DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Part 447

[CMS–2345–FC]

RIN 0938–AQ41

Medicaid Program; Covered Outpatient Drugs

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

ACTION: Final rule with comment period.

SUMMARY: This final rule implements provisions of the Patient Protection and Affordable Care Act of 2010, as amended by the Health Care and Education Reconciliation Act of 2010 (collectively referred to as the Affordable Care Act) pertaining to Medicaid reimbursement for covered outpatient drugs (CODs). This final rule also revises other requirements related to CODs, including key aspects of their Medicaid coverage and payment and the Medicaid drug rebate program.

DATES: *Effective Date:* The final rule is effective on April 1, 2016.

Compliance Date: State Medicaid Agencies must comply with the requirements of § 447.512(b), § 447.518(a), and § 447.518(d) by submitting a State Plan Amendment (SPA) by June 30, 2017 to be effective no later than April 1, 2017.

Comment Date: To be assured consideration, comments must be received at one of the addresses provided below, no later than 5 p.m. on April 1, 2016. (See the **SUPPLEMENTARY INFORMATION** section of this final rule with comment period for a list of provisions open for comment.)

ADDRESSES: In commenting, please refer to file code CMS–2345–FC. Because of staff and resource limitations, we cannot accept comments by facsimile (FAX) transmission.

You may submit comments in one of four ways (please choose only one of the ways listed):

1. *Electronically.* You may submit electronic comments on this regulation to *www.regulations.gov.* Follow the instructions for ''submitting a comment.''

2. *By regular mail.* You may mail written comments to the following address ONLY:

Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS–2345–FC, P.O. Box 8013, Baltimore, MD 21244–8013.

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 to the following address ONLY:

Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS–2345–FC, Mail Stop C4–26–05, 7500 Security Boulevard, Baltimore, MD 21244–1850.

4. *By hand or courier.* If you prefer, you may deliver (by hand or courier) your written comments before the close of the comment period to either of the following addresses:

a. For delivery in Washington, DC—Centers for Medicare & Medicaid Services, Department of Health and Human Services, Room 445–G, Hubert H. Humphrey Building, 200 Independence Avenue SW., Washington, DC 20201.

(Because access to the interior of the Hubert H. Humphrey 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.)

b. For delivery in Baltimore, MD—Centers for Medicare & Medicaid Services, Department of Health and Human Services, 7500 Security Boulevard, Baltimore, MD 21244–1850.

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.

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

FOR FURTHER INFORMATION CONTACT: Ruth Blatt, (410) 786–1767, for issues related to the definition of covered outpatient drug, including drug category, and rebates for line extensions.

Brian Du, (410) 786–6814, for issues related to the offset of rebates and collection of information.

Emeka Egwim (410–786–1092), for issues related to 340B and the Federal Upper Limits.

Lisa Ferrandi, (410) 786–5445, for issues related to 340B, rebates for drugs dispensed by Medicaid managed care organizations, requirements for states, the Collection of Information Requirements, and the Regulatory Impact Analysis.

Renee Hilliard, (410) 786–2991, for issues related to the definitions of states and United States.

Christine Hinds, (410) 786–4578, for issues related to authorized generics, nominal price, blood clotting factor, and exclusively pediatric drugs.

Gail Sexton, (410) 786–4583, for issues related to Federal upper limits and the definitions of actual acquisition cost and professional dispensing fee.

Terry Simananda, (410) 786–8144, or Wendy Tuttle, (410) 786–8690, for issues related to the determination of Average Manufacturer Price (AMP), identification of 5i drugs, the determination of Best Price, and manufacturer reporting requirements.

Andrea Wellington, (410) 786–3490 for issues related to the Regulatory Impact Analysis.

Wendy Tuttle, (410) 786–8690, for all other inquiries.

SUPPLEMENTARY INFORMATION:

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.regulations.gov.* Follow the search instructions on that Web site to view public comments.

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

Provisions open for comment: We will consider comments that are submitted as indicated above in the **DATES** and **ADDRESSES** sections on the following subject areas discussed in this final rule with comment period: The definition and identification of line extension drugs.

To assist readers in referencing sections contained in this document, we are providing the following Table of Contents.

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Acronyms

Because of the many organizations and terms to which we refer by acronym in this final rule, we are listing these acronyms and their corresponding terms in alphabetical order below:

5i drug Inhalation, infusion, instilled, implanted or injectable drugs
AAC Actual acquisition cost
ADA Antibiotic drug application
AI/AN American Indians and Alaska Natives
AMP Average manufacturer price
ANDA Abbreviated New Drug Application
APA Administrative Procedures Act
APD Advanced planning document
ASP Average sales price
AWP Average wholesale price
BLA Biologics license application
BMN Brand medically necessary
COD Covered outpatient drug
CPI–U Consumer Price Index—Urban
DDR Drug data reporting [for Medicaid system]
DRA Deficit Reduction Act
EAC Estimated acquisition cost
ELA Establishment license application
FDA Food and Drug Administration
FFP Federal financial participation
FFDCA Federal Food, Drug and Cosmetic Act
FQHC Federally qualified health center
FR Federal Register
FSS Federal supply schedule
FUL(s) Federal upper [reimbursement] limit(s)
GPO Group purchasing organization
HCERA Health Care and Education Reconciliation Act
ICR Information Collection Requirement
I/T/U IHS, Tribal, and Urban Indian Organizations
IHS Indian Health Services
MCO Managed care organization
MDR Medicaid drug rebate
MMIS Medicaid Management and Information Systems
NADAC National average drug acquisition cost
NCPDP National Council for Prescription Drug Plans
NDA New Drug Application
NDC National drug code
NSDE NDC Structured Product Labeling (SPL) Data Elements
OBRA '90 Omnibus Budget Reconciliation Act of 1990
OBRA '93 Omnibus Budget Reconciliation Act of 1993
OIG Office of Inspector General
OPA Office of Pharmacy Affairs
OTC Over-the-counter
PBM Pharmacy Benefit Manager
PHS Public Health Service
PHSA Public Health Service Act
PLA Product license application
REMS Risk Evaluation and Mitigation Strategy
SPA State plan amendment
SPAP State pharmacy assistance program
SPL Structured Product Labeling
U&C Usual and customary
URA Unit rebate amount
WAC Wholesale acquisition cost

I. Background

A. Introduction

Under the Medicaid program, states may provide coverage of prescribed 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. Section 1927 of the Act governs the Medicaid Drug Rebate (MDR) Program and payment for covered outpatient drugs (CODs), which are defined in section 1927(k)(2) of the Act. In general, for payment to be made available under section 1903(a) of the Act for CODs, manufacturers must enter into a National rebate agreement (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 formulas for calculating rebate payments, and requirements for states for CODs.

This final rule implements changes to section 1927 of the Act made by sections 2501, 2503, and 3301(d)(2) of the Patient Protection and Affordable Care Act of 2010 (Pub. L. 111–148, enacted on March 23, 2010), and sections 1101(c) and 1206 of the Health Care and Education Reconciliation Act of 2010 (HCERA) (Pub. L. 111–152, enacted on March 30, 2010) (collectively referred to as the Affordable Care Act). It also implements changes to section 1927 of the Act as set forth in section 202 of the Education Jobs and Medicaid Assistance Act (Pub. L. 111–226, enacted on August 10, 2010). As discussed in the proposed rule published in the February 2, 2012 **Federal Register** (77 FR 5318) and summarized in this section, these revisions are consistent with the Secretary's authority set forth in section 1102 of the Act to publish regulations that are necessary to the efficient administration of the Medicaid program.

B. Changes Made by the Affordable Care Act

Section 2501(a) of the Affordable Care Act amended section 1927(c) of the Act by increasing the minimum rebate percentage for most single source and innovator multiple source drugs from 15.1 percent of the average manufacturer price (AMP) to 23.1 percent of AMP. Section 2501(a) of the Affordable Care Act also amended section 1927(c) of the Act by establishing a minimum rebate percentage of 17.1 percent of AMP for certain single source and innovator multiple source clotting factors and single source and innovator multiple source drugs approved by the Food and Drug Administration (FDA) exclusively for pediatric indications. Section 2501(a) of the Affordable Care Act also added section 1927(b)(1)(C) to the Act to make changes to the non-Federal share of rebates by specifying that the amounts attributable to the increased rebate percentages be remitted to the

federal government. The amendments made by section 2501(a) of the Affordable Care Act were effective January 1, 2010.

Section 2501(b) of the Affordable Care Act amended section 1927(c) of the Act by increasing the rebate percentage for noninnovator multiple source drugs from 11 percent of AMP to 13 percent of AMP, effective January 1, 2010.

Section 2501(c) of the Affordable Care Act amended section 1903(m)(2)(A) of the Act by specifying new conditions for managed care organization (MCO) contracts, including that CODs dispensed to individuals eligible for medical assistance under Title XIX of the Act who are enrolled with a Medicaid MCO shall be subject to the same rebate required by the rebate agreement authorized under section 1927 of the Act. The Affordable Care Act also amended section 1903(m)(2)(A) of the Act to establish that MCO capitation rates shall be based on actual cost experience related to rebates and subject to federal regulations at 42 CFR 438.6 regarding actuarial soundness of capitation payments. The legislation also provided that MCOs are responsible for reporting to the state certain utilization data and such other data as the Secretary determines necessary for the state to access the rebates authorized by this provision.

Section 2501(c) of the Affordable Care Act also made conforming amendments to section 1927(b)(1)(A) of the Act by requiring manufacturers that participate in the MDR program to provide rebates for drugs dispensed to individuals enrolled with a MCO, if the MCO is responsible for coverage of such drugs. It also amended section 1927(b)(2)(A) of the Act by requiring states to include information on drugs paid for by Medicaid MCOs under the state plan during the rebate period when requesting rebates from manufacturers. Finally, section 2501(c) modified section 1927(j)(1) of the Act to specify that CODs are not subject to the rebate requirements if such drugs are both subject to discounts under the 340B of the Public Health Service Act (PHSA) and dispensed by health maintenance organizations (HMOs), including Medicaid MCOs. The amendments made by section 2501(c) were effective March 23, 2010.

Section 2501(d) of the Affordable Care Act added a new section 1927(c)(2)(C) of the Act effective for drugs paid for by a state on or after January 1, 2010. This provision modifies the unit rebate amount (URA) calculation for a drug that is a line extension (new formulation) of a single source or innovator multiple source drug that is an oral solid dosage form.

Section 2501(e) of the Affordable Care Act amended section 1927(c)(2) of the Act by adding a new subparagraph (D) and establishing a maximum on the total rebate amount for each single source or innovator multiple source drug at 100 percent of AMP, effective January 1, 2010.

Section 2501(f) of the Affordable Care Act made conforming amendments to section 340B of the PHSA, but those amendments are not addressed in this final rule.

Section 2503(a)(1) of the Affordable Care Act amended section 1927(e) of the Act by revising the Federal upper reimbursement limit (FUL) to be no less than 175 percent of the weighted average (determined on the basis of utilization) of the most recently reported monthly AMPs for pharmaceutically and therapeutically equivalent multiple source drug products that are available for purchase by retail community pharmacies on a nationwide basis. Additionally, it specifies that the Secretary shall implement a smoothing process for AMP which shall be similar to the smoothing process used in determining the average sales price (ASP) of a drug or biological product under Medicare Part B. Section 2503(a)(2) of the Affordable Care Act amended section 1927(k) of the Act by revising the definition of AMP to now mean the average price paid to the manufacturer for the drug in the United States by wholesalers for drug distribution to retail community pharmacies and retail community pharmacies that purchase drugs directly from the manufacturer.

Section 2503(a)(3) of the Affordable Care Act also amended the definition of multiple source drug to specify in the definition that the sales of such drugs shall be specifically within the United States. Section 2503(a)(4) of the Affordable Care Act added to section 1927(k) of the Act definitions of retail community pharmacy and wholesaler for purposes of section 1927 of the Act.

Section 2503(b) of the Affordable Care Act amended section 1927(b) of the Act by establishing a requirement that manufacturers report, not later than 30 days after the last day of each month of a rebate period under the agreement, on the manufacturer's total number of units that are used to calculate the monthly AMP for each COD. It also amended the preexisting requirement that the Secretary disclose AMPs to instead require the Secretary to post, on a Web site accessible to the public, the weighted average of the most recently reported monthly AMPs and the average retail survey price determined for each multiple source drug in accordance with section 1927(f) of the Act. The amendments made by section 2503(b) of the Affordable Care Act were effective October 1, 2010.

Section 2503(c) of the Affordable Care Act amended section 1927(f) of the Act by clarifying that the survey of retail prices described in such subsection applies to retail community pharmacies. Section 2503(d) of the Affordable Care Act specified that the amendments made by section 2503 of the Affordable Care Act were effective October 1, 2010. Section 2503(d) of the Affordable Care Act further specified that the amendments made by section 2503 shall take effect without regard to whether final regulations to carry out such amendments have been issued by October 1, 2010.

Section 3301(d)(2) of the Affordable Care Act included a conforming amendment to the definition of best price (BP) under Medicaid at section 1927(c)(1)(C)(i)(VI) of the Act. This amendment provides that any discounts provided by manufacturers under the Medicare coverage gap discount program under section 1860D–14A of the Act are exempt from a manufacturer's best price calculation, effective for drugs dispensed on or after July 1, 2010.

Section 7101(a) of the Affordable Care Act expanded the drug pricing program under section 340B of the PHSA to include certain children's hospitals, freestanding cancer hospitals, critical access hospitals, rural referral centers, and sole community hospitals.

Section 204 of the Medicaid Extenders Act of 2010 (Pub. L. 111–309) revised section 340B of the PHSA by removing children's hospitals from the orphan drug exclusion described in section 2302 of HCERA.

Section 1101(c) of HCERA also includes a conforming amendment to the definition of AMP under Medicaid at section 1927(k)(1)(B)(i) of the Act by providing that discounts provided by manufacturers under the Medicare coverage gap discount program under section 1860D–14A are excluded from a manufacturer's determination of AMP, effective March 30, 2010.

C. Other Changes Concerning the Medicaid Drug Rebate Program

This final rule also implements other miscellaneous provisions pertaining to CODs. It implements changes to section 1927 of the Act as set forth in section 221 of Division F, Title II, of the Omnibus Appropriations Act, 2009, (Pub. L. 111–8, enacted on March 11, 2009) (the Appropriations Act). It

codifies other requirements in section 1927 of the Act pertaining to the MDR program, revises certain regulatory provisions presently codified at 42 CFR part 447, subpart I, and makes other changes concerning rebate requirements.

II. Summary of Proposed Provisions, Analysis of and Responses to Public Comments, and Provisions of the Final Rule

The proposed rule for implementing the requirements of section 1927 of the Act, as revised by the Affordable Care Act, and the requirements related to coverage and payment for CODs, was published on February 2, 2012 (77 FR 5318). As discussed in the proposed rule, we specifically proposed provisions that would revise the MDR program (77 FR 5320), including the calculation of AMP (77 FR 5326), drug rebate payments (77 FR 5338), and upper limits for multiple source drugs (77 FR 5345).

We received approximately 425 comments from drug manufacturers, membership organizations, law firms, pharmacy benefit managers, state Medicaid agencies, advocacy groups, not-for-profit organizations, consulting firms, health care providers, employers, health insurers, health care associations, as well as individual citizens. The comments ranged from general support or opposition to the proposed provisions to very specific questions or comments regarding the proposed changes.

The following summarizes comments about the proposed rule, in general, or about issues not addressed in the proposed regulations:

Comment: Several commenters expressed support for the proposed rule, noting that it was a significant undertaking and important for CMS to require adequate state and federal reimbursement for CODs under the Medicaid program.

Response: We appreciate the support the commenters expressed about the proposed rule and we believe that the final policies we are adopting in this final rule will continue to allow the federal and state governments the flexibility to provide adequate reimbursement for the cost of CODs under the Medicaid program.

Comment: One commenter emphasized the importance of pharmacists in the health care team and the need to provide reasonable reimbursement for both prescription and cognitive services to ensure beneficiary access.

Response: We appreciate the comment and agree that pharmacists play a vital role in the health care delivery system. We have provided for payment consistent with the statute and regulations which contemplate reimbursement for appropriate professional dispensing fees, which we have defined to include certain prescription and beneficiary counseling services.

Comment: While many commenters were supportive of the proposed rule, some voiced concerns regarding its impact on the economy or pharmacy payments. Some commenters also voiced concerns with the implementation of Medicare Prescription Drug Coverage, the birth control mandate, and coverage of mental health benefits.

Response: While we appreciate these comments, issues regarding the implementation of Medicare Prescription Drug Coverage, the birth control mandate, and coverage of mental health benefits are beyond the scope of this rulemaking. As we discuss later in the final rule, we do not believe this rule will have an adverse impact on the economy or pharmacy payments; this final rule is designed to ensure that pharmacy reimbursement is aligned with the acquisition cost of drugs and that the states pay an appropriate professional dispensing fee. Discussions regarding the impact on the economy and pharmacy payments are discussed in the Regulatory Impact Analysis section of this final rule.

Comment: One commenter requested that CMS evaluate every aspect of the proposed rule and revise it in favor of simplicity versus complexity and clarity versus complication.

Response: To the extent practical, we have made every effort to ensure that the provisions of this final rule are simple and clear.

Comment: One commenter expressed general concerns that, if CMS finalized the proposed rule as drafted, it would violate the Administrative Procedure Act (APA) because CMS's interpretations are either contrary to statute or are arbitrary and capricious under 5 U.S.C. 706(2)(A). The commenter stated that many of CMS's proposals (such as AMP, line extensions, inclusion of territories, and 340B issues in best price) in the proposed rule are entirely conclusory, failed to consider important aspects of the problem, or are internally inconsistent, and constitute unreasonable interpretations. The commenter urged CMS to revise its proposals related to calculating AMP using a buildup versus presumed inclusion methodology; AMP for 5i drugs not generally dispensed through retail community pharmacies, line extensions, territories, 340B issues in best price, and bundled sales arrangements.

Response: We disagree with the commenter. We believe that we have sufficiently met the requirements of the APA. In particular, in the proposed rule, we identified the legal authority for our proposals, sufficiently described the substance of the proposed rule and the subjects involved, as well as proposed regulation text. The proposed rule also identified the data, information, and assumptions supporting our proposals. After consideration of public comments, we are issuing this final rule and, as discussed in greater detail in the sections that follow, we demonstrate that we have examined the relevant information, considered the significant issues relevant to the proposed rule, and sufficiently explained our final policies. The detailed comments and responses pertaining to issues concerning AMP, best price, line extensions, and bundled sales arrangements can be found in subsequent sections of this final rule. In those sections, we explain why our proposals are consistent with the relevant provisions of the statute, and our authority to implement those provisions, as well as consistent with our understanding of congressional intent and recent Affordable Care Act amendments. We also explain in response to comments why we either finalized a proposed provision or revised a proposed provision based on comments. Accordingly, we believe that we have taken the necessary steps to comply with the requirements of the APA and that the requirements of this final rule are neither arbitrary nor capricious.

Comment: Several commenters requested that CMS specifically identify any provisions that are retroactive and specify the effective date and legal basis for the retroactive application. Many commenters requested that the final rule be implemented on a prospective basis only and believe that it is reasonable that manufacturers, states and territories will require a lead time of 6 to 12 months from the publication date of the final rule to implement the significant changes in the proposed rule. One commenter noted that allowing all parties equal time for implementation would recognize that all parties (manufacturers, states and territories) have equal responsibility to comply with the program requirements. Another commenter believed that stakeholders and manufacturers are not bound by the proposed rule because it is non-binding.

Response: The final rule is effective on April 1, 2016. We believe our final

policies will allow adequate time for implementation and where appropriate, have extended time for compliance. We further note that the Affordable Care Act established earlier effective dates for certain statutory provisions without regard to this rulemaking, as discussed in the proposed rule (77 FR 5319). To the extent any provisions are not new and merely emphasize or clarify longstanding agency policy, we have endeavored to note that as such.

Comment: One commenter requested that CMS confirm that manufacturer's use of reasonable interpretations of the statute is permissible prior to the effective date of the final rule.

Response: Manufacturers are always encouraged to interpret the statute in a manner consistent with the requirements and intent of section 1927 of the Act and federal regulations, as discussed in prior rules regarding the MDR program (see, for example, 72 FR 39167 (July 17, 2007)) and consistent with the national rebate agreement. However, in accordance with the requirements of the national rebate agreement, manufacturers must maintain adequate documentation supporting any assumptions.

Comment: One commenter requested that CMS provide the states flexibility to come into compliance with final regulations or guidance due to variations in timing of state legislative sessions and state procurement procedures. The commenter was particularly concerned with the provisions relating to reimbursement at AAC and the professional dispensing fee.

Response: We appreciate the concerns expressed by the commenter. As discussed in this section, we have included a compliance date that specifies that states will have 1 year after the effective date of this final rule to submit a state plan amendment (SPA) which would incorporate the requirements of the final rule. We expect to issue subregulatory guidance to the states regarding this process.

A. Basis and Purpose (§ 447.500)

Section 2501(c) of the Affordable Care Act established new requirements for manufacturers that participate in the MDR program to pay rebates for drugs dispensed to individuals enrolled with a Medicaid MCO, if the MCO is responsible for coverage of such drugs. To effectuate those changes, we proposed to add § 447.500(a)(4), to specify sections 1903(m)(2)(A)(xiii) and 1927(b) of the Act as the basis for requiring that manufacturers provide rebates for CODs dispensed to individuals eligible for medical assistance who are enrolled in Medicaid MCOs (77 FR 5320). We proposed to add § 447.500(a)(5) which would add section 1902(a)(30)(A) as an additional statutory basis for calculating payments for CODs. We received no comments concerning the proposals to add § 447.500(a)(4) and (5), and therefore, for the reasons we noted, we are finalizing these provisions as proposed. We note that the comments and responses pertaining to the proposed requirements regarding the calculation of rebates for drugs dispensed through Medicaid MCOs are discussed later in the Medicaid Drug Rebates (§ 447.509) section (section II.G.3.) of this final rule.

B. Definitions (§ 447.502)

1. 5i drug

Section 202 of the Education, Jobs and Medicaid Assistance Act (Pub. L. 111–226), enacted on August 10, 2010 and effective on October 1, 2010, amended the definition of AMP under section 1927(k)(1)(B)(i)(IV) of the Act to include sales for inhalation, infusion, instilled, implanted, or injectable drugs that are not generally dispensed through retail community pharmacies.

Given this amendment, we included a proposed definition, which defined a ''5i drug'' to mean an inhalation, infusion, instilled, implanted, or injectable drug that is not generally dispensed through a retail community pharmacy (77 FR 5359). We did not receive any comments specific to this proposed definition of 5i drug, but we received a number of comments concerning the identification of such drugs for purposes of the calculation of AMP. We address comments pertaining to the identification of and other 5i drug issues in section II.C. of this final rule.

At this time, we do not believe a definition of 5i drug is necessary and therefore we are not finalizing any definition for 5i drug that was proposed in § 447.502 (77 FR 5359). However, we note that the acronym ''5i drug'' has already been widely adopted in the nomenclature of many stakeholders, including drug manufacturers, retail community pharmacies, consulting firms and even CMS as simply a convenient way to condense the list of the five specific drug types (inhalation, infusion, instilled, implanted, or injectable drugs). Therefore, we will use the ''5i drug'' acronym to refer to all inhalation, infusion, instilled, implanted, or injectable drugs when discussing the identification of such drugs. Therefore, for the reasons discussed in this section, we have decided not to finalize in § 447.502 the definition of 5i drug that was proposed (77 FR 5359).

2. Actual Acquisition Cost

In proposed § 447.502, we proposed to replace the term, ''estimated acquisition cost'' (EAC) with ''actual acquisition cost'' (AAC) and to define AAC as the agency's determination of the pharmacy providers' actual prices paid to acquire drug products marketed or sold by specific manufacturers (77 FR 5320 and 5359). As discussed in the proposed rule, we believe that this definition provides a more accurate estimate of the prices available in the marketplace, while assuring sufficient beneficiary access, consistent with section 1902(a)(30)(A) of the Act (77 FR 5320 through 5321). We received the following comments concerning the proposed revised definition of AAC:

a. Support for Proposal To Define/Implement AAC

Comment: One commenter supports CMS's efforts to provide states with accurate reference prices upon which to base reimbursement for CODs and to replace EAC with AAC. Several commenters appreciated CMS's desire to move away from an estimated reimbursement based on average wholesale price (AWP) or wholesale acquisition cost (WAC) and to substitute instead a requirement that states adopt AAC payment formulas. Another commenter stated that drug reimbursement based on AAC as opposed to AWP seems to present a fair cost-based approach to pharmacy reimbursement and allows pharmacies to negotiate for their true value in the healthcare system in the professional dispensing fee.

Response: We agree with these comments and believe that reimbursement based on AWP or WAC may fail to represent accurate purchase prices, because (unlike prices based on AAC) prices based on AWP or WAC do not necessarily include the discounts and price concessions available in the marketplace.

Comment: One commenter stated that CMS should require states to implement AAC as the exclusive means to reimburse drugs. The commenter expressed concern that allowing states to include AAC in their existing lower of reimbursement formulas would result in inconsistent and inadequate reimbursement. The commenter also noted that CMS should require states to adopt an adequate professional dispensing fee with their AAC reimbursement methodology.

Response: In accordance with the provisions of section 1902(a)(30)(A) of

Act, which requires, in part, that states have methods and procedures to assure that payment for Medicaid care and services are consistent with efficiency, economy, and quality of care, we proposed to replace the term EAC with AAC, which revises the reimbursement standard for prescription drugs. We believe that this change is necessary to require that states calculate reimbursement prices based on the prices actually available to pharmacies in the marketplace. However, we recognize that there may be instances when a survey price, such as the National average drug acquisition cost (NADAC), is not available for a specific drug product, and therefore, we believe that states should have some flexibility for establishing reimbursement rates.

Furthermore, as discussed in the State Plan Requirements, Findings and Assurances section (section II.M.) of this final rule, we have revised § 447.518(d) of this final rule such that when states are proposing changes to either the ingredient cost reimbursement or the professional dispensing fee reimbursement, they will be required to evaluate their proposed changes in accordance with the requirements of this final rule to ensure that total reimbursement to the pharmacy provider complies with the requirements of section 1902(a)(30)(A) of the Act. States are responsible for providing adequate information to support any proposed changes to either or both of the components of the reimbursement methodology.

b. Opposition to Proposal To Define/Implement AAC

Comment: Several commenters believe that states should be able to use an EAC or an AAC for pharmacy reimbursement. One of the commenters stated that to implement an AAC methodology, a state would have to conduct their own regular, costly survey or depend on the NADAC. The commenter added that some states may think that the NADAC does not truly represent the costs to pharmacies in that state, especially where a state has a disproportionate share of independent pharmacies.

Response: EAC was defined, in part, as the states' estimate of the prices generally and currently paid for a drug, and states traditionally used published compendia prices such as the AWP to establish this estimate. The HHS Office of Inspector General (OIG) has published several reports (OIG Audit reports—A–06–00–00023, A–06–01–00053, A–06–02–00041),[1] which demonstrate that, because of the flawed nature of an AWP-based reimbursement, states have often reimbursed too much for CODs; thus, the OIG has recommended that we work with states and the Congress to base reimbursement on an amount that more accurately reflects pharmacy acquisition cost. We believe that a change to AAC is more consistent with the statutory provisions at section 1902(a)(30)(A) of the Act as AAC requires states to calculate reimbursement prices based on the prices actually paid by pharmacy providers. We have cited examples in the proposed rule (77 FR 5350) that the states can use to develop or support an AAC. As discussed further below, states retain the flexibility to establish an AAC reimbursement based on several different pricing benchmarks, but they have the responsibility to ensure that Medicaid pharmacy providers are adequately reimbursed in accordance with the requirements of section 1902(a)(30)(A) of the Act.

Comment: One commenter stated that the phrase ''actual acquisition cost'' is misleading, as pharmacy providers' reimbursement will not be based on their actual price. The commenter stated that, for example, a yearly national survey cannot simultaneously or accurately reflect actual ingredient costs in different states and believes that AAC is no better a price indicator than the EAC. A few commenters stated that EAC should be used for pharmacy reimbursement because it may be unrealistic for a state to determine any pharmacy's AAC for a drug product, net of rebates, incentives, or other purchasing arrangements because invoice reviews will not provide the actual cost, will only apply to a particular timeframe, drug prices change rapidly, and the dispense date may be different than the actual date it was purchased. A few commenters stated that the methodology for calculating the AAC should be referenced in the definition. One commenter also stated that because prices paid may be different due to pharmacy provider's wholesaler agreements, EAC or average invoice cost or ''average actual acquisition cost'' would be a more accurate terminology.

Response: We believe that AAC is a better price indicator than EAC. As discussed in this section, there has been longstanding concern by the OIG that states continue to overpay for Medicaid CODs, as states traditionally used published compendia prices such as the AWP to establish the EAC. As we stated in the proposed rule, (77 FR 5350), states retain the flexibility to establish an AAC reimbursement based on several different pricing benchmarks, including, but not limited to, a national survey of AACs, a state survey of retail pharmacy providers, or AMP data. The AMP is based on actual sales data and reported and certified by drug manufacturers, and could be considered as a reimbursement metric, provided that the use of such a metric is consistent with section 1927(b)(3)(D) of the Act. The state can determine the relationship of the AMP to factors such as the wholesaler markup, which covers the cost of distribution and other service charges by the wholesaler, to determine a reasonable reimbursement that would appropriately compensate pharmacies.

As we stated in the proposed rule (77 FR 5321 and 5350), we realize that states may have difficulty determining the actual price of each drug at the time it was purchased. However, as states have flexibility to establish a methodology to determine AAC, we decline to include a specific methodology for calculating AAC in the definition.

Comment: One commenter stated that the proposal to move to AAC for branded drugs was not authorized by the Congress, and therefore, should not be undertaken. The commenter further stated that the Congress legislated specific limits on Medicaid pricing for drugs subject to FULs, but changes to brand drugs were absent. One commenter stated that when CMS issued the AMP final rule on the Deficit Reduction Act (DRA) in July 2007, they declined to modify the definition of EAC because CMS stated that the DRA did not modify the definition. Another commenter stated that by proposing a shift from EAC to AAC, CMS has introduced an issue that is not germane to the implementation of the AMP changes in the Affordable Care Act for rebate and FUL purposes.

Response: While we agree with the commenter that these changes are not expressly required by the Affordable Care Act, as discussed previously in this section, we are authorized to make these changes under section 1902(a)(30)(A) of the Act. Furthermore, we believe that AAC will be more reflective of actual prices paid, as opposed to unreliable published compendia pricing, while

[1] ''Medicaid Pharmacy—Actual Acquisition Cost of Brand Name Prescription Drug Products,'' (A–06–00–00023), August 10, 2001; ''Medicaid Pharmacy—Actual Acquisition Cost of Generic Prescription Drug Products'' (A–06–01–00053), March 14, 2002; ''Medicaid Pharmacy—Additional Analyses of the Actual Acquisition Cost of Prescription Drug Products,'' (A–06–02–00041), September 16, 2002.

continuing to provide sufficient payment to assure beneficiary access. At the time that we issued the proposed rule, certain states had already begun to incorporate survey data based on pharmacy invoice prices into their pharmacy reimbursement methodologies to calculate more accurate payment rates.[2] Since the publication of the proposed rule, additional states have incorporated the use of acquisition costs, based on survey data, as a reimbursement metric for CODs, including Colorado, Idaho, Iowa, and Louisiana. In addition, using a commercially published reference price as the basis for Medicaid pharmacy reimbursement has been problematic for both the states and the federal government because reimbursement based on published compendia prices, as discussed in several reports issued by the OIG, is often significantly inflated, and not necessarily reflective of a pharmacy's actual purchase price for a drug.[3] Therefore, we have decided to finalize the requirements concerning AAC in this final rule.

Comment: One commenter stated that some states have requested that CMS establish a national benchmark based on AAC; however, the commenter believed that Congressional intent was not for CMS to mandate that an AAC benchmark be implemented by states.

Response: The definition of AAC in this final rule does not mandate that states use a specific formula or methodology to establish their AAC reimbursement. As we stated in the proposed rule, (77 FR 5350), states continue to retain the flexibility to establish an AAC reimbursement based on several different pricing benchmarks, including, but not limited to, NADAC files, AMP, or surveys—such as a state survey of retail pharmacy providers—because all of these measures are based on actual market prices of drugs. The state may use WAC to develop and support an AAC model of reimbursement, if the state can provide data to support a model of reimbursement using the WAC prices consistent with § 447.512(b) of this final rule.

[2] Alabama–10–008, effective date September 22, 2010 (Alabama AAC Survey information available at *http://www.mslc.com/Alabama/*) and Oregon–10–13, effective date January 1, 2011 (Oregon AAC Survey information available at *http://www.mslc.com/Oregon/*)

[3] *http://oig.hhs.gov/oas/reports/region6/60000023.htm; http://oig.hhs.gov/oas/reports/region6/60100053.htm*;*http://oig.hhs.gov/oas/reports/region6/60200041.htm*;

c. Language Changes to the Proposed Definition of AAC

Comment: A few commenters stated that the AAC definition should be amended to require that the word ''currently'' be included in the definition between ''prices'' and ''paid'' (that is, ''actual prices currently paid'') to ensure payment is not based on outdated pricing and also stated that this is especially important for brand drugs which are responsible for 80 percent of all Medicaid drug spending.

Response: We do not believe that it is necessary to incorporate the term ''currently'' into the definition of AAC. We have defined AAC to require that states establish payment rates based on actual prices paid to acquire drug products, and we expect that those prices would reflect current prices. The pricing benchmarks we provide to states, for example, the weekly NADAC files, and the monthly and quarterly AMP, are updated to reflect current prices. Further, if a state chooses to conduct a state survey to create a database of acquisition cost data, then the timing of the collection of that data would be at the state's discretion subject to federal approval.

Comment: A few commenters indicated that the AAC definition in the proposed rule should be more explicit and should address implementation issues such as a requirement that the AAC be recalculated whenever the state makes a change in the professional dispensing fee.

Another commenter stated that the language in the proposed rule is confusing regarding the cost of the product, and that the proposal to replace EAC with AAC seems to create a mandate for states to move to a reimbursement mechanism that uses a close estimate of the pharmacy's AAC, but is not clear in that respect.

Response: We appreciate the comments. We have revised § 447.518(d) to require states to consider both the ingredient cost reimbursement and the professional dispensing fee reimbursement when proposing changes to either of these components of the reimbursement for Medicaid covered drugs. Additionally, we have addressed such implementation concerns by noting that states that need to revise their payment methodologies in accordance with this final rule must submit a SPA no later than 4 quarters from the effective date of this final rule to revise their payment methodology for CODs in accordance with the requirements of §§ 447.512(b) and 447.518(d).

For the reasons we articulated, we are finalizing the definition of AAC at § 447.502 as proposed (77 FR 5359).

