirement.

State Plan Requirements, Findings and Assurances (§ 447.518)

Comment: One commenter requested that CMS insert language in the final rule that would require States to consult with Tribes in the development of any SPA which would modify existing payment methodologies for prescription drug reimbursement. This would allow each Tribe the opportunity to work with its State to assess local impacts prior to submission of SPAs.

Response: A State Medicaid Director letter dated November 9, 2006 was sent

encouraging States to consult with Tribes in open, good faith dialogue, on the DRA provisions that have the potential to impact Tribes and American Indian and Alaska Native Medicaid beneficiaries. The letter stated that it is important to maintain ongoing communication between States and Tribes in the redesign of Medicaid Programs and services.

Comment: One commenter requested that CMS insert language in the final rule to encourage States to maintain their current level/type of reimbursement and filling fees to Tribal and IHS pharmacies. Tribal and IHS providers should be explicitly recognized as essential safety net pharmacies.

Response: We appreciate the comment and will take this suggestion into consideration as we consider revisions to State payment rates. In accordance with longstanding policy, we believe that States should have the flexibility to establish payment rates and reasonable dispensing fees, consistent with the upper limits and standards set forth in our regulations.

Comment: One commenter believed that the SPA process must be more deliberative and transparent than the process that has been used to date by States to make changes in their payment methodologies. States need to be more diligent and transparent in providing public notice about reimbursement methodologies and substantiating the impact that the changes could have on Medicaid beneficiaries' access to community retail pharmacies.

Response: We disagree with the commenter. States must follow Federal regulations at 42 CFR 430 subpart B for all State plans.

Comment: One commenter suggested to amend § 447.518(b)(1) by adding another § 447.518(b)(1)(iii), which would say, "in the aggregate, the dispensing fees paid to pharmacies cover the costs described in § 447.502 and are designed to encourage the utilization of multiple source drugs where appropriate."

Response: We disagree with the commenter. In accordance with longstanding policy, we believe that States should have the flexibility to establish payment rates and reasonable dispensing fees, consistent with the upper limits and standards set forth in our regulations.

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

We received many comments regarding the requirement that State Medicaid Agencies provide for the submission of NDCs on claims for

physician-administered drugs, as discussed below:

Comment: Several commenters stated that CMS has failed to define outpatient drugs that are physician-administered as required by the statute. The commenter further stated that CMS is incorrectly interpreting the law by including drugs administered in the outpatient hospital setting.

Response: In light of the definition of covered outpatient drug provided in section 1927 of the Act, we have chosen not to define what is meant by a covered outpatient drug that is administered by a physician. We believe that the DRA amendments to section 1927 of the Act were intended to emphasize that where covered outpatient drugs are administered by a physician and separately billed to Medicaid, States are required to collect rebates from manufacturers for these drugs. The law requires that States obtain information on the claims forms that will allow them to bill manufacturers for rebates for specific covered outpatient drugs in accordance with section 1927 of the Act.

Comment: A few commenters stated that the statute permits the use of J-codes as well as NDCs.

Response: The statute allows the Secretary to specify the required codes. We proposed to allow J-codes, also known as HCPCS codes, to be used beginning January 1, 2006 for single source physician-administered drugs. We also specified that the NDC be required for single source drugs and the 20 multiple source drugs identified by the Secretary beginning January 1, 2007. We are finalizing these requirements in this final rule.

Comment: Several commenters asked that CMS provide a list of NDCs within the J series of HCPCS codes that are subject to rebates under the Medicaid Drug Rebate Program.

Response: At this time, CMS does not intend to publish a list of NDCs for each physician-administered drug that is subject to Medicaid rebates, as such a list would be quite expansive. However, CMS provides monthly files of drugs of manufacturers that have a national rebate agreement under the Medicaid Program. CMS also maintains a list of NDCs within HCPCS that can be found on our Web site at http://www.cms.hhs.gov/McrPartBDrugAvgSalesPrice/01a_2007aspfiles.asp#TopOfPage.

Comment: One commenter asked that CMS revise the HCPCS J-code crosswalk to NDCs on our Web site to identify: (1) physician-administered drugs not routinely covered by Medicare but covered by Medicaid, (2) the sole source and 20 multiple source drugs for which

NDCs must be collected, and (3) NDCs for manufacturers that participate in the Medicaid Drug Rebate Program.

Response: At this time, we do not intend to revise the HCPCS crosswalk to identify drugs not routinely covered by Medicare but covered by the Medicaid Drug Rebate Program. However, the publicly available AMP pricing data will be listed with NDCs which will indicate manufacturers participating in the Medicaid Drug Rebate Program as well as the products covered by the program. The list of the top 20 multiple source physician-administered drugs are posted on CMS' Web site at <http://www.cms.hhs.gov/DeficitReductionAct/Downloads/Top20PhysicianAdministered.pdf>.

Comment: Several commenters asked that CMS clarify the prospective nature of the proposed definition of physician-administered drug.

Response: The DRA requirement that States collect information sufficient to bill for rebates on single source drugs was effective January 1, 2006 and States must bill for rebates to collect a Federal match on these drugs. For single source physician-administered drugs and the 20 specified multiple source physician-administered drugs, States must collect NDCs beginning January 1, 2007. However, Federal match remains available until January 1, 2008, at which time we expect that States will be in compliance with this requirement. We would note that the requirement for States to submit utilization data to collect rebates on covered outpatient drugs in section 1927(b) of the Act predates the DRA requirements and inasmuch as physician-administered drugs are covered outpatient drugs, we believe that the January 1, 2006 effective date was reasonable. The DRA emphasized physician-administered drugs because these drugs historically have been billed by providers in such a way that prevented States from collecting rebates for these drugs.

Comment: Many commenters expressed the opinion that manufacturer rebate liability should be proportional to State Medicaid expenditures when Medicaid is the secondary payer. They contended that this is more consistent with the overall intent of the rebate program to reduce the cost of drugs to Medicaid and to ensure Medicaid the best price provided to other purchasers. Other commenters believed that CMS' position concerning the intent of the Medicaid statute that full rebates are due when Medicaid pays any amount of the claim is incorrect and is procedurally invalid because this policy was not established through formal notice-and-comment rulemaking.

Another commenter wished CMS to continue with the historical practice of having Medicaid claim rebates on the total amount paid for the drug by all parties.

Response: We disagree that the rebate should be proportional to the amount of the claim paid by Medicaid. Neither the law nor the national rebate agreement makes provision to reduce the rebate liability based on the amount of payment made by the Medicaid Program. Rather, the law provides formulas for rebate payments for single source, innovator multiple source, and noninnovator multiple source drugs that are used when Medicaid makes payment for a drug. This has been the consistent policy position of the Agency since the start of the Medicaid Drug Rebate Program.

Comment: One commenter said that CMS should not deny Federal matching funds for physician-administered drugs not covered by the national rebate agreement.

Response: The statute requires drug manufacturers to participate in the Medicaid Drug Rebate Program in order for their drugs to be covered by Medicaid. We recognize that States may not always be aware of what drug was administered when a bill is submitted using a HCPCS code. However, when the law requires billing with an NDC, a State Medicaid Agency cannot knowingly pay that claim and collect the Federal match.

Comment: Some commenters said that the requirement that outpatient hospitals record NDCs would have a negative impact on patient safety because it would disrupt the workflow for dispensing drugs and divert limited staff from accurate dispensing.

Response: We have no reason to believe that patient safety will be affected by this requirement.

Comment: One commenter stated the belief that contrast agents, typically used during hospital-based radiological procedures, are excluded from Medicaid rebates.

Response: Only physician-administered drugs that are separately billed to Medicaid as covered outpatient drugs will be considered physician-administered drugs for the purposes of this rule. If the contrast agents are not billed to Medicaid as outpatient drugs, they would not be considered physician-administered drugs for purposes of this provision.

Comment: One commenter stated that the regulation should exempt drugs administered in an emergency room from this provision because physicians should not need to concern themselves with whether the patient is a Medicaid

beneficiary and because the physician does not know at the time drugs are administered if the patient will be admitted or sent home.

Response: Drugs administered incident to an emergency room service that are billed separately as covered outpatient drugs, as defined by section 1927(k)(2) of the Act, are covered under the Medicaid Drug Rebate Program and must be billed using the NDC in order for States to collect the Federal match. Drugs that are billed as part of an emergency room service as described in section 1927(k)(3) of the Act, where the cost of the drug is bundled within the cost of the service, are not covered by the Medicaid Drug Rebate Program.

Comment: One commenter asked if HCPCS will be assigned to drugs that do not currently have them.

Response: We do not plan to assign HCPCS to drugs as the provisions addressed in this rule require the submission of NDCs on claims when billing Medicaid for physician-administered drugs.

Comment: One commenter asked CMS to clarify in the final rule that claims for physician-administered drugs must meet all covered outpatient drug requirements, specifically, that the drug must be subject to a Medicaid rebate, not have a termination date prior to the date of service, and not be a drug with a DESI value of five or six.

Response: The commenter is correct that all requirements for Medicaid drug coverage apply to physician-administered drugs.

Comment: Several commenters believe that CMS went beyond congressional intent by including outpatient hospitals and clinics in the requirement for States to collect NDC-level information on pharmacy claims. Commenters stated that the OIG report on this topic addressed only drugs administered in physicians' offices and that this report was the impetus for the legislation.

Response: We base our interpretation on the language in the statute which does not differentiate between providers in requiring that States collect information sufficient to bill for rebates for covered outpatient drugs under section 1927(k)(3) of the Act. To the extent that providers bill for covered outpatient physician-administered drugs separately; that is, the cost of the drug administered is a separate line item from the service provided, we believe that, in accordance with the statute, States should be seeking rebates with respect to such drugs.

Comment: Several commenters wrote that the DRA does not change the existing statute at section 1927(j)(2) of

the Act that exempts from Medicaid drug rebates drugs administered to patients in hospital outpatient clinics and departments.

Response: We agree that the DRA did not change the exclusion of drugs from Medicaid rebates when dispensed in an outpatient hospital setting as long as Medicaid is billed at the hospital's purchasing costs. However, hospitals commonly bill Medicaid without regard to their costs and accept the full reimbursement provided under the Medicaid State plan. When this is the case, drug manufacturers are responsible for paying rebates with respect to those drugs that qualify as covered outpatient drugs under section 1927(k)(3) of the Act.

Comment: One commenter said that rebates should not be collected on hospital outpatient drugs because they are not part of the retail pharmacy class of trade for AMP.

Response: The commenter is not correct in that sales to hospital outpatient departments are considered in the retail pharmacy class of trade and are included in the calculation of AMP at the option of the drug manufacturer, as specified in this final rule. Physician-administered drugs will be excluded from the Medicaid Drug Rebate Program requirements only when hospital outpatient departments have dispensed these drugs using drug formulary systems, and have billed Medicaid at acquisition costs, consistent with section 1927(j)(2) of the Act.

Comment: Several commenters stated that 340B hospitals should not need to forgo receiving discounts on drugs as a result of Medicaid collecting rebates on them and have asked to be exempted from the requirement.

Response: This provision of the DRA does not apply to 340B hospitals that receive discounted drugs and bill Medicaid at the acquisition cost of the drug as determined under the State plan.

Comment: One commenter noted that certain safety-net hospitals receive discounts under the 340B Program and that the law provides that such drugs not be also subject to Medicaid rebates.

Response: We agree with the commenter that drug manufacturer sales to safety-net hospitals under the 340B Program are not subject to Medicaid rebates as long as they are billed to Medicaid at acquisition cost as determined under the State plan.

Comment: One commenter asked that HRSA post the National Provider Identifiers (NPI) of providers who will be billing for physician-administered drugs from 340B covered entities on its

Web site in addition to the NPIs of 340B covered entities.

Response: We are not addressing the concerns of other agencies within the Department of Health and Human Services in this rule. Instead, we suggest that the commenter should address HRSA regarding the posting of NPIs on its Web site.

Comment: One commenter noted that physicians will not know which drugs are included in the Medicaid Drug Rebate Program to be able to administer only those drugs to Medicaid patients. Several commenters noted that physicians need to know which manufacturers participate in the Medicaid Drug Rebate Program because drugs of non-participating manufacturers will not be covered by Medicaid.

Response: We understand the commenter's concern and believe that compliance with this provision will depend upon the level of education/coordination provided by States to the provider community regarding the resources available to them. As previously discussed in this rule, AMPs for drugs covered by the Medicaid Drug Rebate Program will be publicly available and listed by NDC on our Web site. We believe that this resource, along with State information, will assist physicians to make informed decisions regarding the list of covered outpatient drugs available under Medicaid.

Comment: Several commenters asked that CMS develop standard literature for physicians to assist in education and outreach about the requirement for including NDCs on bills for Medicaid.

Response: States traditionally are responsible for provider outreach and education. Materials will vary by State based on processes and procedures determined by each State. We believe that States can avoid duplication of effort by working through the National Association of State Medicaid Directors to share materials and best practices concerning this new requirement.

Comment: One commenter asked CMS to develop a form for hospitals to use to bill States with NDCs because the UB04 billing form does not allow for the inclusion of NDCs. The commenter believed this would be more efficient than each State developing its own form.

Response: CMS would be happy to work with States if they wish to develop a model form.

Comment: A few commenters asked that CMS develop a standard UB04 form that allows for the reporting of the NDC quantity and unit of measure.

Response: CMS cannot specify what is included on the UB04 form. The

National Uniform Billing Committee determines the content of the form. Both CMS and State Medicaid Agencies are represented on this committee and need to work together to establish the need for any changes to the form and to obtain approval for the changes.