3. Authorized Generic Drug

We proposed moving the definition of ''Authorized generic drug'' from § 447.506(a) to § 447.502 (discussed in more detail at 77 FR 5321). However, we did not propose any revisions to the definition presently set forth at § 447.506(a). To clarify, for purposes of the MDR program, we define an authorized generic drug as any drug sold, licensed, or marketed under a New Drug Application (NDA) approved by the FDA under section 505(c) of the Federal Food, Drug and Cosmetic Act (FFDCA) that is 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 name drug. We did not receive any comments concerning the proposal to move the definition of authorized generic drug. Therefore, we are finalizing the definition of authorized generic drug in § 447.502 as it was proposed.

4. Bona Fide Service Fee

In proposed § 447.502, we proposed to revise the definition of bona fide service fee to mean fees paid by a manufacturer to wholesalers or retail community pharmacies 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 is 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. The fee includes, but is not limited to, distribution service fees, inventory management fees, product stocking allowances, and fees associated with administrative service agreements and patient care programs (such as medication compliance programs and patient education programs) (77 FR 5321 and 5359).

We received the following comments concerning the proposed revision to the definition of bona fide service fee:

a. Application of Bona Fide Service Fees Exclusion to Limited Entities

Comment: Many commenters supported the proposed definition of bona fide service fee at proposed § 447.502. One commenter indicated there are a wide variety of legitimate service arrangements with wholesalers and other direct purchase customers, and those arrangements frequently

change to address new patient needs and new challenges in the drug distribution chain. These commenters further stated that retention of the existing standard set forth in § 447.502 for bona fide service fee facilitates manufacturer compliance and allows manufacturers to develop new business models and contractual relationships to adapt to the changing prescription drug market.

However, many commenters expressed their concerns regarding the proposed definition of bona fide service fee because it contains a recipient limitation. The proposed definition limited the application of the bona fide service fee exclusion to fees paid by manufacturers to only wholesalers and retail community pharmacies and does not account for other direct purchase customers further recognized in the calculation of AMP under the proposed regulation and statute. One commenter indicated that CMS proposed to include in the AMP transaction many other entities, such as those CMS view as ''conducting business as'' wholesalers or retail community pharmacies, secondary manufacturers for authorized generics, and a wide spectrum of entities that dispense 5i drugs not generally dispensed through retail community pharmacies; and while the commenter does not believe all these transactions should be included in the calculation of AMP, to the extent transactions with other entities are included in AMP, any bona fide service fees paid to those entities should also be excluded.

Several commenters stated that the Congress did not amend the statute to define ''bona fide service fee,'' but amended the AMP provision of the statute to provide examples of bona fide service fees. Many of the commenters stated that in light of those amendments, the revised reference from ''an entity'' to ''wholesalers and retail community pharmacies'' was a drafting error by CMS, and does not make sense for AMP calculations for 5i drugs not generally dispensed through retail community pharmacies and best price determinations because such calculations include transactions to other direct customers other than retail community pharmacies and wholesalers. Other commenters believed there was a drafting error in the proposed definition at § 447.502 because in proposed § 447.505, the proposed rule expressly included fees paid to group purchasing organizations (GPOs), which are not wholesalers or retail community pharmacies. Another commenter provided, as an example, that if a manufacturer was to purchase ''pharmaco-economic data'' from a health plan at fair market value and the arrangement otherwise satisfied the four-part test for bona fide service fees, it would not make sense to treat this payment as a discount merely because it was not paid to a wholesaler or a retail community pharmacy.

One commenter noted that including bona fide service fees paid by manufacturers to any entity in AMP for 5i drugs not generally dispensed through retail community pharmacies and including bona fide service fees in best price as discounts or price concessions would result in an artificially low AMP for such 5i drugs calculation and a lower best price determination for all single source or innovator multiple source drugs. Another commenter indicated that limiting the definition would be operationally difficult to do since manufacturers would need to recognize the same fee as a discount/price concession in some government pricing programs, but as a legitimate fee for service in others.

Several commenters also noted that under the existing regulation (definition of bona fide service fee at § 447.502 based on the 2007 AMP final rule (72 FR 39240)) bona fide service fee is defined in relevant part to mean, ''fees paid by a manufacturer to an entity'' and that the reference to ''an entity'' from this current rule has been replaced with ''wholesalers and retail community pharmacies.'' The commenters stated that ''an entity'' language is more appropriate for purposes of defining bona fide service fee because the definition applies not only to the calculation of AMP, but also to the calculation of AMP for 5i drugs not generally dispensed through retail community pharmacies and best price determinations as well. One commenter stated that CMS's proposed definition was unreasonable in that fees would need to be treated as discounts because the customer, while included in the AMP and best price calculation, did not qualify as a wholesaler or retail community pharmacy.

Response: We appreciate the support for the proposed definition of bona fide service fee and comments that raised concerns regarding our changes we proposed given the specific changes to the AMP calculation as added by section 2503(a)(2) of the Affordable Care Act. After considering the issues raised by the commenters, we have decided to amend the definition at § 447.502 in this final rule to remove the references to wholesalers and retail community pharmacies. We agree with commenters that there is no indication that the Congress intended to limit the definition of bona fide service fees for best price. Section 1927(k)(1)(B)(i)(II) of the Act, as added by section 2503(a)(2) of the Affordable Care Act, excludes from the definition of AMP bona fide service fees paid by manufacturers to wholesalers and retail community pharmacies and it includes examples of those fees included in that exclusion. However, section 1927(k)(1)(B)(i)(II) of the Act does not provide an express definition of what constitutes a bona fide service fee generally, nor does it directly apply to Best Price. Therefore, we believe the proposed definition may have been too limiting with regard to the entities that were identified. Accordingly, in this final rule we are revising the definition of bona fide service fee at § 447.502 to remove the reference to ''wholesalers and retail community pharmacies'' and replace it with ''an entity'' so that manufacturers can apply the definition with regard to their calculation of both AMP and best price. Further discussion regarding what is included and excluded from the determination of AMP and best price is included in sections II.C (§ 447.504(c) and (f)) and II.D (§ 447.505(c)) of this final rule.

b. Four-Part Test

Comment: Commenters stated that the proposed definition of bona fide service fee has no basis in the statute and stated that the Congress chose not to adopt the 2007 AMP final rule (72 FR 39142) definition because it is too limiting. Commenters also questioned whether the Congress intended that distribution fees, inventory management fees, and product stocking allowances be subject to fair market value, as the statutory language makes no reference to such a test, but stated they are to be excluded. A commenter noted that the proposed rule does not offer any criteria for whether a particular amount does or does not satisfy the test, thereby leaving manufacturers potentially at risk of inappropriately excluding a fee from their calculation of AMP.

A commenter also provided that it is not clear why the decision of the service provider to pass on all, or a portion of, the service fee to a client should have any bearing on the determination as to whether a service was provided in return for the fee. One commenter agreed with CMS that the 2007 ''four-part test'' remains a definitive test to qualify a payment as a bona fide service fee and the four-part test should be applied to all agreements, regardless of the agreements referenced in the Affordable Care Act. The commenter requested that CMS establish the same

policy for treatment of bona fide service fees (that is, allow manufacturers to presume, in the absence of such evidence, that a bona fide service fee is not passed on in whole or in part to the client) in AMP, best price, and ASP.

Response: Section 1927, along with our general rulemaking authority in section 1102 of the Act, provides the requisite authority for CMS to define and interpret certain terms such as bona fide service fees in regards to calculation of AMP and best price. Although the Affordable Care Act amendments to the AMP definition address such fees in regards to the exclusions from AMP, section 1927(k)(1)(B)(i)(II) of the Act does not provide an actual definition of bona fide service fee or apply directly to best price. Therefore, even though these statutory amendments to section 1927(k)(1)(B)(i)(II) of the Act are instructive and provide examples of the types of fees that would qualify as bona fide, we believe that the statutory amendments do not prohibit us from proposing a general definition of bona fide service fee that incorporates the four-part test we proposed and have been using in light of the definition in the present regulations (at § 447.502). We agree with the commenter that the four-part test remains a definitive test to qualify a payment as a bona fide service fee and that manufacturers are responsible for meeting all four parts of the definition before a fee can qualify as a bona fide service fee. We believe the element regarding fees paid by a manufacturer that are not passed on in whole or in part to a client or customer of an entity is a major factor in distinguishing bona fide service fees from price concessions, such that if a fee is passed on in whole or in part to a client or customer of an entity, the fee would be considered a price concession and therefore would be included in the calculation of AMP. Price concessions reduce the price realized by the manufacturer for drugs distributed to retail community pharmacies as they do not reflect any service or offset of a bona fide service performed on behalf of the manufacturer. In light of comments regarding the need for the same application of the four-part test in the AMP, best price and ASP calculations, we have decided to revise our position taken in regards to the 2007 AMP final rule for the ''not passed on'' prong of the bona fide service fee test to more fully align with the ASP policy. Specifically, in the 2007 AMP final rule (72 FR 39183), our approach to this part of the four-part test differed slightly from the ASP policy. At that time, we believed that there must be no evidence or arrangement indicating that the fee is passed on to the member pharmacy, client or customer of any entity included in the calculation of AMP for the manufacturer to exclude these fees from the determination of AMP. However, based on comments received, we are revising our position and adopting the policy set forth in the CY 2007 Physician Fee Schedule (PFS) final rule, published December 1, 2006 (71 FR 69669), in which CMS allows manufacturers, for certifying to the accuracy of their ASP calculations, to presume, in the absence of any evidence or notice to the contrary, that the fee paid is not passed on to a client, or customer of any entity (if a fee paid meets the other elements of the definition of bona fide service fee).

Therefore, if a manufacturer has determined that a fee paid meets the other elements of the definition of bona fide service fee, then the manufacturer may presume, in the absence of any evidence or notice to the contrary, that the fee paid is not passed on to a client or customer of any entity.

Comment: One commenter pointed out that there are three slightly different definitions of bona fide service fee in the proposed rule: (1) The proposed definitions section at § 447.502 which is limited to retail community pharmacies and wholesalers; (2) the proposed determination of AMP section at § 447.504(c)(14) which is limited to retail community pharmacies, wholesalers and GPOs; and (3) the proposed determination of best price section at § 447.505(c)(16) which includes any other entity that conducts business as a wholesaler or a retail community pharmacy.

Several commenters urged CMS to replace these three definitions with one uniform bona fide service fee definition. The commenters specifically recommended using the proposed definition from the definitions section which includes the traditional four-part criteria, as well as the statutory examples of bona fide service fee. Some commenters recommended that CMS simplify the definition of bona fide service fee to mean the fair market value for services performed, and should eliminate the other requirements of the bona fide service fee definition. Another commenter stated that regardless of who receives a bona fide service fee, the payment is fair market value compensation for work done and not a price concession.

Response: We agree with the commenter that the proposed definition of bona fide service fee is inconsistent in §§ 447.502, 447.504 and 447.505; furthermore, it was not our intent to have three definitions of bona fide service fee. As discussed in this section, we have replaced the limiting phrase ''to wholesalers or retail community pharmacies'' with ''an entity'' in the definition of bona fide service fee at § 447.502 and have streamlined §§ 447.504 and 447.505 to refer to the definition of bona fide service fee at § 447.502, rather than restate the definition, to avoid inconsistencies. Additionally, we disagree with the commenters that suggested we simplify the definition of bona fide service fee by eliminating the requirements (specifically the four-part test). As discussed in this section, the statutory amendments do not prohibit CMS from proposing a general definition of bona fide service fee that incorporates the four-part test CMS proposed, and has been using since the 2007 AMP Final Rule. We continue to believe that the four-part test provides a standard for manufacturers to use when determining whether or not a fee is bona fide. Furthermore, as discussed in this section, we are revising our position on ''the passed on in whole or in part'' prong of the four-part test to be consistent with ASP and are adopting the policy provided by CMS in CY 2007 PFS final rule (71 FR 69669). The application of the exclusion of bona fide service fee is more fully addressed in the determination of AMP and best price sections of the regulations text (§§ 447.504 and 447.505). Additional discussion regarding these changes are addressed in sections II.C (§ 447.504(c) and (f)) and II.D (§ 447.505(c)) of this final rule.

Comment: Several commenters noted that the proposed definition of bona fide service fee does not capture all the fees that a manufacturer may pay to AMP/best price-eligible customers and indicated that they wanted specific examples, or a list of bona fide service fees in the regulations text. The commenters indicated that certain categories of wholesaler services—such as financial services (for example, managing manufacturers' contracted discounts, processing chargebacks, and handling credits and re-bills to correct for mistakes in the assessment of 340B or Federal Supply Schedule (FSS) eligibility), marketing and sales services, and data management services—should be included as bona fide service fees. Another commenter stated that manufacturers must enlist wholesalers and distributors to perform the services associated with the returns and they pay them for these services on a fair market value basis as a bona fide service fee.

Therefore, the commenter urged CMS to exclude from AMP payments for returned goods handling and processing, reverse logistics, and drug destruction, if such payments meet the definition of a bona fide service fee.

One commenter recommended that an initial stocking allowance not be considered a bona fide service fee, as it is normally a one-time event, is intended to promote the sales of products, and does not meet the definition of either bona fide service fee or a customary prompt pay discount. Commenters also suggested that the cost of providing data management services should be identified in the regulations text as being bona fide service fee eligible. The commenter also stated that because AMP will play a role in reimbursement for multiple source drugs, it is necessary for the final rule to acknowledge that the sales and marketing services wholesalers provide to generic manufacturers are also candidates for bona fide service fee treatment.

One commenter believed that the lists of bona fide service fees in the Affordable Care Act are examples, rather than an exhaustive list, and was pleased that the proposed rule concurs with that assessment. This commenter stated that attempting to specify all bona fide service fees in regulations text would limit future flexibility and hamper innovation in a highly competitive marketplace.

Response: We appreciate the comments but do not agree that we should provide further examples, an all-inclusive list, or additional types of bona fide service fees. Although we do not believe the bona fide service fee examples provided in the Affordable Care Act amendment to the AMP definition is an exhaustive list, we believe that the examples provided in the Affordable Care Act amendments (including stocking allowances) to the AMP definition are bona fide service fees and sufficient to provide manufacturers with a general sense of the types of such fees.

Comment: One commenter requested guidance from CMS regarding the kinds of agreements encompassed within the term ''administrative service agreements'' as provided in the proposed rule.

Response: While we are not defining the term administrative service agreements in this final rule, we would consider administrative service agreements to include, but not be limited to, activities of a clerical, managerial, or processing nature that the manufacturer would otherwise perform (or contract for) in the absence of the administrative service agreement.

Comment: Several commenters suggested that in the final rule CMS should clarify in the definition of bona fide service fee that not all service fees paid by manufacturers need to be subject to the bona fide service fee test, and may be automatically ignored. As examples of such fees, the commenter stated fees paid by the manufacturer to its tax preparer, or to its landscaping company, are clearly not fees that would be considered price concessions. Therefore, the commenter suggested that CMS consider adding, ''Only fees paid to an entity in the chain of distribution or payment of CODs must be evaluated under the bona fide service fee test'' to the definition of bona fide service fee to makes clear that not all fees to any entity need to be subject to the test.

Response: We agree with the commenters that for purposes of the MDR program certain fees unrelated to the sale of a drug or drugs but rather to the overall business of the manufacturer, such as tax preparation services, would not need to be treated as a bona fide service fee because the transactions to such entities (tax preparers) would not be included in the determination of AMP or best price. However, we do not believe it is necessary to further amend the regulation to note the fees or transactions that are not subject to or excluded from the definition of bona fide service fee.

c. Fair Market Value

Comment: Several commenters supported CMS's decision not to define fair market value and leave this determination to the manufacturer. The commenters believed this flexibility is critical due to the wide array of service providers and fee arrangements present in the marketplace. One commenter stated that this approach provides manufacturers with the needed flexibility to use the most appropriate methodology for the arrangement being evaluated, while still ensuring that the fair market value determination is documented and available for review as appropriate. Another commenter stated that this approach appropriately balances the need for a clear standard with the need for flexibility to adapt to a changing market.

Response: We agree with the commenters. Given the continually changing pharmaceutical marketplace, we will continue to allow manufacturers the flexibility to determine the fair market value of a service when evaluating whether the service fee is bona fide or not.

Comment: Several commenters had concerns with CMS not defining fair market value as part of this rule. The commenters urged CMS to set forth clear criteria to utilize in determining whether or not given fees satisfy the fair market value requirement.

One commenter stated that language in the preamble regarding potential fraud concerns may have the effect of increasing manufacturers' concerns over possible litigation regarding alleged inflation of the prices reported for Medicaid rebates. Another commenter stated that without clear guidance on fair market value, some manufacturers will continue using unrealistic, overly restrictive fair market value assumptions that could undermine the industry's fee-based distribution business model and inappropriately complicate negotiations over service fees that permit wholesalers to provide appropriate services to manufacturers and bring efficiencies to the supply channel.

Several commenters encouraged CMS to provide guidance on the concept of fair market value, stating that without more specificity about what CMS considers reasonable it may encourage some manufacturers to adopt unrealistic restrictive fair market value assumptions. Further, CMS should supplement the definition in the final rule by clarifying how manufacturers are expected to determine fair market value to increase uniformity in price reporting between manufacturers. Another commenter stated that CMS should establish more specific grounds for establishing fair market value when service fees for a variety of services are combined and stated as a percentage of sales payment. Finally, another commenter encouraged CMS to acknowledge that many or most of the fee arrangements that are common in the industry tend to be percentage based agreements and that manufacturers can establish a fair market value rationale for a percentage based fee through industry benchmarking by comparing types of specific services outlined in an agreement with ranges of payments observed throughout the industry.

Response: We do not agree that we should further define fair market value for purposes of the bona fide service fee definition in § 447.502. We continue to believe that manufacturers should retain flexibility in determining whether service fees are paid at fair market value in light of constant changes in the pharmaceutical marketplace. We agree with the discussion in the CY 2007 PFS final rule (71 FR 69669) that the appropriate method for determining whether a fee represents fair market

value may depend upon specific contracting terms and the services involved. Therefore, we are not mandating a specific method or providing further guidance on fair market value at this time.

Comment: Several commenters requested that if CMS does not define fair market value, it should identify the nature and scope of what it would consider to be adequate fair market value documentation and establish some ground rules for establishing fair market value. For example, the rule could state that it would be sufficient to document hard-fought negotiations between wholesalers and manufacturers over the scope of services to be provided and the fees paid, including the manufacturer's assessment of alternatives such as using internal resources or other service providers, or going without. Documentation of negotiations between manufacturers and wholesalers over fee arrangements should be sufficient to establish that any agreed upon fees are consistent with a meeting of the minds by the parties, which is the essence of the definition of fair market value. One commenter indicated that CMS should clarify that adequate documentation does not require third party appraisals and rather requires that the contract between the parties show the agreed upon price.

Response: We appreciate the comments but have decided not to specify the type or scope of documentation that is necessary to support a manufacturer's determination of fair market value as part of this final rule because, we believe the determination of fair market value is by nature subjective and many factors can contribute to its determination, and as a result, it can be a range of values. Therefore, we believe that any documentation can be used, provided that it makes clear the methodologies or factors the manufacturer used in making its fair market value determination. We expect such determination of fair market value and documentation be made contemporaneously with the manufacturer's agreement to pay the fee. As with other reasonable assumptions, in accordance with the requirements of the national rebate agreement, each manufacturer must maintain adequate documentation supporting its assumptions.

Comment: One commenter stated that CMS should require manufacturers to disclose to the service provider the portion of the service it will treat as bona fide, and if not 100 percent, its basis for excluding a portion. The commenter also said that CMS should issue some guidelines, based on the data it has collected (that is, for purposes of determining direct or indirect remuneration under Medicare Part D), as to what it will accept as a reasonable fair market value determination or method. The commenter also indicated that guidance should not be exclusive, but in the form of safe harbors so that the parties can work to meet the safe harbor and know that, if they do, the arrangement will be respected. While the commenter understands CMS's concern that discounts may be disguised as services fees, the commenter does not believe that providing guidance on fair market value will make this practice more likely (discounts disguised as service fees). Instead the commenter believes such guidance will give the parties the means by which to demonstrate in a manner acceptable to CMS when service fees are in fact legitimate.

Response: As we noted previously, we have decided not to provide additional guidance regarding fair market value given that a fair market value determination may depend on the details of the specific arrangements regarding the services being performed. We believe that any documentation can be used, provided that it clarifies the methodologies or factors the manufacturer used in making its fair market value determination, and, the manufacturer maintains adequate documentation supporting its determination.

Furthermore, we are not responsible for establishing such safe harbors, as the OIG of the U.S. Department of Health and Human Services is responsible for issuing such advisory opinions related to health care fraud and abuse under section 1128D(b) of the Act.

Comment: A few commenters urged CMS to rely on the GPO safe harbor associated with the federal anti-kickback statute as it defines which fees would qualify as bona fide. The commenter stated that the final rule should state that a fee satisfying the anti-kickback statute safe harbor requirement meets the fair market value prerequisite and is a bona fide service fee. Another commenter believed fees paid to GPOs may qualify as a bona fide service fee based upon the fact that GPOs are non-purchasing entities whose main business is acting as a brokering agent to negotiate pricing for the operational costs of managing the agreements and memberships.

Response: We believe that to adopt a categorical exclusion of administrative fees if they fall within the GPO safe harbor provisions would be inconsistent with our guidance regarding an actual determination as to whether or not the fee is bona fide because it would mean that the manufacturer has not evaluated the details of the specific arrangements regarding the services being performed. Additionally, we do not agree that we should adopt the safe harbor provisions associated with the federal anti-kickback statute as part of this rule as it does not address bona fide service fee determinations for purposes of determining included and excluded transactions related to a manufacturer's determination of AMP and best price.

d. ''Not Passed on In Whole or In Part''

Comment: One commenter stated that the CY 2007 PFS Final Rule (71 FR 69624) would somewhat resolve the proposed rule's silence on CMS's interpretation of ''not passed on'' requirement that remains in the proposed bona fide service fee definition. The commenter requested that CMS clarify that unless a manufacturer has specific knowledge that a service fee is being passed through to a member, the manufacturer does not need to account for it in AMP and best price reporting. Further, the commenter requested that at the very least manufacturers have no affirmative duty to ascertain from GPO members information about any GPO service fee, and to the extent that such information must be reported by the manufacturer, the GPO should furnish the information. Moreover, any reporting obligation should be triggered only when such services are uniformly based on member purchases of the manufacturers' products and not based on any GPO allocations methods, GPO incentive programs, GPO ownership interests, or other factors.

Another commenter encouraged CMS to consider ways to facilitate such reporting if CMS elects not to affirmatively continue the not-passed through presumption. One commenter stated that administrative fees paid to pharmacy benefit manufacturers (PBMs) under the national rebate agreement should be presumed to be retained by the PBM and not intended to adjust the purchase price, unless there is evidence that the PBM intends to pass them through. Additionally, the commenter believed that a rule that treats these types of fees paid to non-purchasers as distinct from discounts provided to the beneficiaries of their services is consistent with the Medicaid statute and safe harbors, and is far easier to administer through manufacturers' drug price reporting systems.

Response: As discussed earlier in this section, we have revised our position taken in regards to the 2007 AMP final rule for the not passed on prong of the

bona fide service fee test to more fully align with the ASP policy which allows manufacturers, for certifying to the accuracy of their ASP calculations, to presume, in the absence of any evidence or notice to the contrary, that the fee paid is not passed on to a client, or customer of any entity (if a fee paid meets the other elements of the definition of bona fide service fee).

Therefore, for the calculation of AMP and best price, we are now allowing that if a manufacturer has determined that a fee paid meets the other elements of the definition of bona fide service fee, then the manufacturer may presume, in the absence of any evidence or notice to the contrary, that the fee paid is not passed on to a client or customer of any entity. However, when a manufacturer does have specific knowledge that a fee is being passed on in whole or in part, it must be accurately accounted for in the determination of AMP and best price.

Furthermore, fees, including but not limited to, distribution service fees, inventory management fees, product stocking allowances, fees associated with administrative service agreements and patient care programs (such as medication compliance programs and patient education programs) and other fees paid to GPOs that meet the definition of bona fide service fees as defined in this final rule, are excluded from the calculation of AMP and best price. If a manufacturer has an agreement with the GPO that any of these fees are passed on to the GPO's members or customers, they would be considered price concessions and not excluded as bona fide service fees. When there is evidence or knowledge that the fee or other price concession is passed on to the GPO's member or customers (for example, the contract between the manufacturer and GPO or other service provider may contain a provision that indicates the fee be used by the provider to further discount the price paid by the wholesaler or retail community pharmacy), the manufacturer must account for such fee or price concession in its calculation of AMP as described elsewhere in this final rule. This is consistent with the statutory requirement at section 1927(k)(1)(B)(ii) of the Act which specifies, in part, that any other discounts, rebates, payment or other financial transactions that are received by, paid by, or passed through to, retail community pharmacies shall be included in the AMP for a COD.

Comment: A few commenters requested that CMS provide guidance as to whether the ''passed on'' portion of a service fee would cause the entire fee to fail the bona fide service fee test thus making the entire fee a discount, or whether only that portion of a fee which is passed on would be treated as a discount.

Response: As discussed earlier in this section of this final rule, as well as the CY 2007 PFS final rule (71 FR 69668), a fee is not a bona fide service fee if even a portion of the fee is passed on. However, the manufacturer would need to conduct further analysis as to whether there is an adjustment of price for an entity included in the AMP or best price calculation to determine if the fee is passed on, in whole or in part. As discussed in prior responses, we believe that by making the application of the exclusion of bona fide service fees consistent with the ASP rule, manufacturers will be less likely to have compliance concerns.

e. Buildup Approach Implications

Comment: One commenter noted that if the buildup approach is adopted into rule, manufacturers are concerned about valuation of the increased data services at fair market value in bona fide service fees to wholesalers. The commenter specified that manufacturers raised concerns with their ability to evaluate fair market value of the necessary expanded data services.

Response: We appreciate the comments and, as discussed in greater detail section II.C. of this final rule, in regards to the buildup model, we have decided to retain the option that manufacturers may make reasonable assumptions and presume, in the absence of guidance and adequate documentation to the contrary, that prices paid to manufacturers by wholesalers are for drugs distributed to retail community pharmacies. We believe that the concerns raised by commenters regarding data services in the context of bona fide service fee determinations under a buildup model have been addressed by this change as the buildup model is not being finalized.

Therefore, in light of the comments and for the reasons we articulated in this section, in this final rule we are finalizing the definition of bona fide service fee and replacing the specific reference to ''wholesalers or retail community pharmacies'' with ''an entity'' under § 447.502.

5. Bundled Sales

In proposed § 447.502, we proposed to revise the bundled sale definition by reformatting its structure to separate the additional clarifying characteristics of bundled sales from the main definition. This was accomplished by creating two paragraphs at the end of the definition that provided further clarification regarding characteristics of a bundled sale. We also proposed, in response to prior manufacturer questions, to add the phrase ''including but not limited to those discounts resulting from a contingent arrangement'' to paragraph (1) to clarify which discounts should be allocated under the bundled arrangement (as discussed in more detail at 77 FR 5321). We received the following comments concerning the proposed bundled sales revised definition:

Comment: We received several comments regarding the statement added to the existing definition of bundled sale at § 447.502, concerning discounts in a bundled sale which include, but are not limited to, those discounts resulting from contingent arrangements. Several commenters expressed concern that the phrase ''including but not limited to'' will require manufacturers to allocate non-contingent discounts provided on drugs included in bundled sales (as well as any contingent discounts on those drugs) across all products in the bundled sale. The commenters indicated that non-contingent discounts are not part of bundled arrangements and should not be subject to allocation. Commenters noted that CMS could add an explicit element to the definition of bundled sale to indicate that a bundled sale does not exist where a discount or price concession is established independently and not conditioned upon any other purchase or performance requirement, or where the discount is not greater than if purchased outside of the multi-product arrangement.

One commenter stated that the preamble language intended to clarify that, where discounts for different products in a single contract are each determined independently and with no contingencies across products, a bundled sale does not exist and no discount allocations across products are required. However, this is inconsistent with CMS's proposed regulations text and CMS needs to make its final regulations text consistent with this approach.

One commenter indicated that if CMS's intent to have the new paragraph on non-contingent sales specifically require the allocation of non-contingent discounts on drugs that are part of a bundled sale along with any contingent discounts on these drugs, it is important for CMS to recognize that this may require a change to the discount allocation method some manufacturers have implemented based on the current definition. Furthermore, if this

paragraph is adopted in this final rule, CMS should clarify requirements are effective the date of the final rule on a prospective basis.

Several commenters provided reasons why we should not require that a non-contingent discount be considered as part of a bundled arrangement and allocated across the entire bundled sale, such as AMP and/or best price reporting uncertainties, 340B ceiling price calculation uncertainties, and reduction in Medicaid rebate liabilities. Several commenters provided detailed mathematical equations and examples (with very similar scenarios) to demonstrate that the including but not limited to language should be removed.

In one of these examples, the commenter provided that it does not make sense to treat a discount as bundled when it is not contingent and included the following examples: If 3 drugs are part of the same contract, and a contingent discount is offered on drug A and B if they are placed on a preferred formulary tier and a non-contingent discount is offered on drug C, drug C should not be considered as part of the drug A and B bundled arrangement simply because drug C is covered by the same contract as Drug A and B. Another example provided if 2 drugs are part of the same contract and 5 percent discount is offered on Drug A if X volume is purchased and/or 5 percent discount is offered on Drug A if Drug A and B are both placed on a preferred formulary tier, the volume discount should not be considered as part of any bundled arrangement with Drug B simply because the non-contingent volume discount is included in the same contract as the contingent formulary discount. The commenter requested that CMS remove the including but not limited language to clarify that in the first scenario only drugs A and B should be considered a bundle arrangement and not Drugs A, B and C, and that in the second scenario only the formulary tier discount should be considered a part of a bundled arrangement and not the volume discount.

Response: We did not intend to revise the policy expressed in the 2007 AMP final rule but rather to reiterate that when a bundled sale exists, manufacturers are required to allocate all discounts across all the products in the bundled arrangement. As discussed in the 2007 AMP final rule, we consider all drugs to be within the bundled sales if: (1) Any drug must be purchased to get a discount on any drug in the bundle regardless of whether any drug is purchased at full price; (2) there is a performance requirement (such as inclusion or tier placement on a formulary or achieving a certain level or percentage of sales for one drug to receive a discount on another drug); or (3) price concessions are greater than those which would have been available had the bundled drugs been purchased separately or outside the bundled arrangement. When a manufacturer offers discounts on multiple products under a single contract (for example, to minimize the administrative burden of developing several single contracts which offer separate discounts on the multiple products) no bundled sales arrangement exists as long as all of the following conditions are met: (1) A discount or price concession is established independently for each product within the contract; (2) the purchase price under the contract is not contingent upon any other product in the contract or upon some other performance requirement (such as the achievement of market share or inclusion or tier placement on a formulary); and (3) the discount provided for any product under the contract is no greater than if the product was purchased outside of the contract. We understand the commenters' concerns regarding the proposed language ''but not limited to'' in the definition as proposed at § 447.502, and therefore, in this final rule, we are not finalizing that proposed language in paragraph (1), and reiterate that all discounts in a bundled sale would need to be allocated proportionally to the total dollar value of units of all drugs or products sold under the bundled arrangement.

Comment: Several commenters requested or encouraged CMS to use specific illustrative examples to further explain these bundled sales issues in the final rule, just as it did in the AMP final rule, including examples of multi-product contracts with no contingencies, multi-product contracts with both contingent and non-contingent discounts, multi-product contracts in which one or more discounts is contingent on the purchase or the achievement of other performance requirements, and multi-product contracts in which one of the discounts or other price concessions are greater than those which would have been available had the product been purchased separately.

Response: As we noted previously, we are finalizing § 447.502 without the proposed language ''but not limited to'' in the definition of bundled sales. As noted above, we have identified the conditions that must be met for a multi-product sales arrangements to fall outside the bundled sales definition, so illustrative examples of bundled arrangements with non-contingent discounts are not needed.

Comment: A commenter recommended that CMS revise the language in paragraph (1) to read as follows: ''(1) All discounts on all products included in a bundled sales arrangement, including those discounts on such products that do not result from a contingent arrangement, are to be allocated proportionally to the dollar value of the units of all products sold under the bundled arrangement,'' because this language specifically addresses the treatment of non-contingent and contingent discounts. Another commenter requested the following language be added to the regulatory definition of bundled sale: ''No bundled sale exists where multiple products are included in a single arrangement and the discount on each product is determined independently of the discount, pricing, and performance as to any other product in the arrangement, and the discounts offered are not greater than would be the case if the products were purchased outside of the multi-product arrangement.'' The commenter believed the addition of this language would make it explicit that a multi-product contract that includes no cross-product contingencies does not constitute a bundled sale.

Response: We appreciate the comments and suggested changes. In this final rule, we are not retaining the ''but not limited to'' language we proposed in the definition of bundled sale at § 447.502. We believe that the removal of this proposed language in the final regulation, and our responses above regarding the treatment of multi-product sales reflect our long-standing policy regarding bundled sales.

Comment: A commenter indicated that the proposed change in the definition of a bundled sale could have an adverse impact on wholesaler contractual relationships with certain manufacturers, unduly complicating the aggregation and allocation of discounts associated with wholesaler purchases of multiple products for inclusion in the portfolio of products offered to pharmacies under generic sourcing programs.

Response: We believe that not finalizing the proposed phrase ''but not limited to'' in the definition of bundled sale in this final rule will address the commenter's concerns with any potential adverse impact on the contractual relationships between wholesalers and manufacturers since the final bundled sale definition reiterates that all discounts in the bundled arrangement must be allocated

proportionally to the total dollar value of the units of all drugs or products sold under the bundled arrangement. While the issue of bundled sale in the context of AMP and best price was not addressed as a subject within the Affordable Care Act, as we stated in the proposed rule, we believe clarification on this subject was necessary as manufacturers had previously raised questions after the publication of the 2007 AMP final rule (77 FR 5321). Our intent in reiterating views previously expressed to questions raised in the 2007 AMP final rule (77 FR 5321) was to provide clarification and ensure that all manufacturers adopt a consistent approach when accounting for bundled arrangements in the determination of AMP and best price.

Comment: A few commenters indicated that the broader term, products, should be used rather than drugs because the DRA final rule specifically recognized that bundled sale arrangements can involve CODs, as well as some other purchase requirement. These commenters noted that the suggested modifications include the term, product, rather than drugs because as CMS recognized in the 2007 AMP final rule, bundled sales arrangements can include CODs, as well as some other purchase requirement.

Response: We agree and have revised the final bundled sale definition at § 447.502 to add the term product, because bundled arrangements can include CODs, as well as other product purchases as part of the bundled sale requirement. A discount based upon the purchase of another non-drug product within a contingent arrangement (for example, discounts on drug purchases contingent upon sales of non-drug products) is considered a bundled arrangement.

Comment: One commenter stated that the terms, bundled sale and bundled arrangement, are synonymous because they appear to be used interchangeably and without distinction in the definition of bundled sale in the proposed rule. The commenter asked that CMS provide additional guidance and make clarifying edits to the proposed definition of bundled sale to further the goal of ensuring AMP and best price reflect true and accurate prices.

Response: We agree with the commenter that bundled sale and bundled arrangement are used interchangeably. Therefore, we do not believe that further changes to the definition are needed since these terms are used interchangeably.

Comment: A few commenters were concerned that the proposed procedures would require vendors to keep two sets of books—one for financial reporting purposes in which product-specific sales are recorded at the contracted discounted price assigned to each product reduced by the allocated amount of any overarching performance driven volume discount, and a second shadow set of books for government price reporting purposes that reflect the reallocated product-specific prices that flow from sales made under different contracts that nominally use identical product pricing.

A few commenters believed that, absent changes in common contract terms, the new definition would require the incorporation of complex manual steps into the calculation of monthly AMPs and complicate the difficult process of completing these calculations in compliance with applicable timelines. The commenters were worried about the economic waste associated with having to renegotiate a large number of contracts if they cannot manage the manual process that the bundled sale aggregation and allocation would require. The penalties for late AMP filing adds to these concerns and the commenters encouraged CMS to forego implementing the changed definition of bundled sales.

A few commenters stated that the revised definition of bundled sales in the proposed rule could complicate the aggregation and allocation of discounts associated with sales of multiple source products to large customers including wholesalers and retail community pharmacies.

Response: We are not requiring manufacturers to change their generally accepted accounting practices. Moreover, it was not our intention to create a significant change to the definition of bundled sales; rather, we only intended to provide additional clarification as noted in the proposed rule (77 FR 5321). We believe the revision we are making to the definition of bundled sale in this final rule by removing the ''but not limited to'' language will address the concerns raised by these commenters regarding manufacturers development of contracts specific to bundled sales.

For the reasons we articulated in this section, we are finalizing our proposed definition of bundled sales at § 447.502, except that, in response to the comments, we are omitting ''but not limited'' in paragraph (1); and have revised paragraph (2) to add ''or products'' before ''in the bundle'' at the end of the paragraph.

6. Clotting Factor

Section 2501(a) of the Affordable Care Act established a minimum rebate percentage of 17.1 percent of AMP for a single source drug or an innovator multiple source drug that is a clotting factor for which a separate furnishing payment is authorized under section 1842(o)(5) of the Act and which is included on a list of such factors specified and updated regularly by the Secretary. We proposed a definition of clotting factor consistent with these provisions in proposed § 447.502 (77 FR 5321 and 5359).

We did not receive any comments about the proposed definition of clotting factor under § 447.502, so we are finalizing it as proposed, except to remove the word ''the'' prior to the first reference to CMS. This technical revision is not intended to change the meaning of this definition.

7. Covered Outpatient Drug (COD)

In accordance with section 1927 of the Act, manufacturers that have entered into a rebate agreement with the Secretary are responsible for paying rebates to states for their CODs for which payment has been made under the state plan. Manufacturers are responsible for submitting certain drug product data for each of their CODs. As discussed in the proposed rule (77 FR 5321 through 5323, 5359 through 5360), we proposed to add a definition of COD to § 447.502. We proposed that a drug is considered a COD when the drug may be dispensed only upon prescription (except as discussed later in this section for certain non-prescription drugs), and it meets at least one of the criteria as described in section 1927(k)(2) of the Act.

Consistent with section 1927(k)(3) of the Act, we proposed (77 FR 5322 and 5360) that except as discussed later in this preamble section, a drug, biological product, or insulin would not be considered a COD when that drug or product is billed as a bundled service with, and provided as part of or incident to and in the same setting as, any of the following services (and payment is made as part of that service instead of as a direct reimbursement for the drug):

- Inpatient Hospital Services;
- Hospice Services;
- Dental Services, except that drugs for which the State plan authorizes direct reimbursement to the dispensing dentist are CODs;
- Physician services;
- Outpatient hospital services;
- Nursing facility and services provided by an intermediate care facility for individuals with intellectual disabilities;[4]

[4] Please note that since publication of the proposed rule there has been a change in

Continued

• Other laboratory and x-ray services; or

• Renal dialysis.

Additionally, in accordance with section 1927(k)(2) of the Act and the requirements of section 510 of the FFDCA, we proposed that a drug would only be treated as a COD if the drug is required to have a National Drug Code (NDC) and is listed electronically with FDA (77 FR 5322). We further proposed that manufacturers submit any relevant FDA approved application numbers for drugs reported to the MDR program (77 FR 5322). For drugs that are CODs that do not have an approved application number, we proposed that the manufacturer must provide evidence demonstrating that its drug meets the statutory definition of a COD (77 FR 5323). These additional standards were designed to ensure compliance with the definition of COD in section 1927(k) of the Act.

We received the following comments concerning the proposal to add a definition of COD to § 447.502:

a. Consistency With Medicare

Comment: One commenter suggested that CMS reconsider its interpretation of ''covered Part D drug'' under Medicare Part D to make the definitions consistent between Medicaid and Medicare, which is especially important for dual-eligible individuals.

Response: We appreciate the comment; however, this rule is designed to implement the Medicaid provisions regarding CODs as set forth in section 1927(k) of the Act. We are not addressing the definition of a Medicare covered Part D drug in this final rule.

b. FDA (Electronic Listing, Drug Approval Status, Application Number, etc.)

Comment: A few commenters noted that for a product to meet the definition of a COD, it is not categorically required to have an FDA approval, and that there are other ways for a product to meet the definition. A few commenters stated that CMS's goals are to provide safe, functional and low-cost benefits to beneficiaries, and that these goals are not dependent on an FDA approval.

Response: We agree that there are some drugs on the market that do not have an FDA approved application but, nonetheless, meet the definition of a COD. However, for drugs without FDA approval to satisfy the definition of COD, those drugs must still meet the definition of COD in section 1927(k)(2) of the Act. We believe this will ensure that only drugs that meet the statutory definition of COD are dispensed to Medicaid beneficiaries and that Medicaid dollars are spent consistent with the statute.

Comment: One commenter asked how states will be informed as to the status of drugs without approved FDA numbers and what will be used to make the determination and the reasoning or algorithm used to make that determination.

Response: In accordance with the requirements of the MDR program, manufacturers are required to report to CMS drugs that meet the definition of a COD. Beginning July 19, 2014, manufacturers have been reporting the FDA application number, if applicable, and the COD status code as part of their product data information via the Drug Data Reporting for Medicaid (DDR) system to demonstrate how their drugs that are reported to the MDR program meet the statutory definition of a COD. This is a set of codes that identify either the type of FDA approval or other authority under which the drug is marketed. The COD status code provides information which the states can utilize to determine how a drug without an FDA approval meets the definition of a COD. States have information via DDR or by accessing the CMS's quarterly rebate drug product data file on *www.Medicaid.gov.*

Comment: A few commenters stated that because the information found on FDA's databases is not up to date, fully accurate, nor fully electronic and because CMS has no oversight over FDA, that FDA's data should not be used to administer CMS's programs. Commenters recommended that CMS states how it will ensure that information relied on by states for administration of pharmacy benefits will be maintained in a current fashion. Several commenters also expressed concern regarding their lack of control over the time it takes FDA to transfer files from paper to the electronic database, if FDA agrees to do so.

Response: Given the comments received, we have decided not to finalize the electronic FDA listing requirement that was included in the proposed COD definition. Specifically, we have decided not to finalize proposed paragraph (3)(ii) which excludes from the definition of COD, a drug that is not listed electronically with the FDA.

However, we are clarifying that manufacturers are responsible for submitting accurate data to CMS. We also note that for CMS to be able to verify that NDCs reported to the MDR program meet the definition of a COD, we will be using drug information listed with FDA such as Marketing Category and Drug Type, for example, to verify that an NDC meets the statutory definition in section 1927(k) of the Act. Additionally, when a drug is electronically listed with FDA, we have the ability to consult with FDA staff regarding the regulatory status of the drug. Therefore, manufacturers should ensure that their NDCs are listed with FDA (*See* 21 CFR 207.20, 207.21(b), 207.30) and should contact FDA if discrepancies or omissions are identified. Drug information can be searched by NDC or by downloading a comprehensive NDC Structured Product Labeling (SPL) Data Elements file (NSDE) file at FDA's Online Label Repository at *http://labels.fda.gov.* FDA updates the Online Label Repository on a regular basis with the most recent drug listing information that companies have submitted to FDA. Manufacturers may email FDA at *eDRLS@fda.hhs.gov* for assistance with regulatory questions or *SPL@fda.hhs.gov* for technical questions.

Further, we appreciate the comments concerning our use of the FDA listing to verify if a product meets the definition of COD for purposes of our program. Given the statutory definition of COD under section 1927(k)(2) of the Act, we have used that listing as a basis to seek additional information from manufacturers regarding product submissions. For example, we have previously published a file containing products that were not listed with FDA (the non-listed product file) on Medicaid.gov at *http://www.medicaid.gov/Medicaid-CHIP-Program-Information/By-Topics/Benefits/Prescription-Drugs/Medicaid-Drug-Rebate-Program-Data.html.* This non-listed product file was created by matching the NDCs in the MDR program against FDA's Online Label Repository's comprehensive NSDE file to determine which NDCs in the MDR program were not listed with FDA.

We have updated the non-listed product file on Medicaid.gov and we have also notified manufacturers that report products to CMS that are not listed with FDA. If we are not able to verify if a product meets the definition of a COD, we will delete these products from the MDR file after providing notice to manufacturers of these products and to states. A deleted drug may be reinstated into the MDR program once we are able to verify that the drug meets the statutory definition of a COD. In such situations, we will use information submitted by the manufacturer (for example, letter of approval from FDA or

terminology and the phrase ''mentally retarded'' has been replaced with ''individuals with intellectual disabilities.''

application number) to verify that the drug meets the statutory definition of a COD.

Additionally, we appreciate the commenters' concerns about relying on FDA's electronic database. We recognize that the electronic database is not published for the purposes of the MDR program. As discussed in this section, we use FDA's electronic database to consider manufacturer submissions and seek additional information, if necessary, to confirm that products meet the COD definition in section 1927(k) of the Act.

Comment: One commenter expressed concern regarding FDA's method of publishing the NDCs of drugs that are packaged with one NDC–11 on inner package and a different NDC–11 on the outer package. The commenter was concerned because FDA does not list each NDC–11 as a separate drug listing on the new NDC Directory, and therefore, CMS would be unable to confirm that each NDC–11 met the FDA listing requirement found in the proposed rule. The commenter asked for assurance that FDA's handling of the inner/outer NDCs would not jeopardize their drugs' inclusion in the MDR program.

Response: As discussed previously in this section, we are not relying on the NDC Directory information for verification that a drug reported to CMS meets the definition of a COD. We recognize that the NDC Directory does not identify the different NDC–11s that could affect the reporting of the inner and outer packages. Therefore, as discussed previously in this section, we use FDA's NSDE file, which can be found by accessing FDA's Online Label Repository Web page at *http://labels.fda.gov,* to seek additional information about the status of products submitted by manufacturers. If manufacturers have any problems with the reporting of products for the purpose of CMS verifying whether a product meets the definition of CODs, the manufacturers can contact CMS for further information on how they can demonstrate compliance with section 1927(k)(2) of the Act.

Comment: A few commenters requested clarification on the proposed requirement to list all drugs electronically with FDA for a drug to meet the definition of a COD if the current manufacturer is not the original submitter of the registration to FDA, or if the drug was not originally listed by electronic means. A commenter stated that in the case of the current manufacturer having purchased the drug from another manufacturer, the only way for the current manufacturer to submit updates to the listing information is by paper submission, as part of FDA's Waiver process. Another commenter noted that although some of their products were submitted using the old paper process, the products nonetheless appear on FDA's new NDC Directory. This commenter asked if old paper filings would need to be resubmitted electronically, or if CMS will use the new NDC Directory to verify that the electronic listing requirement has been met.

Response: We recognize the concerns that commenters have regarding difficulties that may be encountered when a manufacturer attempts to submit their NDC information to FDA electronically. We encourage manufacturers to check the FDA's NSDE file or Online Label Repository to confirm that their NDCs are properly listed there, especially those NDCs which may have been submitted to FDA on paper. Additionally, we encourage manufacturers to ensure that their drugs are listed on FDA's NSDE file or Online Label Repository, whether or not there have been updates to their drugs. We are aware that since the publication of the proposed rule, FDA has been updating the NSDE file/Online Label Repository on a daily basis and has been assisting manufacturers with questions/issues regarding listing their drugs electronically, whether the current manufacturer was the original submitter or not, or if the original information was submitted on paper. Additionally, as previously stated, we have decided not to finalize the electronic FDA listing requirement that was included in the proposed COD definition. Specifically, we have decided not to finalize proposed paragraph (3)(ii) which excludes from the definition of COD, a drug that is not listed electronically with the FDA.

Comment: One commenter suggested that the electronic listing requirement in the proposed definition of COD be changed to include any NDC that is listed with FDA and for which updates are filed (whether by paper or electronically) may qualify as a COD if all other requirements are met.

Response: We appreciate the comment, but as noted previously in this section, we have decided not to finalize this requirement and so this change is not necessary. However, as discussed previously in this section, we will still use the FDA NSDE file as a source to verify that drugs reported to the MDR program meet the definition of a COD as defined in section 1927(k)(2) of the Act.

Comment: One commenter asked if a manufacturer should electronically list their entire over-the-counter (OTC) line of products, or only those that have been approved under an NDA or an ANDA. Another commenter noted that sometimes prescriptions are written for OTC products and these products are not listed with FDA. One commenter stated that they have some OTC products that are not listed electronically with FDA because the products are not approved by FDA, nor will the manufacturer be seeking approval, and they asked for a solution for this situation.

Response: FDA requires all prescription and OTC drugs, regardless of the marketing authority or FDA approval status, to be listed electronically with FDA (21 CFR part 207). We will use the FDA listing as a source to verify whether drugs qualify as CODs but as noted previously, manufacturers have other options to demonstrate that their products meet the definition of COD in section 1927(k)(2) of the Act.

Comment: One commenter stated that some approved products, such as biologics, are not listed on Drugs@FDA and the commenter asked if this is the sole source for obtaining and providing application numbers.

Response: To our knowledge, Drugs@FDA was the only source at the time of publication of the proposed rule to list biological products approved for sale in the United States. Since that time, FDA has created the Purple Book: Lists of Licensed Biological Products which also contains information on application numbers for biologics and can be found at *http://www.fda.gov/Drugs/DevelopmentApprovalProcess/HowDrugsareDevelopedandApproved/ApprovalApplications/TherapeuticBiologicApplications/Biosimilars/ucm411418.htm.* As noted previously, although we are not finalizing our proposal to require electronic FDA listing as was included in the proposed COD definition, we will use the FDA listing to help verify that the product meets the definition of a COD. However, manufacturers have other options to demonstrate that their products meet the definition of COD in section 1927(k)(2) of the Act.

Comment: One commenter stated that they market some products ''approved as other'' but the products are listed in FDA's new NDC Directory and questioned if that is sufficient.

Response: Although, as previously noted, we are not finalizing the electronic FDA listing requirement that was included in the proposed COD definition, if manufacturers list their drugs with FDA, and those drugs are included on FDA's NSDE file, then CMS

will be able to use the listing information to verify whether a drug meets the statutory definition of a COD for purposes of the MDR program.

Comment: We received many comments regarding the proposal that, in the case where a product does not have an FDA application number, manufacturers provide evidence demonstrating that the product meets the statutory definition of a COD under section 1927(k)(2) through (4) of the Act (77 FR 5323). One commenter requested that we withdraw the proposal requiring manufacturers to submit evidence that a drug is not a new drug. The commenter stated that requiring such evidence is beyond the authority of CMS, that the requirement usurps FDA's role in the determination of legally marketed products, and that CMS lacks technical expertise to evaluate the evidence.

Another commenter asked who, such as CMS or pharmaceutical professionals, will decide if the evidence provided is sufficient to prove a product's status as a COD. Several commenters also asked for detailed guidance, or a protocol, on what information to submit as evidence. One of these commenters asked if, in the case of OTC products, quoting an OTC monograph would be sufficient evidence. Another commenter suggested that when a manufacturer reports a product to CMS as a COD and the manufacturer certifies that product data, the certification could serve as the evidence that the product meets the definition of a COD.

Response: We appreciate the comments received concerning the need to clarify our proposal regarding the submission of evidence concerning the COD status (77 FR 5323). We have the responsibility of administering the MDR program and ensuring that the information we provide to states is accurate. Manufacturers who have signed the national rebate agreement have the responsibility of reporting to the program drugs that meet the definition of a COD. Manufacturers have, at times, submitted erroneous product information to CMS, where the products do not qualify as CODs. Therefore, for CMS to be able to ensure compliance under section 1927 of the Act, we need to have adequate information to verify whether drugs entering the MDR program meet the statutory definition of a COD. We believe our list of COD Status codes is broad enough for manufacturers to have various options to choose from to support how their drugs meet the definition of a COD.

We also appreciate the comments concerning our authority to require information that demonstrates that a product is not a new drug. As noted previously, although we are not finalizing the requirement that a drug be listed electronically with the FDA to meet the definition of COD, we will use the FDA listing to verify that the product meets that definition; however, manufacturers have other options to demonstrate that their products meet the definition of COD in section 1927 of the Act. In addition to the broad list of COD Status codes that manufacturers can select from to support how their drugs meet the definition, manufacturers could submit the FDA application number or other information (for example, approval letter) to demonstrate that their products meet the COD definition if the list of COD Status codes does not provide enough information. Manufacturers can also email CMS at *mdroperations@cms.hhs.gov* if they have questions about how to report their drugs or how to determine if their drugs meet the definition of a COD.

Finally, we disagree with the commenter that specifically asked us to withdraw the proposal to submit evidence that a drug is not a new drug or a COD. As discussed previously in this section, manufacturers are responsible for submitting product data regarding CODs as defined in section 1927(k) of the Act. The submission of evidence requested in the proposed rule was designed to address this responsibility and to establish that a drug satisfies the criteria in section 1927(k)(2) of the Act. We are also clarifying that CMS does not make determinations regarding whether or not a drug is legally marketed, but only determines whether the products reported to the MDR program meet the statutory definition of a COD.

We note that we do not intend to usurp FDA's role regarding whether or not a drug is legally marketed. Rather, we are only requesting that manufacturers submit information needed for CMS to make a determination regarding coverage under the MDR program. We believe that the clarifications provided in this final rule will address the commenters' concerns.

Comment: We received several comments regarding the proposed requirement to submit supporting evidence, including evidence about specific products and how such products meet the COD statutory definition. For example, commenters provided regulatory background, history of products, and comparisons of one type of product to another to demonstrate why certain products or types of products meet the definition.

Response: We appreciate the various explanations and other information that was submitted regarding the regulatory background and history of specific products and types of products that could be used to evaluate the COD status under the statutory definition. As previously noted in this section, manufacturers are able to submit information, such as the COD status code, FDA application number, or approval letter, to provide evidence that a drug qualifies as a COD which will allow us to verify whether a product meets the statutory definition of a COD.

Comment: One commenter requested clarification about language in the proposed definition of COD regarding two groups of drugs that are defined based on their relationship to the Drug Amendments of 1962. The commenter asked if there is a list of these drugs published on FDA's Web site, and if CMS will publish a list of these drugs or if CMS will use a marker on the quarterly tape of the DDR for Medicaid system to track these drugs.

Response: The FDA does not publish a list of those drugs which qualify as CODs under section 1927(k)(2) of the Act based on their relationship to the Drug Amendments of 1962. At this time we are not planning on publishing a list or using a marker to identify those drugs that meet the definition of a COD based on their relationship to the Drug Amendments of 1962. However, we publish a list of all products reported to the MDR program quarterly on Medicaid.gov, which includes a COD status for each product, which may provide the information the commenter seeks.

Comment: One commenter questioned how the application number for a product will be submitted to CMS and if the type of application needs to be submitted. A few commenters asked for information regarding what application number should be listed if a drug holds multiple approved application numbers, how application numbers will be submitted, and what other information needs to be submitted. Additionally, one commenter asked how long manufacturers will have to submit application numbers.

Response: Starting July 19, 2014, through product data fields in DDR, manufacturers have been able to report the FDA application number, if applicable, and the COD status code to CMS. Manufacturers may continue to email CMS at *mdroperations@cms.hhs.gov* if they have specific questions, such as the above, about entering their product information.

c. Over-the-Counter (OTC) Products

Comment: Several commenters questioned OTC products and their status as CODs. One commenter believed that there should be additional clarity and guidance for manufacturers as to when OTC products are defined as CODs. The commenter noted that sometimes prescriptions are written for OTC products and questioned whether these products are rebate-eligible, and if so, how rebates are calculated. Another commenter stated that the proposed definition of COD excludes some products, such as OTCs that are not drugs. Another commenter asked CMS to instruct states on how to cover OTCs that are not drugs and wanted to ensure that states permit seamless pharmacy reimbursement through processes in place for CODs.

Response: Section 1927(k)(4) of the Act provides that if a state plan for medical assistance includes coverage of prescribed drugs, as described in section 1905(a)(12) of the Act, and permits coverage of OTC drugs, then such drugs are regarded as CODs and, states have the option of covering OTC drugs. As required by section 1927(k)(4) of the Act, they must be prescribed by a physician or other authorized practitioner and must be specifically addressed in the state plan.

Manufacturers are responsible for reporting pricing information on OTC drugs and calculating a URA based on the statutory and regulatory requirements. This information is included in the MDR drug product data file posted on Medicaid.gov. Drugs listed on the drug product data file, which may be accessed by states through the DDR system or on Medicaid.gov, have been reported and certified by manufacturers for inclusion in the MDR program.

Comment: One commenter requested that CMS create or adopt a list of critical OTC products that are CODs.

Response: States are responsible for determining coverage of OTCs and describing that coverage in their state plan. Given that coverage will vary, depending on each state plan, we will not create or adopt a list of critical OTCs; however, we will continue to maintain the drug product data file posted on Medicaid.gov which includes all drugs that are reported to the MDR program.

d. Radiopharmaceuticals

Comment: One commenter suggested that due to distinct features of radiopharmaceuticals, such products do not meet the statutory definition of CODs. The commenter stated that radiopharmaceuticals traditionally have not been viewed as CODs because they are specially compounded to prepare patient-ready unit doses. The commenter noted that most radiopharmaceuticals are used in diagnostic imaging and not therapeutic regimens, but acknowledged that some are used therapeutically. According to the commenter, the components of radiopharmaceutical doses are analogous to excipients and active pharmaceutical ingredients (APIs), which have been confirmed not to meet the definition of a COD.

Another commenter stated that CMS needs to provide more specific guidance on how radiopharmaceuticals would be reported for purposes of the administration of the MDR program. Generally, the commenters noted challenges that would occur in the reporting of radiopharmaceuticals to the MDR program.

Response: We disagree with the commenter that radiopharmaceuticals do not meet the statutory definition of CODs. Section 1927(k)(2)(A) of the Act defines a COD, in part, as a drug which is approved for safety and effectiveness as a prescription drug under section 505 or 507 of the FFDCA or which is approved under section 505(j) of such Act. Radiopharmaceuticals meet the definition of a COD if they are approved under section 505 of the FFDCA unless the limiting definition in section 1927(k)(3) of the Act applies. The statute does not differentiate between diagnostic and therapeutic drugs; both drugs may be considered CODs if they meet the statutory COD definition. While section 1927(k)(3) of the Act limits the definition of a COD, such that the term does not include any such drug ''provided as part of, or as incident to and in the same setting as'' certain specified services (and for which payment may be made as part of payment for those services and not as direct reimbursement for the drug, in situations where the product is separately reimbursed), radiopharmaceuticals qualify as a COD because of the approval process undergone with FDA under section 505 of the FFDCA. Therefore, radiopharmaceuticals are to be reported to the MDR program in the same manner as other CODs for the purposes of the administration of the MDR program.

Further, radiopharmaceuticals approved under section 505 of the FFDCA used in compounding patient-ready doses are also considered CODs because they are required to be assigned NDCs, as well as meet the other requirements in section 1927(k) of the Act to be considered CODs. Unlike radiopharmaceuticals, APIs are not approved as drugs under section 505 of the FFDCA, or as biological products, or insulin. In addition, they are not otherwise covered as described in section 1927(k)(4) of the Act. Therefore, APIs, the individual bulk ingredients used to prepare other compounded prescriptions, are not similar to radiopharmaceuticals, which are subject to FDA's approval process.

Finally, we are aware that several manufacturers have identified potential challenges in reporting product and pricing information for radiopharmaceuticals to the rebate program. We have been working with the radiopharmaceutical manufacturers to address questions and concerns regarding the reporting of these drugs. If a manufacturer has a specific question regarding certain aspects of the reporting requirements specific to radiopharmaceuticals, they should contact CMS for further discussion. We will continue to be available to assist manufacturers with questions on these drugs.

e. Drugs Billed as Part of Bundled Service

Comment: One commenter noted that there was a difference between section 1927(k)(3) of the Act, as compared with the proposed rule, regarding exclusion of drugs from the definition of COD provided incident to and in the same setting as specified services. The commenter stated the statute applies an exclusion for drugs for which payment *may be* made as part of specified services, while the proposed rule applies that exclusion if payment *is* made as part of those services. The commenter stated that the definition in the proposed rule may imply that a drug's status as a COD may vary from state to state and unit to unit, and would be unworkable.

Response: We agree with the commenter and have decided to revise the definition in light of the statutory language in section 1927(k)(3) of the Act. We are revising proposed § 447.502, paragraph (2) of the COD definition to change ''and for which payment is made as part of that service . . .'' to ''and for which payment may be made as part of that service . . .''. As discussed in the proposed rule (77 FR 5322), a drug which is billed as part of a bundled service with, and provided as part of or incident to and in the same setting as the services described in section 1927(k)(3) of the Act meets the definition of a COD if the state authorizes and provides a direct payment for the drug, consistent with

the applicable state plan, separately from the service. While we agree with the commenter that the drug's status as a COD may vary from state to state depending on the state plan and how the drug is paid, we do not agree that states cannot appropriately handle rebate invoicing and utilization reporting. States are currently reporting these CODs, for which the state has provided direct reimbursement, for rebate purposes.

Comment: We received a few comments regarding the status of a drug as a COD, if the drug is paid in part by Medicare as being billed to Medicare as part of a bundled service, and then the billing is subsequently unbundled and a portion of that drug is paid for by Medicaid. One commenter presented the scenario of a dual eligible patient who received treatment for End Stage Renal Disease (ESRD) and Medicare, the primary payer, is billed under the bundled services payment methodology that became effective January 1, 2011. The provider then unbundled the charges and billed the secondary payer, Medicaid, using the NDC for the individual drugs. The commenter asked, since Medicaid is being billed and paying for the claim at an NDC level, if the drug would be rebate-eligible.

Another commenter requested confirmation that if the drug is bundled together with the service for billing purposes, then the drug is not subject to rebates. The commenter believed that if the drugs are paid for under the Medicare ESRD bundled payment rate, and a state Medicaid program paid for any portion of that bundled rate, then the drugs included in the bundled payment rate do not qualify as CODs, and are, therefore, not rebate-eligible.

Response: Generally, if a state Medicaid program provides any payment for a COD that has been billed separately from a service, then in accordance with section 1927(b)(1) of the Act, the drug is subject to a manufacturer rebate under the MDR program. Alternatively, if the drug is provided as part of a bundled service and not separately reimbursed, then the drug does not qualify as a COD, in accordance with section 1927(k)(3) of the Act, and is not subject to rebates.

We note, however, that section 1881(b)(14)(A)(i) of the Act provides that for services furnished on or after January 1, 2011, payments by Medicare for ESRD renal dialysis services, including certain drugs, generally are made under a bundled payment system. We have interpreted these provisions to provide that manufacturers are not required to pay rebates for drugs that are included in the bundled payment, regardless of the state payment. For more information please refer to Manufacturer Release #85 (October 26, 2012).

Comment: One commenter supported CMS's effort to define a COD, especially for the exclusion from the definition of a drug that is reimbursed as part of a bundled service. The commenter asked CMS to clarify that the statement ''and for which payment is made as part of that service instead of as a direct reimbursement for the drug'' does not require a manufacturer to have data for every unit's ultimate reimbursement (that is, government program, private insurer, or patient payment).

Response: We agree that the definition of a COD does not impose a requirement on the manufacturer to have data regarding the ultimate payer for each unit for the purposes of the MDR program. States are responsible, in accordance with section 1927(b)(2) of the Act, for collecting and reporting to manufacturers information for all CODs for which payment was made under the state plan.

Comment: One commenter asked if CMS will maintain a list of products that must be reported as CODs if they are billed separately from a service. If not, the commenter asked if CMS will be providing access to a central repository of information.

Response: In accordance with section 1927 of the Act, manufacturers are responsible for reporting product data for all of their drugs that meet the definition of a COD. States have access, through the DDR system, to a list of all of the drugs that manufacturers report to CMS, which is also posted on Medicaid.gov. At this time, we do not have plans to delineate that data further by identifying those drugs that are considered CODs if they are billed separately from a service.

Comment: One commenter asked if a drug is provided as part of a bundled service, will the manufacturer be required to submit information stating that the drug is billed separately from the service to be used as evidence that the drug is a COD. If yes, then the commenter asked us to elaborate on what type of information.

Response: If a drug meets the statutory definition of a COD, the drug must be reported to the MDR program by participating manufacturers. The manufacturer does not need to submit information stating that the drug may be billed separately from the service.

f. Prescription Prenatal Vitamins, Fluoride, and Medical Foods

Comment: A few commenters supported the statement in the proposed rule that prescription prenatal vitamins without approved applications meet the definition of a COD. One of the commenters encouraged CMS to allow reimbursement for these products during the time that CMS is resolving their regulatory status. The commenter also noted that CMS should explain why it may make determinations regarding the COD status of a product when other agencies may make differing statements. The commenter noted that CMS has different goals than FDA, and should not be bound by FDA's recommendations.

Another commenter expressed concern that the narrow interpretation of the term COD may deny coverage of prescription prenatal vitamins and fluoride. The commenter asked CMS to clarify that prescription prenatal vitamins and fluoride meet the definition of a COD.

Response: Section 1927(d)(1) of the Act provides that states may exclude or otherwise restrict certain CODs. Section 1927(d)(2)(E) of the Act specifically provides that the list of drugs subject to restriction may include prescription vitamins and mineral preparations, except prescription prenatal vitamins and fluoride preparations. We read these provisions in context to provide that prescription prenatal vitamins and fluoride preparations would qualify as CODs, which in accordance with section 1927(d)(2)(E) of the Act states may not restrict or exclude from coverage. Additionally, we note that the COD term is a term used for the purposes of the MDR program, and other agencies' statements regarding the term may not be relevant to the MDR program.

Comment: A commenter expressed concern regarding the requirement that to meet the definition, a product must be used for an accepted medical indication as substantiated by citations in medical compendia. The commenter stated that ample literature shows that prescription prenatal vitamins meet the definition of a COD based on medically accepted use and that compendia requirement may not apply.

Response: Section 1927(k)(3) of the Act specifically excludes from the definition of CODs, those drugs or biological products used for a medical indication which is not a medically accepted indication. Section 1927(k)(6) of the Act, in turn, defines medically accepted indication to mean any use approved by the FDA or use supported by one or more citations in certain compendia identified in section 1927(g)(1)(B)(i) of the Act. Accordingly, states may not exclude or restrict coverage of prescription prenatal vitamins when prescribed for medically

accepted indications unless such exclusion or restriction is otherwise permitted by section 1927(d)(1)(B) of the Act.

Comment: One commenter stated that medical foods should meet the definition of a COD under the same rationale as prescription prenatal vitamins and older drugs. The commenter listed several statutory criteria and stated that demonstrating any one of these would provide for a product to meet the definition. The commenter cited: (1) A compelling justification for medical need; (2) the product must be used for a medically accepted indication; or (3) the drug was commercially used or sold in the United States before October 10, 1962 or is identical, related, or similar to such a drug. The commenter contended that medical foods meet the definition because medical foods can be shown to fulfill each of these criteria.

Response: We appreciate the detailed information provided by the commenter. However, we disagree with the commenter that medical foods meet the statutory definition of a COD. These products are not addressed in section 1927(d)(2) of the Act and these products are not treated as prescribed drugs for purposes of section 1905(a)(12) of the Act. Therefore, in light of these provisions and the definition of COD provided in section 1927(k) of the Act, medical foods do not meet the definition of a COD.

g. Medically Accepted Indications

Comment: We received a few comments regarding the requirement in the definition of COD to ensure that the use of a drug is limited to ''medically accepted indications.'' Some of the commenters requested clarification on the intent of the language, guidance on how to ensure compliance, and CMS's expectations for states. Other commenters stated that the determination of the indication for which each prescription is written is difficult, unworkable, and would cause undue burden to states and providers.

Response: Section 1927(k)(3) of the Act excludes from the definition of COD a drug or biological product used for a medical indication which is not a medically accepted indication. Consistent with this provision, the proposed regulatory definition of a COD, which we are finalizing, excludes drugs used for a medical indication which is not a medically accepted indication. This language regarding the exclusion of a drug or biological product for an indication that is not medically accepted was not revised under the Affordable Care Act, and we are not changing the requirement. States are responsible for the coverage of CODs consistent with this definition and their state plans. As noted, states have the flexibility to require prior authorization to ensure that CODs prescribed and dispensed by providers are used for medically accepted indications.

Comment: One commenter requested that the requirement for determining that a drug is used for medically accepted indications be met by the presence of an NDC and electronic listing with FDA, or another definition listed in the chapter.

Response: We disagree with the commenter that simply having an NDC, along with electronic listing with FDA, would substantiate that a drug was being utilized for a medically accepted indication. These two elements would not provide sufficient information regarding the medical indication for which the drug is being utilized for a particular beneficiary.

h. Miscellaneous Comments

Comment: One commenter pointed out that in the preamble to the proposed rule, in the section discussing the definition of COD, and in the statutory definition of COD, reference is made to a drug which was commercially used or sold in the United States, but in the proposed regulations text, the language omitted the phrase ''used or.''

Response: We appreciate the comment. We inadvertently failed to include the reference in the proposed text. Accordingly, in the definition we are finalizing in this final rule, we have revised the definition of CODs in § 447.502 to reference a drug that was ''commercially used or sold in the United States.''

Comment: One commenter asked if CMS will include definitions, or references to definitions of ''ANDA,'' ''NDA,'' and ''FFDCA.''

Response: ANDA and NDA are terms defined by FDA and CMS does not see a need to include those definitions in the regulation. FFDCA is the acronym for the Federal Food, Drug, and Cosmetic Act. We inadvertently did not write out the expansion of ANDA where it first appears in the regulation, and therefore, have revised the definition of COD to include the written out expansion of ANDA where it first appears in the regulatory text under § 447.502.