Comment: A few commenters noted that not all Durable Medical Equipment Regional Carriers (DMERC) pass through the NDC to the Medicaid agency. The commenters believed that the provision that States allow for the submission of NDCs on claims for physician-administered drugs should also apply to claims for supplies/durable medical equipment for which Medicaid is the secondary payer so that States are able to collect rebates on these claims.

Response: We are aware that not all DMERCs provide the NDC to the Medicaid agency when Medicaid is the secondary payer. We also agree with the commenter that States should be collecting NDCs with respect to separately reimbursed drugs in order to secure rebates under section 1927 of the Act to the extent that they are not included within a bundled rate.

Comment: Several commenters asked that the Secretary use the waiver authority provided by statute to delay the requirement for States to collect NDC-level information from hospitals to provide additional time for them to reconfigure their systems to capture this information.

Response: The statute provides for a hardship waiver for States that require additional time to implement necessary changes to their reporting systems. We will consider States' requests on a case-by-case basis.

Comment: One commenter noted that CMS stated in the proposed rule that we do not expect States to need hardship waivers to postpone the requirement that States collect NDCs on claims for physician-administered drugs by January 2008. The commenter believed that States may find it difficult to meet this date because of other priorities for systems such as the NPI.

Response: We anticipate that many States will have had ample time to meet the January 1, 2008 deadline to comply with the DRA requirements since the DRA was enacted nearly two years prior to that deadline and CMS guidance was given to State Medicaid Directors (SMDL 06-016, <http://www.cms.hhs.gov/smdl/downloads/SMD071106.pdf>) nearly 18 months prior to the deadline.

Comment: One commenter suggested that CMS should re-examine this requirement as it will result in reduced access to care for Medicaid beneficiaries

because of the non-standard billing requirements it imposes.

Response: While we appreciate the comment, we have no reason to believe that the DRA requirement will result in reduced access to care.

Comment: One commenter noted that not all package labels carry the 11-digit NDC which is needed for billing. Some carry a 10-digit number and knowledge of conversion conventions is needed to translate the number to the 11-digit NDC. Another commenter stated an inability of some billing systems to capture the 11-digit NDC. Another commenter noted that the billing units of certain drugs are different from the units used for Medicaid rebates. This will cause confusion and require translation.

Response: As we have previously stated, the education of the provider community by the States will be paramount in ensuring proper billing procedures and the successful implementation of this requirement.

Comment: Several commenters stated that it will be nearly impossible for hospitals to accurately record the NDCs for some drugs. This will occur when drugs are bought in bulk or for cases in which a portion of the drug unit is used. The commenter noted that the difficulty will likely be encountered in instances when multiple drugs are mixed into a treatment "cocktail" and injected or infused into the patient.

Response: We recognize the operational difficulties that may exist for some hospitals but note that the law, as amended by the DRA, makes no exceptions for physician-administered drug claims billed by hospital outpatient departments. This process should be easier when hospitals use the Uniform Product Codes for drugs dispensed.

Comment: One commenter asked that CMS bill manufacturers for rebates directly as opposed to implementing this requirement.

Response: This request is not feasible because States, not CMS, receive claims data necessary to bill manufacturers for rebates. Drug manufacturers do not know which or how much of their drugs are supplied to Medicaid beneficiaries until States submit utilization data as required in section 1927(b)(2) of the Act.

Comment: One commenter suggested that it would be more appropriate for States to obtain detailed NDC information from the drug manufacturers rather than from the community hospitals. The commenter noted that drug manufacturers have access to detailed NDC information and other detailed purchasing information because the drug company

representatives often call the community hospital pharmacy directors to inform them of the number of items hospitals have purchased and how many items are returned for credit.

Response: While we appreciate the commenter's suggestion, this approach would not be operationally feasible because manufacturers would not have utilization data to determine the unit amounts of drugs dispensed to patients.

Comment: One commenter stated that his hospital uses drug dispensing machines located throughout the hospital that have unit dosages of drugs that are not differentiated by NDC. Compliance with this provision would require the hospital to limit each slot on the machine to one NDC, ordering only one NDC for each drug, or billing by unit dose, all of which would be costly and inefficient.

Response: We understand that some hospitals and providers' offices will require systems modifications and changes in dispensing and billing procedures in order to comply with the billing requirements of this provision.

Comment: One commenter asked CMS to specify how compounded drugs should be billed. The commenter suggested that only the NDC and quantity for the NDC that most closely ties to the HCPCS narrative description be required.

Response: We require that NDCs and corresponding quantities for those NDCs for each drug be included on the claims for Medicaid reimbursement.

Comment: One commenter expressed concern that the requirement that providers submit NDCs for physician-administered drugs will create an administrative burden for both the providers and the State Medicaid Agencies. The requirement is impractical with respect to the CMS-1500 because the claims are usually submitted after the drugs are administered making it difficult for the provider to capture the NDC administered to the patient on the claim. Providers will need access to a list of rebatable NDCs and have them in stock, which could result in a delay in administering the necessary medication. The requirement may in fact impair patients' access to necessary medication.

Response: The law requires States to collect rebates on physician-administered covered outpatient drugs in order to receive a Federal match for the cost of the drugs. Because NDCs are required by the manufacturer in order for States to collect rebates on these drugs, providers are required to submit NDCs for physician-administered covered outpatient drugs. We encourage

States to educate the provider community regarding the resources available to them that may assist them in their transition to the requirements. We have no reason to believe that this requirement will have a negative impact on providers or patients' access to medication therapies in an outpatient hospital setting.

Comment: One commenter asked CMS to include a provision in the final rule to encourage States to provide a furnishing fee for blood clotting factors modeled after that provided by Medicare.

Response: State Medicaid programs have sufficient latitude under other provisions of the statute to determine in their State plans how they will reimburse adequately for blood clotting factors. This final rule does not revise options that States have under other provisions of the statute and the State plan to ensure access.

Comment: One commenter noted that the HCPCS crosswalk is only effective for single source drugs where there is a one-to-one relationship between HCPCS code and NDC. There are, in fact, several single source drugs for which there is one J-code but numerous NDCs.

Response: We agree with the commenter that the HCPCS crosswalk is only effective for certain single source drugs and believe that this fact fully supports the need for NDCs to be submitted on claims for physician-administered drugs as set forth in statute and required by this rule.

Comment: Several commenters noted that Part B carriers will need to provide the NDC on the crossover claim for the Medicaid agency to have the information needed to invoice drug manufacturers for rebates. One commenter asked that CMS ensure that Medicare carriers provide NDCs on crossover claims sent to Medicaid. Another commenter noted that the quantity administered for each NDC must also be recorded.

Response: If the NDC is on the electronic claim submitted (CMS-837), the Part B carrier will include it on the crossover claim sent to the Medicaid agency. Although the new CMS-1500 claim form does allow entry of the NDC, the UB04 claim form does not contain a section to capture the NDC. As previously stated, States will need to make it clear that providers must submit claims, complete with the NDC information, to the Medicaid agency. We encourage States to provide educational outreach to providers to inform them of the manner in which the NDCs and corresponding quantities should be recorded on the claims forms as they deem necessary for the accurate

billing of drug manufacturers for rebates.

Comment: One commenter asked us to develop a better remedy for States than rejecting the claim and asking the provider to rebill when an NDC is not provided on a crossover claim. The commenter believes this method is costly, results in delay, is counter to the intent and spirit of HIPAA, and may result in a loss of access for Medicaid beneficiaries to needed drugs.

Response: It is crucial for States to communicate to the provider community the importance of including NDCs on the claims when billing Medicaid for physician-administered drugs. In cases where providers have not included NDCs on claims for physician-administered drugs, we recommend that States coordinate with provider billing offices in any manner that they deem appropriate in order to obtain the NDCs necessary for States to bill manufacturers for rebates as required by the statute.

Comment: One commenter stated that the burden of recording the NDC will fall on clinicians, not support staff. Because Medicaid is the secondary payer for most of these claims, the clinicians may note that the patient has Medicare, which does not require NDCs for billing, and may overlook the Medicaid requirement.

Response: We encourage States through provider education to convey the importance of including the NDCs on the claim in order for States to process claims and payment for the service.

Comment: One commenter believed that the top 20 list of multiple source drugs published on the CMS Web site incorrectly included Factor VII Recombinant and Factor VIII plasma-derived because the commenter did not believe these products meet the statutory definition of multiple source drug.

Response: We agree with the commenter and will remove these products from the top 20 list of multiple source drugs published on our Web site.

Comment: One commenter questioned the inclusiveness of the list of the 20 multiple source physician-administered drugs for which billing with the NDC will be required. The commenter stated that the list should include all NDCs with a particular HCPCS code.

Response: At this time, we do not intend to include all NDCs for a given HCPCS code.

Comment: One commenter asked when the list of 20 drugs will be updated.

Response: We intend to annually review the list of top 20 multiple source

physician-administered drugs on our Web site and update it as necessary.

Comment: One commenter asked that we specify the file format for the submission of claims for physician-administered drugs using NDCs for the top 20 drug list.

Response: States are responsible for determining the file format to be used for the submission of claims. We encourage the States through provider education to inform providers of the correct file format to use when billing for physician-administered drugs using NDCs.

Comment: Several commenters said that State Medicaid Agencies should be required to bear the cost for hospitals to change their systems in order to meet the NDC reporting requirement, as some outpatient hospital departments' systems do not currently capture NDC level utilization data for patient billing.

Response: We do not believe that the law requires Medicaid agencies to pay hospitals for systems modifications that may be necessary to document claims for payment in a manner that would comply with DRA requirements to identify the NDC. States have the option to pay for overhead costs, such as a provider billing systems, through dispensing fees to pharmacies or other providers.

Comment: One commenter stated that many State Medicaid processing systems are not designed to capture NDCs on outpatient hospital bills and that implementation of this provision should be delayed until alternate systems can be designed. Another commenter stated that the manual coding of NDCs would come at the expense of staff resources and would disrupt administrative operations.

Response: The timeframe for implementing this provision is set by statute. The DRA was signed into law on February 8, 2006. While States were required to start billing manufacturers for rebates for single source drugs on claims beginning January 1, 2006, States could crosswalk HCPCS to NDCs for these drugs. States continue to have until January 1, 2008 to collect NDCs on the 20 multiple source physician-administered drugs identified by the Secretary before losing Federal match for these drugs. States that cannot meet this deadline can request a waiver from the Secretary to implement this requirement at a later date.

Issues Not Addressed in the Proposed Rule

We received several comments on issues that were not addressed in the proposed rule. A summary of those comments and our responses follow.

Posting AMP

Comment: Many commenters requested that CMS should delay any public posting of the AMP data on a public Web site until after the final regulation has been issued and AMPs are determined to be reliable and accurately reflect the prices paid to manufacturers by wholesalers for sales to the retail pharmacy class of trade. Commenters contended that AMP data may be flawed and to post the flawed AMP data may cause confusion to the general public and adversely affect community retail pharmacies if Medicaid Programs and commercial markets use these data for reimbursement purposes. They pointed out that CMS already delayed release of these data once, and urged CMS to consider delaying the release of the data again. Delaying the posting of AMP data could permit manufacturers time to adjust the submission of their data consistent with the requirements of the final regulation and allow community retail pharmacies time to validate that the AMPs are consistent with congressional intent.

One commenter concurred with the OIG's findings in its May 2006 report that future errors or inconsistencies in manufacturers' AMP calculations could lead to inaccurate or inappropriate reimbursement amounts as well as rebate errors.

One commenter raised concerns that the public disclosure of manufacturer-specific AMPs negates the confidentiality provisions of section 1927 of the Act. The commenter expressed the opinion that such disclosure must be implemented through notice-and-comment rulemaking, and that failure to do so would violate the Administrative Procedures Act. Another commenter asked that we not make AMPs publicly available. The commenter noted concern that public release of AMP would stifle competition among manufacturers, ultimately driving up the price of generic drugs.

Response: We disagree with the commenters about the need to further delay the public release of AMP. By statute, CMS is required to update AMP data posted on a Web site accessible to the public. Furthermore, effective January 1, 2007, the confidentiality provisions of the statute were amended to permit public disclosure of AMP data. CMS has interpreted these provisions to mean that we must publicly disclose data that the manufacturers report following January 1, 2007. We understand the importance of the accuracy of the AMP data;

however, it is also important that we carry out the DRA amendments to make the AMP data publicly available. We also disagree that the public disclosure of AMP negates the confidentiality provisions of section 1927(b)(3)(D) of the Act. The DRA amended section 1927(b)(3)(D)(v) to provide for the release of AMP data to the public.

Comment: A few commenters expressed concern that CMS' failure to provide AMP data to the retail industry has hampered its ability to provide definitive and accurate commentary related to this matter. The commenter further said the final rule should be delayed until adequate information is provided to the retail industry to allow for statistically significant evaluation of the AMP data. Another commenter urged CMS to provide AMPs to community retail pharmacies on a confidential basis for the 77 multiple source drugs provided to the GAO because this would allow community retail pharmacies to speak with specificity as to the costs that they will bear under the proposed regulation.

Response: We disagree with the commenters. The DRA amended section 1927(e) of the Act to require that the FULs be calculated based on AMP data. The DRA also required that we publish the regulation clarifying requirements concerning AMP by July 1, 2007. In accordance with the effective date of the amendments to section 1927(b)(3)(D) of the Act, we consider AMP data prior to January 1, 2007 to be confidential; therefore, we did not publicly disclose the AMP data in the proposed rule. However, in accordance with the amendments to the confidentiality provisions and section 1927(b)(3) of the Act, we will post this information on the Web site and update that information on at least a quarterly basis.