Comment: One commenter asked several questions regarding state drug files and their relationship to other data sources, such as pricing compendia. The commenter asked if state covered-drug files should match DDR for Medicaid in terms of the new COD definition. They stated that FDA updates their electronic file twice monthly and the state receives weekly updates regarding new products from an external pricing compendium. The commenter also asked how these new products will be priced during the lag time between an addition to the state files and being listed with FDA. The commenter also noted that variable formats between FDA's file and the state drug files make comparison of the two files difficult.

Response: As states are primarily responsible for developing their own drug file based on drug coverage under their approved state plan, a state's drug file may not be identical to DDR (for example, it may contain additional NDC's for products such as experimental drugs or APIs). However, a state's drug file should include the NDCs of the CODs of those labelers that have signed the national rebate agreement. Those NDCs are available on Medicaid.gov at *http://www.medicaid.gov/Medicaid-CHIP-Program-Information/By-Topics/Benefits/Prescription-Drugs/Medicaid-Drug-Rebate-Program-Data.html* and may also be found in the DDR system. Data provided by the MDR program, such as via DDR, should be the primary source of information used by states in developing their MDR file. States have flexibility to use external pricing compendia to supplement the information provided by CMS; however, states are responsible for operating their programs in accordance with the requirements of the MDR program. All states should have access to DDR, which is updated daily to reflect new drugs entering the MDR program, as well as updates or changes to existing drugs.

Comment: One commenter stated that CMS should ensure it establishes a process to evaluate COD status and create a process for a quick appeal of a negative decision.

Response: We agree that there should be a process to evaluate a drug's COD status and manufacturers may submit a request to CMS for reconsideration of their drug's status. We will make every attempt to provide a timely response to such requests.

Comment: One commenter stated that by requiring approval information to be submitted to the MDR program, it imposes a burden on the manufacturers of updating and maintaining more fields in their product master.

Response: We understand that the new requirements will result in manufacturers having to report and maintain additional information. However, as some manufacturers continue to report products that do not meet the statutory definition, we believe

that this additional information is necessary for CMS to improve the administration of the MDR program and to ensure that federal and state funds are being utilized appropriately, as recommended in an OIG report from October 2011. Specifically, the OIG report (*A–07–10–06003 Multi-State Review of Centers for Medicare & Medicaid Services Medicaid Drug Expenditure Controls*) stated that cost savings to Medicaid could be realized if CMS worked with drug manufacturers to ensure that the information that manufacturers report is complete and accurate. In light of such concerns, CMS will be able to use manufacturer reported information, such as the COD status code, in combination with information available on FDA's NSDE file, to verify that the NDCs reported to the MDR program as CODs qualify as such.

Based on the comments received, and for the reasons discussed, we are finalizing the definition of COD in § 447.502 as specified in the proposed rule with the following changes. In addition, in light of the discussion in the innovator multiple source drug definition (section II.B.9. of this final rule), we are deleting the reference to NDA and ANDA from the final definition of COD, and instead are tracking the language of the statutory definition.

- The addition of ''of this definition'' at the end of the parenthetical clause ''(except as provided in paragraphs (2) and (3))'' to ensure this exception is appropriately identified.
- The replacement of ''and also'' with ''or'' in paragraph (1)(i). This change is technical in nature and not intended to alter the meaning or intent of the definition.
- The deletion of the phrases ''where the manufacturer has obtained a NDA'' and ''where the manufacturer has obtained an ANDA'' from paragraph (1)(i) to more closely mirror the statutory definition of covered outpatient drug at section 1927(k)(2) of the Act. This final change is not intended to alter the meaning or intent of the definition.
- The addition of ''used or'' in paragraph (1)(ii) to more closely mirror the statutory definition of COD at section 1927(k)(2) of the Act.
- The change in paragraph (2) of the regulatory text from ''and for which payment is made as part of that service . . .'' to ''and for which payment may be made as part of that service . . .''
- The change in terminology in paragraph(2)(vi) from ''mentally retarded'' to ''individuals with intellectual disabilities'' as there has been a change in terminology since the publication of the proposed rule, and the phrase ''mentally retarded'' has been replaced with ''individuals with intellectual disabilities.''
- The deletion of proposed paragraph (3)(ii) from the regulatory text, which excluded any drug product that is not listed electronically with the FDA from the definition, and renumbering paragraphs (3)(iii), 3(iv), and (3)(v) to 3(ii), (3)(iii), and (3)(iv), respectively.
- The replacement of the term ''biologic product'' with ''biological product'' as we want to be consistent with the statutory definition of covered outpatient drug, which at section 1927(k)(2) of the Act uses the term ''biological product''. This change is technical in nature and not intended to alter the meaning or intent of the definition.

8. Customary Prompt Pay Discounts

We proposed to add a definition of customary prompt pay discount to ensure consistent application of such discounts among manufacturers when calculating AMP (77 FR 5323 and 5360). In proposed § 447.502, we proposed to define customary prompt pay discounts as 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 timeframe and consistent with its customary business practices for payment (77 FR 5360). We received no comments concerning the proposed definition of customary prompt pay discount, and therefore, we are finalizing the definition under § 447.502 as proposed. Comments pertaining to the application of customary prompt pay discounts to the determination of AMP can be found in section II.C.6. of this rule.

9. Innovator Multiple Source Drug

As currently defined in § 447.502, an innovator multiple source drug means a multiple source drug that was originally marketed under an original NDA approved by FDA, including an authorized generic drug. It also includes a drug product marketed by any cross-licensed producers, manufacturers, or distributors operating under the NDA and a COD approved under a product license approval (PLA), establishment license approval (ELA), or antibiotic drug approval (ADA). In the proposed rule (77 FR 5323 and 5360), we proposed to add multiple source drugs originally marketed under a Biologics License Application (BLA), as the BLA approval process is a successor to the PLA and ELA, and drugs sold under a BLA are explicitly referenced in the proposed regulatory definition of single source drug (77 FR 5326 and 5361).

In addition, we proposed to clarify that, for purposes of the MDR program, an original NDA is equivalent to an NDA filed by the manufacturer for approval under section 505 of the FFDCA for purposes of approval by FDA for safety and effectiveness (77 FR 5323 and 5360). In light of this definition, we also proposed to use the term ''NDA'' when addressing such application types for brand name drugs and not use the term ''original NDA'' when referring to such drugs throughout the proposed rule (77 FR 5323).

We received many comments that provided concerns regarding the term ''original NDA'' as well as a few comments regarding products approved under a BLA. The issues in these comments are relevant to both the proposed definitions of single source drug and innovator multiple source drug. Given the overlap of these issues (they are not unique to either definition), we have decided to address the comments relating to the term ''original NDA'' and products approved under a BLA in the innovator multiple source definition section of this final rule (and we will provide a cross-reference to this section in the single source drug definition regarding these comments). We also addressed in this section additional comments we received that were specific to the definition of innovator multiple source drug, including older drug approvals, the timing of the changes, as well as the effect of the revised definition of innovator multiple source drug on manufacturers. We received the following comments:

a. ''Original NDA''

Comment: We received many comments regarding our proposal to provide that for purposes of the MDR program, an original NDA is equivalent to an NDA filed by the manufacturer for approval under section 505 of the FFDCA for purposes of approval by the FDA for safety and effectiveness. Some commenters maintained that CMS has no authority to read out any word from the statute because no word is insignificant and by doing so, we are violating the cardinal principle of statutory construction that no language shall be superfluous, void, or insignificant. A few commenters noted that by reading out the word ''original,'' we are defining a brand name drug as any drug approved under an NDA, regardless of the circumstances surrounding the approval, ignoring the changing history of FDA's approval

process, and that we have done so without consideration of policy or legal implications.

Another commenter stated that there is no justification why manufacturers of certain ''generics'' must pay higher rebates only because they are approved under an NDA. The commenter stated that many NDAs are as ''abbreviated'' as ANDAs are, and it is those NDAs that are not original. One commenter stated that the Congress included the word ''original'' because it intended for only the first NDA for that drug to be considered a ''brand.'' Another commenter stated that the term ''original new drug application'' is unique to section 1927(k)(7)(A) of the Act and nowhere else where an NDA is discussed is the term ''original NDA'' used as a synonym for NDA. The commenter stated, therefore, that the word ''original'' must have meaning, especially because the word is used in a provision of the statute that is intended to clarify the meaning of statutory terms. The commenter also stated that the term ''original NDA'' clarifies the concept of an innovator drug by clarifying the distinction Congress made between innovator and generic drugs and not the less meaningful and sometimes non-existent difference between drugs approved in NDAs and ANDAs. Additionally, the commenter stated that if Congress merely wanted to differentiate between NDA and ANDA, they would have used only those terms, like they did elsewhere and they would not have introduced the term ''original NDA.''

Another commenter stated that the intent of the MDR statute is to impose a higher rebate liability on new chemical entities, marketed for the first time under the NDA process, and which received some form of market protection. Another commenter stated that actions that will be required by manufacturers, based on the proposed definition of original NDA, including the reevaluation of their drug categories and having to utilize the higher rebate percentage to calculate URAs, will result in a substantial financial burden without adequate justification or consideration within the economic analysis of the proposed rule.

Response: We appreciate the comments and agree with the commenters who have stated that we cannot read out the word ''original'' from the statute. However, we do not believe that either the proposed rule or this final rule ignore the word ''original'' as it is used in the context of the statute.

Section 1927(k)(7)(A) of the Act provides a definition for each of the drug categories that are used in the MDR program to identify the rebate percentage used to calculate the URA for each drug. Specifically, section 1927(k)(7) of the Act defines drugs to include single source drugs, innovator multiple source drugs, and noninnovator multiple source drugs. Section 1927(k)(7)(A)(iv) of the Act defines a single source drug, in part, to mean a covered outpatient drug produced or distributed under an original NDA, including a drug product marketed by any cross-licensed producers or distributors operating under the NDA. Our understanding is that a single source drug is typically the first drug on the market; it has been produced or distributed under an NDA, other than an ANDA, approved by the FDA for the drug and has no therapeutic equivalents. Similarly, our understanding is that an innovator multiple source drug is a drug that was initially marketed under an NDA, other than an ANDA, approved by FDA but is rated therapeutically equivalent to at least one other product in the FDA's 'Approved Drug Products with Therapeutic Equivalence Evaluations' (Orange Book) that is sold or marketed in the United States during the rebate period. Section 1927(k)(7)(A)(iii) of the Act defines noninnovator multiple source drugs as multiple source drugs that are not innovator multiple source drugs, which are typically marketed under an ANDA, as opposed to an NDA, approved by FDA. In accordance with these provisions, we disagree with the commenter that Congress needed to use the specific terms NDA and ANDA to differentiate between those drugs which are to be considered single source drugs or innovator multiple source drugs and those which are to be considered noninnovator multiple source drugs. Therefore, in light of the comments received and in accordance with the statutory definitions of innovator multiple source and single source drugs, when read in context with the statutory scheme, we believe that the term ''original NDA'' is designed typically to mean an NDA (including an NDA filed under section 505(b)(1) or (2) of the FFDCA), other than an ANDA, which is approved by the FDA for marketing.

There may be very limited circumstances where, for the purposes of the Medicaid Drug Rebate (MDR) program, certain drugs might be more appropriately treated as if they were approved under an ANDA and classified as a noninnovator multiple source drug. For example, certain parenteral drugs in plastic immediate containers, for which FDA required that an NDA be filed, might be more appropriately treated, for purposes of the MDR program, as if they are marketed under an ANDA and classified as a noninnovator multiple source drug. Likewise, certain drugs approved under a paper NDA prior to the enactment of the Hatch-Waxman Amendments of 1984 or under certain types of literature-based 505(b)(2) NDA approvals after the Hatch-Waxman Amendments of 1984 might be more appropriately treated as if they were approved under an ANDA and classified as a noninnovator multiple source drug, depending on the unique facts and circumstances of the particular situation. We plan on issuing additional guidance on the scope of these very limited circumstances in the future. In the meantime, we remind manufacturers that these limited circumstances constitute very narrow exceptions to the rule that drugs marketed under NDAs (including section 505(b)(2) NDAs), other than ANDAs, should be classified as either single source or innovator multiple source drugs. For example, the narrow exception will not be considered applicable to drugs marketed under NDAs that were not approved under either the paper NDA process prior to 1984 or under certain types of literature-based 505(b)(2) approvals, or for drugs that received patent protection or statutory exclusivity.

Drugs reported to the MDR program for the first time on or after the effective date of the final rule, including drugs newly marketed under an NDA, other than an ANDA; and drugs previously marketed under an NDA, other than an ANDA, and are reported to the MDR program because, (1) the drug was not reported previously, or (2) the manufacturer receives a new rebate agreement on or after the effective date of the final rule, should be classified as single source or innovator multiple source drugs. If a manufacturer believes that a drug marketed under an NDA, other than an ANDA, and reported to the MDR program on or after the effective date of the final rule should qualify for the narrow exception referenced above because it was approved under the paper NDA process prior to 1984 or an NDA approved under certain types of literature-based 505(b)(2) approvals after 1984 and the unique facts and circumstances warrant reclassification, the manufacturer should submit materials to CMS demonstrating the basis of how the drug might be subject to the narrow exception to classify the drug as a noninnovator multiple source drug. CMS will review these materials and: (1) Confirm in writing that this narrow

exception does apply to the drug at issue and permit reclassification as a noninnovator multiple source drug; or (2) state that the exception does not apply, and the manufacturer must continue to report the drug as either a single source or innovator multiple source drug.

For drugs marketed under an NDA and reported currently to MDR program as noninnovator multiple source drugs, manufacturers are reminded of their statutory and regulatory reporting obligations to report such drugs as innovator multiple source drugs or single source drugs, as applicable. However, manufacturers of such drugs will have up to four quarters after the effective date of the final rule to apply for an exception and, if applicable, make the required data changes to bring their reporting efforts into statutory and regulatory compliance before CMS takes any administrative action, if appropriate, against such manufacturers. To the extent any such manufacturer believes that a drug should qualify for the narrow exception, allowing such drugs to be reported as noninnovator multiple source, that manufacturer may also submit materials to CMS demonstrating the basis of how the drug may be subject to the narrow exception to classify the drug as a non-innovator multiple source drug. CMS will review these materials and: (1) Confirm in writing that this narrow exception does apply to the drug at issue; or (2) state that the exception does not apply, and the manufacturer must report the drug as either a single source or innovator multiple source drug. To the extent a manufacturer has previously reported a drug marketed under an NDA, other than an ANDA, as a noninnovator multiple source drug, or believes it has approval from CMS to do so, that manufacturer must submit materials and receive a written determination from CMS as described above pursuant to this final rule.

Therefore, while drugs marketed under an ANDA are noninnovator multiple source drugs, drugs marketed under an NDA, other than an ANDA, approved by the FDA are innovator multiple source or single source drugs, unless the narrow exception has been determined by CMS to apply. CMS's decision to allow manufacturers up to four quarters to come into compliance before taking administrative action in no way relieves manufacturers of other potential liability.

Our interpretation regarding original NDA results in consistent treatment of multiple source drugs, such that those multiple source drugs, which were initially approved for marketing by the FDA under an original NDA, as opposed to an ANDA, would be considered innovator multiple source drugs. For these reasons, and after considering the comments, we have revised the proposed definitions of single source drug and innovator multiple source drug that are found in the proposed rule at 77 FR 5360 and 5361. We are finalizing a change to the definitions of single source drug and innovator multiple source drug by including a reference to an original NDA. With regard to the meaning of the term ''original NDA'' within the definitions of single source drug and innovator multiple source drug under the MDR program, in this final rule we have revised the proposed definition of ''original NDA'' to reference an NDA, other than an ANDA, approved by the FDA for marketing, unless the narrow exception discussed above applies (which requires the manufacturer's written submission to CMS, and CMS's response confirming that the exception applies).

Comment: One commenter noted that the proposed rule fails to recognize that duplicate and paper NDAs, although filed under section 505(b) of the FFDCA, were not filed for ''purposes of approval by FDA for safety and effectiveness'' because safety and effectiveness were established by the Drug Efficacy Study Implementation (DESI) notice (used for drugs marketed prior to 1962) or the approval of the NDA referenced by the paper NDA, in that clinical trial data are not included in either type of filing.

Response: The reference to applications approved on the basis of DESI notices refers to the fact that ANDAs that relied on those notices were approved under section 505(b) of the FFDCA, since section 505(j) was not part of the statute until 1984. While those applications were approved under section 505(b), if they were classified by FDA as ANDAs we consider the drugs to have been approved under ANDAs. The reference to paper NDAs refers to applications that were also approved under section 505(b), but as noted in response to other comments, the FDA's paper NDA policy incorporated two types of approvals—one for duplicates of approved NDAs (now approved under section 505(j)), and one for other than those for duplicate products (now approved under section 505(b)(2)). As section 505(b)(2) applications are NDA applications, not ANDA applications, these drugs should be classified as single source or innovator multiple source drugs, unless the narrow exception applies, as discussed above pursuant to this final rule. In the proposed rule, the proposed regulatory definitions for innovator multiple source drug and single source drug (77 FR 5360 through 5361) included that ''for the purposes of the MDR program, an original NDA is equivalent to an NDA filed by the manufacturer for approval under section 505 of the FFDCA for purposes of approval by the FDA for safety and effectiveness.''

We agree with the commenter that NDAs that were approved prior to 1962 were approved for safety only, and not efficacy. We do not believe that section 1927(k)(7) of the Act provides that the definition of single source drug and innovator multiple source drug should be limited to only those drugs approved in 1962 or later. Therefore, in addition to the previously discussed modification, we are further modifying the regulatory definitions of innovator multiple source drug and single source drug. Specifically, in this final rule, we are finalizing the definitions for single source drug and innovator multiple source drug under § 447.502 by eliminating the proposed language ''approval under section 505 of the FFDCA for the purposes of approval by the FDA for safety and effectiveness'' to clarify that single source and innovator multiple source drugs are not limited to only those drugs approved in 1962 or later.

As discussed above, drug products marketed under NDAs, other than ANDAs, should be classified by manufacturers as either single source or innovator multiple source drugs for the purposes of the MDR program unless the narrow exception applies, as discussed above pursuant to this final rule. If the manufacturer believes that a drug approved under an NDA prior to 1962, including a drug approved under one of the NDA processes to which the commenter refers, should be classified as a noninnovator multiple source drug, the manufacturer should submit materials to CMS demonstrating why a drug should be classified as a noninnovator multiple source drug. CMS will review these materials and: (1) Confirm in writing that this narrow exception does apply to the drug at issue and the manufacturer must report the drug as a noninnovator multiple source drug; or (2) state that the exception does not apply, and the manufacturer must report the drug as either a single source or innovator multiple source drug.

b. Older Drug Approvals

Comment: A few commenters discussed older drugs, which were marketed initially with no approval but later received an NDA approval under a section 505(b)(2) application. The

commenters stated that when these drugs were initially marketed, they were not marketed under an NDA and were not new drugs that would require a section 505(b)(1) approval; therefore, they would not meet the innovator multiple source drug definition, which states that the drug was ''originally marketed under an original new drug application.''

Another commenter stated that the proposed rule provides that pre-1962 drugs that were originally marketed without an NDA as noninnovator multiple source drugs and, prior to the effective date of this rule, were reviewed by FDA and received an NDA under FDA's section 505(b)(2) provision, would continue to be treated as noninnovator multiple source drugs, per the guidance found in the preamble to CMS's proposed rule (60 FR 48453), published in 1995. The commenter additionally stated that they believe CMS intends for pre-1962 drugs that receive an NDA subsequent to the effective date of this rule would have their status changed to innovator multiple source drugs. The commenter concluded that if the section 505(b)(2) application was submitted as a supplement or change to an innovator multiple source drug, then the drug should be treated as an innovator multiple source drug; however, if the section 505(b)(2) application did not reference an innovator multiple source drug, it should be treated as a noninnovator multiple source drug. The commenter indicated that if their interpretation of CMS's intent was correct, that CMS would be eliminating the statutory requirement that an innovator multiple source drug be originally marketed under an original NDA.

Response: We disagree with the commenter that the 2012 proposed rule would contradict the statutory requirement that an innovator multiple source drug be originally marketed under an original NDA. We interpret the phrase ''originally marketed'' in the context of the definition of an innovator multiple source drug to reference a drug that was initially marketed as a single source drug. Specifically, section 1927(k)(7) of the Act defines a single source drug as a drug that is produced or distributed under an ''original NDA'' approved by the FDA, with no therapeutic equivalents. Once that single source drug has therapeutic equivalents, it falls within the definition of an innovator multiple source drug.

We disagree with the commenter that there will be different treatment regarding drug category determinations of previously unapproved drugs that subsequently received FDA approval, depending on whether the FDA approval occurred before or after the effective date of this final rule. Section 1927(k)(7) of the Act provides definitions for single source drugs, innovator multiple source drugs, and noninnovator multiple source drugs. It is possible that based on the approval of a previously unapproved drug, that drug may require a change in reported drug category. Additionally, the portion of the proposed 1995 rule referred to by the commenter was not finalized and is not determinative. In the final rule published on July 17, 2007, we provided, in part, that due to changes in the prescription drug industry, we do not plan to finalize the provision from the proposed 1995 rule to which the commenter refers (72 FR 39143). If a manufacturer believes that a drug marketed under a section 505(b)(2) NDA is subject to this narrow exception discussed above, the manufacturer should submit materials to CMS outlining the basis for classifying the drug as a noninnovator multiple source drug. CMS will review these materials and: (1) Confirm in writing that this narrow exception does apply to the drug at issue and the manufacturer must report the drug as a noninnovator multiple source; or (2) state that the exception does not apply, and the manufacturer must report the drug as either a single source or innovator multiple source drug.

All drugs marketed under an NDA, other than an ANDA, regardless of when they were approved, should be categorized as single source or innovator multiple source drugs, unless CMS determines that a narrow exception applies as discussed above pursuant to this final rule. The final rule does not release manufacturers from any reporting liabilities. If a manufacturer determines a drug category change is needed, the manufacturer is responsible for contacting CMS to request that change.

Accordingly, we have modified the definition of innovator multiple source drug in the proposed regulatory text (77 FR 5360) to include the term ''originally marketed.'' Specifically, in this final rule, in response to comments and as discussed in this section, we are finalizing the definition of innovator multiple source drug under § 447.502 to provide that an innovator multiple source drug means a multiple source drug that was originally marketed under an original NDA approved by FDA, including an authorized generic drug, unless the narrow exception discussed above applies (which requires the manufacturer's written submission to CMS, and CMS's response confirming that the exception applies).

c. Timing of Changes

Comment: Many commenters requested that the changes in the definitions of the drug categories be made prospectively, not apply to prior reporting periods, and that sufficient lead time be allowed to accommodate the changes. One commenter suggested that we not adopt the new definition of innovator multiple source drug at all because the changes would be financially harmful and operationally difficult to implement retrospectively. Further, a commenter stated that if the changes are implemented prospectively, they will be inconsistent with past treatment of some drugs.

Response: This final rule is designed to clarify existing policy regarding the definitions of original NDA and single source drugs, innovator multiple source drugs, and noninnovator multiple source drugs. To address the commenters who requested sufficient lead time to change their practices, we will allow manufacturers up to 4 quarters after the effective date of the final rule to make the necessary data changes in accordance with the definitions we are finalizing for single source drug and innovator multiple source drug in this final rule, before CMS takes any administrative action, if appropriate.

Manufacturers are responsible for reporting drugs that were marketed under an original NDA as single source or innovator multiple source drugs, unless the narrow exception applies as noted previously. We understand that some manufacturers may need to make operational changes to their pricing systems, such as calculating a base date AMP and best price for a drug that should be categorized as innovator drugs. Therefore, we are allowing manufacturers up to 4 quarters after the effective date of the final rule to make the necessary data changes before CMS takes any administrative action, if appropriate.

d. Effect on Manufacturers

Comment: We received many comments claiming that many drugs historically viewed as generics, including some that never benefited from patent protection or other forms of exclusivity, would now be classified as brand, subjecting them to higher rebate liability, even though they would likely continue to be priced and reimbursed like a generic. In addition, they would be subject to additional rebate penalties, line extension penalties, lower VA and 340B prices, TRICARE rebates, Medicare

coverage gap discounts, and the branded prescription drug fee program. Commenters noted that these higher liabilities will discourage manufacturers from continuing production of these lower cost drugs, such as drugs approved prior to the enactment of the Hatch-Waxman Act in 1984, including drugs approved under FDA's paper NDA process; drugs approved under section 505(b)(2) of the FFDCA; drugs that were required by FDA to submit for NDA approval solely based on the need for safety testing of their plastic immediate containers; and grandfathered products that subsequently received NDA approval.

Several commenters stated that simply because the ANDA process of approval was not utilized, and instead an alternative approval process was utilized, this should not be the basis of determining a drug to be an innovator multiple source drug. One commenter stated that FDA sometimes requests that a manufacturer submit a 505(b)(2) application or other short-form application for approval of an older generic drug which, the commenter concluded, cannot reasonably be viewed as an innovator multiple source drug. The commenter stated that CMS should provide some flexibility regarding the classification of these drugs. Several commenters cited an FDA-proposed rule that referred to pre-Hatch-Waxman NDAs as ''duplicate'' drugs and commented that if a drug is a duplicate of another, then it should be considered to be a noninnovator product.

Response: In this final rule, we are providing a regulatory definition for single source drug and innovator multiple source drug so that manufacturers report drug categories in accordance with section 1927 of the Act on a consistent basis. Manufacturers are responsible for reporting drugs that are marketed under an original NDA as innovator multiple source drugs. However, we believe it is important for manufacturers to continue production of such drugs and we did not intend that this rule would have any impact on their production; rather, we are providing our interpretation of section 1927(k) of the Act for how manufacturers should report drug categories under the rebate program. As described in FDA's draft guidance for industry found at *http://www.fda.gov/downloads/Drugs/Guidances/ucm079345.pdf,* entitled ''Applications Covered by Section 505(b)(2)'' in 1999, a section 505(b)(2) application type is submitted under section 505(b)(1) and approved under section 505(c). However, for a drug to be a noninnovator multiple source, the final rule published on July 17, 2007 (72 FR 39143), provided that the drug should be marketed under an ANDA, which is approved specifically under section 505(j) of the FFDCA. Additionally, the review process for a drug approved under section 505(b)(2) is distinct from the review under section 505(j). Therefore, based on our interpretation of the statute and the applicable FDA approval process, we do not believe that most drugs approved under a section 505(b)(2) application meet the definition of a noninnovator multiple source drug unless the narrow exception discussed above applies (which requires the manufacturer's written submission to CMS, and CMS's response confirming whether or not the exception applies). Additionally, FDA proposed rules, as cited by a commenter, are not applicable to drug rebate provisions.

Regarding a grandfathered drug, or a drug that was previously marketed without approval and subsequently received approval of an NDA, as opposed to an ANDA, that drug should be reported as a single source drug or innovator multiple source drug, whichever is applicable, unless the narrow exception discussed above applies. The final rule does not release manufacturers from any reporting liabilities. If a manufacturer determines a drug category change is needed, the manufacturer is responsible for contacting CMS to request that change.

Comment: We received several comments noting that enacting the proposed definition would require manufacturers to report a base date AMP and best price for older drugs that require a drug category change due to the clarification in the definitions of single source and innovator multiple source drug. Several commenters asked how manufacturers should report the base date AMP or best price for these drugs in the absence of data, which may occur especially if the drug was purchased from another company, and data going back to the original market date may not be available. The commenters were also concerned about data not being available to establish a market date and asked for guidance in addressing the gap in data.

Response: If a drug is purchased from another company, then the purchasing manufacturer needs to report a purchased product date (PPD) for this drug (please see Manufacturer Release #90 (April 18, 2014) for more information). Once a PPD is reported and the PPD is later than both the Market Date quarter and the Omnibus Budget Reconciliation Act of 1993 (OBRA '93) Base date AMP quarter, the system will not require the purchasing manufacturer to report a best price for the base AMP quarter. However, manufacturers are still required to report the base date AMP based on the original market date of the drug and if manufacturers have reported their quarterly pricing in compliance with the rebate program, the CMS system will use the quarterly AMP from the base date AMP quarter (which is based on the original market date of the drug, when the drug was first marketed), to populate the base date AMP for the drug. However, if there is any missing pricing information for the base date AMP quarter, then the manufacturer is responsible for providing CMS with that base date AMP information via DDR.

e. Prior Regulation and Proposed Rule

Comment: Many commenters referenced information from the 1995 proposed rule (60 FR 48453) where we discussed that it was our understanding that the term ''original NDA'' was included in the statute by Congress with the intent of extracting larger rebates from those drugs that received some form of patent or marketing protection for a specific period of time. Some commenters stated that this was the only guidance issued by CMS on this topic and that manufacturers have been relying on that guidance for their drug category determinations.

Response: In the final rule published on July 17, 2007 (72 FR 39143), we stated that we were not finalizing most provisions from the 1995 proposed rule (60 FR 48453). Therefore, the discussion in the 1995 proposed rule regarding patent protection and exclusivity was not determinative for drug category determinations. Based on the given statutory definition, which categorizes a drug based on the marketing under an original NDA and not on patent protection or exclusivity, we are finalizing this final rule without sole consideration of patent protection or exclusivity as a factor in determining a drug category for the purposes of the MDR program. Rather, in accordance with this final rule, drugs marketed under an original NDA are categorized as single source drugs or innovator multiple source drugs according to those definitions in section 1927(k)(7) of the Act. In contrast, drugs marketed under an ANDA are categorized as noninnovator multiple source drugs. Because many of the drugs that receive patent protection and exclusivity have original NDAs, we believe this final rule serves the Congressional interests identified in the 1995 proposed rule and codified in the Act.

Comment: One commenter suggested that while pre-Hatch-Waxman ''generic

drug NDAs'' are technically NDA approvals, and thus, would fall within the proposed single source drug or innovator multiple source drug definition, this is inconsistent with CMS's definition of noninnovator multiple source drug. The commenter stated that the inconsistency stems from CMS's response to a comment that was received in response to the proposed rule that was finalized on July 17, 2007 (72 FR 39142) and addressed in § 447.502. In the 2007 rule, the commenter asked for the appropriate classification of a drug that (1) is ''the only COD remaining on the market'' and (2) was approved in an ANDA. The commenter noted that CMS responded to this comment by deeming the drug to be a noninnovator multiple source drug.

Response: We do not agree that our definitions of single source drug or innovator multiple source drug are inconsistent with the definition of noninnovator multiple source drug. Our response to the comment in the July 17, 2007 final rule (72 FR 39162) stated that we do not believe that it would be consistent with the statute to modify the definition of an innovator multiple source drug to include drugs marketed under an ANDA and we continue to believe that to be true.

f. Miscellaneous Comments

Comment: Some commenters maintained that an original NDA is not equivalent to an NDA because drugs approved under an original NDA may not have been the original drug on the market or may not be the reference drug in the Orange Book.

Response: We disagree with the comments regarding whether a drug's appearance in the Orange Book as a reference drug is determinative for the reporting of a drug category for purposes of the MDR program. In particular, we are not relying on whether a drug may have been the reference drug in the Orange Book to determine whether a drug is a single source drug, innovator multiple source drug, or noninnovator multiple source drug, but instead we are interpreting provisions of section 1927 of the Act for purposes of the MDR program. The status of a drug as the listed reference drug in the Orange Book does not mean that the drug is an innovator multiple source or single source drug as defined by section 1927 of the Act for the purposes of the MDR program.

Comment: Some commenters discussed that, under the enactment of Hatch-Waxman in 1984, certain drugs were transferred to FDA's Division of Generic Drugs. The commenters stated that because the regulation of these drugs was transferred to the Division of Generic Drugs, that the drugs are considered to be generic drugs by FDA and should, therefore, be treated by CMS as noninnovator multiple source drugs.

Response: We disagree. The FDA's transfer of a drug to its Division of Generic Drugs does not necessarily indicate that the drug should be categorized as a noninnovator multiple source drug for purposes of the MDR program. While FDA may assign their regulatory processes or oversight to any division they believe is appropriate, the internal administrative process of FDA does not have an impact on the categorization of innovator or noninnovator multiple source drugs for the purposes of the MDR program. Section 1927 of the Act does not specify that CMS consider which FDA division has oversight for a drug in determining drug category. As discussed previously in this section, drugs reported to the MDR program should be categorized based on the provisions in section 1927 of the Act, not based on the division of FDA that is assigned oversight of the drug.

Comment: Several commenters stated that it would be inappropriate to include a drug approved in a BLA in the definition of innovator multiple source drug because there are no therapeutic equivalents for drugs approved under a BLA. One of the commenters also acknowledged that although CMS correctly states that the BLA technically replaced the PLA as the approval vehicle for drugs under the PHSA, the approval standards under the PHSA are different than those under FDA. The commenter explained that although there may be a time when FDA approves a BLA as an interchangeable biosimilar under the PHSA, such a product is not likely to ever receive a therapeutic equivalent or pharmaceutical equivalent rating from FDA. The commenter concluded that at this time, it is inappropriate for CMS to include BLAs in the definition of innovator multiple source drug. Another one of the commenters requested that CMS clarify that biologics should be recognized as single source drugs consistently across Medicaid and Medicare. The commenter stated that the proposed definition of innovator multiple source drug, including biologicals, does not align with Medicare's definition. The commenter stated that under Medicare, biologicals are single source drugs with the exception that, if there was more than one drug within a billing and payment code as of October 1, 2003, then they may be considered multiple source drugs.

Response: We agree with the commenter that, given our proposed definitions, no currently marketed BLA drugs would be considered multiple source drugs. Accordingly, given the definitions we are finalizing in this final rule, a drug marketed under a BLA would be considered a single source drug. On March 30, 2015, CMS issued Medicaid Drug Rebate Program Notices for Participating Drug Manufacturers (No. 92) and for State Technical Contacts (No. 169) clarifying that biological products licensed under a BLA, including biosimilar biological products, fall within the definition of single source drug. We further note that the identification of a drug under the definitions for multiple source drugs under the MDR program are unaffected by billing and payment codes the commenter referenced; therefore, such coding does not apply to Medicaid.

Comment: We received one comment that expressed concern regarding the use of the terms ''brand'' and ''generic,'' rather than ''innovator'' and ''noninnovator,'' because the commenter stated that some ''generic'' drugs may have been given branded names and that alone does not categorize a drug as an innovator drug.

Response: We understand the commenter's concern regarding the words ''brand'' and ''generic,'' and note that these terms generally have been used interchangeably with ''innovator'' and ''noninnovator'' within the industry. For the purposes this rule, we will not use the terms interchangeably but instead focus on the terms single source and innovator multiple source, except when used within the summary of comments received in response to the proposed rule. For the purpose of drug categorization in the MDR program, a drug category is determined based on the drug's approval status with FDA, such as under an ANDA or NDA, and single source, innovator multiple source, and noninnovator multiple source will be used regardless of whether the drug has been given a branded name or not.

Comment: We received several comments regarding CMS's use of the word ''clarification'' in our discussion of the proposed definition of innovator multiple source drug. The commenters stated that rather than clarification, the proposed definition is instead a reversal of previous policy, or a major change to standard industry practice, which could potentially have the effect of imposing retrospective liability for manufacturers.

Response: We disagree with the commenters that our interpretation of the definition of single source and innovator multiple source drug could be

perceived as a change or reversal of policy. Our proposed language was not designed to change CMS policy, but rather to provide further clarification that an ''original NDA'' means an NDA, other than an ANDA, approved by the FDA for marketing, unless the narrow exception discussed above applies.

The final rule does not release manufacturers from any reporting liabilities. If a manufacturer determines a drug category change is needed, the manufacturer is responsible for contacting CMS to request that change. The statute requires a different rebate formula for single source and innovator multiple source drugs, which results in higher rebates owed for those drugs than for noninnovator multiple source drugs. We encourage manufacturers to properly classify their drugs for rebate calculation purposes.

Comment: One commenter was concerned about the plain meaning of the words ''original'' and ''duplicate.'' The commenter stated that the meaning of the word ''original'' has an opposite meaning to the word ''duplicate'' and, therefore, CMS cannot make the claim that an ''original NDA'' has the same meaning as a ''duplicate NDA.''

Response: FDA published draft guidance for industry entitled ''Applications Covered by Section 505(b)(2)'' in 1999. In that draft guidance, FDA describes that it historically utilized a ''paper NDA policy'' which had ''permitted an applicant to rely on studies published in the scientific literature to demonstrate the safety and effectiveness of duplicates of certain post 1962 pioneer drug products (46 FR 27396, May 19, 1981).''

The draft guidance states, in part, that section 505(b)(2) and (j) of the FFDCA replaced FDA's paper NDA policy. The draft guidance also states that ''enactment of the generic drug approval provision of the Hatch-Waxman amendments ended the need for approvals of duplicate drugs through the paper NDA process.'' Specifically, section 505(j) of the FFDCA allows for approval of duplicates of approved NDAs on the basis of chemistry and bioequivalence data. Section 505(b)(2) of the FFDCA allows for approval of applications other than those for duplicate products. The draft guidance also states that a section 505(b)(2) application is an NDA submitted under section 505(b)(1) and approved under section 505(c) of the FFDCA.

As FDA indicated in the draft guidance, two types of approvals replaced FDA's paper NDA policy—one for duplicates of approved NDAs (now approved under section 505(j)) and one for applications other than those for duplicate products (now approved under section 505(b)(2)). Accordingly, it follows that not all products that were approved under FDA's paper NDA policy can be considered noninnovator products.

Therefore, even though a duplicate of a drug approved under an NDA may have historically been approved under FDA's paper NDA policy, if it would now be approved under section 505(j) and result in an ANDA approval, it would be classified as a noninnovator multiple source drug. However, drugs which are not such duplicates, although they may have historically been approved under the paper NDA policy, but which are now approved under section 505(b)(2) and receive an NDA approval should be classified as either a single source drug or innovator multiple source drug, unless the narrow exception discussed above applies (which requires the manufacturer's written submission to CMS, and CMS's response confirming that the narrow exception applies).

Comment: One commenter suggested that CMS recognizes that Chemical Types, assigned by FDA when approving NDAs, reflect the newness of a drug or a measure of innovation. For example, the commenter identified CMS's discussion of Chemical Types 3 (new formulation) and 5 in the line extension section of the proposed rule (77 FR 5339) as evidence of CMS's position that such drugs are not innovative. The commenter further suggested that our proposed use of Chemical Types elsewhere in the proposed rule implies our acceptance that certain NDAs, if assigned particular Chemical Types, are recognized as noninnovator.

Response: Our discussion of the use of Chemical Types in the proposed rule (77 FR 5339 through 5340) was only for the purposes of identifying line extension drugs. Although in the line extension discussion in the proposed rule we did take into consideration the use of Chemical Types, the provisions regarding line extensions in the proposed rule were designed to address rebate calculations for single source and innovator multiple source drugs that are new formulations. However, we did not discuss the use of Chemical Types for the purpose of reporting drug categories to the MDR program or how these Chemical Types could apply to single source drugs, innovator multiple source drugs, and noninnovator multiple source drugs.

Comment: One commenter stated that our proposed definition of innovator multiple source drug would include parenteral products packaged in plastic and that these products have been identified by the VA as non-covered drugs.

Response: We appreciate the comment; however, we note that the VA program is operated separately from the MDR program. We make determinations for the MDR program based on our specific statutory provisions. If a parenteral drug packaged in plastic has been approved by FDA under an ''original NDA,'' then under the statutory provisions of the MDR program, the drug is a single source drug or an innovator multiple source drug according to those definitions in section 1927(k)(7) of the Act, unless the narrow exception discussed above applies.

Comment: One commenter requested the development of an appeals process if a manufacturer disagrees with CMS's determination of drug category.

Response: We currently do not have an appeals process established. However, if manufacturers disagree with CMS on any determination, manufacturers may contact CMS for further discussion.

For the reasons we noted in this section, and based on the comments received and detailed in this section, we are finalizing the definition of innovator multiple source drug under § 447.502 by:

- Revising the introductory sentence to add ''that was originally'' prior to the word ''marketed'' and to delete ''a'' and replace it with ''an original'' prior to the phrase ''new drug application.''
- Adding the word ''also'' between the words ''It'' and ''includes'' in the second sentence. This change is technical in nature and not intended to alter the meaning or intent of the definition.
- Revising the final sentence to specify that for purposes of this definition and the MDR program, an original NDA means an NDA, other than an Abbreviated New Drug Application (ANDA), approved by the FDA for marketing, unless CMS determines that a narrow exception applies.
- Replacing the word ''approval'' with ''application'' in the three instances in which it is used in this definition as the correct terminology is ''Product License Application (PLA)'', ''Establishment License Application (ELA)'', and ''Antibiotic Drug Application (ADA)''. These changes are technical in nature and not intended to alter the meaning or intent of the definition.
- Changing the word ''biologic'' to ''biologics'' as the correct terminology is ''Biologics License Application (BLA)''.

This change is technical in nature and not intended to alter the meaning or intent of the definition.

10. Line Extension Drug (New Formulation)

The Affordable Care Act established a separate calculation for the URA for a drug that is a line extension of a single source drug or an innovator multiple source drug that is an oral solid dosage form. Section 1927(c)(2)(C) of the Act, added by section 2501(d) of the Affordable Care Act, defines line extension to mean a new formulation of a drug, such as an extended release formulation. We proposed to define line extension as a single source or innovator multiple source drug that is an oral solid dosage form that has been approved by FDA as a change to the initial brand name listed drug in that it represents a new version of the previously approved listed drug, such as new ester, new salt or other noncovalent derivative; a new formulation of a previously approved drug; a new combination of two or more drugs; or a new indication of an already marketed drug. We additionally proposed that regardless of whether the drug is approved under an NDA or a supplemental NDA, if the change to the drug is assigned to one of the above changes, it will be considered a line extension drug (77 FR 5323).

We received numerous comments regarding our proposed definition of line extension drug. The comments addressed reasons that various changes to drugs should not be included in the definition of a line extension drug. For example, comments addressed why new combinations, new indications and new ester, new salt or other noncovalent derivatives should not be included in the definition of a line extension. Other comments included concerns that our definition was too broad and not supported by legislative history and suggestions for alternative definitions of line extension drugs.

We appreciate the comments that were provided, however, at this time we have decided not to finalize the proposed regulatory definition of line extension drug at § 447.502. Instead, we are requesting additional comments on the definition of line extension drug as we may consider addressing this in future rulemaking.

11. Manufacturer

For purposes of the MDR program, we proposed to clarify our current definition of manufacturer by revising it to state that a manufacturer means any entity that holds the NDC for a COD or biological product (77 FR 5324, 5360). We received no comments concerning the proposed revision to the manufacturer definition under § 447.502, and therefore, are finalizing it as proposed, except to add the phrase ''meets the following criteria:'' after the word ''and'' in the introduction in order to provide further clarity as to the criteria to be met. This edit is not intended to change the meaning of the definition.

12. Multiple Source Drug

In accordance with section 1927(k) of the Act, as amended by the Affordable Care Act, we proposed to define multiple source drug in proposed § 447.502 as a COD for which there is at least one other drug product which—

- Is rated as therapeutically equivalent as reported in FDA's most recent publication of ''Approved Drug Products with Therapeutic Equivalence Evaluations'' which is available at *http://www.fda.gov* or can be viewed at FDA's Freedom of Information Public Reading Room at 5600 Fishers Lane, Room 12A–30, Rockville, MD 20857 or successor publications and Web sites;
- Is pharmaceutically equivalent and bioequivalent, as determined by FDA; and
- Is sold or marketed in the United States during the rebate period.

This proposal is discussed in more detail at 77 FR 5324. We received the following comments concerning the proposed definition of multiple source drug:

Comment: One commenter stated that robust availability of multiple source products should be a second criterion to the bioavailability criteria in the discussion. The commenter stated that it should not be confused with functional availability or acceptability for use of the product. State substitution laws should also be considered by the states when using this proposed definition and latitude to do so should be given by CMS.

Response: We appreciate the comment but, in light of the statutory definition of multiple source drug at section 1927(k)(A) of the Act, we do not agree that state substitution laws or robust availability should be referenced in the final regulatory definition.

Comment: A few commenters stated that a drug can be considered a multiple source drug if it is sold or marketed in any state in the United States during the rebate period; however, for the purpose of determining FULs, the commenters stated that the drug should be sold or marketed during the most immediate monthly rebate period.

Response: We have not revised the definition of multiple source drug in this final rule, given our reading of the statutory definition of multiple source drug at section 1927(k) of the Act; however, as discussed in the proposed rule (77 FR 5346 and 5366), section 1927(e)(5) of the Act requires the Secretary to calculate the FUL as no less than 175 percent of the weighted average (determined on the basis of utilization) of the most recently reported monthly AMPs for pharmaceutically and therapeutically equivalent multiple source drug products that are available for purchase by retail community pharmacies on a nationwide basis. If a pharmaceutically and therapeutically equivalent multiple source drug product does not have any utilization for that most recently reported monthly period, that is, there are zero AMP units reported for that drug for that monthly period, we consider that the drug was not sold or marketed during that monthly period, and we will not use that drug in the calculation of the FUL. We received no other significant comments concerning the proposed definition of multiple source drug. Thus we are finalizing the definition at § 447.502 as proposed, except to make the following technical edit which is not intended to change the meaning of the definition:

- We are adding the phrase ''meets the following criteria:'' after the word ''and'' in the introduction in order to provide further clarity as to the criteria to be met.

Other comments received about multiple source drugs, as they relate to the calculation of the FUL are discussed in detail in the Upper limits for multiple source drugs section (section II.K.) of this final rule.

13. National Drug Code

We proposed to revise the definition of NDC to mean the numerical code maintained by FDA that includes the labeler code, product code, and package code. For purposes of this subpart, the NDC is considered to be an 11-digit code, unless otherwise specified in this subpart as being without regard to package size (that is, the 9-digit numerical code) (discussed in more detail at 77 FR 5324). We did not receive any comments concerning the proposed definition of NDC at § 447.502; therefore, for the reasons we noted, we are finalizing the definition as proposed.

14. Noninnovator Multiple Source Drug

We proposed to amend the definition of a noninnovator multiple source drug to also include other drugs that have not gone through an FDA approval process but otherwise meet the definition of

COD (77 FR 5324). We also proposed to amend the definition of noninnovator multiple source drug to clarify that for purposes of Medicaid payment and rebate calculations, the term shall include noninnovator drugs that are not therapeutically equivalent (77 FR 5324 and 5360). These revisions are discussed in more detail in the proposed rule at 77 FR 5324. In this section we address the comments we received concerning the proposed noninnovator multiple source drug definition.

Comment: One commenter noted that part of our proposed definition for noninnovator multiple source drugs was in conflict with the proposed definition of multiple source drug. The commenter stated that what we proposed in the definition of noninnovator multiple source drug included noninnovator drugs that are not therapeutically equivalent. The proposed definition of multiple source drug, however, includes therapeutic equivalence requirements.

Response: In the preamble of the proposed rule, we specified that the amended definition of noninnovator multiple source drug, which includes other drugs that are not therapeutically equivalent, was for purposes of clarifying the Medicaid rebate calculations (77 FR 5324). Section 1927(c)(3) of the Act provides that for those drugs that are not single source drugs or innovator multiple source drugs the rebate should be calculated based on an applicable percentage, which after December 31, 2009, is 13 percent. In light of this provision, we proposed to include drugs which do not qualify as single source or innovator multiple source drugs within the noninnovator multiple source definition to clarify the applicable rebate calculation. However, we recognize the conflict that the commenter identified and have removed the language that references drugs that are not therapeutically equivalent from the regulatory text definition by deleting proposed paragraph (5) from the noninnovator multiple source drug definition. This deletion is not designed to have any rebate implications as the rebate calculation for noninnovator multiple source drugs remains subject to the formula in section 1927(c)(3) of the Act. We additionally note that paragraphs (3) and (4) in the definition of noninnovator multiple source drug also reference drugs that meet the definition of a COD and may not qualify as single source or innovator multiple source drugs. Furthermore, given the deletion of proposed paragraph (5), as previously noted, we have renumbered paragraph (6) to paragraph (5) in the definition of noninnovator multiple source drug.

Comment: One commenter expressed concern that a product originally approved under an ANDA, that was later required by FDA to file an NDA, would require a drug category change to an innovator multiple source drug, although it has been affirmed by CMS to be a noninnovator multiple source drug in the past, and it has been treated as a noninnovator multiple source drug since its inception. The commenter stated that making this change from noninnovator multiple source drug to innovator multiple source drug has significant consequences and could require reviews and restatements back to inception of MDR program. The commenter requested that such a change be made on a prospective basis only, and not subject to prior reporting periods.

Response: The definitions of single source drug, innovator multiple source drug, and noninnovator multiple source drug that we are finalizing in this final rule are clarifications of existing statutory language, and we encourage manufacturers who may have incorrectly classified their drugs in the past to take appropriate action now. The final rule does not release manufacturers from any reporting responsibilities. If a manufacturer determines a drug category change is needed, the manufacturer is responsible for contacting CMS to request that change.

Comment: One commenter suggested a new NDC be required if a non-approved product subsequently receives FDA approval to avoid confusion between the approved and unapproved versions.

Response: Because the proper issuance of NDCs is within the purview of FDA and the responsibility of the manufacturer, this issue is outside the scope of the proposed rule.

Comment: One commenter suggested that if a product was reported as a noninnovator multiple source drug and subsequently receives FDA approval, which requires a recategorization to single source or innovator multiple source, that the base date AMP should be based on the first quarter after FDA approval was issued and that the ''market date'' should be the date of the launch of the newly approved NDC–9.

Response: In the specific example provided by the commenter, where the newly approved drug is launched under a different 9 digit NDC, the manufacturer could report a base date AMP for the drug based on the first full quarter after the newly approved drug's market date. As previously stated in this section, the provisions of this final rule are effective on a prospective basis only.

After considering the public comments, and for the reasons we articulated, we are finalizing the definition of noninnovator multiple source drug under § 447.502, except—

- As noted earlier, we are deleting paragraph (5) (Any noninnovator drug that is not therapeutically equivalent) from the regulatory text and renumbering paragraph (6) to paragraph (5); and
- In the new paragraph (5), we are making a technical correction to state that if any of the drug products listed in this definition of a noninnovator multiple source drug subsequently receives an NDA or ANDA approval from FDA, the product's drug category changes to correlate with the new product application type. This change is technical in nature and not intended to alter the meaning or intent of the definition.

15. Oral Solid Dosage Form

We proposed to interpret oral solid dosage form in accordance with FDA regulation at 21 CFR 206.3, which defines solid oral dosage form to mean capsules, tablets, or similar drug products intended for oral use. In addition, we also proposed to further interpret an oral route of administration as any drug that is intended to be taken by mouth. The proposed definition is discussed in more detail at 77 FR 5324 through 5325. We received the following comments regarding this definition:

Comment: We received several comments supporting this proposed definition of oral solid dosage form, stating that this interpretation is consistent with the statute and will not impede innovation.

Response: We appreciate that support. Based on the comments and for the reasons we discussed previously, we are finalizing the definition of oral solid dosage form at § 447.502 as proposed.

16. Over-the-Counter (OTC) Drug

We proposed to add a definition of OTC drugs to clarify which products would be treated as OTC drugs in the Medicaid program (77 FR 5325). We proposed to define OTC drugs as drugs that are appropriate for use without the supervision of a health care professional such as a physician, and which can be purchased by a consumer without a prescription (77 FR 5360 through 5361). These proposed revisions are discussed in more detail at 77 FR 5325. We received no comment concerning the proposed OTC drug definition at § 447.502. For the reasons we noted in

the proposed rule, we are finalizing it as proposed.

17. Pediatric Indication

Section 2501(a) of the Affordable Care Act established a minimum rebate percentage of 17.1 percent of AMP for single source and innovator multiple source drugs approved by FDA exclusively for pediatric indications. To implement this requirement, we proposed to clarify which drugs would be subject to this minimum rebate percentage (77 FR 5325). We proposed to apply this definition at proposed § 447.502 only to drug products whose FDA-approved labeling includes indications only for children from birth through 16 years of age or a subset of this group (77 FR 5325 through 5326). We also proposed to apply such a definition only when this specific pediatric population age cohort appears in the ''Indication and Usage'' section of FDA-approved labeling. We received the following comments concerning the definition of pediatric indication:

Comment: We received several comments regarding the application of the FDA prescription drug labeling regulation when determining a drug is pediatric indicated. The commenters requested that CMS define pediatric indications for purposes of the MDR provision to include indications for minors up to 17 or 18 years of age and not use the age cut-off described in FDA prescription labeling regulations at 21 CFR 201.57 and 21 CFR 201.80. Some commenters noted that FDA and other HHS programs may have referred to a pediatric age group to include a population up to, and including, the age of 21. Another commenter stated that CMS acted without explanation, justification, or analysis when relying on FDA prescription labeling regulations at 21 CFR 201.57 and 21 CFR 201.80 to support the definition of ''pediatric indications.'' Another commenter stated that CMS's proposed definition would create unjust and arbitrary outcomes by excluding certain drug products that are approved by FDA for pediatric indications, which are not rigidly restricted by a chronological age cut-off specified in the ''Indications and Usage'' section of FDA labeling. Commenters opined that CMS's decision to select an old FDA standard of 16 years of age was arbitrary and capricious and that this standard is inconsistent with the statute and violates the APA.

A few commenters indicated that CMS should not redefine terms that are inconsistent with FDA's application of what it interprets as pediatric so as to obtain additional Medicaid rebates. The commenters referenced debates leading up to the 2002 reauthorization of the Best Pharmaceuticals for Children Act (BPCA), Representative Stupak was quoted in the Congressional Record (Cong. Record p. 147562 (Oct. 31, 2001)) as saying that, ''we created the pediatric exclusivity bill to make sure an opportunity was provided to have more studies done to make sure the proper dosage, the amount and the type of drug would be beneficial to young people, those under 18 years of age.'' The commenter discussed a drug which initially was approved by the FDA on the condition that the manufacturer perform pediatric studies under the Pediatric Research Equity Act (PREA) on pediatric patients 13 to 17 years and stated that the FDA approved a second product for the same indication but required three post marketing studies in the pediatric population up to age 17. This commenter, as well as other commenters stated that FDA has approved drugs for ''pediatric use'' up to 18 years of age and CMS should be consistent with these approvals.

A few commenters also stated that the proposed rule, if finalized, undermines the incentives the Congress created (under BPCA and PREA) to encourage development of drugs for children and adolescents. The commenters also noted that CMS's interpretation of pediatric indication, which uses a lower age limit, results in a manufacturer incurring a higher rebate obligation while FDA's higher age limit imposes more stringent testing requirements on the same manufacturer.

Another commenter stated that FDA regulations cited by CMS were not designed to identify products approved ''exclusively for pediatric indications'' but rather used by the FDA to define the pediatric population for the purpose of distinguishing it from the adult population in which a product may be studied and approved. This commenter noted that although the FDA labeling regulations seem to establish the criteria of pediatric population to include up to age 16 that is not how the regulations have been applied by the FDA when it comes to setting age criteria for required clinical trials.

And finally, a commenter noted that adopting this definition of pediatric would not be consistent with the definition of pediatric patients in other CMS programs and rules, including the Pediatric Vaccine Distribution Program (definition of child as ''an individual 18 years of age or younger''), CMS-Supported Pediatric Renal Facilities (''pediatric facility . . . a renal facility at least 50 percent of whose patient are individuals under age 18 years of age''), and the Medicare Hospital Inpatient Prospective Payment System interpreting ''pediatric'' (up to the age of 18).

Response: We appreciate these comments regarding the adoption of an age limit when defining pediatric indication, as well as comments addressing congressional concerns associated with the passage of PREA and BPCA, which concerned research in the pediatric populations to assure that drugs are safe to use in the pediatric populations. However, we are not persuaded by the commenters that our proposed adoption of a standard of birth through 16 years of age should be revised as part of this final rule. The age range in the proposed definition of pediatric indication is consistent with the age range contained within the FDA regulations at 21 CFR 201.57 and 21 CFR 201.80 which define pediatric use to refer to usage by a pediatric age group from birth to 16 years of age. We further note that, contrary to the commenters' claims that FDA regulation is ''old,'' the FDA regulations at 21 CFR 201.57 and 21 CFR 201.80 are current and in force. FDA continues to refer to these regulations in its more recent guidance documents. See, for example, ''Draft Guidance for Industry and Review Staff, Pediatric Information Incorporated Into Human Prescription Drug and Biological Products Labeling,'' dated February 2013, *http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM341394.pdf.* Consistent with this draft guidance, the definitions of pediatric population found at 21 CFR 201.57 and 21 CFR 201.80 encompass the age groups from birth through age 16 years (younger than 17 years of age.)

Furthermore, we recognize that commenters referenced examples of when the FDA has required certain manufacturers to perform certain studies in pediatric patients, which includes populations' ages 13 to 17 years of age, or up to 18 years of age, consistent with the requirements of PREA and BPCA. While FDA may have required an individual manufacturer to perform studies in age groups over the age of 16, we believe such decisions are driven by FDA's clinical and scientific reasoning (see ''Draft Guidance for Industry and Review Staff, Pediatric Information Incorporated Into Human Prescription Drug and Biological Products Labeling,'' dated February 2013) that the drug be evaluated in groups beyond age 16. While FDA may have required such studies, FDA has not revised Part 201's definitions of pediatric populations.

We believe that adopting a definition of pediatric indication in this rule that contains the pediatric age groups specified in FDA's prescription drug labeling regulations is consistent with the statute at section 1927(c)(1)(B)(iii)(II)(bb) of the Act, which provides for the application of a minimum rebate percentage to drugs approved by the FDA exclusively for pediatric indications. We further believe that while some commenters noted that FDA and other HHS programs may have referred to a pediatric age group to include a population up to, and including, the age of 21, we do not agree that such a definition should be used in the MDR program. We see no reason to adopt a definition which would include age populations through 21 years of age; doing so would be inconsistent with the FDA regulations discussed previously.

Therefore, we are finalizing our proposal to adopt a specific age range within our definition of pediatric indication in this final rule to indicate that the product is approved exclusively for use by the pediatric population age group, meaning the drug's label references from birth through 16 years of age, or a subset of this group, as specified in the ''Indication and Usage'' section of the FDA approved labeling, or an explanation elsewhere in the labeling that makes it clear that the drug is approved for use only in the pediatric age group, or a subset of this group.

Comment: One commenter asked that CMS clarify whether the definition of pediatric indication meant that a patient has not reached their 16th birthday or they have not yet reached their 17th birthday.

Response: The definition of pediatric indication means that a patient has not reached 17th birthday. This interpretation is consistent with the regulations, as discussed in our prior response.

Comment: One commenter discussed a product that is prescribed to treat growth failure in children, stating that while the ''Indications and Usage'' section does not specifically state an age range, other information appears in the approved labeling stating that the drug should not be administered after the growth plates fuse at the end of puberty and is not to be used in adults. This commenter believed that these statements in the approved label along with information about the condition being treated make it clear that the product is intended for use exclusively in the pediatric population. The commenter urged that CMS be flexible and proposed that CMS adopt the following definition of pediatric indication at § 447.502: ''a specifically stated indication for use by the pediatric age group, meaning either (1) from birth through 16 years of age, or a subset of this group, as specified in the ''Indications and Usage'' section of FDA approved labeling, or (2) language in the ''Indications and Usage'' section that, when combined with other information in FDA approved labeling about the product make it clear that the product is only for use in a pediatric population.''

Another commenter believed that requiring the ''Indications and Usage'' section to contain an explicit age range is too rigid, when FDA approved a drug to prevent serious lower respiratory disease in children at high risk of developing that disease. The commenter noted that the FDA approved labeling states elsewhere that this product ''is not for adults or for children older than 24 months of age,'' thus supporting that an age-specific reference is not required in the indication statutorily.

Response: We agree with the commenters that we need to consider other information in FDA approved labeling when determining whether a drug is exclusively pediatric. We recognize that there may be instances when the ''Indications and Usage'' section of the labeling may not contain a specific age range; however, other parts of the labeling includes a reference to an age range that the drug is indicated for use exclusively in the pediatric age group or a subset of this group. Therefore, we are amending the proposed definition of pediatric indication to state that manufacturers may consider other information in the FDA approved labeling; specifically, an explanation elsewhere in the labeling that makes it clear that the drug is for use in that pediatric age group (birth through 16 years of age), or subset of that group.

Comment: Several commenters referenced dosage and administration to distinguish pediatric indication. One commenter attached FDA approved labeling (commonly known as package inserts) for several different products to illustrate that in these instances, the FDA approved labeling includes information for the use in adult and pediatric patients beyond the age of 16, and gives more specific information in the ''Dosage and Administration'' section of the label with further information in the ''pediatric use'' section.

Another commenter provided an example of a product where in its ''Indications and Usage'' section, there were dosages for several different indications; however, there was no upper age limit, only ''X'' years and older. The dosage and administration section showed the higher strength product for use in 15 years and older. This commenter suggested that CMS revise the proposed definition to include the full product labeling, including, but not limited to the ''Dosage and Administration'' section to read ''pediatric indication means a specifically stated indication for use by the pediatric age group, meaning from birth through 16 years of age, or a subset of this group, as specified in the full FDA approved labeling.''

Response: As previously stated, we have revised the definition of pediatric indication at § 447.502 in this final rule to add that we will consider an explanation elsewhere in the labeling that clarifies that the drug is for use exclusively in the pediatric age group or subset of that group. However, we do not consider strengths or dosage forms of the same drug that are intended for use in the adult population to qualify as approved by the FDA for exclusively pediatric indications since it is indicated for use in the adult population.

Comment: One commenter remarked that drug labeling and FDA approvals can change over time for a particular drug. A drug with a pediatric indication could become labeled for adult use, or a drug with adult and pediatric indications might lose labeling for the adult indication. The commenter requested that CMS clarify what would happen when a drug's status changes in the middle of a rebate period.

Response: If a drug's labeling is changed resulting in that drug being exclusively pediatric for less than one rebate period, the 17.1 percent minimum rebate amount would continue to be applicable for that rebate period consistent with section 1927(c)(1)(B)(iii)(II)(bb) of the Act, which does not require that the minimum rebate percentage of 17.1 percent be applied to the drug more often than once a rebate period. We believe this is consistent with the rebate statute in section 1927(c)(1)(B)(iii)(l) of the Act which provides that the minimum rebate amount is for ''rebate periods'' which is defined at section 1927(k)(8) of the Act as the calendar quarter or other period specified by the Secretary for payment of rebates under the drug rebate agreement.

Comment: One commenter believed that Congress created the lower minimum rebate to incentivize manufacturers to invest in new therapies with pediatric indications, or expand use of existing therapies to pediatric populations.

Response: While we appreciate the commenter's opinion, the regulations are not designed to create incentives; rather, they are designed to interpret the rebate provisions, as enacted.

Comment: One commenter stated it was unclear whether certain strengths of a drug product would qualify as exclusively pediatric if there were multiple strengths of the product listed within the dosage and administration section of the label of the product. The commenter asked if a particular strength of a drug indicated for the pediatric population would qualify for pediatric exclusivity.

A few commenters expressed dissatisfaction with CMS's proposed definition of Pediatric Indication, because it would exclude many strengths of a drug approved for pediatric indications and would potentially evaluate drugs at a different level than the level at which URAs are calculated. The commenter included labeling information for a few products and explained that one product had both adult and pediatric indications in the ''Indications and Usage'' section, noting that the pediatric products were approved under a separate NDA. However, there is only one label approved for all of the various dosage forms and age groups. The commenter referenced another product label which had separate adult and pediatric indications at the product level but does not specify which dosage forms apply to which age groups. The commenter stated that since these products are within the same product codes that were approved under a separate NDA, those products should be approved as exclusively for pediatric indication by CMS.

Response: We agree that there may be a drug with multiple strengths that may have a particular strength that is effective for use only in the pediatric age group, or a dosage form used only by the pediatric age group. In such cases, only the specific dosage form or strength that is indicated exclusively for pediatric indication in the drug's FDA approved labeling would qualify for the lower rebate percentage. Our revision to the definition of pediatric indication to consider additional information in the drug's FDA approved labeling will permit manufacturers to consider such information when determining whether or not a drug meets the criteria to qualify for the lower minimum rebate percentage.

After consideration of the public comments, and for the reasons we explained previously in this section, we are revising the proposed definition of pediatric indication under § 447.502 to align with the FDA's interpretation of pediatric population to mean a specifically stated indication for use by the pediatric age group, from birth through 16 years of age, or a subset of this group, as specified in the ''Indication and Usage'' section of the FDA approved labeling or in an explanation elsewhere in the labeling that makes it clear that the drug is for use only in the pediatric age group, or a subset of this group.

18. Professional Dispensing Fee

We proposed in § 447.502 to replace the term ''dispensing fee'' with ''professional dispensing fee'' as the drug ingredient cost is only one component of the two-part formula used to reimburse pharmacies for prescribed drugs dispensed to Medicaid beneficiaries (77 FR 5361). We also proposed to require states to reconsider the dispensing fee methodology consistent with the revised requirements (discussed in more detail at 77 FR 5326). We received the following comments concerning professional dispensing fee provisions:

Comment: One commenter supported the change from dispensing fee to professional dispensing fee and supported CMS's position that pharmacies providing prescription medications are providing professional services, not merely dispensing drugs. Another commenter agreed with CMS that the professional dispensing fee should reflect the pharmacist's professional services and costs associated with ensuring that possession of the appropriate COD is transferred to a Medicaid beneficiary.

Response: We appreciate the support that the commenters have expressed.

Comment: One commenter requested that CMS provide stronger and more specific language to require the appropriate adjustment in professional dispensing fee to recognize the pharmacist's role. Several commenters noted that state and federal policymakers have focused on reimbursing pharmacies for the drug product, but there has been little discussion on the importance of reimbursing pharmacies accurately for the cost to dispense. Another commenter stated that states have traditionally shown little interest in determining actual dispensing costs and even less interest or ability to act on the information regarding such actual costs and the commenter stated that this practice must change to avoid impact on access. Several commenters stated that CMS must require that states can only use AAC if they increase their dispensing fees to reflect pharmacy's cost to dispense. Another commenter was concerned that a move to require states to use AAC for brand drugs without a requirement that dispensing fees be increased will negatively impact patient access.

Response: Our proposal to revise the term dispensing fee to professional dispensing fee is designed to reinforce our position that the dispensing fee should reflect the pharmacist's professional services and costs to dispense the drug product to a Medicaid beneficiary. In light of the issues raised in the comments, we have clarified the language in § 447.518(d) of this final rule to indicate that when states are proposing changes to either the ingredient cost reimbursement or professional dispensing fee reimbursement, they are required to evaluate their proposed changes in accordance with this final rule, and states must consider the impacts of both the ingredient cost reimbursement and the professional dispensing fee reimbursement when proposing such changes to ensure that total reimbursement to the pharmacy provider is in accordance with the requirements of section 1902(a)(30)(A) of the Act. Further, states must provide information supporting any proposed change to either the ingredient cost or dispensing fee reimbursement which demonstrates that the change reflects actual costs and does not negatively impact access.

Comment: Many commenters agreed with our proposal, and stated that they appreciate the policy to require states to reconsider their dispensing fee methodology as states change their payment for ingredient cost based on AAC. Several commenters stated that in the states where AAC is currently in use, CMS has required a comprehensive review and adjustment of dispensing fees, and commenters believed that this practice should continue.

Response: We appreciate the support the commenters expressed.

Comment: Many commenters commended our recognition that reimbursement for drug ingredient cost and professional dispensing fee must be adjusted in tandem. Many commenters noted that if a cost-based product reimbursement (AAC) is utilized, it must be directly tied to an adequate and regularly updated (such as annually) dispensing fee. Several commenters stated that the two components of reimbursement, ingredient and the professional dispensing fee, should be linked and should not be allowed to independently change. A few commenters stated that rather than asking states to ''reconsider'' dispensing

fees, they requested that CMS require states to reevaluate dispensing fees to assure that they adequately cover costs and to include specific factors on assessing dispensing fess in the final rule.

Another commenter stated that CMS should reflect congressional intent to provide adequate pharmacy reimbursement for retail pharmacies participating in the Medicaid fee-for-service (FFS) program by ensuring that states are adhering to an economically rational reimbursement methodology. Another commenter added that CMS recognizes this by stating in the proposed rule that both ingredient cost and professional dispensing fee need to be looked at in the total and this is why CMS is encouraging states to move toward an AAC payment with a corresponding higher professional dispensing fee (where appropriate) to cover costs and overhead.

Response: We agree that pharmacy providers should be reimbursed adequately for their professional services within the requirements of this final rule. While we are not requiring states to update their professional dispensing fees at specific intervals or frequencies, such as on an annual basis, they will be required to evaluate each component when they propose changes. We afford the states the flexibility to adjust their professional dispensing fees when necessary to assure sufficient access in accordance with the requirements of section 1902(a)(30)(A) of the Act.

Comment: One commenter stated that the use of the new AMP-based FULs or any version of AAC should be limited to those states than can provide evidence of adequate professional dispensing fees based on services rendered. Another commenter stated that unless dispensing fees are raised at or prior to the time that AMP-based FULs are finalized, pharmacies will be reimbursed at less than their total cost.

Response: As discussed previously in this section, and in accordance with the regulations text, states must provide adequate data in support of any proposed changes in payment methodology for prescription drugs which we will review through the formal review process. As discussed in more detail in the comments and responses in section II.K, we believe that our revised process by which a higher multiplier will be used to calculate the FUL will address concerns regarding pharmacies being reimbursed at their acquisition cost.