Comment: A few commenters urged CMS to preface any Web postings of the AMP data with an introductory discussion explaining the current shortcomings of AMP as a measure of retail prices and pharmacy acquisition costs and highlighting the potential for changes in the calculation methodology underlying AMP over the next year.

One commenter also expressed that CMS should post a disclaimer stating that limited instructions were provided to guide manufacturers' January AMP calculations. Posted data should be viewed as preliminary and may not accurately reflect prices available in the market to community retail pharmacies. The commenter stated that similar disclaimers should be sent to the States with their download tapes or new electronically transmitted price report files. These disclaimers should also be

reiterated in a State Medicaid Director letter.

Response: We will consider this comment when we issue further clarification regarding the provisions of this final rule.

Comment: A few commenters recommended that CMS develop clear guidelines for the electronic format and standardized unit reporting. Although the proposed rule requires submission of data by manufacturers in an electronic format, data specifications and unit reporting are not provided in adequate detail.

Response: CMS will post the AMP data file including labeler code, product code, package size code, the calendar month and year of the most recently reported AMP, and the AMP per unit per product code for the month and year covered, based on the sales. If a drug is distributed in multiple package sizes, there is one weighted AMP for the product, which is the same for all package sizes. We will address most of the procedural issues, such as data specifications and unit reporting, in guidance documents and on our Web site.

Comment: A few commenters recommended that AMP data should be posted on a secured password-protected internet Web site that can only be accessed by authorized practitioners, providers, and government agencies. The commenter argued that open access to this information could allow competitor manufacturers to access AMP information that can lead to information intelligence on specific products and affect both commercial and Medicaid supplemental rebate offers.

Response: We disagree with the commenter. By statute, CMS is required to post AMP data on a Web site accessible to the public. To post the AMP data on a secured Web site would limit access to the AMP data.

Comment: One commenter wanted to know how often the posted AMP data will be updated and which AMP data will be posted so that AMPs reflect the most accurate AMPs filed by the manufacturers. The commenter contended that failure to keep publicly available AMPs accurate and in agreement with revised AMPs reported by manufacturers is going to invite controversy from others interested in AMPs.

Response: We expect that AMP data will be updated on a monthly basis once posted on a Web site accessible to the public. We will post the most recently reported monthly and quarterly AMP data received from manufacturers, as well as any revised monthly and

quarterly AMPs for a period not to exceed twelve quarters from the quarter in which the data were due.

Comment: A few commenters recommended that AMP data should be made available in an easily downloadable format.

Response: The AMP data will be posted in a flat text file format for easy conversion to other file formats.

Comment: One commenter requested that CMS permit manufacturers to review monthly and quarterly AMP data prior to its publication by CMS to ensure its accuracy and give manufacturers opportunity to bring any concerns about the accuracy of the data to CMS' attention before it is used by States for reimbursement purposes.

Response: We disagree with the commenter. Monthly and quarterly AMP data that will be posted are those originally submitted by manufacturers; thus, manufacturers should be reviewing their data for accuracy prior to submitting them to us.

Comment: A few commenters requested that CMS provide the U.S. territories with access to the new AMP data so they may leverage the information in their calculations for reimbursement on brand name and generic drugs, as well as on rebate negotiations with the drug companies. Access to the proposed new AMP data would provide a benchmark in the rebate negotiation process, maximizing the utilization of available Medicaid funds.

Response: By statute, CMS is required to post the AMP data on a Web site accessible to the public. This requirement allows everyone to have access and to view the AMP data.

Comment: One commenter requested that the AMP data accurately reflect the reimbursement methodologies for hemophilia factor therapies. The commenter stated that if the AMPs reported to the States under the DRA do not reference the additional furnishing fee for blood clotting factors, they can potentially create inadequate reimbursement. The commenter argued that if States rely solely on the AMPs in setting their reimbursement levels and do not take into account the furnishing fee payment that Congress recognized as critical, then payment amounts may be too low. The commenter recommended we include this information in the AMP data.

Response: We disagree with the commenter. The AMPs to be posted are defined in the laws and these regulations. In accordance with these definitions, AMPs do not include wholesaler or retailer mark-up, dispensing fees, or furnishing fees.

Elsewhere in this final rule, we have encouraged States to examine dispensing fees to assess whether they are reasonable. Some of the fees for furnishing hemophilia factors could also be paid in other Medicaid service categories.

Comment: Several commenters offered alternatives to publishing the monthly and quarterly AMPs for each manufacturer's drugs. A few commenters recommended that we publish an aggregated, industry-wide weighted average that combines individual manufacturer AMPs into one AMP for each drug. One commenter suggested that we publish an AMP that represents the weighted average of all of the 11-digit AMPs for the manufacturers' most commonly dispensed retail package size that is widely and nationally available for purchase by community retail pharmacies. This commenter also suggested that CMS release a limited number of AMPs initially to allow the marketplace to assess the validity of the data. This would be similar to the approach CMS used in adopting the use of ASP for Part B drug reimbursement.

Response: We considered these comments, but we want to reiterate our belief, which is supported by the legislative history of the DRA, that the intent in making AMPs available to the public is to bring about increased transparency in prescription drug pricing for the Medicaid Program. The OIG and the GAO have consistently found over the years that Medicaid reimbursement for prescription drugs is well in excess of the cost of the drugs. Limiting access to the data or masking individual manufacturer's data by publishing aggregate AMPs across different manufacturers would counteract the overarching purpose of the Medicaid drug provisions of the DRA.

Comment: One commenter raised concerns over the lack of controls and accountability measures for manufacturers submitting AMP data. The commenter suggested that CMS' processes have been insufficient in monitoring and managing the prescription drug files submitted by manufacturers. The commenter stated that this lack of updated data will undoubtedly result in inappropriate calculations. The commenter also argued that these erroneous calculations will impose an unforeseen burden on States to identify and subsequently report any inaccuracies to CMS. The commenter urged CMS to implement system checks and measures to hold manufacturers accountable for the quality of data they provide, including

the reporting or not reporting of accurate data.

Response: We disagree with the commenter. Manufacturers are fully accountable for the accuracy of their data and subject to civil monetary penalties under section 1927(b)(3)(C) of the Act in situations where they report untimely or false information. While we encourage further scrutiny of these AMPs, there is no further burden on the States imposed by this regulation to review those numbers.

Comment: A few commenters raised concerns that the monthly AMP data file that CMS sends to States contains only the drug name. States have to translate the drug descriptions in the file to analyze the impacts of the FUL with their processed claims. In addition, having only the drug name may lead to misinterpretations and lack of identification of applicable products with their NDCs that are necessary to process claims. The commenter recommended that CMS provide on at least a monthly basis descriptive drug information, unique identifiers, and pricing data, and include updated NDC codes to the nationally recognized pricing compendia.

Response: CMS is not considering providing any data to the pricing compendia. CMS has been sending States AMP data files on a monthly basis since July 1, 2006. The AMP data file includes the labeler code, product code, package size code, the calendar month and year of the most recently reported AMP, and the AMP per unit per product code only for the month and year covered, based on the sales. If a drug is distributed in multiple package sizes, there is one weighted AMP for the product. The posted AMPs will also have this level of detail.

Comment: One commenter asked that CMS refrain from making quarterly AMP data publicly available. The commenter contended that only monthly AMP data should be made available. Unlike monthly AMP, which may be used to set reimbursement rates, there is no need for the public to have access to quarterly data, which can lead to confusion.

Another commenter also expressed concern with publishing both monthly and quarterly AMPs on the CMS Web site. The commenter noted that having two different AMP values could lead to confusion. The commenter urged CMS to only publish the last month's AMP data for the quarter. Another commenter urged CMS to publish AMP quarterly, not monthly.

Response: AMPs reported by manufacturers beginning January 1, 2007 are no longer confidential. By

statute, CMS is required to post AMP data on a Web site accessible to the public. CMS has interpreted this provision to mean that we must publicly disclose AMP data, monthly or quarterly, that the manufacturers report.

Comment: One commenter requested that CMS provide the AMP data for numerous drugs covered in the GAO study for review. The commenter was troubled by reports that CMS demanded data to support suggested changes to the AMP definition but refused to make the same data available for public review. In addition, the commenter contended that CMS rejected the findings of the GAO study on the issue and that if CMS was going to dismiss the GAO report it should make a sampling of the AMP data available for the public to review and use in their comments on the proposed rule.

Response: In accordance with section 1927(b)(3)(D) of the Act, AMP data prior to January 1, 2007 are considered confidential and cannot be released to outside parties. CMS rejected GAO's findings because we found GAO's conclusion to be premature, contrary to the DRA AMP revision, and unsupported by the report. The study could not be thoroughly analyzed or replicated because GAO was not willing to release the data on which the study was based.

340B Drug Pricing Program

Comment: Many commenters noted that HRSA has adopted a different definition of AMP from the definition of AMP described in this final rule. In effect, HRSA is asking manufacturers to report two different AMPs; one for Medicaid, and one for the 340B Program. Most of these commenters objected to HRSA's interpretation and urged the Department to encourage consistency between the two agencies. One commenter provided a detailed analysis of alternatives available to CMS and HRSA to resolve the issue, while another noted that requiring different AMP calculations will further strain manufacturer resources. One commenter forwarded us a copy of the letter HRSA issued on January 30, 2007.

Other commenters expressed support for HRSA's position and asked CMS to clarify that the AMP described in this final rule is not applicable in calculating 340B ceiling prices. One commenter urged CMS to support HRSA's interpretation and for CMS to provide the data required for the calculation of two AMPs. The commenter also suggested that this final rule should specify that HRSA will receive the specific data needed to calculate the

340B ceiling prices from drug manufacturers and/or from CMS.

Response: The question of whether HRSA should use the same definition of AMP for the 340B Program that CMS uses for the Medicaid Program is beyond the scope of this regulation. This final rule implements the revisions to AMP and best price as described in the DRA, as well as regulatory provisions related to the Medicaid Drug Rebate Program.

Comment: A few commenters expressed concern with the impact of the provisions in §§ 447.504 and 447.505 on the calculation of prices available to covered entities that participate in the 340B Program under the PHS Act. Commenters also noted that the economic impact estimates do not include the potential costs to the 340B Program and the costs manufacturers incur to meet the 340B Program requirements. Commenters asked CMS to analyze the fiscal effect of these changes and revise the rule in order to retain the most favorable pricing for covered entities.

Response: This final rule is designed to implement the DRA amendments and other provisions concerning the Medicaid Drug Rebate Program, not provisions concerning section 340B of the PHSA. In addition, we note that because the 340B Program is administered by HRSA, that agency, not CMS, is the appropriate source for clarification on the rules for the 340B Program.

Comment: A few commenters urged CMS to exempt hospital outpatient clinics from the requirement to bill Medicaid using the NDC code; otherwise, the facilities represented by the commenters will forego the benefits of 340B Program discounts.

Response: The requirement to bill Medicaid using the NDC code for physician-administered drugs is established by statute; therefore, we are not creating an exemption for such facilities in the final rule.

Comment: Section 6004 of the DRA amends section 1927(a)(5)(B) of the Act to provide a basis for the participation of certain children's hospitals in the 340B Program. A few commenters noted that CMS did not address section 6004 in the proposed rule. One commenter asked HHS to address this provision through a **Federal Register** notice. Other commenters noted that the Medicaid drug rebate statute was amended to include children's hospitals in the definition of "covered entity" for purposes of the best price exclusion; however, the definition of "covered entity" under the PHS Act was not amended. Commenters asked us to

clarify whether prices to such children's hospitals will be eligible for the nominal price exclusion for AMP.

Response: CMS believes that HRSA is the appropriate agency to address the issue of which entities may participate in the 340B Program. As to the question of whether prices to children's hospitals will be eligible for the nominal price exclusion for AMP, section 6004 of the DRA amended section 1927(a)(5)(B) of the Act by adding certain children's hospitals to the definition of covered entity. Section 6004 did not amend the PHS Act, which governs the 340B Program, nor did it amend section 1927(c)(1)(D) of the Act, which addresses the nominal price exemption from best price. Therefore, we do not believe that prices to children's hospitals can be considered within the list of entities addressed in the nominal price exemption.

RPS

Comment: Several commenters raised concern that 6001(e) of the DRA, which provides for a survey of retail prices and State performance rankings, is not addressed in the proposed regulation which does not allow for comment.

Response: The DRA requires the Department to enter into a contract with a vendor to perform the survey. While this provision of the DRA did not necessitate public comment on the method of the survey, when the RPS is published, the methodology will be made available.

Policy Inquiries

Comment: One commenter noted that the drug rebate operations area at CMS has an e-mail address for manufacturers to send operational questions. The commenter asked whether the Division of Pharmacy in CMS' Center for Medicaid and State Operations (CMSO) has a similar resource. If not, the commenter asked to whom manufacturers should send policy inquiries.

Response: Formal policy inquiries should be addressed to the Director of CMSO within CMS.

Cost of Healthcare

Comment: Some commenters noted that a good way to control the cost of healthcare in America is to educate people about prevention, disease management, and the proper use of medications through medication therapy management programs. Other commenters pointed out that it should not be the entire responsibility of pharmacies to mitigate the cost of decreasing expenditures on prescription medication. All parties involved in the

production to dispensing of a prescription medication should share proportionately in the cost sharing involved in reducing medical expenditures.

Response: We appreciate the ideas shared by the commenters about ways to control the cost of healthcare, but at this time, we are not planning to add new provisions to this regulation to control drug costs.