Comment: Several commenters supported the inclusion of a professional dispensing fee but stated that the actual definition should be amended to include the cost of compounding prescriptions, that it should vary for different health care settings and that it should be based on an annual cost of dispensing study by the state. Several commenters also stated that the final rule should be modified to state that all costs, both professional and operational, should be considered when determining the dispensing fee. Another commenter requested that the final rule be revised to set forth a more complete and inclusive list of all of the categories of costs that can be included in the determination of the professional dispensing fee.

Response: We appreciate the comment but we believe that the proposed definition of professional dispensing fee (77 FR 5361) is sufficient to capture the activities involved with the dispensing of a drug to a Medicaid beneficiary in that it specifies a number of activities, including, but not limited to, the pharmacist's time in performing drug utilization review activities, measurement and mixing of the drug, and patient counseling. We do not agree that the regulations text should be revised to require an annual cost of dispensing study or that fees should vary based on setting, but rather we will continue to allow the states the flexibility to adjust their dispensing fees as necessary.

Comment: One commenter stated that the professional dispensing fee for home infusion pharmacies is unique and significantly different from and more intensive than the professional services performed at retail pharmacies and therefore, that CMS should establish a separate definition of professional dispensing fee for home infusion therapy pharmacies. Another commenter stated that the definition of professional dispensing fee must also include ''warehousing, refrigeration, repackaging, insurance fees, pharmacist consultation with beneficiary's health care providers, 24-hour access to a pharmacist, and self-infusion instruction'' to capture the additional professional dispensing fee services of the Hemophiliac Treatment Center (HTC) pharmacist.

Response: We appreciate the comment but, at this time, we do not see a need to revise the definition of professional dispensing fee. States retain the flexibility to establish the professional dispensing fee that is representative of pharmacy costs associated with ensuring that possession of the appropriate COD is transferred to a Medicaid beneficiary, including establishing fees for specific pharmacy types overhead, and drugs dispensed. While we recognize that home infusion pharmacies and HTCs may offer services to Medicaid beneficiaries in addition to the activities related to dispensing a COD, such services would not be covered under the pharmacy benefit, but other service categories, such as home health. Therefore, we are not revising the definition of professional dispensing fee to include payment for these additional services.

Comment: One commenter stated that the professional dispensing fee definition should include ''reasonable profit'' as an element of the definition.

Response: We have not separately identified profit in the definition of professional dispensing fee, as we believe the components of the dispensing fee we have already identified include a reasonable profit.

After considering the comments and for the reasons we discussed in this section, we are finalizing the definition of professional dispensing fee in § 447.502 as proposed (77 FR 5361).

19. Single Source Drug

As currently defined in § 447.502, a single source drug refers to a COD that is produced or distributed under an original NDA approved by FDA, including a drug product marketed by any cross-licensed producers or distributors operating under the NDA. It also includes a COD approved under a BLA, PLA, ELA, or ADA.

In the proposed rule (77 FR 5326, 5361), we proposed to define single source drug to mean a COD that is produced or distributed under an NDA approved by FDA and has an approved NDA number issued by FDA, including a drug product marketed by any cross-licensed producers or distributors operating under the NDA. It also includes a COD approved under a BLA, PLA, ELA, or ADA. We also proposed that for purposes of the MDR program, an original NDA is equivalent to BLA, PLA, ELA, or ADA. Additionally, proposed was that for purposes of the MDR program, an original NDA is equivalent to an NDA filed by the manufacturer for approval under section 505 of the FFDCA for purposes of approval by FDA for safety and effectiveness. These proposed provisions are discussed in more detail at 77 FR 5326.

We received some comments regarding the definition of single source drug which included comments about the interpretation of the phrase ''original NDA'' as well as comments regarding products approved under a BLA. However, the comments received regarding the proposed definition of

single source drug, and specifically regarding the interpretation of ''original NDA'', as well as products approved under a BLA, were not unique to the single source drug definition and were made in association with or as part of the same comments regarding the definition of innovator multiple source drug. As the phrase ''original new drug application approved by the Food and Drug Administration'' is present in both definitions, to avoid providing the same comment summary and responses in both this section that discusses the proposed definition of single source drug and also in the section that discusses the proposed definition of innovator multiple source drug, the comments regarding the term ''original NDA'' have been addressed in the innovator multiple source definition section of this final rule since these comments pertain to both the definitions of innovator multiple source drug as well as single source drug. Additionally, as the proposed definitions of both single source drug as well as innovator multiple source drug include reference to BLA applications, to avoid duplicate discussion, we are summarizing the comments and responses that pertain to BLA applications as related to these definitions in the innovator multiple source drug section. We received no comments that exclusively applied to the definition of single source drug.

Based on the comments received about the meaning of the term ''original NDA'' that apply to the definition of single source and as summarized in the innovator multiple source drug definition section of this final rule, and for the reasons we articulated in our response to the comments about the meaning of that term in the innovator multiple source drug definition, we are finalizing the definition of single source drug under § 447.502 by:

- Inserting the term ''original'' before the initial reference to ''NDA'' in the introductory sentence of the definition.
- Revising the final sentence to specify that for purposes of this definition and the MDR program, an original NDA means an NDA, other than an ANDA, approved by the FDA for marketing, unless CMS determines that a narrow exception applies.
- Replacing the word ''approval'' with ''application'' in the three instances in which it is used in this definition as the correct terminology is ''Product License Application (PLA)'', ''Establishment License Application (ELA)'', and ''Antibiotic Drug Application (ADA)''. These changes are technical in nature and not intended to alter the meaning or intent of the definition.
- Changing the word ''biological'' to ''biologics'' as the correct terminology is ''Biologics License Application (BLA)''. This change is technical in nature and not intended to alter the meaning or intent of the definition.

20. States and United States

We proposed to revise the definition of states to include the 50 states, the District of Columbia, and the territories (defined as the Commonwealth of Puerto Rico, the Virgin Islands, Guam, the Northern Mariana Islands and American Samoa), as discussed in more detail at 77 FR 5326, 5361. We also proposed to add a definition of United States to include the 50 states, the District of Columbia, and the territories (the Commonwealth of Puerto Rico, the Virgin Islands, Guam, the Northern Mariana Islands and American Samoa) (77 FR 5326, 5361). Because the effect of these two definitions is essentially the same for purposes of the MDR program, we are responding to the comments we received on them together as detailed in this section. Specifically, we received the following comments concerning the proposed definitions:

a. Legal Authority

Comment: One commenter expressed support for expanding the MDR program to the territories. A commenter acknowledged that CMS may have the authority to reverse the position of excluding territories from the MDR program.

Response: We appreciate these comments. We agree that we have the requisite authority to include the territories in the MDR program. We note that the authority to include the territories in the MDR program is based on section 1101(a)(1) of the Act which defines ''states'' to include the territories; and therefore, we are amending the regulatory definition of states under § 447.502 to include the territories which also assures the regulatory definition of states is consistent with the definition of states under section 1101(a)(1) of the Act.

Comment: Many commenters expressed strong opposition to the policy. Commenters stated that the rebate program extension to the territories is unexplained and not prompted by any change in the rebate statute. One commenter stated that never during the congressional debate for changes to the MDR program during the development of the Affordable Care Act did the Congress discuss expanding the program to the territories. Commenters stated that in light of the discounts that many manufacturers already provide in the territories, CMS has not explained the justification for this expansion of the scope of the MDR program, particularly inasmuch as these territories' Medicaid programs simply do not function in the same manner as those of the states and the District of Columbia. The commenter further stated that there are too many unanswered questions about this policy for CMS to proceed with its proposed expansion of the rebate program to the territories at this time. A commenter contended that CMS does not have the authority under the definition of ''states'' in the national rebate agreement to expand the program to the territories since all rebate agreements executed by manufacturers define the scope of the agreement as reaching only to drug sales in the 50 states and the District of Columbia and all prohibit any amendments without the written consent of both parties. Commenters stated that manufacturers cannot be required to pay rebates for utilization in the territories.

One commenter requested that CMS provide the legal basis and rationale for this expansion prior to requiring companies to undergo extensive contract and pricing adjustments that would be necessary; stating that CMS should substantively demonstrate the need for this expansion beyond a generalized belief that doing so will benefit the territories. A few commenters also stated that a statutory change would be a prerequisite to expanding the MDR program to the territories. One commenter stated that this policy should be considered as part of a new rulemaking that sets forth detailed criteria for the operation of the Medicaid rebate program in the territories.

Response: Our justification for including territories in the definitions of states and United States was not only related to rebates the territories may receive under section 1927 of the Act, but also whether the territories should be included in these definitions in light of the definitions in section 1101 of the Act. We note that while the territories may have some unique features in their respective programs, the rebates would be applied and be due in the same manner as in other states, consistent with the terms of section 1927 of the Act. We appreciate the comments and realize that the definition represents a change in policy; however, upon further consideration of the definitions in the statute, we believe that the territories should be included in the MDR program. As previously stated in this section, in this final rule we have decided to amend the definition of

states in § 447.502 to align with the definition of states under section 1101(a)(1) of the Act. We further note that detailed criteria that states use to operate the rebate program has been provided through the statute, regulations, and subregulatory guidance; therefore, we believe it is not necessary to set forth additional detailed criteria for the operation of the MDR program in the territories as part of this final rule. We further emphasize that we are available to provide technical assistance to the territories during their participation in MDR program.

In addition, in light of the comments and as discussed more in this section, we have decided to delay including the territories in the definitions of states and United States until 1 year after the final rule becomes effective. We also will consider allowing a territory to use existing waiver authority to elect not to participate in the MDR program consistent with the statutory waiver standards. For example, the Northern Mariana Islands and American Samoa may opt out under the broad waiver that has been granted to them in accordance with section 1902(j) of the Act. Puerto Rico, Virgin Islands and Guam may use waiver authority under section 1115(a)(1) of the Act to waive section 1902(a)(54) of the Act, which requires state compliance with applicable requirements of section 1927 of the Act.

We further note that should a territory exercise its waiver option not to participate in the MDR program, the definitions of states and United States would still include the territories 1 year after the effective date of the final rule. We appreciate the comments; however, we continue to note that it is consistent with the definitions in section 1101(a) of the Act to include the territories in the definition of states under the MDR program.

Comment: One commenter requested clarification regarding why the federal government should share in the value of any drug rebates paid for use by Medicaid enrollees in the territory. The commenter further stated that the territory should receive 100 percent of the rebate for the territory and not share a portion of the rebate payment with the federal government.

Response: Similar to all other states, the territories receive federal matching payment for Medicaid expenditures. In accordance with section 1927(b)(1)(B) of the Act, the rebates paid under the MDR program shall be considered a reduction in the amount expended under the state plan in the quarter for medical assistance purposes under section 1903(a) of the Act. Because these rebates have the effect of reducing federal matching funds, the federal government, in accordance with section 1927(b) of the Act, will share in the rebates that the drug manufacturers pay to the territories.

Comment: One commenter asked CMS to clarify whether there will be a separate CMS regional office to handle the territories or will they be assigned to one or more current regional offices.

Response: The oversight of the territories' Medicaid programs are currently assigned to the following CMS regional offices: Puerto Rico and the Virgin Islands are assigned to the CMS regional office in New York, NY. American Samoa, Guam, and Northern Mariana Islands are assigned to the CMS regional office in San Francisco, CA. We also note that CMS Central Office staff are also available to provide technical assistance to the territories.

b. Implementation Timeframe

Comment: We received many comments concerning the need for sufficient lead time prior to expanding the MDR program to the territories. Several commenters stated that CMS should provide manufacturers with a significant amount of lead time before the effective date of the expansion. The commenters stated that this change in policy, if finalized, represents a substantial financial impact to manufacturers and creates a significant number of operational complexities for both manufacturers and territories that require resolution prior to implementing the expansion to the territories.

Similarly, several commenters noted that the proposed rule recognizes that the territories will need additional time to come into compliance with MDR program requirements but the proposed rule does not address that manufacturers may need similar lead time as the territories to implement aspects of this provision. Several commenters stated that the completion timeline for manufacturers to comply with CMS requirement should be 6 to 12 months after the approval of the ruling.

Several commenters further stated that CMS should require that manufacturers are obligated to pay rebates on territory utilization on a prospective basis only as of the effective date. In addition, a few commenters stated that the proposed rule does not address the potential for territories to implement rebate liability on manufacturers on a voluntary basis and on an earlier timetable than the proposed rule's timeline, which could result in manufacturers facing the possibility that territories could submit rebate claims to them faster than the manufacturers are able to accomplish systems upgrades. Another commenter asked if CMS would provide manufacturers with drug utilization estimates if the territories are not prepared to do so by the time of the effective date.

Many commenters also stated that the collection of data concerning drug sales in the territories require significant time for manufacturers and territories to revise, set up, and to operationalize price reporting policies and systems to collect, report, validate, test, track and perfect pricing data collections from those sales which are necessary to calculate and pay rebates for CODs utilized in the territories. Commenters further noted that lead time is needed to amend contracts, and implement software changes.

Response: We appreciate these comments and recognize that the proposed rule only addressed a proposed delay concerning implementation of the state reporting requirements for territories until 1 year after the effective date of this final rule (77 FR 5345). Furthermore, we recognize that the proposed rule did not propose to delay inclusion of the territories in the definition of states and United States. After considering the comments, we recognize the need to delay the inclusion of the territories in the definitions of states and United States to give the territories and manufacturers additional time to implement provisions necessary to include territories in all aspects of the MDR program. Accordingly, we are finalizing the definitions of states and United States in the final rule as of the effective date of the final rule; however, neither definition of states or United States will include the territories until 1 year after the effective date of the final rule. We agree with commenters that delaying the inclusion of the territories in the MDR program for 1 year is necessary to give territories and manufacturers an adequate amount of time to make the necessary system changes and develop the mechanisms and processes necessary to comply with the requirements of the MDR program. We note that a 1 year implementation period is consistent with the delay we proposed for applying these requirements for states. We have received no compelling comments which support delaying implementation beyond the 1 year period or which convince us that a different implementation timeframe would be more appropriate. Manufacturers will not be responsible for providing rebates prior to 1 year after the effective date of the final rule.

As a result, the related requirements we are adopting in this final rule, including the Requirements for States in § 447.511, will not apply to the territories until 1 year after the definitions for states and United States go into effect. As a result of using a later implementation date for the inclusion of the territories into the definitions of states and United States, the related requirements concerning these revised definitions that apply to the manufacturers, including the Determination of AMP in § 447.504, the Determination of Best Price in § 447.505, MDRs in § 447.509, and the Requirements for Manufacturers in § 447.510, will not immediately be applicable to the territories (the Commonwealth of Puerto Rico, the Virgin Islands, Guam, the Northern Mariana Islands and American Samoa) as of the effective date of the final rule.

Comment: A few commenters noted concerns with the territories' ability to participate in the MDR program and asked CMS to consider delaying this provision to allow for further study. One commenter noted that the costs involved in developing and maintaining MDR systems within the territories may outweigh the incremental benefit of the program to the territories and recommended further study involving the territories before CMS moves forward with this proposal. Another commenter noted that there has been no public discussion of this policy in a territory, including the technical and complex questions that it raises. The commenter asked CMS to take additional time to consider the high costs of implementation and the dangerous precedent that it could serve.

Response: We appreciate the concerns raised by these commenters and recognize that the territories may have challenges complying with these requirements. Our justification for including the territories in the definitions of states and United States was not only related to rebates the territories may receive under the Act, but also on our reexamination of the applicable definitions. As discussed previously in this section, after considering the comments, we decided to include the territories in the definitions of states and United States 1 year after the effective date of the final rule. We decided that delaying the inclusion of the territories in the MDR program for a 1 year period will give territories and manufacturers an adequate amount of time to make system changes and develop the mechanisms and processes necessary to comply with the requirements of the MDR program. We further note that, as discussed previously in this section, we will also consider allowing a territory to use existing waiver authority to elect not to participate in the MDR program consistent with the statutory waiver standards.

In addition, we also disagree with the comment concerning the dangerous precedent that our definitions could set. As discussed previously in this section, our definitions are based on our reexamination of the applicable provisions and what we consider to be an appropriate definition of states and United States in light of the statute.

c. Financial and System Implications

Comment: One commenter stated that manufacturers already offer voluntary rebates to the territories through a number of mechanisms and CMS has offered no basis for concluding that any additional rebate revenue through a Medicaid expansion will justify the burden on territories or manufacturers that will result from this expansion. The commenter believed that CMS should first substantively demonstrate the need for the expansion to territories beyond a generalized belief that doing so will benefit the territories.

Response: We did not propose this change based only on the amount of additional rebates that would be generated to the territories. As discussed previously in this section, we believe that such rebates would be in the best interest of the program, so that territories achieve savings in their drug expenditures. As discussed in the proposed rule, territories over the years have expressed an interest in participating in the rebate program (77 FR 5326). After considering that interest, we reexamined our definitions and proposed this change to apply the statutory definition of states and the United States under section 1101(a)(1) of the Act in the context of the MDR program.

Comment: One commenter stated that there is nothing in the rebate statute that allows for a ''rebates first—compliance later'' approach. The commenter further stated that the statute does not provide for CMS to grant participating states exemptions or deferrals of their obligations.

Response: We did not propose a ''rebates first-compliance later'' approach in the proposed rule and are not including such an approach in the final rule. The territories will need to meet the same requirements as other states to collect rebates. If the territories need additional time to implement the MDR program in accordance with the requirements, we would consider allowing them to use existing waiver authority under section 1902(j) of the Act for the Northern Mariana Islands and American Samoa and section 1115(a)(1) of the Act for Puerto Rico, Virgin Islands and Guam, if they meet the necessary standards for such a waiver.

Comment: One commenter expressed support for the rebate program expansion to a territory but stated that it is impossible to estimate the costs of implementation at this time and a detailed analysis of all systems and processes is required to estimate the administrative costs for this territory. The commenter further expressed concerns regarding the expected increase in administrative costs could adversely impact the territory's section 1108 cap unless CMS allows the territory to claim the systems and related contract costs necessary to set up the manufacturer and CMS reporting systems for the MDR as Medicaid Management and Information Systems' (MMIS) costs that are outside of the section 1108 cap and receive enhanced 90 percent and 75 percent matching rates.

Response: We appreciate the commenter's support for the CMS MDR rebate program. We also recognize the challenges addressed by the commenter in trying to determine the costs that a territory would incur in establishing the systems necessary to comply with the MDR program. We further note that the territories may claim Title XIX MMIS funding that has been approved by CMS in an MMIS Advanced Planning Document (APD) under authority granted at section 1903(a)(3) of the Act. However, such advanced MMIS funding approval for the CMS MDR program is considered outside of the section 1108 limitations of total payments to each territory in accordance with section 1903(a)(3) of the Act; therefore, the territories' related improvements to their MMIS systems do not apply against the Medicaid funding cap in accordance with section 1108(g) of the Act. Once the territory implements and receives CMS certification for the MMIS, then the administrative costs could be paid at 75 percent federal share after a CMS approved APD. Additional economic impact information regarding this component is further discussed under the Regulatory Impact Analysis section of this rule.

Comment: Many commenters expressed concern about financial and operational challenges for both the territories and manufacturers to establish the unique Medicaid program structure in the territories. The commenters stated that the pricing structure and systems in the territories

are different from the MDR program. One commenter noted that the MDR program does not capture sales to the territories and the proposed change would require financial and operational changes for the manufacturer to identify all territory sales and associated discounts (direct and indirect) for consideration in the calculations. The commenter further stated that pricing in one territory is, in many instances, government mandated and that prices mandated by government have historically been excluded from government pricing metrics.

One commenter noted concerns with the territories' ability to capture accurate utilization data and the feasibility of a disputes process. Manufacturers' systems are not designed to process sales data generated in the territories, making compliance with the program very difficult. The commenter stated that the territories' foreign pricing structures would require an operational change in their Medicaid price reporting system and the calculations from which the URA is derived. The commenter also stated that many of the entities that sell in the territories do not conduct business in the United States; therefore, the commenter would need to purchase systems necessary to generate accurate indirect sales data to ensure the integrity of the data from foreign entities.

Another commenter expressed concerns that the claims received from these newly included territories will not be valid or verifiable under the current sophisticated MDR reporting system. The commenter stated that combining the domestic and foreign operations for purposes of reporting sales in the territories would also require new databases for the manufacturers and additional staff to manage expanded reporting obligations.

Response: We recognize that there are unique issues involving the financial and operational challenges for both the territories and manufacturers that pertain to the territories' pricing, utilization data and systems structure, as well as other differences between the manufacturers' and territories' operations. We believe that delaying the inclusion of the territories in the definitions of states and United States until 1 year after the effective date of the final rule will allow additional time for CMS to work with both the territories and manufacturers to address these concerns. We anticipate issuing additional guidance on implementation issues and will be available to provide technical assistance.

Comment: A commenter stated that putting aside the potential for higher total Medicaid rebate liability, the requirement to process invoices for as many as five additional jurisdictions would represent approximately a 10 percent increase in the administrative burden associated with the preparation of quarterly remittance advices and other increases. The commenter also stated that drugs sold to customers in the territories may have different WACs than drugs sold in the United States due to territory-specific statutory caps. The commenter further noted that these caps apply to commercial, as well as government purchases. The commenter stated that the rule does not address how manufacturers are to account for these situations in their domestic government price reporting.

Response: While we recognize that there may be various administrative needs that could result in potential increased administration costs for manufacturers, we have no reason to believe that these difficulties would be any different from those that manufacturers first encountered when the rebate program was established. As noted in this section, we anticipate issuing additional guidance on implementation issues and will be available to provide technical support to manufacturers.

d. Implications for Manufacturers

Comment: One commenter stated that CMS offers no insight as to how manufacturers are to address the five territories' wide variation in outpatient prescription drug coverage, drug reimbursement methodology, preferred drug list, prior authorization and payments through a PBM that are currently receiving federal funding for their covered outpatient prescription drugs.

Response: We note that the variation in the five territories' prescription drug coverage, reimbursement methodology, preferred drug list and prior authorization as well as payments through a PBM is essentially no different than the 50 states and District of Columbia who are currently participating in the MDR program. As for prices and payments made through PBMs, manufacturers are to treat such prices and payments to PBMs located in one of the territories in the same manner in which they treat such prices and payments to PBMs located within one of the 50 states and the District of Columbia. In addition, the treatment of sales to entities within the territories in AMP and best price is discussed further in the determination of AMP and best price sections of this final rule. We will continue to work with both the territories and manufacturers to address any technical concerns regarding implementation and their responsibilities under the MDR program.

Comment: One commenter asked how manufacturers are to accrue on their domestic general ledger Medicaid rebate liabilities associated with sales to territories. The commenter further stated that different divisions within the manufacturer's international corporate structure could book sales to customers in the United States and customers in the territories separately which will complicate collection of data. A commenter noted that inclusion of sales or rebate liability across separate corporate, legal entities (that is, separate labelers) would be highly problematic from an accounting and legal perspective. Another commenter stated that manufacturers will need to establish a process to accrue rebate liability associated with sales to the territories.

Response: We recognize that manufacturers will encounter challenges in identifying and including sales to the territories in their calculations of AMP and best price. As discussed previously in this section, we decided to provide a 1-year delayed implementation period regarding these provisions, which we believe will give territories and manufacturers an adequate amount of time to make the necessary systems changes and develop the mechanisms and processes necessary to comply with the requirements of the MDR program. We have received no compelling comments which support delaying implementation beyond the 1-year period or which convince us that a different timeframe would be more appropriate.

After considering the comments, we are finalizing the definition of states under § 447.502 to mean the 50 states and the District of Columbia and beginning April 1, 2017, also includes the Commonwealth of Puerto Rico, the Virgin Islands, Guam, the Northern Mariana Islands and American Samoa.

We are also finalizing the definition of United States to mean the 50 States and the District of Columbia and beginning April 1, 2017, also include the Commonwealth of Puerto Rico, the Virgin Islands, Guam, the Northern Mariana Islands and American Samoa.

21. Wholesaler

Given the definition of ''wholesaler'' in section 1927(k)(11) of the Act, as added by the Affordable Care Act, we proposed to define wholesaler to mean a drug wholesaler that is engaged in wholesale distribution of prescription drugs to retail community pharmacies,

including but not limited to, manufacturers, repackers, distributors, own-label distributors, private-label distributors, jobbers, brokers, warehouses (including manufacturer's and distributor's warehouses, chain drug warehouses, and wholesale drug warehouses), independent wholesale drug traders, and retail community pharmacies that conduct wholesale distributions (77 FR 5326, 5361). We did not propose that a wholesaler be licensed by the state inasmuch as that is not a requirement of the Act, in comparison to the definition of retail community pharmacy, where state licensing is required. These proposed provisions are discussed in more detail at 77 FR 5326. We sought comments on our proposed definition, as well as additional information that may help further clarify the term wholesaler (77 FR 5326). We received the following comments concerning the proposed wholesaler definition:

Comment: We received several comments supporting the definition of wholesaler which includes manufacturers that are engaged in wholesale distribution of prescribed drugs. One commenter believed that the definition as written in the proposed rule is sufficient to convey to manufacturers which merchant middlemen sales are to be considered for inclusion in AMP, assuming, if the buildup model is finalized, that the tracing information shows such sales flow through to retail community pharmacies or to entities included in the calculation of AMP for 5i drugs not generally dispensed through retail community pharmacies.

Response: We appreciate the support and feedback regarding the definition of wholesaler. As discussed in more detail in the comments and responses in section II.C., the Determination of AMP, we have decided not to require manufacturers use a buildup methodology when calculating AMP. As will be discussed in the Determination of AMP section of this final rule (section II.C.), manufacturers may continue to make reasonable assumptions, in the absence of adequate documentation to the contrary, that prices paid to them by wholesalers are for CODs distributed to retail community pharmacies, or, in the case of AMP for 5i drugs not generally dispensed through retail community pharmacies, those eligible entities listed in § 447.504(d).

Comment: One commenter urged CMS to provide specific guidance as to when a secondary manufacturer should be considered a wholesaler since including the term ''manufacturer'' in the definition of ''wholesaler'' leads to circular reasoning; a manufacturer is considered a wholesaler when it functions as a wholesaler, and a wholesaler is defined to include manufacturers. The commenter believed this may result in manufacturers treating dissimilar types of manufacturers (including entities whose primary purposes is redistributing products to retail community pharmacies or secondary manufacturers of authorized generics) in the same way and has resulted in different treatment of sales to secondary manufacturers in the AMP calculations of the primary manufacturer.

Response: The proposed definition of wholesaler in the proposed rule is identical to the statutory definition of wholesaler found at section 1927(k)(11) of the Act. While this statutory definition indicates that the term wholesaler includes manufacturers, it does not mean all manufacturers are wholesalers. Manufacturers that are considered wholesalers under this definition must meet the first prong of this definition by being engaged in wholesale distribution of prescription drugs to retail community pharmacies. Therefore, a manufacturer will be considered a wholesaler when that manufacturer is engaged in wholesale distribution of prescription drugs to retail community pharmacies. If a manufacturer sells a drug to another manufacturer (a second manufacturer) and that second manufacturer is not engaged in wholesale distribution of prescription drugs to retail community pharmacies, then the second manufacturer will not be treated as a wholesaler, and the sales price of a COD from the first manufacturer to the second manufacturer should not be included in the primary manufacturer's AMP.

Comment: We received several comments concerning the requirement for wholesalers to be licensed by the state to meet the definition of a wholesaler. One commenter applauded CMS's decision to not include the state licensure requirement, as not all states require wholesale distributors to be licensed and state requirements vary as to whether manufacturers are licensed as such or as wholesale distributors. Another commenter indicated that since wholesalers perform a variety of services for manufacturers and those services change with evolving business needs, the commenter supported allowing manufacturer flexibility in determining which services performed by another manufacturer constitutes ''acting as a wholesaler'' for purposes of the AMP calculation and the authorized generic provisions.

Several commenters indicated that the definition of wholesaler should include the requirement for wholesaler to be licensed by the state. Commenters indicated that they did not understand why CMS would not require wholesaler licensure just because it is not in the statute and that licensure as a wholesaler should be considered when determining the status of an entity whose business is an intermediary between the original manufacturer of a drug and the dispensing pharmacy. Another commenter stated that chain pharmacy distribution centers are generally licensed as wholesalers in the states in which they are located.

One commenter stated that reporting AMPs for products distributed through unlicensed wholesalers would not be reflective of prices that are available to retail community pharmacies from licensed wholesalers. The commenter recommended that manufacturer sales to unlicensed wholesalers should not be included in AMP, or alternatively, CMS should exclude manufacturer's transactions with unlicensed wholesalers for purposes of calculating FULs.

A few commenters indicated that state licensure should permit a manufacturer to conclude that an entity does qualify as a wholesaler and asked that CMS confirm that state licensure is a reasonable basis for determining that an entity is a wholesaler for purposes of the MDR program.

Response: We do not agree with restricting the definition of wholesaler to only include state licensed wholesalers as we believe it would be inconsistent with the definition of wholesaler at section 1927(k)(11) of the Act. Section 1927(k)(11) of the Act does not include such a limitation, and in fact includes entities that may not necessarily be recognized by the state as a licensed wholesaler (for example, manufacturers acting as wholesalers). Therefore, we are not including a licensure requirement; rather, we are adopting the definition as proposed which mirrors the statutory definition at section 1927(k)(11) of the Act.

Comment: One commenter stated that many of the national chain pharmacies place strict guidelines on their subsidiaries which mandate that they purchase drugs from their warehouses. The commenter continued to state that typically a chain warehouse is considered to be a separate entity within the national chain's corporate structure. Thus, when the chain warehouse buys the prescription drugs from a manufacturer, the chain's warehouse determines the ''wholesale prices'' which will be charged to the retail

community pharmacies owned by the chain. The commenter asked that CMS consider that inclusion of the chain drug warehouses will artificially inflate the AAC of the drugs at most, if not all locations.

Response: The statutory definition of wholesaler includes warehouses and makes specific reference to chain drug warehouses that are engaged in wholesale distribution of prescription drugs to retail community pharmacies. Therefore, given the statutory definition and express inclusion of chain drug warehouses, we see no reason to alter the definition in this final rule.

Comment: One commenter requested that CMS consider whether the definition of wholesaler should include a wholesaler that takes title to, or possession of, the drug(s) as to eliminate potential confusion regarding whether manufacturers would need to consider transfer of products to third party logistics providers (3PLs) in their calculations, if such 3PLs do not take title of the drug(s) but, instead, deliver the drug(s) to wholesalers for distribution to the manufacturers' end customers.

Response: We do not believe it is necessary to further add that drug wholesalers must take title to, or possession of, the drugs to meet the definition of wholesaler since we are the definition of wholesaler as defined in section 1927(k)(11) of the Act, which does not add this level of specificity. We note, however, that we believe that it is implied in the AMP definition that a wholesaler takes possession or title to the drug because AMP includes the average prices paid by wholesalers for CODs distributed to retail community pharmacies. What is not clear from the comment is whether these 3PL entities pay a price for the drug, or are paid a service fee to provide packaging services to the manufacturer. In the event there is a price paid for the drug by the 3PL, this price should be included to the extent that the 3PL entity meets the definition of wholesaler at section 1927(k)(11) of the Act. Further discussion on the inclusion of sales to wholesalers in the calculation of AMP can be found in section II.C. of this final rule.

After considering the comments, and for the reasons we articulated in this section and in the proposed rule, we are finalizing the definition of wholesaler under § 447.502 without modification.

22. Existing Definitions Without Modifications

In proposed § 447.502, we included the existing definitions, without modification, for Brand Name Drug, Consumer Price Index-Urban, Lagged Price Concession, National Drug Rebate Agreement, Nominal Price, and Rebate period (77 FR 5359 through 5361). We did not receive any comments and we are finalizing these definitions in § 447.502.

C. Determination of Average Manufacturer Price (§ 447.504)

1. AMP Historical Background

The Omnibus Budget Reconciliation Act of 1990 (OBRA '90) (Pub. L. 101–508) added section 1927 to the Act, which established the MDR program and defined the AMP for a COD of a manufacturer for a rebate period as 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. Manufacturers who entered into and had in effect a rebate agreement with CMS were required to report AMP on a quarterly basis. The AMP was used to calculate the rebates paid by manufacturers to the states for drugs dispensed to their Medicaid beneficiaries for which payments were made under their state plans.

The DRA of 2005 made significant changes to the Medicaid prescription drug provisions of the Act. In particular, 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. The DRA defined AMP, in part, to mean, for a COD of a manufacturer 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. CMS published the Medicaid Program; Prescription Drugs final rule (the AMP final rule) on July 17, 2007 (72 FR 39142) to implement the provisions of the Deficit Reduction Act of 2005 (DRA) pertaining to prescription drugs under the Medicaid Program.

Following the enactment of the Affordable Care Act, in the November 15, 2010 **Federal Register** (75 FR 69591), ''Withdrawal of Determination of Average Manufacturer Price, Multiple Source Drug Definition, and Upper Limits for Multiple Source Drugs,'' we withdrew § 447.504 ''Determination of AMP'' from the AMP final rule following a period of notice and comment on the proposed withdrawal.

2. AMP Under the Affordable Care Act

On March 23, 2010, the Affordable Care Act was enacted. Section 2503 of the Affordable Care Act revised the definition of AMP in section 1927(k) of the Act to eliminate the reference to retail pharmacy class of trade and to identify specific entities that manufacturers should include or exclude when calculating AMP. In the proposed rule, we proposed a new § 447.504 ''Determination of AMP,'' (discussed in more detail at 77 FR 5327), based on section 1927(k)(1) of the Act, as amended by the Affordable Care Act, and further amended by section 202 of the Education Jobs and Medicaid Assistance Act.

We received comments concerning the proposal to require manufacturers to report AMP based upon their actual sales to retail community pharmacies or wholesalers for drugs distributed to retail community pharmacies, the definition of retail community pharmacy, other terms used in the determination of AMP, the entities proposed for inclusion in and exclusion from AMP, and our proposed policy regarding the treatment of inhalation, infusion, instilled, implanted, or injectable drugs (also referred to as 5i drugs) that are not generally dispensed through a retail community pharmacy in the determination of AMP.

We note that commenters used a variety of terms to distinguish AMP calculated for 5i drugs that are not generally dispensed through retail community pharmacies. With regard to the calculation of AMP and drugs generally dispensed through retail community pharmacies, some commenters referred to the ''standard AMP'' methodology, ''the non-5i methodology,'' ''the retail community pharmacy methodology'' or the ''regular AMP methodology.'' Commenters also referred to ''5i AMP'' methodology, ''non-retail community pharmacy AMP'' methodology, and the ''alternate'' or ''alternative AMP'' methodology when discussing the AMP methodology used to calculate AMP for 5i drugs that are not generally dispensed through retail community pharmacies.

As discussed earlier in the definition of ''5i drug'' in section II.B., we have been using the term ''5i drug'' as an acronym to refer to all inhalation, infusion, instilled, implanted, or injectable drugs, regardless of whether they are or are not generally dispensed through a retail community pharmacy. Furthermore, we note that section 1927 of the Act only authorizes one AMP and we did not propose more than one AMP calculation. Therefore, for purposes of summarizing comments and providing responses to comments, when appropriate, we will specifically refer to AMP for 5i drugs not generally dispensed through retail community pharmacies when making a distinction

between which sales are to be included in or excluded from AMP.