Medicare Part B

Comment: Commenters noted that revisions to the calculation of AMP could cause AMP to decrease for certain drugs and biologicals. A decrease in AMP would increase the likelihood that the applicable threshold percentage will be triggered, forcing the substitution of AMP for ASP under Medicare Part B. In such circumstances, the commenters asked CMS to refrain from substituting AMP for ASP when the threshold is triggered due to the revised definition of AMP.

Response: This issue is not addressed in the proposed rule; therefore, we cannot consider these comments as we consider revisions to be included in the final rule. Issues regarding ASP substitution and the applicable threshold were discussed in recent Medicare notice-and-comment rulemaking concerning the payment for Part B drugs and biologicals (see 71 FR 48981, 49004 (Aug. 22, 2006) and 71 FR 69624, 69680 (Dec. 1, 2006)).

Comment: One commenter noted that CMS advised manufacturers during an Open Door Forum to look to their customary business practices and their AMP procedures for guidance whenever the Act and the ASP regulations left doubts about the proper handling of a particular issue with regard to ASP reporting. Given the similarities between the calculation methodologies for AMP and ASP, the commenter urged CMS to consider including a discussion in the preamble to this final rule explaining when, or whether, manufacturers should apply new instruction from the AMP regulation to their ASP policies. Another commenter asked CMS to clarify that the treatment of bona fide service fee should be the same in ASP as it is for AMP.

Response: These issues are not addressed in the proposed rule; therefore, we cannot consider these comments as we consider revisions to be included in the final rule. Inquiries regarding the definition of ASP should be addressed to the director of the Center for Medicare Management in CMS.

Medicare Part D

Comment: One commenter urged CMS to require electronic data transfer to support community pharmacy's efforts to obtain electronic funds transfer (EFT) reimbursement payment from PBMs for Part D claims submitted via EFT by pharmacies. Other commenters expressed concern that Medicare Part D had already cut pharmacy profits by 30 percent. One commenter noted that independent pharmacies made Medicare Part D work by loaning medicine and taking out loans to make ends meet. Another commenter noted that his pharmacy has stopped charging copayments for Medicare Part D enrollees because they can't afford the copayments.

Response: These issues are not addressed in the proposed rule; therefore, we cannot consider these comments as we consider revisions to be included in the final rule. Questions regarding Medicare Part D should be addressed to the Director of the Center for Beneficiary Choices in CMS.

Comment: One commenter noted that inconsistent policies in Medicaid and Medicare Part D will lead to confusion and burdensome administrative recordkeeping requirements for drug manufacturers, health plans, wholesalers, and pharmacies.

Response: To the extent practicable, we have made every effort to ensure the provisions of this final rule are clear and concise, with the minimum administrative burden for all affected parties. The authorizing statutory provisions for the Medicaid Drug Rebate Program and Medicare Part D are fundamentally different, making it difficult to streamline the regulatory requirements for these two programs.

Industry Price Controls

Comment: One commenter suggested that CMS regulate the pharmaceutical industry so prices would only increase every six months, and there would be a 60-day advance notice of pricing changes. Another commenter suggested that all drug companies should be required to sell their products to all pharmacies at the same price. Other commenters expressed concern that the government is promoting unfair competition because certain purchasers (for example, mail order pharmacies, hospital outpatient department, and outpatient clinics) can receive better prices than independent pharmacies. One commenter suggested that manufacturers be required to report to CMS any anticipated pricing increases with a 90-day advance notice.

Response: This rule is not designed to promote unfair competition or negotiate

drug prices. These issues are not addressed in the proposed rule; therefore, we cannot consider these comments as we consider revisions to be included in the final rule.

Comment: One commenter urged CMS to address severe price fluctuations, which currently can take months to address and correct. Another commenter urged CMS to identify atypical manufacturer pricing practices and recommend remedies to Congress to address such practices.

Response: These issues are not addressed in the proposed rule; therefore, we cannot consider these comments as we consider revisions to be included in the final rule.

Comment: One commenter requested that CMS develop a specific methodology for timely verification of the integrity and accuracy of calculations and price information reported by manufacturers.

Response: We appreciate the comment and will work with the OIG in HHS to ensure the integrity of drug rebate data.

State Supplemental Rebate Agreements

Comment: One commenter noted that some States are promoting the use of brand name versions of generically-available drugs because they are receiving supplemental rebates from branded manufacturers that lower the net cost of the brand to that of the generic. This practice has potential negative implications for generic drug use in Medicaid because it can discourage the overall availability of generic drugs in the marketplace. The commenter urged CMS to prohibit States from entering into such agreements with manufacturers.

Response: We believe any adverse impact on generic drug use by the implementation of State supplemental rebates is mitigated by the fact that the overall FULs cap is applied to multiple source brand name drugs as well as generics.

State Rebate Claims

Comment: A few commenters expressed concern with the lack of Federal regulation regarding the time limit for States to submit rebate claims to drug manufacturers under the Medicaid Drug Rebate Program. The commenters noted that CMS (then the Health Care Financing Administration) proposed a 60-day time limit in the 1995 NPRM, but that provision was never promulgated in a final rule. The commenters requested that CMS enact a time frame not to exceed one year to prevent continued State submission of

untimely rebate claims to manufacturers.

Response: We encourage States to submit timely rebate claims to manufacturers, but we are not establishing a regulatory timeframe in this final rule.

Comment: One commenter urged CMS to require States to use an electronic claims system to invoice manufacturers for rebates.

Response: States currently have the option to submit electronic invoices; we are not establishing this as a requirement in this final rule.

Medicaid Eligibility

Comment: One commenter expressed concern with individuals potentially abusing the public health system and costing taxpayers money. Rather than cut reimbursement to pharmacies, CMS should enforce who is covered under the Medicaid and Medicare Programs.

Response: We appreciate the commenter's concerns; however, this issue is not addressed in the proposed rule. We will keep this suggestion in mind for future revisions of the regulations.

Consistency in CMS Policies

Comment: One commenter noted that this final rule should be consistent with established Medicaid rebate policies, definitions and terms set forth in current CMS guidance, such as Medicaid Program Releases and the national rebate agreement created under the OBRA 90. The commenter also believed the final rule should be consistent in treating similarly-situated entities, while recognizing entities that are not similarly situated.

Response: We believe the provisions in this final rule are, in large part, consistent with the policies we have previously adopted. To the extent that we have clarified or revised our policies, we have so noted in the final rule.

IV. Provisions of the Final Regulations

For the most part, this final rule incorporates the provisions of the proposed rule. Those provisions of this final rule that differ from the proposed rule are as follows:

In § 447.300, we updated a statutory reference.

In § 447.502, we added definitions of three terms: lagged price concession, noninnovator multiple source drug, and States. We also moved the definition of bona fide service fee to § 447.504 and clarified that bona fide service fees mean payment for an expense that would have been paid by the manufacturer at the same rate had these

services been performed by the manufacturer or other entity. We also clarified that bona fide service fees are paid by a manufacturer to an entity.

In § 447.502, in the definition of dispensing fee, we inserted "or service" after, "is incurred at the point of sale."

In § 447.502, we clarified that an innovator multiple source drug includes an authorized generic drug. We also clarified that term to include any labelers operating under the NDA.

In § 447.502, we clarified that a single source drug includes a covered outpatient drug approved under a BLA.

In § 447.504(c), we revised the definition of customary prompt pay discount by inserting "frame and consistent with industry standards and normal business practices for payment" after "a specified time."

In § 447.504(d), we revised the definition of net sales by inserting "except customary prompt pay discounts extended to wholesalers," after "cash discounts allowed."

In § 447.504(e), we removed PBMs from the definition of retail pharmacy class of trade. We also removed entities that arrange for the purchase of drugs from this definition.

In § 447.504(f), we removed "a pharmacy, chain of pharmacies, or PBM" and "arranges for the sale of" from the definition of wholesaler. We also inserted "those entities in the retail pharmacy class of trade" after "including."

In § 447.504(g)(3) and (h)(4), we clarified that direct and indirect sales to hospitals that cannot be identified with adequate documentation as being used in the outpatient pharmacy for outpatient use are not included in AMP.

In §§ 447.504(g)(6), 447.504(h)(22), and 447.504(i)(1), we clarified that discounts, rebates, or other price concessions to PBMs are excluded from the determination of AMP, except for purchases through the PBMs' mail order pharmacies.

In § 447.504(g)(8), we clarified that sales to outpatient facilities (for example, clinics, surgical centers, ambulatory care centers, dialysis centers, and mental health centers) are included in AMP.

In §§ 447.504(g)(9) through (13), we added sales to home infusion providers, specialty pharmacies, home health care providers, and physicians to the list of sales included in AMP.

In § 447.504(g)(15), we removed manufacturer coupons redeemed by any entity other than the consumer from the list of entities included in AMP. In § 447.504(h)(15), we clarified that manufacturer coupons redeemed by an agent, pharmacy, or other entity acting

on behalf of the manufacturer are excluded from AMP. We further clarified that such coupons are excluded as long as the full value of the coupon is passed on to the consumer, pharmacy, agent, or other entity does not receive any price concession.

In § 447.504(g)(15), we clarified that sales of drugs reimbursed by third party payers are included in AMP, provided such drugs are provided to the retail pharmacy class of trade. We further clarified that third party payers include a qualified retiree prescription drug plan under section 1860D-22(a)(2) of the Act, HMOs and MCOs that do not purchase or take possession of drugs, and TRRx. In § 447.504(h)(23) we added associated rebates, discounts, or other price concessions to third party payers including the Medicare Part D Program, an MA-PD, a qualified retiree prescription drug plan under section 1860D-22(a)(2) of the Act, SCHIP, SPAPs, TRRx, and Medicaid programs to the list of prices excluded from AMP.

In § 447.504(h)(5), we clarified that sales to HMO or MCO-operated pharmacies that purchase or take possession of drugs are excluded from AMP.

In § 447.504(h)(6), we clarified that sales to nursing facility pharmacies, contract pharmacies for the nursing facility where these sales can be identified with adequate documentation, and other entities where the drugs are dispensed through a nursing facility pharmacy, such as assisted living facilities, are excluded from AMP.

In §§ 447.504(h)(7) through (12), we added sales to hospices (inpatient and outpatient), veterinarians and prisons, sales outside the 50 States and the District of Columbia, sales to State, county, and municipal entities, and sales to patient assistance programs to the list of sales excluded from AMP.

In § 447.504(h)(16) and (17), we added that manufacturer vouchers and manufacturer-sponsored drug discount card programs are excluded from AMP.

In § 447.504(h)(19), we clarified that bona fide service fees to any entities included in the retail pharmacy class of trade are excluded from the determination of AMP.

In § 447.504(h)(21), we clarified that returned or replaced goods, when accepted or replaced in good faith, are excluded from AMP.

In § 447.504(h)(24), we added Medicaid rebates under the national rebate agreement or a CMS-authorized State supplemental rebate agreement are excluded from AMP.

In § 447.504(i)(1), we clarified that AMP includes cash discounts except

customary prompt pay discounts extended to wholesalers. We also clarified that other fees are included in AMP.

In § 447.504(i)(2), we revised the methodology for calculating quarterly AMP to be the weighted average of monthly AMPs in the quarter.

In § 447.505(c)(2), we deleted PBMs from the list of entities included in best price. We also added “PBM rebates, discounts, or other price concessions except mail order purchases” to the list of prices excluded from best price in § 447.505(d)(13).

In § 447.505(c)(12), we removed “manufacturer coupons redeemed by any entity other than the consumer” from the prices included in best price. We also added manufacturer coupons redeemed by an agent, pharmacy or other entity acting on behalf of a manufacturer, as long as the full value of the coupon is passed on to the consumer and the pharmacy, agent or other entity does not receive any price concession, to the list of prices excluded from best price in § 447.505(d)(8).

In § 447.505(d)(3), we limited the SPAP best price exemption to any prices or price concessions provided to designated SPAPs.

In § 447.505(d)(4), we deleted TRICARE from the list of prices excluded from best price.

In § 447.505(e)(2), we clarified the reference to the nominal price provisions in § 447.508.

In § 447.506(a), we removed the phrase “directly or indirectly” from the definition of authorized generic drug.

In § 447.506(b), we revised the initial provision requiring the manufacturer holding title to the original NDA to include the authorized generic sales of the secondary manufacturer in the AMP of the brand drug by specifying that the manufacturer holding title to the original NDA of an authorized generic must include the sales of authorized generics in the AMP of the manufacturer holding title to the original NDA only when the products are sold directly to a wholesaler.

In § 447.506(c), we removed the initial provision that requires the manufacturer holding title to the original NDA to include the sales of the secondary manufacturer in the best price of the brand drug. We added language that would require sales from the manufacturer holding title to the original NDA to the secondary manufacturer to be included in the best price of the manufacturer holding title to the original NDA. We also added language to state that the best price is the lowest price at which the authorized generic drug is sold.

In § 447.510(a)(3), we clarified that customary prompt pay discounts shall be reported for each covered outpatient drug at the 9-digit NDC level. We also clarified that this term includes discounts provided to all wholesalers in the rebate period.

In § 447.510(a)(4), we clarified that nominal prices include all sales of single source and innovator multiple source drugs to the entities listed in § 447.508(a) of this subpart.

We added § 447.510(b)(2) to specify that manufacturers should not revise AMP when the revision would solely be as a result of data pertaining to lagged price concessions.

In § 447.510(c)(1), we changed the timeframe in which a manufacturer must report base date AMP to CMS from the first full calendar quarter following publication of this final rule to the first four full calendar quarters following publication of this final rule.

In § 447.510(c)(2)(i), we clarified that a manufacturer’s recalculation of base date AMP must only reflect the revisions to AMP as provided for in § 447.504 of this subpart, as opposed to § 447.504(e) of the same.