The following are general comments we received pertaining to the determination of AMP section:

Comment: One commenter stated that the degree of specificity in the proposed rule's various classes of trade definitions is appropriate and that further details about class of trade classification questions should be spelled out and documented in manufacturers' reasonable assumptions. The commenter went on to state that while more specificity in the regulatory definitions may have some advantages, the commenter believed that the scope and pace of change in the pharmaceutical industry supports the adoption of regulatory definitions that are flexible enough to accommodate changes in the industry and in the functions of its participants with manufacturers' reasonable assumptions filling in the details needed as the industry evolves. One commenter requested that CMS acknowledge in the final rule that manufacturers may use reasonable assumptions for defining those classes of trade that are included in the requirement for AMP but are not explicitly defined by CMS.

Another commenter noted that using reasonable assumptions is preferred because manufacturers are accustomed to using this approach for their current AMP reporting; small manufacturers often lack sophisticated customer master systems but generally are able to utilize reasonable assumptions that meet their business purposes and comply with the spirit of AMP rules; and the features and functions of healthcare providers are continually changing and the inherent flexibility of reasonable assumptions is appropriate for this reality.

Another commenter stated that manufacturers' assumptions should address the categorization of companies that plausibly could fall into two or more classes of trade. For example, there are pharmacies that provide retail pharmacy services, compounding pharmacy services, infusion services, medical equipment and respiratory services so the class of trade will depend on the particular product. Therefore, the commenter suggested that CMS should confirm in the final rule the important role a manufacturer's documented reasonable assumptions have in making decision rules for class of trade issues.

Response: We appreciate the support of our position and believe that with this final rule manufacturers will have an improved understanding as to which sales should be included in, or excluded from AMP, when calculating AMP consistent with section 1927(k)(1) of the Act. In this rule we have clarified that manufacturers may continue to make reasonable assumptions, in the absence of guidance and adequate documentation to the contrary, that prices paid to manufacturers by wholesalers are for drugs distributed to retail community pharmacies in their calculation of AMP, provided those assumptions are consistent with the requirements and intent of section 1927 of the Act and federal regulations. Such assumptions should be documented by each manufacturer and as applicable, consistently applied to all CODs reported in MDR.

Comment: One commenter asked whether detailed instructions will be forthcoming for manufacturers, or will they be mostly on their own to interpret which sales to include or exclude from AMP.

Response: Manufacturers must include or exclude sales in their determination of AMP consistent with the regulation and the statute. As noted in this section, in the absence of guidance and adequate documentation to the contrary, manufacturers may make reasonable assumptions that are consistent with the requirements and intent of section 1927 of the Act and federal regulations. We expect to issue further operational guidance, if needed, regarding various aspects of the MDR program including the reporting of AMP. Such guidance, when available, will be posted to the CMS Web site.

Comment: One commenter stated that only sales that are consumer focused and delivered in a statutorily mandated packaging and labeling should be included in the determination of AMP and that there is no justification for supporting dual classes of trade when services and outputs are equal.

Response: We disagree with the commenter. Section 1927(k)(1) of the Act does not include such limitations regarding the calculation of AMP such that it only includes consumer focused sales or statutorily mandated labeling or packaging.

Comment: One commenter noted that AMP is an essential component of setting the 340B ceiling price calculation and applauds CMS for recognizing in the proposed rule the importance of generating an AMP for all CODs. The commenter requested that CMS keep in mind the 340B provisions of the Medicaid statute, and ensure that the final rule not render these provisions meaningless by allowing for a drug to not generate the AMP necessary to calculate a 340B price.

Response: We appreciate the concerns regarding the need for a COD to generate an AMP and recognize the impact of the AMP calculation on the 340B ceiling price. As discussed in greater detail in section II.C.3., we have decided not to adopt a requirement that manufacturers use a buildup methodology to calculate AMP which we believe will generally result in AMP calculations for all CODs.

3. Presumed Inclusion vs. Buildup Methodology

We proposed that, consistent with section 1927(k)(1)(A) of the Act, sales to wholesalers for drugs distributed to retail community pharmacies are to be included in the determination of AMP (77 FR 5330). As part of the discussion in the preamble to the proposed definition of retail community pharmacy within the Determination of AMP section, we considered two approaches manufacturers may take for determining which sales are included in AMP when such sales are made to wholesalers for drugs distributed to retail community pharmacies (77 FR 5328). One approach, referred to as the ''presumed inclusion'' approach, is that the manufacturer presumes, in the absence of adequate documentation to the contrary, that certain prices paid to manufacturers by wholesalers are for drugs distributed to retail community pharmacies, without data concerning that actual distribution (77 FR 5329). The other approach for determining AMP is when the manufacturer only includes in its AMP calculation those prices where there is adequate, verifiable documentation showing that the drug was actually distributed to a retail community pharmacy, either directly or indirectly through the wholesaler (77 FR 5330). This approach is referred to as the ''buildup'' methodology. We sought comments regarding these approaches in the proposed rule.

In response to our request, we received numerous comments requesting CMS's continued support of the presumed inclusion approach. These comments and our responses are summarized in this section. We note that commenters used a variety of terms to distinguish between these two approaches for calculating AMP. Some commenters referred to the ''presumed inclusion'' methodology as ''the default rule,'' ''the top down approach'' or the ''gross to net method'' for calculating AMP. Commenters also referred to the CMS ''buildup'' methodology as the ''bottom up,'' and the ''presumed exclusion'' approach. For purposes of summarizing comments and providing responses, we will refer to either the

''presumed inclusion'' methodology or the ''buildup'' methodology.

Comment: We received many comments expressing opposition to CMS's proposal that drug manufacturers use a ''buildup'' methodology in identifying sales to retail community pharmacies in the determination of AMP noting that the buildup methodology is a significant change from the way manufacturers have traditionally calculated AMP. Commenters noted that the presumed inclusion methodology provides the framework for historical AMP trends and methodological assumptions on which all other aspects of the proposed rule rely, and that the rejection of the presumed inclusion method would undermine the reasonableness and feasibility of the proposed rule as a whole. Several commenters believed that the presumed inclusion methodology should be preserved as it promotes stabilization of AMP from period to period, ensure greater consistency in AMP calculation methodologies across manufacturers, and allow AMPs to be calculated for products that might otherwise have no AMP-eligible sales. One commenter stated that a stable AMP benefits manufacturers, pharmacies, and CMS, because manufacturers are better able to predict their Medicaid liability and 340B pricing, pharmacies are better able to rely on predictable FUL reimbursement rates, and CMS is better able to predict its reimbursement cost and rebate revenue.

Response: After consideration of the comments received, we are persuaded that an approach where manufacturers calculate AMP based solely upon their actual, documented sales to retail community pharmacies or wholesalers for drugs distributed to retail community pharmacies (the ''buildup approach'') is a less practical approach which would represent a significant change from the methodology manufacturers have traditionally used to calculate AMP. We have permitted manufacturers, in the absence of specific guidance, to make reasonable assumptions when calculating AMP, provided those assumptions are consistent with requirements and intent of section 1927 of the Act and federal regulations. We believe it is reasonable that manufacturers continue to make reasonable assumptions, consistent with these provisions, and presume in the absence of guidance and adequate documentation to the contrary, that prices paid to manufacturers by wholesalers are for drugs distributed to retail community pharmacies. A presumed inclusion approach is consistent with this policy, as well as the longstanding practice that permits manufacturers (using chargeback data) to make certain assumptions in the absence of guidance, when calculating AMP. As noted in the proposed rule (77 FR 5330), we expressed concerns regarding both the presumed inclusion and the buildup methodology, based primarily on our understanding of the adverse consequences resulting from manufacturers including non-retail community pharmacy sales data in their AMP calculations (77 FR 5329). Based on the comments, however, we realize that such concerns may have been overstated given that manufacturers have successfully calculated AMP using chargeback data and reasonable assumptions since the beginning of the program. For these reasons and based on the comments, we believe that a manufacturer's use of the presumed inclusion approach is a reasonable approach that is consistent with the pharmaceutical marketplace practices, where manufacturers often receive sales data based on chargeback arrangements that manufacturers have in place for institutional and other non-retail community pharmacy purchases. Therefore, as discussed more fully in this section, in response to further comments on the use of a buildup methodology, we have decided not to adopt the buildup approach.

Comment: Commenters noted that the proposed rule expressly recognized that the presumed inclusion methodology is a reasonable alternate approach to implement AMP provisions and that it did not identify any considerations that could justify the substantial burdens of abandoning this time tested approach. One commenter believed that the Congress ratified CMS's longstanding interpretation of a presumed inclusion methodology because it merely changed the class of customers included in AMP without modifying the rule that sales to wholesalers are included in AMP except for sales that can be identified with adequate documentation as being subsequently sold to an excluded entity. Therefore, the commenter believed CMS cannot require manufacturers to change to the buildup methodology without further legislative change. Furthermore, a few other commenters stated that the rejection of the presumed inclusion methodology is contrary to all of the regulatory simplification mandates included in Executive Orders 12866 and 13563.

Response: We agree that manufacturers have had the option of making certain reasonable assumptions that prices paid to manufacturers by wholesalers are for drugs distributed to retail community pharmacies when calculating AMP and acknowledge the concerns raised by commenters that the buildup methodology may impose undue administrative burdens. As discussed in this section, in light of such concerns, we have decided not to adopt a requirement for a buildup methodology and will continue to allow manufacturers to make reasonable assumptions, and presume, in the absence of guidance and adequate documentation to the contrary, that prices paid to manufacturers by wholesalers are for drugs distributed to retail community pharmacies, provided those assumptions are consistent with the requirements and intent of section 1927 of the Act and federal regulations.

Comment: A few commenters stated that CMS rejected the presumed inclusion method because it would lead to inclusion of sales by a manufacturer to entities not contemplated in the statutory definition and further noted that CMS ignores the fact that a buildup methodology has the suboptimal result of excluding sales that are contemplated in the statutory definition because manufacturers do not have information on the end customer. The commenter stated that given both approaches are imperfect, there are good reasons to adopt presumed inclusion: It is familiar to manufacturers that have been operating on this basis for over 2 decades; their policies, procedures and automated systems are designed to implement a presumed inclusion methodology; and changing to a buildup method would require reconfiguring automated systems for manipulating sales and chargeback data and calculating AMP at a great expense, time and effort. Many commenters stated that the change from the presumed inclusion methodology to a buildup methodology would require manufacturers to invest significant time and financial resources in updating their government pricing systems to calculate AMP using this new methodology.

Response: After reviewing the comments concerning the calculation of AMP using a buildup method versus presumed inclusion approach, as noted in prior responses, we believe the better alternative for calculating AMP is the presumed inclusion approach. As noted by this commenter, a buildup approach has its weaknesses as it would result in a manufacturer excluding sales that should be included in AMP as defined at section 1927(k)(1) of the Act, because the manufacturer does not have access to data on the end customer.

We also appreciate the insight that commenters provided regarding the financial impact and operational

difficulties associated with manufacturers revising their government pricing and data collection systems to comply with the buildup approach. In light of these concerns, we have decided to retain the option that manufacturers may make reasonable assumptions and presume, in the absence of guidance and adequate documentation to the contrary, that prices paid to manufacturers by wholesalers are for drugs distributed to retail community pharmacies.

Comment: One commenter explained that the presumed inclusion approach uses three data sources most manufacturers have available for the calculation of AMP: direct sales data, indirect sales data (identified by chargebacks submitted by the wholesaler to the manufacturer for contracted sales), and rebate payment data. With the presumed inclusion approach, direct sales are the starting point and the data can be reconciled to the manufacturer's financial system. The commenter noted that a branded manufacturer could have a large volume of sales, but only a small number of identifiable sales to retail pharmacies because they do not typically contract with retail community pharmacies but do have many non-retail contracts, such as contracts with hospitals, PBMs or GPOs. As a result, under the buildup approach, the AMP calculation would be skewed based upon the small number of identifiable sales and would not be representative of actual sales of the products to retail pharmacies. The commenter also stated that unlike its branded counterparts, generic manufacturers may have agreements with retail community pharmacies, such as chain retail stores and therefore, generic manufacturers may have a larger number of sales that are identifiable as retail. The commenter further explained that as a result of the larger volume of sales the generic manufacturers' calculated AMPs could be lower. The resulting calculated FUL, based on aggregate AMPs of both the branded and the generic AMPs could then be lower based upon the volume and weighting of the retail AMPs and could result in inconsistent and varying FULs from quarter-to-quarter.

Response: We appreciate the commenter's explanation of the sales data manufacturers use to calculate AMP, as well as the processes many manufacturers use to reconcile their sales data with their financial accounting system. We recognize that while the buildup approach could result in lower AMPs and rebates, manufacturers would prefer not to change their pricing systems to use a buildup methodology because of the manufacturer's cost and burden of tracking sales data and relying on third party data sources, as well as the additional contracts that would be required to generate the data needed to calculate AMP.

We agree that inasmuch as the commenters urged a policy that would have the potential to raise their AMPs, their statements reflect the realities of the marketplace where data required by the buildup approach is not typically available to the manufacturer. Therefore, in light of the concerns raised and as discussed previously, we have decided not to require that manufacturers adopt the buildup approach when calculating AMP.

Comment: A few commenters noted that retaining the presumed inclusion methodology could actually increase a manufacturer's AMP which would result in a higher rebate. Another commenter indicated that despite the possibility of having to pay higher rebates, they support the presumed inclusion methodology to calculate AMP, because of serious concerns with data collection and compliance issues, as well as the cost and burden associated with implementing the buildup methodology.

Response: We appreciate the comments. As discussed previously in this section, and based upon the comments we have received regarding the two approaches, we have decided not to require that manufacturers adopt the buildup methodology.

Comment: Many commenters were concerned that manufacturers would have to obtain third party data or CMS would require manufacturers to purchase data from third parties in an effort to attribute each wholesaler sale to an end-user customer. Commenters indicated that to do so would be costly and manufacturers would not be able to evaluate the accuracy of the data purchased or audit it in time to certify the AMP data on a monthly basis.

Further, commenters noted that there is no commercially available data set which would provide sufficient information regarding wholesaler customers and stated that while there are commercial services that attempt to estimate blinded data concerning customer sales, their methodologies vary, resulting in different manufacturers potentially using different data standards, creating inconsistencies among the AMP calculations from manufacturer to manufacturer. A few commenters had concerns that the verification of reseller sales would require access to proprietary and confidential information that would be difficult if not impossible to obtain and could raise legal issues as well.

Commenters also stated that CMS lacks the legal authority to require manufacturers to purchase data to participate in the Medicaid program and that such a requirement would reduce the reliability, stability, and accuracy of reported AMPs and cause a host of operational problems with no satisfactory solution. A few commenters believed this requirement to purchase data is not authorized by the Medicaid rebate statute and would be considered arbitrary and capricious and thus improper under the APA. Commenters were also concerned that intermediaries with access to the data would have significant negotiation leverage and could charge excessive fees for the data which would place manufacturers in a difficult position regarding government price reporting and federal and state fraud and abuse laws if they are required to purchase data that could readily exceed an objectively determined fair market value.

Other commenters identified challenges to utilizing third party data for calculating AMP, including differentiating returns from sales because both returns and product transfers between wholesaler locations look like sales; fields on wholesaler records, which differ by wholesalers; and the classes of trade assigned by wholesalers do not always align with those of the manufacturer.

Response: As noted by many commenters, adopting a buildup approach could have required manufacturers to purchase third party data, integrate such data into its government pricing systems (which include computer systems used by manufacturers to track sales and calculate government prices, such as AMP, Average Sales Price (ASP) and 340B sales), and consider such information when calculating AMP. We appreciate the many challenges noted by commenters associated with manufacturers' use of third party data to complete their AMP calculation. While we did not require that manufacturers use third party data to calculate AMP under the buildup approach, we agree with commenters that to calculate an accurate AMP it could have been necessary. Furthermore, we have been persuaded that the statutory revisions to section 1927(k)(1) of the Act made by the Affordable Care Act did not require that manufacturers obtain or purchase third party data in order to calculate AMP. Therefore, we have decided not to require that manufacturers change their methodology for calculating AMP to use

the buildup methodology, especially given the concerns regarding the need to purchase third party data.

Comment: A few commenters believed that a buildup methodology shifts the Medicaid price reporting function from manufacturers to wholesalers and others. They state that a buildup methodology could expose wholesalers and others in the supply chain to False Claims Act allegations because of the role may play in the government pricing function.

Response: As noted earlier we are not requiring that manufacturers adopt the buildup approach when determining AMP. We appreciate the concerns regarding the shift in the price reporting functions and note that it is the manufacturer's responsibility to determine which sales to include in AMP calculations and to make reasonable efforts to identify customer data in making such calculations.

Comment: A few commenters indicated that as part of their overall compliance and certification process manufacturers generally tie all the data that they use in their government pricing calculations to the General Ledger in each reporting period. The commenters noted that this compliance best practice has been required by the HHS OIG in cases where the OIG has audited government pricing calculations. A few commenters recommended that CMS consult with the OIG before it considers adopting a rule that would prevent manufacturers from meeting the OIG audit requirements. A few commenters provided specific suggestions as to how the certification language would need to be revised to account for the use of third party data that they could not verify was complete and accurate.

Response: We recognize that the compliance and certification process that manufacturers complete would be more burdensome to the extent that calculations are based on third party data. We also recognize the concerns regarding a manufacturer's ability to certify the accuracy of the data used to calculate AMP when based on such third party data. As previously discussed in this section, we are not adopting a requirement that the buildup methodology be used for calculating AMP. Therefore, we are making no changes to the certification language currently used by manufacturers when they submit and certify their AMP data and also see no conflict with OIG audit requirements.

Comment: A few commenters believe that the buildup methodology will deliver AMP figures that are inferior both qualitatively and quantitatively and as a theoretical matter the buildup methodology will generate a lower AMP than the presumed inclusion methodology, even when the underlying manufacturer sales and discounts are exactly the same. The commenters believed this undermines CMS's proposal to use AMP as a basis for reimbursement through FULs, as well as AAC, and will lower pharmacy reimbursement rates. A few commenters noted that for AMP to serve reimbursement related purposes it is important for CMS to make reported AMPs align more closely with pharmacy acquisition costs and abandoning the presumed inclusion methodology would be step backward from that goal.

Response: We agree that AMP serves two purposes—it is used by manufacturers to calculate rebates and by CMS to calculate FULs. Because of these two competing purposes, the definition of AMP and the sales included in or excluded from the calculation of AMP affects not only manufacturers, but also pharmacy groups, the federal and state governments, and Medicaid beneficiaries. As discussed previously in this section, we understand that manufacturers may face significant challenges when using the buildup approach to calculating their AMP. Therefore, as discussed previously, we are not adopting a requirement that manufacturers use a buildup methodology to calculate AMP. Rather, they may continue to use the presumed inclusion approach and make reasonable assumptions, provided those assumptions are consistent with the requirements and intent of section 1927 of the Act and federal regulations.

Comment: Several commenters expressed concern that the buildup methodology would result in certain products having no AMP-eligible sales because manufacturers lack visibility into end users of some products. This in turn would lead to an increased number of zero-dollar AMPs. A few commenters requested that CMS provide guidance regarding zero-dollar AMPs and further suggested that manufacturers be required to report the most recent positive AMP so as to be consistent with the current guidance as to how manufacturers have been instructed to handle zero AMP values.

Another commenter stated that it would not be necessary to establish a regulatory category for specialty pharmacies to have an AMP for oral drugs that are not dispensed primarily through retail community pharmacies if the presumed inclusion rule was retained because there would be some sales to wholesalers at WAC which would not be subsequently identified as excludable. These wholesaler WAC sales would form the basis for calculating AMP. The commenter believed that this solution, although imperfect, is less imperfect than using the buildup approach and establishing a new category of pharmacy not consistently recognized across the industry and directly contrary to a statutory mandate.

Another commenter noted that with a presumed inclusion calculation these non-retail sales would have been included in the gross sales for the product and once chargeback detail from a doctor, clinic, or hospital was processed, a manufacturer could then remove those sales using a 12-month lagged calculation as ineligible sales. While theoretically there would never be an eligible sale, the lagged removal allows an AMP calculation to take place. If the buildup method is finalized, the commenter asked how manufacturers are to remain in compliance with reporting AMP for physician administered products that do not have any retail sales and are not 5i drugs as defined in the proposed rule (77 FR 5328).

Response: Since we are not requiring that manufacturers use the buildup methodology, there would be no change in guidance regarding a manufacturer being permitted to carry forward the prior AMP which was established using its presumed inclusion methodology. Furthermore, we generally agree with commenters that the use of the build-up approach could result in some drugs with no AMP-eligible sales because manufacturers lack information about the ultimate purchaser of such products. However, with the presumed inclusion approach manufacturers may make certain reasonable assumptions when calculating AMP, even when such assumptions are based upon a small percentage of sales of such drugs to wholesalers that distribute to retail community pharmacies or sales directly to retail community pharmacies. This topic is discussed in more detail in section II.C.5.d. of this rule.

Comment: Some commenters provided examples of AMP calculations using the buildup methodology compared to the presumed inclusion methodology demonstrating that the buildup method is more likely to result in the inappropriate exclusion of retail community pharmacy sales because such sales do not generate chargeback data. One commenter documented that under the buildup method, approximately 20 percent of the NDCs had no identifiable AMP-eligible sales and when only considering those

products for which they had records of direct or indirect sales to retail community pharmacies, the AMPs for 40 percent of the products were lower than those calculated using the presumed inclusion method while 27 percent of the products had AMPs that were higher.

Response: As previously noted, in light of concerns raised by commenters, we are not requiring manufacturers to adopt the use of the buildup methodology for calculating AMP. Therefore, in light of this decision, we do not expect that manufacturers will exclude AMP eligible sales as the commenter noted.

Comment: A few commenters also expressed concern that the buildup methodology would introduce a new need for restatement in reported AMPs and there would be no limit on the number of times a manufacturer might be required to restate AMP because of lagged sales. Furthermore, the commenter believed that a ''12 month lagged eligible no contracted sales ratio''—not to be confused with the 12-month lagged eligible price concession ratio—would have to be established and made part of every manufacturer's AMP calculation method if the buildup methodology were finalized.

Response: As discussed in prior responses, we have decided not to require that manufacturers adopt the buildup methodology. Furthermore, the existing regulations do not presently require manufacturers to establish the 12-month lagged ratio and we are not implementing or requiring one in this final rule.

Comment: One commenter believed that the statement in the proposed rule that ''there is a direct relationship between which entities are to be included in, and excluded from AMP calculations and the basis for determining the FUL'' is incorrect because the Affordable Care Act requires CMS to set the FULs at no less than 175 percent of the volume-weighted AMP for a multiple source drug group. The commenter stated that the statute permits CMS to set a FUL that exceeds 175 percent of the volume-weighted AMP as CMS determines appropriate, thereby breaking the link between AMP and FULs.

Response: We disagree and do not view the statute as only using AMP (based on a percentage) for purposes of setting the threshold floor for the FUL. We interpret section 1927 of the Act, as amended by the Affordable Care Act, as continuing to require that FULs be based on AMP, although we have discretion as to setting the percentage of AMP that would apply in the FUL calculation. Since the FUL is based upon a volume-weighted AMP for a multiple source drug group, there will always be a link between AMP and the FUL regardless of the percentage of AMP used to calculate the FUL. For more details on comments related to the proposal to establish the FUL at 175 percent of the volume weighted AMP for multiple source drugs, please refer to the summary and response to comments for proposed § 447.514, ''Upper limits for multiple source drugs,'' found in section II.K. of this final rule.

Comment: Several commenters noted that lower AMPs, as a result of the buildup approach, could have an adverse impact on Medicare Part B reimbursement because of the requirement for AMP substitution for ASP when ASP exceeds AMP by 5 percent, either in the 2 consecutive quarters immediately prior to the current pricing quarter, or in 3 of the previous 4 quarters immediately prior to the current quarter. The commenters noted that AMP calculated with the buildup approach would significantly increase the likelihood that AMP will be substituted for ASP which will not reflect actual pricing in the market and possibly result in lower Part B reimbursement. The commenters also noted that if AMP were to be calculated using fundamentally different methodologies from ASP the substitution of AMP for ASP would not be based on differential discounting, but based on the difference in methodology.

Other commenters noted that the non-Federal Average Manufacturer Price (non-FAMP) also uses a presumed inclusion approach and requiring a manufacturer to implement an entirely different approach for a similar price point is the type of unnecessarily inconsistent and duplicative regulation that agencies are directed to avoid. Another commenter noted that the buildup model would result in an unknown and unanticipated impact on the 340B prices.

Response: As previously noted in this section, we are not requiring manufacturers to adopt the buildup methodology for calculating AMP, and therefore, we believe the concerns raised about AMP being substituted for ASP, as well as the concerns regarding implementing a different approach for another government program price (non-FAMP), are no longer relevant. Furthermore, in light of our decision not to require that manufacturers adopt the buildup methodology, we believe we have addressed the concern regarding the potential impact of the buildup approach on the ceiling prices set under the 340B program.

Comment: One commenter stated that CMS appears to follow the statute and intent of the Congress in creating AMP by excluding from the calculation of AMP many manufacturer sales that are obviously not appropriate. However, the commenter noted that the AMP would be higher under the presumed inclusion methodology and it is difficult to know which approach is correct given that the answer may depend on whether a product is a brand or generic drug.

Therefore, the commenter suggested that CMS require manufacturers to submit their AMP calculations to CMS using both the presumed inclusion method and the buildup method before the rule is made final as this would allow CMS to better understand the pros and cons of both approaches. Another commenter asked CMS to extend the comment period on the adoption or rejection of the buildup methodology requirement until such time a better assessment of indirect sales data can be determined.

Response: We do not believe either one of these suggestions (further analysis and extension of the comment period) is necessary given the feedback and concerns raised by commenters during this rulemaking process. As noted previously in this section, we received many comments regarding both approaches, including comments regarding the burden and cost associated with implementing the buildup approach and the need for manufacturers to purchase sales data to properly calculate an AMP. Based on the comments, we see no reason to require that manufacturers submit AMP calculations to CMS using both the approaches, given that such an option would be costly and burdensome and would not lead to a greater understanding of whether or not to finalize the buildup approach.

Comment: One commenter supported CMS's proposal that manufacturers report AMP based only on actual sales to retail community pharmacies or wholesalers for distribution to retail community pharmacies. The commenter believed the new definition of AMP adopted in the Affordable Care Act requires such affirmative identification.

Response: As discussed previously in this section, we have been persuaded by the many comments we received on this topic that the buildup method would create a significant administrative and financial burden on manufacturers given the extensive changes to manufacturer's government pricing systems and data collection processes. Specifically, as noted by commenters, the buildup approach may not reflect the sales eligible for exclusion from

AMP consistent with the definition of AMP at section 1927(k)(1) of the Act. Also, as noted by the commenters the statutory revisions to the AMP definition did not contemplate that manufacturers make significant revisions to their government pricing systems, especially given the effective date in section 2503 of the Affordable Care Act. Therefore, we have decided not to adopt in this rulemaking the requirement that manufacturers use the buildup approach.

Comment: A few commenters stated that they were concerned about the potential of non-retail sales being included in AMP calculations which may result in AMP-based FULs below pharmacy acquisition cost. The commenters requested that CMS clarify that manufacturers are to include ''non-contracted'' sales to wholesalers only when the manufacturers do not pay chargebacks and does not otherwise know or should know, whether the drugs will be distributed to entities that are not retail community pharmacies.

Response: As stated earlier in this section of the preamble, manufacturers may adopt a presumed inclusion approach when calculating their AMP for covered outpatient drugs and presume that non-contracted sales to wholesalers (that is, non-contracted sales meaning those sales to entities in which the manufacturer has not entered a contractual relationship to provide discounts or special pricing) when there is no chargeback data or other data available that would demonstrate that the drugs were distributed to non-retail community pharmacies.

After consideration of the comments and for the reasons discussed previously, we have decided not to make changes to the regulations text to require that manufacturers calculate AMP based on the buildup methodology.

4. Definitions

The following is a discussion of the specific terms associated with AMP calculations that we proposed to define at proposed § 447.504(a) (77 FR 5327, 5330 through 5334):

a. Average Manufacturer Price (AMP)

We proposed a new definition of AMP based on section 1927(k)(1) of the Act, as amended by section 2503 of the Affordable Care Act (77 FR 5327). Consistent with the statutory definition, we proposed to define AMP to mean, for a COD of a manufacturer (including those sold under an NDA approved under section 505(c) of the FFDCA)) the average price paid to the manufacturer for the drug in the United States by wholesalers for drugs distributed to retail community pharmacies and retail community pharmacies that purchase drugs directly from the manufacturer (77 FR 5361). While we received comments, which are discussed in detail in this section, about which sales, discounts, rebates and other financial transactions are included in and excluded from AMP, we did not receive specific comments about the proposed definition itself. Therefore, we are finalizing the definition of AMP at § 447.504(a), consistent with the statutory definition.

b. Average Unit Price

We proposed to define average unit price to mean 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 (77 FR 5328, 5361). We did not receive any comments concerning the proposed definition of average unit price. Since AMP is calculated and reported to CMS on a per unit basis (for example, tablet, capsule, gram, milliliter) we believed it was important to include in the regulatory text the definition of average unit price to ensure consistent AMP reporting across all manufacturers and therefore, we are finalizing the definition at § 447.504(a) as proposed.

c. Charitable and Not-for-Profit Pharmacies

For the purposes of this subpart, we proposed to define charitable and not-for-profit pharmacies as organizations exempt from federal taxation as defined by section 501(c)(3) of the Internal Revenue Code of 1986 (77 FR 5328, 5361). We proposed to define charitable and not-for-profit pharmacies using specific definitions in the Internal Revenue Code. These terms are referenced in the definition of retail community pharmacy at section 1927(k)(10) of the Act and we established these definitions to ensure that AMP is calculated consistently across all manufacturers in accordance with the definition of AMP in section 1927(k)(1) of the Act. We received no comments concerning the proposed definition of charitable and not-for-profit pharmacies. Therefore, we are finalizing the definition at § 447.504(a) as proposed.

d. Insurers

As discussed in the proposed rule, the Affordable Care Act referenced the term ''insurers'' in section 1927(k)(1)(B)(IV) of the Act (77 FR 5328). Therefore, for the purposes of this subpart, we proposed to define insurers as entities that are responsible for payment of drugs dispensed to the insurer's members, and do not take actual possession of these drugs or pass on manufacturer discounts or rebates to pharmacies (77 FR 5328, 5361). We received no comments concerning the proposed definition of insurers and for the reasons we noted, we are finalizing the definition at § 447.504(a) as proposed.

e. Net Sales

In the preamble to the proposed rule, we proposed to define net sales to mean quarterly gross sales revenue to wholesalers for drugs distributed to retail community pharmacies and retail community pharmacies that purchase drugs directly from manufacturers less cash discounts allowed, and 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 (77 FR 5328). We note that we included language in the proposed regulations text which, while not identical to the preamble language, was designed to codify that proposal (77 FR 5361). Specifically, in the proposed regulatory text (77 FR 5361) we did not include the phrase ''to wholesalers for drugs distributed to retail community pharmacies and retail community pharmacies that purchase drugs directly from manufacturers'' which was erroneously included in the preamble discussion. We did not receive any comments concerning the proposed definition of net sales and thus we are finalizing the regulatory definition as proposed. In addition, because net sales for 5i drugs is calculated to include sales in addition to sales to wholesalers and retail community pharmacies, it would not be appropriate to limit the gross sales from which the net sales are determined to only wholesalers and retail community pharmacies, as discussed in the preamble to the proposed rule (77 FR 5328). Therefore, we have not included such language in the final rule and are finalizing the definition at § 447.504(a) as proposed in the regulatory text.

f. Retail Community Pharmacy

We proposed to define retail community pharmacy to mean an independent pharmacy, a chain pharmacy, a supermarket pharmacy, or a mass merchandiser pharmacy that is licensed as a pharmacy by the state and that dispenses medications to the general public at retail prices (77 FR 5361). We further proposed to incorporate the requirement set forth in

section 1927(k)(10) of the Act that such term does not include a pharmacy that dispenses prescription medications to patients primarily through the mail, nursing home pharmacies, long-term care facility pharmacies, hospital pharmacies, clinics, charitable or not-for-profit pharmacies, government pharmacies, or pharmacy benefit managers (discussed in more detail at 77 FR 5328). We note that in the preamble of the proposed rule our proposal specified the words ''or a mass merchandiser pharmacy,'' (77 FR 5328) but in the proposed regulatory text, we inadvertently included the words ''and a mass merchandiser pharmacy'' (77 FR 5361). Given the explanation of our proposal in the preamble, our intent was to propose regulatory text consistent with section 1927(k)(10) of the Act, which defines retail community pharmacy to include the phrase ''or mass merchandiser pharmacy.'' Therefore, we are modifying the regulatory text in this final rule to specify ''or a mass merchandiser pharmacy,'' to be consistent with the statute. We received the following comments concerning the proposed definition of retail community pharmacy:

Comment: One commenter expressed support for the proposed definition of retail community pharmacy because it reflects the definition of retail community pharmacy as provided in the Affordable Care Act.

Response: We appreciate the support for this proposal and note that the definition we are finalizing in this final rule is based on the statutory definition of retail community pharmacy as set forth in section 1927(k)(10) of the Act.

Comment: One commenter requested clarification regarding whether CMS expects manufacturers to validate the business licenses of entities before including any sales in their AMP calculations since the definition specifies, in part, that it is ''licensed as a pharmacy by the state.''

Response: We did not propose that manufacturers make separate assurances regarding such licensure for Medicaid rebate purposes in the proposed rule and are not including such a provision in this final rule. Therefore, we expect manufacturers to use reasonable assumptions consistent with the requirements and intent of section 1927 of the Act and federal regulations.

Comment: Several commenters requested further guidance as to the meaning of ''primarily through the mail'' as used in the definition of retail community pharmacy, including how it applies to hybrid entities that may operate as retail community pharmacies but also dispense products through the mail. Another commenter noted that business models continue to evolve and venture into models more akin to mail order business models. A few commenters suggested that CMS provide a threshold for determining when a pharmacy is dispensing prescription medications ''primarily through the mail'' to ensure consistent treatment of these entities across the industry. The commenters provided recommendations for a standard, such as 70 percent and 50 percent, for classifying a pharmacy as one that dispenses primarily through the mail. These commenters stated that manufacturers should be able to presume that pharmacies will truthfully report whether they are mail order pharmacies when requested.

Response: We are declining to set a percentage of sales that a pharmacy would have to attain to be considered a pharmacy that primarily dispenses through the mail as part of the regulations text in the final rule because it would not allow flexibility to recognize changes that take place in the pharmaceutical marketplace with regard to mail order business.