In § 447.510(c)(2)(ii), we added a provision to allow a manufacturer to choose to recalculate base date AMP on a product-by-product basis.

In § 447.510(c)(2)(iii), we added a provision to require manufacturers to use actual and verifiable pricing records in the calculation of base date AMP.

In § 447.510(d)(2), we revised the reg text by removing the reference to § 447.504 and replacing it with the requirement that monthly AMP should be calculated as the weighted average for all the manufacturer’s package sizes of each covered outpatient drug sold by the manufacturer during a month. We also added a requirement that a manufacturer must estimate the impacts of its lagged price concessions using a 12-month rolling average to estimate the value of those discounts.

In § 447.510(d)(3), we removed the prohibition against reporting revised monthly AMP and replaced it with a requirement that a manufacturer report revisions to monthly AMP to CMS for a period not to exceed 36 months from the month in which the data were due.

We added § 447.510(d)(4) to prohibit manufacturers from reporting revisions to monthly AMP if the revisions would be solely as a result of data pertaining to lagged price concessions.

We added § 447.510(d)(5) to address monthly AMP reporting requirements for terminated products.

In § 447.510(e)(3), we added a provision to allow pricing reports to be certified by an individual other than a

CEO or CFO who has authority equivalent to a CEO or a CFO.

In § 447.510(e)(4), we allowed pricing reports to be certified by an individual who has the directly delegated authority to perform the certification on behalf of a CEO, a CFO, or an individual with authority equivalent to a CEO or a CFO.

In § 447.512(c)(1), we added language that would allow a physician to indicate that a specific brand is necessary when prescribing by an electronic means.

In § 447.514(a)(1)(ii) we deleted “list the drug which has met” and “based on all listings contained in current editions (or updates) of published compendia of cost information for drugs available for sale nationally.”

In § 447.514(c)(2), we changed “30 percent” to “40 percent” per the outlier policy which will be implemented during the period of the final rule with comment period.

In § 447.514(c)(3), we clarified the regulation text by replacing “innovator single source” with “brand name.”

V. Collection of Information Requirements

Under the Paperwork Reduction Act of 1995 (PRA), we are required to provide 30-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:

Section 447.510 Requirements for Manufacturers

Section 447.510 states that a manufacturer must report, electronically, product and pricing information for covered outpatient drugs 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. These new reporting requirements for drug manufacturers participating in the Medicaid Drug Rebate Program associated with the Medicaid Drug Program Monthly and Quarterly Reporting Form (CMS-367) are approved under OMB# 0938-0578. CMS will revise this collection to include changes in burden based upon this regulation.

Section 447.510(f) requires a manufacturer to retain records (written or electronic) 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 is not a new requirement and is

currently approved under OMB# 0938-0578. 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. It may require some additional record-keeping to retain the monthly, as well as the quarterly data, in the AMP system for manufacturers that do not retain this information there now. However, we believe that most manufacturers already have such monthly sales data (for example, data of sale information) in their system and transferring this to the system for calculating monthly AMP would not be a significant burden.

Section 447.520 FFP: Conditions Relating to Physician-Administered Drugs

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 (for example, 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 (www.bls.gov/news.release/pdf/ecec.pdf). The per claim cost would be under nine cents.

Many hospital outpatient departments will also need to modify their billing systems to capture the NDC on Medicaid claims (hospitals that receive discounted drugs and bill Medicaid at

the actual acquisition cost of the drug and hospitals that use a drug formulary system and bill at the hospital's purchasing cost are exempted). The American Hospital Association (AHA) in 2002 estimated that it would cost \$200,000 per hospital for changes needed to use NDC codes for billing. Inflating this figure by the Consumer Price Index (CPI) would make the current cost approximately \$230,000 for each of the 5,655 hospitals that participate in Medicaid for the total cost to be \$1.3 billion.

We are not adopting this estimate as we believe it to be high. This estimate was developed in 2002 to implement a stand alone NDC system from scratch. Since its development, FDA in 2004 issued a final rule requiring drug manufacturers to include Uniform Product Codes (bar codes) with NDC numbers on drug packages. In their final rule, FDA estimated a significant percent of hospitals would voluntarily start to implement bar-coding systems, in order to lower the number of medication errors and to realize other efficiency gains. Consistent with FDA's findings, some commenters noted that hospitals are planning to use bar codes on drugs in the future. When use of these codes is adopted, hospitals will be able to take the NDC from the bar code when billing Medicaid, minimizing the cost of implementing this provision.

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 only a few States will apply. Therefore, we believe this requirement to be exempt as specified at 5 CFR 1320.3(c)(4). We believe the total estimated annual burden for this rule is 84,492 hours.

OMB No.	Requirements	Number of respondents	Number of burden hours	Total annual burden
0938-0578	447.510	550 Drug Manufacturers	31 hours per quarter	68,200 hours.
None	447.520	20,000 Physicians	15 seconds per claim	16,292 hours.
None/Exempt	447.520(c)	Less than 10 States	NA	NA.
Total Annual Burden	84,492 hours.

We have submitted a copy of this final 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-FC] 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-FC, katherine_astrich@omb.eop.gov. Fax (202) 395-6974.

Comments and Responses on Collection of Information Requirements

A. Section 447.510 Requirements for Manufacturers

Comment: Some commenters stated that CMS greatly underestimated the burden on pharmaceutical manufacturers, including manufacturers that are small businesses, to implement the additional reporting requirement. Commenters asserted that the burden would be significant to implement a new methodology for AMP calculations while quickly implementing monthly reporting of AMP and quarterly reporting of both customary prompt pay discounts and nominal prices. Commenters did not provide revised estimates of the increased hourly annual burden on manufacturers. They believed that CMS' estimated 31 hours per quarter is low by several hundred hours. Some commenters noted that pharmaceutical companies must pay to modify their drug price reporting systems, hire and train additional personnel to meet the reporting requirements, change operating procedures and government pricing systems, and dedicate additional employees to Medicaid price reporting.

Response: Because the comments contained general estimates, but did not provide adequate documentation of the estimates of burden on manufacturers, we have no basis to revise the estimates; therefore, we have retained the same estimates in the final rule.

Comment: One commenter asserted that the estimated start-up cost per manufacturer to implement the rule significantly exceeds the \$50,000 estimate stated in the proposed rule. The commenter suggested that CMS should conduct industry surveys on implementation costs before making such proposals.

Response: The public comment process, of which this comment is a part, is intended to provide an opportunity for interested parties to submit additional information for us to consider before we finalize the estimates. We are not required to conduct a survey and, given the timeframe for issuance of this rule mandated by the DRA, do not have the time and resources to do so.

Comment: One commenter stated that completing monthly AMP data will be very demanding, especially for smaller manufacturers. The commenter further

explained that this burden is increased because the monthly AMP data will be collected using an internet-based system that requires manual data entry by the manufacturer rather than capturing data from an existing system. The commenter further asserted that this will have a major impact to manufacturers.

Response: The commenter did not document the additional burden on manufacturers. We continue to believe that the estimates from the proposed rule best represent the costs that will be incurred by manufacturers. The new data collection system offers two types of data transmission, on-line data entry and file transfer to accommodate the manufacturers that use a file transfer. The new Web-based data collection method should not place any additional burden on manufacturer's existing systems.

Comment: Another commenter asserted that the approximate \$50,000 start-up cost per drug manufacturer appears quite low and that most of their larger pharmaceutical manufacturing clients have already spent more than this amount. The commenter further stated that the \$50,000 start-up estimate does not include the ongoing impact of additional resources required to oversee the twelve additional annual submissions required by monthly AMP reporting and inclusion of authorized generics in AMP and best price.

Response: Our estimate includes the costs to hire one full-time employee (FTE) to undertake the new reporting requirements for larger manufacturers and one half FTE costs for small manufacturers; therefore, we have retained the same estimated ongoing burden in the final rule.

Comment: The commenter believed that the start-up burden for complying with the requirements of the proposed rule of \$50,000 and 208 hours greatly underestimate the costs of developing a system for allocating bundled sales. The commenter further suggested redefining a bundled sale and how such a sale should be treated for purposes of determining AMP and best price.

Response: The requirement for allocating discounts for bundled sales is not new with this regulation. Further discussion of the requirements for bundled sales is discussed earlier in this preamble.

Comment: Commenters asked about how customary prompt pay discounts and nominal pricing data is to be reported and noted that they believe that these new data reporting requirements will have a major impact on manufacturers.

Response: We are adopting in the final rule a quarterly reporting policy

and will collect a single dollar value for nominal and customary prompt pay discounts for each drug. This is the minimal collection possible under the statute.

B. Section 447.520 FFP: Conditions Relating to Physician-Administered Drugs

Comment: Many commenters stated that the RIA concerning the collection of NDCs on outpatient hospital claims was seriously understated. These commenters said that most, if not all, hospital patient accounting systems are not designed to capture NDC data. One commenter estimated that a short-term workaround would require 500 to 1,500 hours per hospital to design, build, and test. Other commenters estimated the cost to be from \$.25 to \$10 per dose. One commenter estimated the systems changes necessary to automate the process to cost \$1.7 million over five years per hospital. Several commenters cited the cost estimate of \$200,000 per hospital, or \$1.3 billion for all hospitals, that was presented by the AHA when the final regulation for electronic health data standards for hospitals was under development in 2002. Other commenters estimated annual costs to update systems with ever-changing NDCs to be up to \$200,000 per hospital per year. Many commenters noted that these costs far exceed the projected saving of \$179 million over five years to Medicaid for this provision.

Response: Based on the comments received, we believe that we may have underestimated the costs to outpatient departments of hospitals. The estimates provided by commenters varied widely and commenters offered little documentation to support their estimates. We have revised the Impact Analysis to acknowledge an estimate, cited by some commenters, provided by the AHA on the proposed rule to adopt modifications to standards for electronic transactions published by the Office of the Secretary on May 31, 2002 (67 FR 38047-38048). The AHA estimated that it would cost a minimum of \$200,000 per hospital for hospital outpatient departments to switch from using HCPCS to NDCs. Costs would vary based on the size of the facility. If this estimate is accurate, the present cost, updating this amount by the CPI from 2002 to 2007 the cost would be \$230,000 for the 5,655 hospitals that participate in the Medicaid Program, or a total of \$1.3 billion.

We do not accept that the cost would be this high. We note, as did some commenters, that the Food and Drug Administration is planning on requiring drug manufacturers to place Uniform

Product Codes (bar codes) on drug products which will include the NDC of the drug. Commenters stated that hospitals are transitioning to use the bar codes on the drugs they dispense. Bar coding will allow hospitals to bill Medicaid with NDCs.

Comment: Many commenters reported that outpatient hospital billing systems capture the NDC only for the primary drug. Hospitals often restock with the same drug of a different manufacturer, without recording the NDC for the restocked drug. Similarly, hospitals are increasingly using automated drug dispensing machines, which do not accommodate multiple NDCs. Drug products of multiple manufacturers are used in a single slot in the machines. The machines do not have the capacity to separate drugs by NDC.

Response: We acknowledge that many hospitals will need to change their procedures to comply with this billing requirement. However, the statute requires States to collect utilization data with respect to covered outpatient drugs in order to identify the manufacturer of the drug to secure rebates.

Comment: Several commenters raised other technical difficulties with recording an accurate NDC on the claim. These include the complexity of translating from units purchased to the amount of the drug dispensed and how to track and record multiple NDCs when a drug administered is comprised of multiple drugs or the same drug from multiple manufacturers; for example, with compounded drugs or injectible drugs.

Response: We recognize that many hospitals will need to institute new procedures to obtain the information with respect to covered outpatient drugs that is required by the statute for billing Medicaid agencies.

Comment: Several commenters noted that the requirement for billing using NDC codes would apply only to Medicaid patients, but that the clinicians delivering the medications do not know the source of payment for patients.

Response: We understand from the comments received that hospitals may need to change procedures to meet this new requirement.

Comment: One commenter said that physician billing systems currently allow for one HCPCS code and cannot accommodate multiple NDCs. The commenter also said that discussions with vendors of billing systems have not offered a solution to accommodate NDCs.

Response: The statute, as revised by the DRA, requires States to collect NDCs with respect to covered outpatient drugs so that they can collect rebates from drug manufacturers. Physician offices and their vendors may need to revise systems as necessary to comply with this new requirement.

Comment: One commenter stated that the claims processing system in the Medicaid agency in his State is incapable of processing outpatient pharmacy claims billed with the NDC, so that his hospital would incur additional costs, but it would not yield additional revenue to Medicaid.

Response: The statute requires States to implement this provision or lose FFP for the drugs administered. The statute requires States to collect NDCs with respect to covered outpatient drugs in order to identify manufacturers and secure rebates. If a State cannot implement the provision, it may request a waiver from the Secretary until the State can come into compliance.

Comment: Several commenters believed that the Regulatory Impact Statement should reflect costs to State Medicaid Agencies for outreach and education of providers concerning this requirement.

Response: We agree that States will incur some costs for outreach and education of physicians and outpatient hospital staff. We have not included State administrative costs. We note again, as we did in the proposed rule, that States will save considerably more from this regulation than the costs they will incur to implement it.

VI. Response to Comments

Because of the large number of public comments we normally receive on **Federal Register** documents, we are not able to acknowledge or respond to them individually. We will consider all comments we receive by the date and time specified in the **DATES** section of this preamble, and, when we proceed with a subsequent document, we will respond to the comments in the preamble to that document.

VII. Regulatory Impact Analysis

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 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). An 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 will save \$8.4 billion over the next 5 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 final rule with comment 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

STATE AND FEDERAL SAVINGS OVER 5 YEARS—Continued

[In millions]

DRA section and provision	FFY Federal State	2007	2008	2009	2010	2011	2007–11 total savings
Section 6003—Reporting of Authorized Generics for Medicaid Rebates	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	1,209	1,310	4,929
	State	350	568	801	865	935	3,519
	Total	843	1,362	1,924	2,074	2,245	8,448

All savings estimates were developed by the Office of the Actuary (OACT) in CMS. We note that the CBO, 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 developed by CMS' OACT were applied to project Medicaid prescription drug spending developed for the President's fiscal year 2007 budget. Savings were phased in over 3 years to allow for implementation lags. On the previous chart, the estimate for FFY 2007 through FFY 2010 includes \$5 million for the RPS.

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—were developed by CMS' OACT and 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 will be small as they involve changes in work processes rather than new activities. The resulting program savings will be many times these costs.

The RFA requires agencies to prepare a regulatory flexibility analysis and 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 substantial 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 SBA'S size standards, drug manufacturers are small businesses if they have fewer than 500 employees (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 will have a small impact on small drug manufacturers. The rule will 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 will 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. Because drug manufacturers provide nominal prices and customary prompt pay discounts, we believe that these figures are available in the manufacturers' existing data systems and do 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 rule will affect the level of rebates due from manufacturers. The DRA provides that customary prompt pay discounts be excluded from AMP. This will 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 will cost manufacturers up to \$160 million (two percent of \$8 billion in rebate payments annually). In this rule, we also will remove sales to PBMs and nursing home pharmacies from AMP as well as provide manufacturers the option to exclude hospital outpatient sales if information is insufficient to accurately identify sales of drugs to hospitals used in the outpatient department. We have been told by industry representatives that nursing home pharmacies and hospitals receive larger discounts than other sectors, thus potentially resulting in an increase in AMP from these changes. Likewise, some commenters believe that the exclusion of PBM sales will increase AMP. However, because we have no independent data on the cost of drugs to these entities, we cannot quantify the

effect of these provisions other than to say that we have been told by the industry that it will increase rebates owed by drug manufacturers. Public comments and responses specifically regarding small businesses including drug manufacturers are discussed under "Comments and Responses on the Regulatory Impact 6. Effects on Small Business Entities."

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 (www.sba.gov/size/sizetable2002.html). The SBA estimates that there are about 18,000 small pharmacies. These pharmacies will 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 will 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 will provide States two new data points to use to set payment rates. After their release in January 2007, States may use AMP and retail survey prices in their payment methodologies when they are released. 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. Public comments and responses specifically regarding small businesses including retail pharmacies are discussed under "Comments and Responses on the Regulatory Impact 6. Effects on Small Business Entities." The analysis in this section, together with the remainder of the preamble and the regulatory impact analysis, constitutes a Final Regulatory Flexibility Analysis (FRFA) for purposes of compliance with the RFA, section 605.

According to the SBA's size standards, physician practices are small businesses if they have revenues of \$9 million or less in 1 year (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 will 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 will 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 (Calendar Year 2004 Medicare Carrier Claims Data in the National Claims History extract). We believe most of the Medicaid beneficiaries who receive physician-administered drugs are also in Medicare because of the severity of the medical conditions of people who require these drugs. We then assume that it will take 15 seconds per claim. Multiplying 3,910,000 by 15 seconds equals 58,650,000 seconds or 16,292 hours (58,650,000/3,600 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 will be under 9 cents. Calculated another way, the annual cost per physician practice will 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 (www.sba.gov/size/sizetable2002.html). As with physician practices, outpatient units of hospitals will need to include NDCs on claims for physician-administered covered outpatient drugs. Outpatient hospital claims for physician-administered drugs are included in the 3,910,000 annual total claims discussed in the previous paragraph. In addition we believe that most hospitals will need to change their billing systems to capture NDC codes. In 2002 when CMS proposed to rescind the use of NDCs for drug claims submitted by institutional providers, the AHA estimated that these changes would cost hospitals a minimum of \$200,000 each (\$230,000 in 2007 adjusted by the CPI). Because this estimate is not documented, CMS is not adopting it for purposes of this impact analysis; however, we do accept that hospitals will incur some costs. We do not have an adequate basis to estimate this cost, however, several commenters noted that hospitals are in the process of instituting bar codes on drugs that contain the NDC. This will minimize the cost for hospitals to implement this provision. 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 will be under nine 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 will impact small rural hospitals to the extent that billing systems will need to be changed to capture NDCs on claims for drugs administered by physicians in the outpatient department. We acknowledge the AHA estimate of \$200,000 per hospital for these changes (\$230,000 in 2007 adjusted by the CPI), but we have no documentation to analyze or verify this estimate. We also believe that hospitals can minimize the cost to the extent that they use bar codes on the drugs they dispense, as this will identify the NDC of the drug needed to bill Medicaid.

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 1 year of \$100 million in 1995 dollars, updated annually for inflation. That threshold level is currently approximately \$125 million. This rule will 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: Effects on Drug Manufacturers) falls far below the threshold and we anticipate this rule will save States \$3.5 billion over the five-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 rule will 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 will 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 will 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 will 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 will 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 will 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 will cost manufacturers up to \$160 million (two percent of \$8 billion in rebate payments annually). In this rule, we also will remove sales to PBMs and nursing home pharmacies from AMP and allow drug manufacturers to exclude sales to outpatient

departments of hospitals when data is not available to separate out drugs administered in the outpatient department from the hospital as a whole. We have been told by industry representatives that PBMs, nursing homes and hospital pharmacies receive larger discounts than other sectors. If this information is accurate, removing these prices will increase AMP. However, because we have no independent data on the cost of drugs to these entities, we cannot quantify the effect of this provision other than to say that we believe it will 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 5-year State savings of over \$3.5 billion. State administrative costs associated with this regulation are minor as States currently pay at or below the 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 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 will 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, total retail prescription sales in the United States, including chain drug stores, independent drug stores, and supermarkets totaled about \$200 billion

in 2006 (www.nacds.org/wmspage.cfm?parm1=507). Based on comments, we decided to exclude mail order and reflect only community-based retail sales in the total sales because the savings will principally come from retail pharmacies. Assuming, conservatively, that sales will rise at only five percent a year, 2007 sales would be over \$210 billion and 2011 sales over \$255 billion, for a 5-year total of \$1160 billion. Dividing the \$8 billion projected Medicaid savings by the \$1,160 billion results in a loss in revenue of less than one percent. Thus, the effect of this rule will be to reduce retail prescription drug revenues by less than one percent, on average. Actual revenue losses will be even smaller because pharmacies have the ability to mitigate the effects of the 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 received general comments that these pharmacies will be greatly impacted by the provisions of this rule; however, we did not receive documented estimates of these effects. Because of the lack of evidence as to the true effect, we have retained our prior conclusion that this proposed rule is likely to have a “significant impact” on some pharmacies.

4. Effects on Physicians

This regulation will 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 will affect hospitals with outpatient departments that provide and bill Medicaid for physician-administered covered outpatient drugs. As discussed above, hospitals with outpatient departments would need to include the NDC on claims for such

physician-administered drugs. We believe this will need to be done manually or will require a one-time systems change. We believe the cost of adding the NDC to each claim would be small. We are not able to estimate the cost to make needed systems changes but note that the AHA has estimated this to be at least \$200,000 per hospital (\$230,000 in 2007 adjusted by the CPI). 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 could also increase the amount of drug rebates that manufacturers will pay as a result of removing customary prompt pay discounts and nursing home sales from AMP, which is used in the rebate calculation. To the extent that PBMs are also excluded from best price, the amount of rebates could decrease. The exclusion of customary prompt pay discounts will cost manufacturers up to \$160 million (two 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 will 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. 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 could 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 may 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 covered outpatient 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 to manually include the NDC on the claim will be under nine 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. Other clarifications of AMP may also raise AMP and result in higher rebate payments. 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.
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. Changes in hospital billing systems will be needed for many hospital outpatient departments. 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 final 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 and 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, mail order pharmacies, and hospital outpatient departments. We chose to exclude sales to PBMs and nursing home pharmacies and to allow drug manufacturers to include or exclude sales to hospital outpatient departments depending on the availability of information to document these sales.

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 not required and it would create a financial burden on manufacturers that was not intended by section 6001 of the DRA.

We considered whether and how to provide for manufacturers to “smooth” the AMP data to account for lagged discounts and other changes to monthly sales. We proposed to allow manufacturers to rely on estimates regarding the impact of their lagged price concessions when calculating monthly AMP. We also requested comments on the possible use of a 12-month rolling average. Many commenters asked for a 12-month rolling average as is used for Medicare Part B. Other commenters suggested that we allow manufacturers to use a four quarter rolling average. We have incorporated the 12-month rolling average in the final rule.

We considered adding other entities to those that may receive drugs at

nominal prices and have those sales excluded from best price. 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 not have a significant impact on how States pay for drugs.

We considered various methods for determining outlier prices in order to avoid the use of such prices in the FUL calculation and to ensure sufficient national supply. We proposed to set the FUL on the lowest AMP that is not less than 30 percent of the next highest AMP for the drug. Based on comments, we considered substituting a greater percentage difference, expanding outliers to include drugs with AMPs above the lowest but below the next highest AMP by a set percentage, and using market share in determining outliers. We decided to change the outlier policy to set the FUL on the AMP that is not lower than 40 percent of the next highest AMP.

D. Other Requirements in the Regulatory Flexibility Act

The RFA lists five general requirements for a FRFA and four categories of burden-reducing

alternatives. We know of no relevant Federal rules that duplicate, overlap, or conflict with the final rule. The preceding analysis, together with the rest of this preamble, addresses all these general requirements.

We have not, however, adopted any of 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 final 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 FFY 2007 TO FFY 2011
[In millions]

Category	Transfers	Discount rate (percent)	From whom to whom?
Total Federal Savings	\$3,927.3	7	Reduction of transfers from the Federal Government to State Governments.
	4,459.0	3	
	4,929.0	0	
Federal Annualized Monetized Transfers (Millions/Year).	957.8	7	
	973.6	3	
	985.8	0	
Total State Savings	2,803.6	7	Reduction of transfers from State Governments to Retail Pharmacies and increased transfers from Drug Manufacturers to the State Governments.
	3,183.3	3	
	3,519.0	0	
State Annualized Monetized Transfers (Millions/Year)	683.8	7	
	695.1	3	
	703.8	0	

F. Conclusion

We estimate savings from this regulation of \$8.4 billion over 5 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.

Comments and Responses on the Regulatory Impact

A. Overall Impact

We have retained most of the original estimates of burden; however, we have updated our impact analysis from what was presented in our December 22, 2006 proposed rule. Our update reflects responses to public comments and improvements to the analysis based on additional information.

B. Anticipated Effects

1. Effects on Drug Manufacturers

Comment: Commenters said that the proposed rule's treatment of PBM rebates will lead to lower AMPs which will reduce the amount of rebates paid by manufacturers for some single source drugs. Commenters further asserted that they do not have access to the data needed to estimate this revenue reduction, but they are confident the losses will be significant.

Response: In this final rule in § 447.504(i), we have excluded PBM rebates, discounts or other price concessions from the determination of AMP and best price, except for purchases through the PBMs' mail order pharmacies. Excluding PBM rebates and price concessions may affect AMP, and, thereby, rebates. However, we do not have information on how manufacturers currently calculate AMP. In its report, the OIG cited inconsistent treatment of PBM rebates by manufacturers in calculating AMP. Therefore, we have no data to estimate the impact of excluding PBM rebates and cannot conclude that the effect would be significant.

2. Effects on State Medicaid Programs

Comment: One commenter expressed concern that States will have insufficient time to prepare to implement the final regulations. States may need to make revisions in the Medicaid Management Information System and manual processes to implement the provisions. States may not have enough staff and funding to meet the deadline. The commenter further stated that the 2006 AMP data received by the States was inaccurate and insufficient to make firm policy decisions. Any changes that are needed to revise the State Medicaid plan or reimbursement structure will take considerable time.

Response: We emphasize that the FUL is the only reimbursement change that States are required to address. States may need to adjust payments to stay

below the FUL in the aggregate. Unless otherwise indicated, these regulations are effective on October 1, 2007 and any adjustments will not be necessary until after CMS issues any revised FULs.

Comment: One commenter suggested that the State savings estimate in the proposed rule is overstated unless it took into account that reimbursement is lower than the FUL in those States that have State MAC programs. This would negate some or most of the savings projected in the proposed rule.

Response: The savings estimates for section 6001 of the DRA were derived from simulations of the new FULs compared to States' current reimbursement levels, including use of State MACs; therefore, we do not believe the savings estimates are overstated.

Comment: One commenter expected that the FUL will be below the average retail acquisition cost and that States will have to increase the dispensing fee to offset the reimbursement reduction expected for pharmacies to ensure accessibility to the drugs. State financial support for increased dispensing fees will subsequently decrease the State savings projected in the proposed rule.

Response: We believe that the new methodology for determining AMP will provide for adequate reimbursement and assure the availability of drugs at or below the FUL price for pharmacies.

3. Effects on Retail Pharmacies

Comment: One commenter stated that the FUL estimates should be published so that commenters can thoroughly and accurately analyze the impact of the proposed rule on the pharmaceutical supply chain and on retail pharmacies, especially those in low-income areas that serve a large percentage of Medicaid beneficiaries. The commenter requested that CMS provide the FUL and extend the comment period by a minimum of 60 days.

Response: We share these concerns and we are analyzing the data to ensure that the new FULs will allow States to reimburse generic drugs adequately and appropriately. We continue to believe that the new FUL will be sufficient to allow all pharmacies to purchase most drugs at or below the FUL price. Additionally, we believe that it is important for us to be sure the data is complete and accurate prior to its release. In response to the commenters' request to extend the comment period, we do not believe that we can reopen the comment period and meet the requirement in the DRA that we must promulgate a regulation by July 1, 2007.

Comment: Many commenters indicated that the drug reimbursement

levels will be inadequate under the revised formula used to establish the FUL. With inadequate reimbursement anticipated, the independent pharmacies asserted that they would go out of business, leaving Medicaid beneficiaries and other patients with limited access to drugs and resulting in loss of jobs for employees. Other commenters stated that pharmacy profit margins will be reduced so patient drug therapy, medication counseling, prescription services in a single location, home drug delivery, transportation services to the pharmacy, prescription services on holidays and translation services will be eliminated. One commenter stated that it may be necessary to increase fees for some patients in order to cover losses from Medicaid.

Response: We are analyzing the FULs data to ensure that it will allow States to provide adequate reimbursement for generic drugs and avoid any serious consequences to the pharmacy community. Additionally, drugs subject to the FUL represent only 8.3 percent of the total drug expenditures under the Medicaid Drug Rebate Program. Medicaid policy allows States to pay above the FULs as long as total expenditures for FULs drugs do not exceed the aggregate FUL amount which is calculated at 250 percent of the relevant AMP. We are confident that FULs calculations for drug reimbursement will allow States to provide adequate reimbursement.

Comment: Many commenters stated that the lack of access to drugs and prescription use services will lead to increased doctor visits, emergency room care, hospital stays and long-term care expenses, resulting in increased costs for Medicaid.

Response: We are continuing to analyze the new FUL to assure that it is sufficient and adequately reimburses community pharmacies. As we have said elsewhere in this regulation, we believe the system for calculating the FUL will permit pharmacies to be reasonably compensated.

Comment: One commenter noted that this rule will be particularly hard on pharmacies that serve Medicaid beneficiaries who suffer from HIV/AIDS which are often pharmacies which receive almost 50 percent of total revenue from Medicaid and participate in the 340B Program. The commenter further stated that even a ten percent cut in Medicaid reimbursement will render these pharmacies non-viable.

Response: We believe that States will ensure that pharmacies serving HIV/AIDS patients on Medicaid will be

compensated adequately to ensure their continued viability.

Comment: One commenter stated that any changes in Medicaid reimbursement may have the unintended consequence of causing Indian health programs that operate in remote rural areas to close.

Response: We believe that the impact of this regulation will be far less than many commenters believe and that States will be able to set appropriate reimbursement rates under the aggregate FULs to allow pharmacies to continue to serve Medicaid and other vulnerable populations.

Comment: Other commenters noted that the impact on long-term care pharmacies and on rural independent pharmacies has not been addressed adequately in the proposed rule. These commenters believed that reimbursement to long-term care pharmacies should remain at the current levels in order for them to be able to afford to provide the needed services. The commenter would like the impact analysis to address long-term care pharmacies independently from retail pharmacies.

Response: We do not have sufficient data to analyze the impact of this regulation on segments such as long-term care of the pharmacy market. However, states will continue to have flexibility to set reimbursement rates. We believe that States are in the best position to set payment levels to appropriately reimburse different sectors of the pharmacy market.

Comment: One commenter stated that if the FUL decreased reimbursement by \$3 to \$4 per prescription, as some have asserted, this reduction will exceed the one percent decreased reimbursement estimated by CMS.

Response: CMS estimates that total reimbursement for drugs will, on average, decline by less than one percent. We derived the \$8 billion five-year savings by dividing it by an estimated \$1,160 billion in total prescription drug revenues for community pharmacies to obtain this figure.

Comment: One commenter noted that analysis in the proposed rule does not take into account decreases in State payments for drugs that are not on the FUL list, which may occur if States use AMP as a reimbursement metric. The commenter suggested that CMS should revise the impact analysis to reflect the projected impact of the use of AMP, rather than AWP, as a reimbursement benchmark for drugs other than those subject to the FUL.

Response: We do not know what changes States may make to reimbursement for drugs not subject to

FULs; therefore, we have no basis to estimate possible savings due to the availability of AMP to States.

Comment: Some commenters believed that the estimate of a one percent loss to retail pharmacies should be revised to only reflect community-based retail pharmacy sales and not mail order sales since there is almost no mail order use in Medicaid.

Response: We have reduced the five-year total sales by \$50 billion to exclude mail order and reflect only community-based retail pharmacy sales because the savings will principally come from retail pharmacies. Even with removing these sales, our original estimate stands; that is, the total loss in the retail prescription drug revenues will be less than one percent, on average.

Comment: Some commenters believed that the reduction to pharmacy reimbursement will exceed the one percent cited. The commenters indicated that retail pharmacy profit ranges from 2.8 percent to 3.6 percent per prescription. Decreasing reimbursement to pharmacies does not change the prices that pharmacies pay to wholesalers or manufacturers or for their costs to support staff and operate stores.

Response: As stated in our prior response, the one percent reduction is to total revenues for drugs to pharmacies, and does not reflect profit levels. We have no data to analyze the effect of these changes on profits.

Comment: One commenter believed that the one percent estimated Medicaid pharmacy revenue reduction for retail pharmacies should be revised to account for the availability of AMP on the Web site which could result in additional reductions to reimbursements to retail pharmacies such as encouraging other non-Medicaid third party payers that represent a majority of the average retail pharmacy business to use the published AMP as a basis for their reimbursement to pharmacies too. Subsequently, this could potentially result in additional reductions of reimbursement to pharmacies beyond Medicaid.

Response: We agree that there is potential for non-Medicaid third party payers to use the published reimbursement methodology established under this rule. However, we do not know if non-Medicaid third party payers will use AMP for reimbursement or what effect it would have on reimbursement levels.

Comment: Another commenter asserted that the published AMP based on a reliable methodology may provide States with a more accurate estimate of prices available to wholesalers, but that

this AMP methodology would not prevent drug manufacturers from continually pricing drugs at a premium.

Response: Neither the DRA or this rule addresses prices set by drug manufacturers.

Comment: One commenter asserted that it is unlikely that pharmacies will have the ability to mitigate the effects of the proposed rule by changing purchasing practices.

Response: We believe that pharmacies will find it in their interest to seek the lower cost drugs.

Comment: One commenter stated that when manufacturer prices are public, the manufacturers will no longer offer better prices to move the market share. In addition, if the manufacturers are forced to lower the prices to certain purchasers, they may need to make up for the loss by raising prices to larger buyers. Public posting of prices would lead to comparable or identical prices and would reduce incentives to offer lower prices because price increases would increase revenues and result in higher reimbursements to retail pharmacies.

Response: We believe that transparency in pricing will introduce competition in the marketplace that will result in more appropriate drug pricing.

Comment: One commenter expressed concern that the private PBMs sector will decrease their reimbursement levels and this could lead to a loss of revenue to pharmacies and cause them to go out of business.

Response: As previously stated, we believe that Medicaid reimbursement will be sufficient to retain access to drugs for Medicaid beneficiaries and that transparency in pricing will introduce competition in the marketplace.

Comment: A few commenters asserted that it is unlikely that most retail pharmacies can make up the estimated loss of pharmacy revenue with increased front-end store sales and sales of non-prescription drug products as these sales are a minority of total sales in most retail pharmacies. In addition, pharmacies would need to invest in larger front-end areas, relocate stores to high visibility areas, add staffing, and make other changes that many pharmacy retailers may not be able to afford or want to do. The commenters said that non-prescription revenue in chain pharmacies is 28 percent of total sales, and only 2 percent of total sales in independent pharmacies.

Response: We agree that we cannot assess the ability of pharmacies to increase non-drug revenue and have removed this language from the impact analysis.

Comment: One commenter asserted that the \$8 billion estimated savings in the RIA will be generated from the reduced reimbursement for multiple source drugs. Savings of \$8 billion out of \$27 billion in spending for generic drugs equates to a 30 percent reduction in reimbursement for generic drugs. Several commenters believed that this change to a lower reimbursement will not cover the pharmacy's acquisition costs of purchasing generic medications.

Response: The new FUL could reduce Medicaid payments to a more reasonable amount and eliminate the opportunity for profits through the reporting of artificially inflated prices. We agree that most of the savings result from lower prices paid for multiple source drugs, as this is what the DRA intended; however, we continue to believe that it is appropriate to compare the savings to overall revenues of drugs to show the impact on pharmacies. As we have said elsewhere in this regulation, we believe the system for calculating FUL will permit pharmacies to be reasonably compensated.

Comment: Many commenters asserted that a reduction of \$8 million in generic drug reimbursement could have a considerable impact on incentives to dispense medications when pharmacies have a choice of dispensing brand versus generic drugs. The commenter believed that pharmacies will receive far less revenue from a generic drug rather than it will with a brand name drug. When brand products are dispensed to Medicaid beneficiaries, they are likely to be paid above the FUL due to a "dispense as written" designation.

Response: The commenters correctly note that a brand name drug in a FUL group is subject to the FUL unless the physician asserts that the brand name drug is medically necessary for the Medicaid beneficiary. States frequently require prior authorization for dispensing a brand name drug; therefore, we do not agree that pharmacists will be able to substitute brand name drugs over generic drugs. Many States also have been requiring the substitution of a generic drug for a brand name drug; therefore, pharmacies do not always have a choice to substitute a brand drug for a generic drug.

Comment: Commenters referred to findings in the GAO report that said the AMP-based FULs would be, on average, 36 percent lower than the average retail pharmacy acquisition cost.

Response: We do not concur with the GAO findings that the AMP-based FUL would be lower than average retail pharmacy acquisition cost. The GAO report looked at drugs subject to the

FUL, which are 8.3 percent of Medicaid expenditures. The GAO also did not remove customary prompt pay discounts or outlier AMPs when calculating FULs as provided in this final rule, or account for the ability of States to set reimbursement levels below or above the FUL as long as expenditures for FUL drugs are less than the aggregate of all FUL prices. We also were not provided the price data used by the GAO. For these reasons, we do not concur with GAO's conclusion.

Comment: Several commenters estimated their losses based on the 36 percent reduction reported in the GAO report.

Response: As noted above, the GAO report only applies to drugs with a FUL which currently accounts for 8.3 percent of Medicaid drug expenditures. We believe that many commenters believed that reimbursement for all generic drugs would be reduced by 36 percent. We also believe that as discussed previously, reimbursement will be sufficient to meet acquisition costs.

Comment: Commenters asserted that States will need to fill the financial gap caused by this rule to avoid pharmacy closings and maintain beneficiary access to community pharmacy services.

Response: We do not believe that States will find that reimbursements under the FUL are insufficient for pharmacies and that they will need to cover a shortfall. We believe that the new FULs methodology sets pharmacy pricing at reasonable levels while allowing States to set reimbursement that is based on true prices, thus ensuring that taxpayers do not overpay for prescription drug benefits provided to Medicaid recipients.

Comment: Several commenters stated that independent pharmacies have assisted CMS in providing outreach and information to Medicare Part D beneficiaries in their communities and it is inappropriate to decrease their Medicaid reimbursement after the pharmacies provided support to CMS. These commenters further stated that their pharmacies are still recovering and experiencing losses from Medicare Part D implementation due to low reimbursement and delays in payment.

Response: We recognize that community pharmacy partners provided considerable assistance to Medicare beneficiaries and helped make the implementation of Medicare Part D a success. Nevertheless, the DRA requires CMS to calculate the FULs based on 250 percent of the AMP for Medicaid outpatient drugs.

Comment: One commenter said that this rule will have a far greater impact on pharmacies than implementation of

the prescription drug sections of the Medicare Part D Program.

Response: We recognize that the DRA and this rule will result in lower reimbursement for some drugs. However, as discussed previously, we believe that pharmacy reimbursement will be adequate for pharmacies to continue to serve Medicaid beneficiaries.

4. Effects on Physicians

See discussion under "V. Collection of Information Requirements for Effects on Physicians."

5. Effects on Hospitals

See discussion under "V. Collection of Information Requirements for Effects on Hospitals".

6. Effects on Small Business Entities

Comment: One commenter believed that CMS grossly underestimated the administrative cost for small pharmaceutical manufacturing businesses participating in the Medicaid Drug Rebate Program to implement the additional reporting requirements. The commenter did not provide an estimate of the hourly annual burden but asserted that small pharmaceutical companies will be required to spend hundreds of thousands of dollars to modify their drug price reporting systems and hire additional personnel in order to meet the additional reporting requirements.

Response: The commenter did not document the estimates provided; therefore, we have no basis to revise the estimated burden in the rule. We do not believe that the burden will be greater for small drug manufacturers than for other drug manufacturers. The data required for monthly reporting of AMP and reporting for customary prompt pay discounts and nominal prices should already exist in the manufacturer's accounting systems.

Comment: Several commenters asked that CMS revise the overall one percent impact on retail pharmacy revenues and quantify an impact specifically on small, predominately independent pharmacies, especially rural independents since small business pharmacies serve a disproportionate number of Medicaid patients and have significantly lower revenues than the broader retail pharmacy community. This could account for the higher cost of doing business in rural areas than in other areas. One commenter noted that data from a recent nationwide survey found that Medicaid accounted for approximately 12 percent of all prescriptions filled by rural pharmacies. (See Grant Thornton LLP, "National

Study to Determine the Cost of Dispensing Prescriptions in Community Retail Pharmacies” (January 2007)).

Response: We recognize that pharmacies with a higher Medicaid prescription volume relative to their overall prescription volume could experience a greater financial impact. However, the method for setting FULs was established by the DRA and we do not have data by subgroups of pharmacies, such as small independent or rural pharmacies, to separately analyze the impact for these segments.

Comment: Some commenters raised the concern that small rural pharmacies will be forced to go out of business as a result of inadequate reimbursements for all patients. The commenters believed a reduction in beneficiary access to prescriptions in rural areas could result in higher costs for other Medicaid services, such as hospitalizations, physician office visits and emergency room visits. The commenters further suggested that CMS provide a public opportunity for small businesses to comment on the revised analysis.

Response: In the proposed rule, we noted that we did not have data to allow us to quantify the effect of this rule on small rural pharmacies. We further requested information to help us better assess those effects before we make final decisions. The commenters did not provide data to allow us to assess separately the burden on pharmacies that are small businesses. Nevertheless, as previously stated, we believe that reduction to reimbursement to pharmacies will not force them to go out of business.

Comment: One commenter suggested that the one percent retail revenue reduction in the proposed rule be revised to comply with the Small Business Regulatory Enforcement Fairness Act (SBREFA).

Response: We believe the estimate complies with the provisions under the SBREFA. It should also be noted that the commenter did not provide specific information as to how the estimated reduction does not comply with this law.

Comment: Several commenters stated that we should analyze the impact on traditional retail pharmacies and institutional pharmacies separately. The institutional pharmacy industry is composed of hundreds of small pharmacies in addition to national companies. These commenters suggested that the number of small business pharmacies should be expanded to include pharmacies in retail chains because these pharmacies operate as independent pharmacies and

must generate enough revenue to cover costs of purchasing, maintaining, and dispensing their pharmaceutical inventory. The commenters estimated that the average total sales in traditional pharmacies are about \$4.5 million per year.

Response: We used the SBA’s size standards for a retail pharmacy of \$6.5 million or less in revenue per year (<http://www.sba.gov/size/sizetable2002.html>). The SBA estimates that there are about 18,000 small pharmacies. We do not believe it is appropriate to expand the number of small business pharmacies to include pharmacies that are not consistent with this standard.

Comment: Several commenters suggested that the final rule should exempt small retail pharmacies from the new reimbursement formula, create a separate reimbursement formula for small retail pharmacies, or exempt pharmacies if their Medicaid business exceeds ten percent.

Response: The law specifies that the FUL is to be set at 250 percent of the lowest AMP and does not provide the Secretary the authority to exempt small pharmacies.

7. Effects on Other Issues

Comment: Several commenters stated that pharmaceutical manufacturers are not impacted by the proposed rule and that Medicaid would achieve more savings if the pharmaceutical manufacturers would offer lower drug pricing as they do in other countries. The commenters also suggested that CMS should mandate more controls on drug payments to manufacturers and issue regulations that require lower payments to drug manufacturers.

Response: The purpose of this regulation is to implement the Medicaid drug pricing provisions of the DRA. These comments are outside the scope of this rulemaking.

Comment: Several commenters suggested that pharmacies under Medicaid and Medicare should have the same negotiating price and contract opportunities that HMOs and PBMs have under Medicare Part D. HMOs and PBMs negotiate cheaper drug prices, insist on mail order for maintenance drugs and sign yearly contracts where the net prices are at least ten times lower than the prices offered to independent pharmacies.

Response: This comment is not within the scope of this rulemaking document.

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 amends 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)(15) 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 through § 447.334 [Removed]

■ 4. Sections 447.331 through 447.334 are removed.

■ 5. 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, drugs of different types (that is, at the nine-digit National Drug Code (NDC) level) or another product 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 total dollar value of the units of all drug sold under the bundled arrangement. For bundled sales where multiple drugs are discounted, the aggregate value of all the discounts in the bundled arrangement shall be proportionally 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 or service 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, 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 (EAC) 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), including an authorized generic drug. It includes a drug product marketed by any cross-licensed producers, labelers, or distributors operating under the NDA and a covered outpatient drug approved under a product license approval (PLA), establishment license approval (ELA) or antibiotic drug approval (ADA).

Lagged price concession means any discount or rebate that is realized after the sale of the drug, but does not include customary prompt pay discounts.

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 (that is, the 9-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 ten percent of the AMP in the same quarter for which the AMP is computed.

Noninnovator multiple source drug means (1) a multiple source drug that is not an innovator multiple source drug or a single source drug, (2) a multiple source drug that is marketed under an abbreviated NDA or an abbreviated antibiotic drug application, or (3) a drug that entered the market before 1962 that was not originally marketed under an original NDA.

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 biological license application, PLA, ELA, or ADA.

States means the 50 States and the District of Columbia.

§ 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 paid to the manufacturer for the drug in the United States by 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 timeframe and consistent with customary business practices for payment.

(d) *Net sales* means quarterly gross sales revenue less cash discounts allowed, except customary prompt pay discounts extended to wholesalers, and all other price reductions (other than rebates under section 1927 of the Act or price reductions specifically excluded by statute or regulation) which reduce the amount received by the manufacturer.

(e) *Retail pharmacy class of trade* means any independent pharmacy, chain pharmacy, mail order pharmacy, or other outlet that purchases 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 those entities in the retail pharmacy class of trade) to which the manufacturer sells 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 the following sales and associated rebates, discounts, or other price concessions—

(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) Direct and indirect sales to hospitals, where the drug is used in the outpatient pharmacy, except those sales that cannot be identified with adequate documentation as being used in the outpatient pharmacy for outpatient use (for example hospital outpatient department, clinic, or affiliated entity);

(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) Sales including discounts, rebates, or other price concessions provided to pharmacy benefit managers (PBMs) for their mail order pharmacy purchases;

(7) Sales directly to patients;

(8) Sales to outpatient facilities (for example, clinics, surgical centers, ambulatory care centers, dialysis centers, and mental health centers);

(9) Sales to mail order pharmacies;

(10) Sales to home infusion providers;

(11) Sales to specialty pharmacies;

(12) Sales to home health care

providers;

(13) Sales to physicians;

(14) 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; and

(15) Sales of drugs reimbursed by third party payers including the Medicare Part D Program, a Medicare

Advantage prescription drug plan (MA-PD), a Qualified Retiree Prescription Drug Plan under section 1860D-22(a)(2) of the Act, State Children's Health Insurance Program (SCHIP), State pharmaceutical assistance programs (SPAPs), health maintenance organizations (HMOs) (including managed care organizations (MCOs)) that do not purchase or take possession of drugs, TRICARE Retail Pharmacy Program (TRRx), 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 section 1927(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) Direct and indirect sales to hospitals, where the drug is used in the inpatient setting or in the outpatient pharmacy for outpatient use where the sales cannot be identified with adequate documentation;

(5) Sales to HMOs (including MCOs, and HMO/MCO-operated pharmacies) that purchase or take possession of drugs;

(6) Sales to long-term care facilities, including nursing facility pharmacies, contract pharmacies for the nursing facility where these sales can be identified with adequate documentation, and other entities where the drugs are dispensed through a nursing facility pharmacy, such as assisted living facilities;

(7) Sales to hospices (inpatient and outpatient);

(8) Sales to veterinarians;

(9) Sales to prisons;

(10) Sales outside the 50 States and the District of Columbia;

(11) Sales to State, county, and municipal entities;

(12) Sales to patient assistance programs;

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

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

(15) Manufacturer coupons redeemed by a consumer, agent, pharmacy or another entity acting on behalf of the manufacturer, but only to the extent that the full value of the coupon is passed on to the consumer and the pharmacy, agent, or other entity does not receive any price concession;

(16) Manufacturer vouchers;

(17) Manufacturer-sponsored drug discount card programs;

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

(19) Bona fide service fees;

(20) Customary prompt pay discounts extended to wholesalers;

(21) Returned or replaced goods when accepted or replaced in good faith;

(22) Discounts, rebates, or other price concessions to PBMs, except for their mail order pharmacy's purchases.

(23) Associated rebates, discounts, or other price concessions to third party payers including the Medicare Part D Program, an MA-PD, Qualified Retiree Prescription Drug Plan under section 1860D-22(a)(2) of the Act, SCHIP, SPAPs, HMOs (including MCOs that do not take possession of drugs) the TRICARE Retail Pharmacy Program, and Medicaid Programs; and

(24) Rebates under the national rebate agreement or a CMS-authorized State supplemental rebate agreement paid to State Medicaid Agencies under section 1927 of the Act.

(i) *Further clarification of AMP calculation.* (1) AMP includes cash discounts except customary prompt pay discounts extended to wholesalers, free goods that are contingent on any purchase requirement, volume discounts, chargebacks, incentives, administrative fees, service fees, distribution fees, (except bona fide service fees), and any other rebates, discounts or other price concessions, 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) Quarterly AMP is calculated as a weighted average of monthly AMPs in the quarter.

(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 rebates, 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 provision of health care.

(c) *Prices included in best price.* Except with respect to those prices identified in paragraph (d) of this section, best price for covered outpatient drugs includes the following prices and associated rebates, discounts, or other price concessions that adjust prices either directly or indirectly—

(1) Prices to wholesalers;

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

(3) Prices to providers (for example, 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, sold by the primary manufacturer in accordance with § 447.506(d) of this subpart;

(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; and

(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.

(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 section 1927(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 provided to a designated SPAP;

(4) Any depot prices 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 under the national rebate agreement or a CMS-authorized supplemental rebate agreement paid to State Medicaid Agencies under section 1927 of the Act;

(7) Prices negotiated under a manufacturer-sponsored drug discount card program;

(8) Manufacturer coupons redeemed by a consumer, agent, pharmacy or another entity acting on behalf of the manufacturer; but only to the extent that the full value of the coupon is passed on to the consumer and the pharmacy, agent, or other entity does not receive any price concession;

(9) Goods provided free of charge under a manufacturer's 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;

(12) Bona fide service fees; and

(13) PBM rebates, discounts, or other price concessions except their mail order pharmacy's purchases or where such rebates, discounts, or other price concessions are designed to adjust prices at the retail or provider level.

(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 package size, 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 § 447.508 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, an authorized generic drug means any drug sold, licensed, or marketed under an NDA approved by the FDA under section 505(c) of the FDCA; and marketed, sold, or distributed under a different labeler code, product code, trade name, trademark, or packaging (other than repackaging the listed drug for use in institutions) than the brand 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 sales of this drug in its AMP only when such drugs are being sold by the manufacturer holding title to the original NDA directly to a wholesaler.

(c) *Inclusion of authorized generic drugs in best price.* A manufacturer holding title to the original NDA must include best price of an authorized generic drug in its computation of best price for a single source or innovator multiple source drug during a rebate period to any manufacturer, wholesaler, retailer, provider, HMO, non-profit entity, or governmental entity in the United States, only when such drugs are being sold by the manufacturer holding title to the original NDA.

§ 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 for each covered outpatient drug at the nine-digit NDC level, provided to all wholesalers 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 of single source and innovator multiple source drugs to the entities listed in § 447.508(a) of this subpart for the rebate period.

(b) *Reporting revised quarterly AMP, best price, customary prompt pay discounts, or nominal prices.* (1) 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.

(2) A manufacturer must report revisions to AMP, except when the revision would be solely as a result of data pertaining to lagged price concessions.

(c) *Base date AMP report.* (1) A manufacturer may report a revised base date AMP to CMS within the first four full calendar quarters following [OFR: insert publication date of the final rule].

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

(ii) A manufacturer may choose to recalculate base date AMP on a product-by-product basis.

(iii) A manufacturer must use actual and verifiable pricing records in recalculating base date AMP.

(d) *Monthly AMP—(1) Definition of Monthly AMP.* 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.* Monthly AMP should be calculated

based on the methodology in section 447.504 of this subpart, except the period covered should be based on monthly, as opposed to quarterly, sales. The monthly AMP should be calculated based on the weighted average of prices for all the manufacturer's package sizes of each covered outpatient drug sold by the manufacturer during a month. 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. Monthly AMP should be calculated based on the best data available to the manufacturer at the time of submission. In calculating monthly AMP, a manufacturer must estimate the impact of its lagged price concessions using a 12-month rolling average to estimate the value of those discounts.

(3) *Timeframe for reporting revised monthly AMP.* A manufacturer must report to CMS revisions to monthly AMP for a period not to exceed 36 months from the month in which the data were due.

(4) *Exception.* A manufacturer must report revisions to monthly AMP, except when the revision would be solely as a result of data pertaining to lagged price concessions.

(5) *Terminated products.* A manufacturer must not report a monthly AMP for a terminated product beginning with the first month after the expiration date of the last lot sold.

(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);

(3) An individual other than a CEO or CFO, who has authority equivalent to a CEO or a CFO; or

(4) An individual with the directly delegated authority to perform the certification on behalf of an individual described in subsections (1) through (3).

(f) *Recordkeeping requirements.* (1) A manufacturer must retain records (written or electronic) for ten 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 ten-year timeframe applies to a manufacturer's quarterly and monthly submissions of pricing data, as well as any revised pricing data subsequently submitted to CMS.

(2) A manufacturer must retain records beyond the ten-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) of this section 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) EAC 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 (or by an electronic alternative means approved by the Secretary) 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 its 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 meet the criteria in paragraph (a)(1)(i) of this section.

(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 AMP (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, the AMP of the lowest priced therapeutically and pharmaceutically equivalent drug that is not less than 40 percent of the next highest AMP will be used to establish the FUL.

(3) When the FUL group includes only the brand name drug and the first new generic or authorized generic drug which has entered 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 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: June 27, 2007.

Leslie V. Norwalk,
Acting Administrator, Centers for Medicare & Medicaid Services.

Approved: June 29, 2007.

Michael O. Leavitt,
Secretary.

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