However, we believe that there is a distinction between an entity that owns a retail community pharmacy and a mail order pharmacy and a retail community pharmacy that provides a delivery service. In those instances when a retail community pharmacy has a home delivery service, which is an additional service offered by the retail community pharmacy to send prescriptions directly to the patient's home, and the pharmacy does not offer prescriptions primarily through the mail, such drug sales would be included in AMP. However, if a single entity owns both a retail community pharmacy and a mail order pharmacy where medication is dispensed primarily through the mail, it is appropriate that manufacturers exclude the sales to the mail order pharmacy when determining AMP, and include the mail order sales when they are calculating AMP for a 5i drug not generally dispensed through retail community pharmacies. We further believe it is appropriate for the manufacturer to make reasonable assumptions that a pharmacy is a retail community pharmacy when the majority of the drugs are not dispensed through the mail. Should business models evolve to the extent that we need to address this in the future, we will issue additional guidance or engage in rulemaking, if needed.

Comment: Several commenters expressed opposition to CMS's efforts to broaden the definition of retail community pharmacy to include specialty pharmacies, home infusion pharmacies, and home health care providers. One commenter stated these are entities that typically operate as closed door pharmacies, stock a limited number of drugs, are not open to the general public in the same manner as a retail community pharmacy, and are able to obtain discounts and price concessions not available to retail community pharmacies. Furthermore, the commenter indicated that the definition of retail community pharmacy as laid out in the Affordable Care Act is unambiguous and not open to interpretation or agency discretion. Therefore these additional entities should not be included in the definition of retail community pharmacy.

One commenter stated that CMS included these entities as a way to provide a means of securing rebates for oral CODs that would not otherwise have an AMP because they do not have a 5i route of administration and are not generally dispensed through retail community pharmacies. The commenter stated that CMS must identify an alternate means to address AMP calculations for these products as its proposal to include specialty pharmacies, home infusion pharmacies and home health care providers in the definition of retail community pharmacy relies on a distorted understanding of the business practices of these entities and is contrary to congressional intent. The commenter stated that by proposing the amendment to section 2503 of the Affordable Care Act, Congress recognized that its own definition of retail community pharmacy excluded sales to specialty pharmacies, home infusion pharmacies and home health care providers and the commenter believed that CMS must do the same. Furthermore, the commenter stated that the agency's proposed interpretation of retail community pharmacy (including specialty pharmacies, home infusion pharmacies, and home health care providers) cannot be sustained under the APA and US Supreme Court precedent that specifies when the statute's language is plain it must be interpreted and enforced according to its terms. Furthermore, the Congress excluded from the definition of retail community pharmacy any pharmacy that ''dispenses prescriptions primarily through the mail'' therefore the commenter believed this demonstrates another reason why specialty pharmacies do not meet the definition of retail community pharmacy because they in particular

dispense prescriptions primarily through the mail.

Yet another commenter stated that if all sales to these entities are included in AMP calculations, AMP based FULs may be insufficient to cover the purchasing cost of retail community pharmacies. The commenter stated that whether or not a rebate will continue to be calculated for a particular drug does not provide CMS with the authority to disregard the intent of Congress and that CMS should be clear that a ''retail community pharmacy'' is limited to the statutory definition.

Response: We proposed to include in AMP those sales, discounts, rebates, payments, or other financial transactions that are received by, paid by, or passed through to entities that conduct business as wholesalers or retail community pharmacies, which includes but is not limited to specialty pharmacies, home infusion pharmacies and home health care providers (77 FR 5329). Based upon the comments received, we realize that adding a separate category of sales (sales to entities conducting business as wholesalers or retail community pharmacies) was unnecessary for purposes of AMP calculations given the definition of retail community pharmacy in section 1927(k)(10) of the Act. Consistent with section 1927 of the Act, we believe the definition of retail community pharmacy could include some home infusion, home health care or specialty pharmacies because in certain situations, they operate as an independent, chain, supermarket, or a mass merchandiser pharmacy that is licensed as a pharmacy by the state and that dispenses medications to the general public at retail prices. In addition, they do not dispense prescription medications to patients primarily through the mail. Therefore, in such situations, these entities would qualify as retail community pharmacies. Accordingly, we are not finalizing our proposal that manufacturers include in the determination of AMP a separate category of entities conducting business as wholesalers or retail community pharmacies. Furthermore, given the comments, we are not expanding the definition of retail community pharmacy to specifically include home infusion, home health care, and specialty pharmacies as we believe these pharmacies may or may not, depending on the business model adopted, qualify as retail community pharmacies in accordance with the definition at section 1927(k)(10) of the Act. Rather, we believe, based on comments received and as discussed further below, sales to home infusion, home health care, and specialty pharmacies should be included in AMP; but only to the extent these pharmacies actually meet the definition of retail community pharmacy as defined at section 1927(k)(10) of the Act.

Retail community pharmacy is defined to mean an independent, chain, supermarket, or a mass merchandiser pharmacy that is licensed as a pharmacy by the state, dispenses medications to the general public at retail prices, and it does not include a pharmacy that dispenses prescription medications to patients primarily through the mail. Section 1927(k)(10) of the Act further excludes nursing home pharmacies, long-term care facility pharmacies, hospital pharmacies, clinics, charitable and not-for-profit pharmacies, government pharmacies, and pharmacy benefit managers. Nowhere in this list of exclusions are specialty pharmacies, home health care pharmacies or home infusion pharmacies specifically excluded by name. Therefore, specialty, home health care or home infusion pharmacies could meet the definition of retail community pharmacy at section 1927(k)(10) of the Act given such pharmacies are not primarily mail order pharmacies and may dispense medications to the general public. In those situations, where the business model is designed so that the pharmacy does not dispense medications primarily through the mail, the pharmacy may qualify as a retail community pharmacy to the extent that the pharmacy operates as an independent, chain, supermarket, or a mass merchandiser pharmacy that is licensed as a pharmacy by the state and that dispenses medications to the general public at retail prices. When these pharmacies do meet the definition of retail community pharmacy, sales to these pharmacies should be included in the manufacturer's calculation of AMP.

For example, in those situations when a specialty, home infusion, or home health care pharmacy is an independent, chain pharmacy, or a mass merchandizer pharmacy that is licensed as a pharmacy by the state and dispenses medications to the general public at retail prices, and does not dispense drugs primarily through the mail, it meets the statutory definition of a retail community pharmacy and its sales should be included when calculating AMP. However, for example, if a specialty, home infusion, or home health care pharmacy does not dispense medications to the general public or provides medications to patients primarily through the mail, sales to such entities should be excluded from AMP. Further discussion as to which entities are included as retail community pharmacies or wholesalers for purposes of AMP can be found in sections II.C.5. and II.C.7. of this rule.

Comment: One commenter thanked CMS for addressing certain drugs left without a methodology to calculate AMP by addressing specialty pharmacies, home health care and home infusion pharmacies. The commenter requested clarification as to whether it was CMS's intent to create three ''buckets'' to calculate AMP (that is wholesalers for direct distribution to retail community pharmacies, sales directly to retail community pharmacies, and sales to other entities acting as wholesalers and retail community pharmacies) or was CMS's intent to expand the retail community pharmacy definition to include specialty pharmacies, home health care providers and home infusion pharmacies.

Response: As discussed previously in this section, we are not finalizing our proposal to include the sales of a separate category of entities that conduct business as retail community pharmacies or wholesalers in the AMP calculation. Instead, as previously discussed and after reviewing the comments, sales to specialty pharmacies, home health care providers and home infusion pharmacies, to the extent they meet the definition of a retail community pharmacy as defined in section 1927(k)(10) of the Act, or the definition of wholesaler as defined in section 1927(k)(11) of the Act, should be included in AMP. Further discussion about these entities can be found in the sections on sales included in AMP and sales included in AMP for 5i drugs (section II.C.5. and II.C.7. of this final rule).

Comment: One commenter stated that home infusion pharmacies should not be included in the definition of retail community pharmacy. The commenter stated that home infusion therapy pharmacies are different than retail community pharmacies because they are primarily pharmacy-based decentralized patient care facilities that provide care in alternate sites to patients with either acute or chronic conditions. Commenters believe they only treat specialized classes of patients who rely on these pharmacies for services that support their therapy regimen as a substitute for hospitalization. Commenters claim that patients who require retail drugs cannot get them from infusion pharmacies. In addition to infusion drugs, infusion pharmacies provide professional pharmacy services, care coordination, infusion nursing services, and supplies and equipment.

The commenter indicated that in regulatory and subregulatory documents for the Medicare Prescription Drug Benefit, CMS has recognized home infusion pharmacies as being different from retail pharmacies and the Healthcare Common Procedure Coding System (HCPCS) codes provides approximately 80 ''S'' codes for home infusion therapy services that may not be used by retail pharmacies for their drug claims. In addition, the National Uniform Claims Committee (NUCC), a coalition of industry and government representatives, has recognized that the home infusion therapy pharmacy and community/retail pharmacy are distinct. The commenter believed that the terminology or classification used by CMS to identify different pharmacies for the purposes of Medicaid payment polices for prescription drug should be consistent with the classification widely used by payers and providers. The commenter urged CMS to follow the classification established by the NUCC by defining home infusion therapy pharmacies separately and distinctly from retail community pharmacies.

Response: As noted earlier in this section, we are not finalizing our proposal to establish a separate category for entities that conduct business as wholesalers or retail community pharmacies. Instead, manufacturers shall include the sales to home infusion pharmacies in AMP to the extent these pharmacies meet the definition of retail community pharmacy at section 1927(k)(10) of the Act. A home infusion pharmacy that is an independent, chain, supermarket or mass merchandiser licensed as a pharmacy in a state and dispenses medications to the general public at retail prices and does not dispense primarily through the mail meets the definition of retail community pharmacy at section 1927(k)(10) of the Act. While home infusion pharmacies may serve patients with certain medical conditions, or may provide drugs that require special handling or packaging, the definition of retail community pharmacy at section 1927(k)(10) of the Act does not specifically exclude such pharmacies. As discussed previously, the statutory definition of retail community pharmacy at section 1927(k)(10) of the Act may encompass home infusion pharmacies to the extent that such pharmacies qualify as independent pharmacies, chain pharmacies, supermarket pharmacies, or mass merchandizer pharmacies that are licensed by the state and that dispense to the general public.

We also do not agree with the commenter that we adopt the same classification of retail pharmacy as established by the NUCC. The purpose of NUCC is to establish universal provider claim standards as it relates to third party reimbursement, whereas the statutory definition of retail community pharmacy at section 1927(k)(10) of the Act is specifically for the purpose of manufacturers' determination of AMP. As stated previously, the definition does not specifically exclude home infusion pharmacies. Therefore, to the extent home infusion pharmacies meet the statutory definition of retail community pharmacy at section 1927(k)(10) of the Act, sales to such pharmacies shall be included in the calculation of AMP.

Comment: One commenter stated that expanding the definition of retail community pharmacy to include home infusion pharmacies and home health care providers puts an undue burden on manufacturers to determine who the end customer is. The commenter further stated that home infusion pharmacies or home health care providers may also service patients in long term care facilities which are excluded from AMP by statute. The commenter believed that including home infusion pharmacies or home health care providers in the definition of retail community pharmacy would cause greater fluctuations in AMP due to the continued changes to price factor calculation methodologies by including drugs most frequently used in inpatient settings to set AMPs.

Response: As discussed in this section, specialty pharmacies, home infusion pharmacies or home health care providers are included in the definition of retail community pharmacy to the extent they meet the definition of retail community pharmacy at section 1927(k)(10) of the Act. We agree with the commenter that some patients that receive drugs sold to home infusion pharmacies may receive their drugs either while residing in an institutional setting or in their home. However, we do not believe, as the commenter suggests, that manufacturers should automatically presume that the home infusion pharmacy that dispenses to patients in an institutional setting does not dispense to the general public nor meet the other criteria provided in the definition of a retail community pharmacy at section 1927(k)(10) of the Act. A home infusion pharmacy that dispenses medications to the general public at retail prices and meets the other criteria for a retail community pharmacy at section 1927(k)(10) of the Act must have its sales included in the calculation of the manufacturer's AMP.

For the reasons we articulated, we are finalizing the definition of retail community pharmacy at § 447.504(a) to mean an independent pharmacy, a chain pharmacy, a supermarket pharmacy, or a mass merchandiser pharmacy that is licensed as a pharmacy by the state and that dispenses medications to the general public at retail prices. Such term does not include a pharmacy that dispenses prescription medications to patients primarily through the mail, nursing home pharmacies, long-term care facility pharmacies, hospital pharmacies, clinics, charitable or not-for-profit pharmacies, government pharmacies, or pharmacy benefit managers.

5. Sales Included in the Determination of AMP

In proposed § 447.504(b), we proposed to identify specific sales, nominal price sales, discounts, rebates, payments, and other financial transactions to include in the determination of AMP (77 FR 5330, 5361). The following comments pertain to general observations regarding the regulatory text at proposed § 447.504(b) and (c).

Comment: A few commenters noted that CMS has not been consistent in the use of terminology in the determination of AMP section of the regulatory text. The commenters noted that in some areas of the proposed regulatory text it refers to ''Sales, Discounts, Rebates, Payments and Other Transactions'' while in other areas it just refers simply to ''sales.'' The commenters stated that they believe CMS intended to include in AMP all transactions involving the enumerated entities, not just sales to those entities. Therefore, the commenters requested that CMS revise the proposed regulatory language to refer consistently to the types of transactions that it intends to include in AMP.

Response: We appreciate this comment and after reviewing the proposed regulatory text of this section, we agree. Consistent with section 1927(k)(1)(B)(ii) of the Act, when a sale to a retail community pharmacy is determined to be included in AMP, any rebate, discount, payment or other financial transaction associated with that sale should also be included in the determination of AMP, unless it is specifically excluded as outlined in § 447.504(c). Accordingly, we are finalizing changes to § 447.504(b) and (c) so that we are consistent in our reference to AMP, as well as the types of transactions that are included in or excluded from AMP. Specifically, we are revising the heading of § 447.504(b) to read ''Sales, nominal price sales, and associated discounts, rebates, payments, or other financial transactions included

in AMP.'' In the introductory text of § 447.504(b) we specify that AMP for CODs includes the sales, nominal price sales, and associated discounts, rebates, payments, or other financial transactions unless specifically excluded as outlined in paragraph (c) of the section. It is our intention that the addition of the term ''associated'' clarifies that it is the sales themselves, as well as the discounts, rebates, payment or financial transactions associated with the sales that are included in the AMP calculation, unless otherwise specifically excluded.

At § 447.504(c), we similarly are revising the heading to include Sales, nominal price sales, and associated discounts, rebates, payments, or other financial transactions excluded from AMP. In the introductory text of § 447.504(c) we specify that AMP excludes sales, nominal price sales, and associated discounts, rebates, payments or other financial transactions. Again, we believe that the addition of the term ''associated'' clarifies that it is the sales or prices themselves, as well as the discounts, rebates, payment or other financial transactions associated with the sales or prices that are excluded from the AMP calculation. Similar changes are being made to § 447.504(d) and (e) to ensure consistency in the AMP and AMP for 5i drugs not generally dispensed through retail community pharmacies. The changes to § 447.504(d) and (e) are discussed later in this section and in section II.C.7.d. of this final rule.

Comment: One commenter requested confirmation that its interpretation of the regulatory language proposed at § 447.504(b) is correct. Specifically, the commenter noted that it does not interpret the proposed rule as including particular transactions in AMP that are otherwise specifically excluded by the statute.

Response: We agree with the commenter that proposed § 447.504(b) was intended to clarify which transactions are to be included in the calculation of AMP, not to include transactions that are otherwise excluded by statute. We believe the changes to § 447.504(b) discussed previously in this section, as well as other changes to this section (as discussed in this section) clarifies which transactions manufacturers are to include in the determination of AMP.

Comment: One commenter asked CMS to confirm that the AMP for an oral product with any amount of retail community pharmacy sales may be based solely on those sales and not the sales through otherwise excluded entities. The commenter further requested that CMS revise § 447.504(b) to read: ''(b) . . . Except for those sales, nominal price sales, rebates, discounts, and other financial transactions identified in paragraph (c) of this section, AMP for CODs includes *all of* the following sales, nominal price sales, rebates, discounts, and other financial transactions *in any amount.''*

Response: While we appreciate the comment, AMP should include only sales to AMP-eligible entities. As specified in earlier responses, the AMP for oral CODs is to be based on the sales, nominal price sales, and discounts, rebates, payments, or other financial transactions associated with the sale to the named entities that are included in AMP, unless specifically excluded as outlined in § 447.504(c). Furthermore, the commenter did not fully explain why they believed these changes would be beneficial and we do not believe it is necessary to add the level of specificity to § 447.504(b) that was suggested by the commenter. We believe the changes we are making in this final rule to § 447.504(b) address the concerns of commenters that requested clarification as to which transactions manufacturers should include in and exclude from the determination of AMP.

Therefore, after considering the comments, and for the reasons discussed in this section, we are finalizing the heading and introductory text of § 447.504(b) and (c) to more clearly specify the type of rebates and transactions that are included in or excluded from the calculation of AMP.

Comments regarding sales excluded from AMP are discussed in more detail later in this section.

a. Sales to Wholesalers (§ 447.504(b)(1))

Based on the definition of AMP in section 1927(k)(1) of the Act, as amended by the Affordable Care Act, we proposed that sales to wholesalers for drugs distributed to retail community pharmacies are to be included in the determination of AMP (77 FR 5330 and 5361). We received the following comment concerning this proposed provision:

Comment: One commenter requested clarification regarding whether the wholesaler is to report to the manufacturer the sales that were made to retail community pharmacies as opposed to those sales made to other entities, such as inpatient hospitals, mail order pharmacies, etc., or is it the intention that the manufacturer must include all sales to a wholesaler that may resell products to retail community pharmacies.

Response: Section 1927(k)(1)(A) of the Act defines AMP to mean, in part, the average price paid to the manufacturer for drugs in the United States by wholesalers for drugs distributed to retail community pharmacies, and retail community pharmacies that purchase drugs directly from the manufacturer. The rule does not impose any wholesaler reporting requirements, and it is the manufacturer's responsibility to calculate and report AMP to CMS. As part of their AMP calculation process, the manufacturer may have independent arrangements with wholesalers to collect sales and chargeback data that will be useful in determining the end customers. As noted previously, we are not requiring the use of the buildup model to calculate AMP; therefore, the manufacturer may continue to make reasonable assumptions and presume, in the absence of guidance and adequate documentation to the contrary, that prices paid to the manufacturer by the wholesaler are for drugs distributed to retail community pharmacies, provided those assumptions are consistent with the requirements and intent of section 1927 of the Act and federal regulations.

After considering the comments, for the reasons discussed in this section, we are finalizing § 447.504(b)(1), as proposed.

b. Sales to Other Manufacturers (§ 447.504(b)(2))

We proposed at § 447.504(b)(2) that sales to other manufacturers who act as wholesalers are to be included in the determination of AMP to the extent that such sales are for drugs distributed to retail community pharmacies, and noted that this provision should be read in concert with the definition of wholesaler in section 1927(k)(11) of the Act (77 FR 5330). We received a few comments concerning sales to manufacturers, but these comments focused on sales between primary and secondary manufacturers of authorized generic drugs. Therefore, we have included our responses to such comments in the discussion concerning authorized generic drugs at section II.E. of this final rule. Therefore, we are finalizing § 447.504(b)(2) as proposed which requires manufacturers to include their sales of CODs to other manufacturers in AMP when such manufacturers are acting as wholesalers in accordance with the definition of wholesaler at section 1927(k)(11) of the Act.

c. Retail Community Pharmacies (Proposed § 447.504(b)(3))

We proposed to include in the determination of AMP, sales, discounts, rebates (other than rebates under section 1927 of the Act), payments, or other

financial transactions that are received by, paid by, or passed through to, retail community pharmacies (77 FR 5330 and 5361). We further explained that we were unsure to what extent the manufacturer has knowledge that such transactions occur and clarified in the preamble to the proposed rule that the manufacturer is to include such discounts where it has evidence or documentation demonstrating that such discounts have been passed through to the pharmacy (77 FR 5330). We received the following comments concerning this proposed provision:

Comment: A few commenters supported CMS's proposal that manufacturers are to include discounts, rebates, payments, or other financial transactions that are passed through to retail community pharmacies only when a manufacturer has evidence to that effect. One commenter indicated that given the limited information available to manufacturers in this area, this was a practical and realistic approach.

Response: We appreciate the support for this provision and are clarifying that when manufacturers have evidence or knowledge of a discount, rebate, payment, or other financial transaction being passed through to a retail community pharmacy, the manufacturer must appropriately account for these transactions in its calculation of AMP, as described elsewhere in this final rule.

Comment: One commenter indicated that CMS should interpret transactions received by, paid by, or passed through to retail community pharmacies as excluding: (1) Bona fide service fees; (2) any payment to retail community pharmacies that the pharmacy does not retain or benefit from (such as patient benefits); and (3) any payments made by retail community pharmacies to any party other than the manufacturer, or to an intermediary acting on the manufacturer's behalf because, while such payments are paid by a retail community pharmacy, a manufacturer would have no knowledge of the payment and they would not affect the sale between the manufacturer and the retail community pharmacy.

Response: We agree with the commenter that financial transactions received by, paid by, or under certain conditions, passed through to retail community pharmacies that meet the definition of a bona fide service fee as defined in this final rule are not included in the determination of AMP. We also agree that any fees made by the manufacturer to retail community pharmacies that the pharmacy does not retain or benefit from (such as patient coupons or voucher programs) given section 1927(k)(1)(B)(i) of the Act, which specifically excludes bona fide service fees and fees associated with patient care programs. We also agree, that payments made by retail community pharmacies to any party other than the manufacturer, or to an intermediary acting on the manufacturer's behalf in the sale of the drug (such as the wholesaler), would be excluded from AMP as long as it does not affect the price paid to the manufacturer for the COD in accordance with the definition of AMP at section 1927(k)(1)(A) of the Act.

Comment: Several commenters requested for CMS to clarify that the requirement to include amounts passed through to retail community pharmacies relates only to those pass-through amounts that are funded by the reporting manufacturer and provided to the wholesaler with the knowledge and the intention that the discounts will be passed through to the retail community pharmacy or other AMP-eligible entity. Commenters also requested for CMS to confirm that absent evidence to the contrary (such as chargeback records), manufacturers can presume that price concessions made by the manufacturer to an intermediary are not passed on to an indirect purchasing AMP-eligible customer. Another commenter stated that if a wholesaler or other intermediary unilaterally offers a retail community pharmacy or other AMP-eligible entity a discount, that discount should not be included in the manufacturer's AMP.

Response: As discussed in previous responses, manufacturers may continue to make reasonable assumptions in their calculation of AMP including assumptions as to whether discounts are passed through to retail community pharmacies, provided those assumptions are consistent with the requirements and intent of section 1927 of the Act and federal regulations. Therefore, we believe the concerns regarding manufacturers having no knowledge of price concessions or other discounts that are passed through to retail community pharmacies have been addressed. However, where manufacturers have evidence or other knowledge of chargebacks or other discounts being passed through to a retail community pharmacy, the manufacturer must appropriately account for these transactions in their calculation of AMP, as described elsewhere in this final rule.

Comment: A few commenters requested clarification regarding the reference in the proposed rule to other financial transactions paid by wholesalers and retail community pharmacies and noted those amounts would already be accounted for in the AMP calculation. The commenter requested clarification regarding whether this language was intended to capture transactions other than purchase payments.

Response: Section 1927(k)(1)(B)(ii) of the Act provides, in part, for the inclusion of other discounts, rebates, payments, or other financial transactions that are received by, paid by, or passed through to retail community pharmacies in the calculation of AMP for a COD. We believe that by including a reference to other financial transactions, section 1927(k)(1)(B)(ii) of the Act provides for the inclusion of financial transactions (other than rebates, discounts, or payments, specifically excluded by section 1927(k)(1)(B)(i) of the Act) that affect the price realized by the manufacturer when those financial transactions or price concessions are provided to, or received by, the retail community pharmacy. Therefore, to give meaning to this part of the statute and ensure applicability to possible other price concessions in the marketplace, we intended the reference to ''other financial transactions'' to address those situations when financial transactions, other than those specifically identified in section 1927(k)(1)(B)(i) of the Act, affect the price paid to the manufacturer for the COD.

After considering the comments received and for the reasons we discussed, we are finalizing § 447.504(b)(3) consistent with the revisions we are making to the introductory paragraph of § 447.504(b) (to add ''associated with'' as discussed in this section), and is not intended to change the general meaning of this provision; rather, to provide clarification and consistency throughout this section.

d. Entities Conducting Business as Retail Community Pharmacies or Wholesalers, Including But Not Limited to Specialty Pharmacies, Home Infusion Pharmacies and Home Health Care Providers (Proposed § 447.504(b)(4))

In light of section 1927(k)(1)(B)(i)(IV) of the Act, we proposed that sales to entities that conduct business as wholesalers or retail community pharmacies should be included in the determination of AMP (77 FR 5330, 5361). We proposed that manufacturers include in the determination of AMP the sales, as well as the associated discounts, rebates, payments, or other financial transactions that are received by, paid by, or passed through to entities conducting business as

wholesalers or retail community pharmacies, which include but are not limited to specialty pharmacies, home infusion pharmacies, and home health care providers (77 FR 5330, 5361). We received the following comments concerning these provisions:

Comment: Many commenters requested clarification regarding the meaning of the phrase ''conduct business as'' in the context of including entities that conduct business as wholesalers or retail community pharmacies in the determination of AMP and requested guidance on how to identify other entity types (besides specialty pharmacies, home infusion pharmacies and home health care providers) that would qualify as entities conducting business as wholesalers or retail community pharmacies. One commenter stated that given the fluid and constantly evolving nature of the healthcare system, CMS was correct not to specify that the list of entities that conduct business as retail community pharmacies was an exhaustive list.

Some commenters requested that CMS provide a separate definition of ''conducting business as'' for wholesaler entities and retail entities. Another commenter favored adopting regulatory definitions that are flexible enough to accommodate changes in the industry, and indicated that manufacturers should be permitted to establish their own assumptions regarding what it means to conduct business as a wholesaler or retail community pharmacy.

Response: We agree with the commenters that the pharmaceutical industry is a changing industry and that crafting an overly specific definition of retail community pharmacy or wholesaler may not accommodate the marketplace. However, as discussed earlier in response to comments about the definition of retail community pharmacy, we have decided not to finalize our proposal to add § 447.504(b)(4) and therefore, we are not utilizing the term ''conducting business as'' in this provision. Rather, as previously discussed, we are clarifying that the sales, as well as the discounts, rebates, payments, or other financial transactions associated with the sales that are received by, paid by, or passed through to entities that meet the statutory definition of a retail community pharmacy at section 1927(k)(10) of the Act are included in the determination of AMP, which could include sales to home healthcare providers, home infusion pharmacies, and specialty pharmacies if these pharmacies meet the definition at section 1927(k)(10) of the Act. Further discussion around ''conducting business as'' in the context of the determination of AMP for 5i drugs not generally dispensed through retail community pharmacies is addressed in section II.C.7. of this final rule.

Additionally, we believe that the definition of retail community pharmacy in both the statute and regulation can accommodate potential changes to the pharmacy provider industry so that it ensures manufacturers' AMPs reflect the sales of their products in the retail community pharmacy market. In other words, by not specifying an exhaustive list of pharmacy providers which fall under the definition of retail community pharmacy, manufacturers must consider its sales to other types of pharmacy providers and wholesaler entities that should be reflected in AMP. And, as previously stated, manufacturers may make reasonable assumptions, in the absence of guidance and adequate documentation to the contrary, that prices paid to manufacturers by wholesalers are for drugs distributed to retail community pharmacies, provided those assumptions are consistent with the requirements and intent of section 1927 of the Act and federal regulations.

Comment: A few commenters noted that broadening the definition of AMP has the potential to threaten drug price competition throughout the marketplace because a broad definition will not accurately reflect the price pharmacists pay for drugs as it includes price concessions not passed on to retail community pharmacies. A few commenters suggested that the inclusion of sales to entities other than retail community pharmacies was a back end way to allow potential mail-order sales in the calculation of AMP, which is prohibited by statute, and would lower AMPs and underpay pharmacies. Another commenter believed that the phrase ''or any other entity that does not conduct business as a wholesaler or a retail community pharmacy'' was included as a catch all to ensure that CMS did not find a loophole to include other manufacturer sales that would lower AMP and thus, underpay pharmacies and reduce rebates paid to states by manufacturers. The commenter stated that the law only permits one situation in which sales to non-retail community pharmacies can be included in the calculation of AMP; namely, when the drug is a 5i drug not generally dispensed through a retail community pharmacy.

Some commenters encouraged CMS to clarify in the final rule whether the instruction to include specialty pharmacy sales in AMP always overrules the instruction to exclude mail order sales or whether manufacturers are to capture only those specialty pharmacy sales that do not involve mail delivery. The commenters noted that failure to provide such a clarification will exacerbate problems with AMP variability because manufacturers will make different reasonable assumptions. The commenters also stated that the same consideration also arises in the context of sales to certain chain warehouses that distribute products to both the chain's retail outlets and its mail-order operations. One commenter noted that mail-order pharmacies (which do act as specialty pharmacies) generally do not have store front operations where a patient could walk in and fill a prescription but instead provide home delivery. The commenter also stated that the provision falsely assumes that unless sales to specialty pharmacies are included in AMP, there would be certain drugs that would have no AMP at all. However, the commenter believed that all but a few drugs either are dispensed by retail community pharmacies or would be in the category of 5i drugs; both of which clearly have an AMP calculation.

Conversely, some commenters supported the conclusion that specialty pharmacies take precedence over its mail order status when determining that pharmacy's AMP eligibility, because such a conclusion acts to ensure that non-5i products that are dispensed through the mail order specialty pharmacies have a base of sales to use in AMP calculation. One commenter urged CMS to include these mail-order sales and discounts in AMP as these entities are conducting business as retail community pharmacies and it would help ensure that all non-5i drugs that are dispensed through mail-order specialty pharmacies have a base of sales to use in calculating AMP. The commenter also stated that manufacturers should not have to evaluate the nature of every specialty pharmacy's business to which they sell to determine if they dispense primarily through the mail.

Several commenters supported CMS's efforts to ensure that all CODs have AMP-eligible sales by including sales to specialty pharmacies, home infusion pharmacies, and home health care providers as entities that conduct business as retail community pharmacies. One commenter also noted that this policy should have no effect on retail community pharmacies because the types of products that are sold through specialty pharmacies are specialty drugs (medications with

particular features that complicate their use such as requiring physician administration, special handling or storage, or significant patient education or Risk Evaluation and Mitigation Strategy (REMS)) that ordinarily have very few retail community pharmacy sales. The commenter also stated that manufacturers must have flexibility to make reasonable assumptions in the process of identifying specialty pharmacies. Additionally, the commenter indicated that including sales to specialty pharmacies in AMP or AMP for 5i drugs not generally dispensed through retail community pharmacies should not impact FULs because the drugs that are sold through specialty pharmacies are generally innovator products, not multiple source products.

Response: As discussed in earlier responses, we are not finalizing the provision at § 447.504(b)(4) and the term ''conducting business as'' in this provision. Instead, as previously discussed, we have decided that sales to home health care, home infusion and specialty pharmacies may be included in the AMP calculation but only to the extent that they meet the definition of retail community pharmacy at section 1927(k)(10) of the Act, which specifically excludes entities that dispense medications primarily through the mail. It is not our intention that pharmacies that dispense medications primarily through the mail would meet the statutory definition of retail community pharmacy at section 1927(k)(10) of the Act. In addition, we do not believe that a retail community pharmacy must have a ''brick and mortar'' store front. Nowhere in section 1927 of the Act does it specify that a pharmacy must maintain such a store front to be considered a retail community pharmacy as defined at section 1927(k)(10) of the Act.

As to the commenter's concern regarding the potential for underpayment to pharmacies, we believe that our decision to include sales to home infusion, specialty, and home health care pharmacies when such pharmacies meet the definition of retail community pharmacies in section 1927(k)(10) of the Act will reflect the prices available in the retail marketplace for these drugs and will not lead to the underpayment of retail community pharmacies. Therefore, we are not convinced that including sales to such entities (such as specialty, home health care and home infusion pharmacies, where such entities qualify as retail community pharmacies) in the calculation of AMP will lead to the underpayment of retail community pharmacies. Furthermore, while it may be true that some 5i drugs will not have FULs because such drugs are typically single source innovator products, it may not be the case for all 5i drugs. For further discussion of the FULs please refer to section II.K. of this final rule.

Comment: One commenter sees no statutory basis for CMS to include sales to specialty pharmacies, home infusion pharmacies and home health care providers in the AMP calculation, nor does the commenter see the basis for CMS's belief that the Congress suggested or intended otherwise. The commenter stated that even if the belief that specialty pharmacies, home infusion pharmacies and home health providers ''dispense medications to the general public at retail prices'' were shown to be true, it is not a sufficient foundation to qualify these entities as retail community pharmacies since this is not the only basis on which the Congress defined the term retail community pharmacy. The commenter recommended that consistent with the statute, specialty pharmacy, home infusion pharmacy, and home health provider transactions should not be included in AMP calculations since these are not retail community pharmacies.

Response: As discussed in more detail in prior responses, we disagree with the commenter that there is no statutory basis to include sales to home health, home infusion, and specialty pharmacies in the AMP calculation in those situations when they may meet the definition of a retail community pharmacy at section 1927(k)(10) of the Act. While we are not finalizing § 447.504(b)(4), manufacturers should include sales to such pharmacies in their calculation of AMP when the pharmacies actually qualify as retail community pharmacies in accordance with section 1927(k)(10) of the Act.

Comment: One commenter requested confirmation from CMS that sales to entities that conduct business as wholesalers or retail community pharmacies are included in AMP for all CODs, not just CODs that otherwise may not have AMP-eligible sales. The commenter noted that a different approach would create three different AMP calculations which would be confusing and burdensome to manufacturers. The commenter also requested clarification as to whether sales to entities that conduct business as wholesalers must be resold to retail community pharmacies.

Another commenter encouraged CMS to clarify in the final rule that only those sales and discounts for oral CODs approved by FDA that are required by a REMS to be dispensed to patients by specialty certified pharmacies, resulting in manufacturers utilizing a restricted network of certified specialty and home infusion pharmacies to dispense those drugs to patients are included. Yet another commenter stated that if CMS does include these classes of trade in the AMP calculation, it should only do so in the cases where the oral COD would not otherwise have an AMP and cannot have an AMP for 5i drugs not generally dispensed through retail community pharmacies because of its route of administration. Finally, one commenter stated that the proposed language at § 447.504(b)(4) could be interpreted as including all of the sales the rest of the rule excludes or at least leaving manufacturers with significant doubt as to the includable and excludable entities. The commenter indicated that the final rule should more clearly implement CMS's intent and eliminate conflict and confusion of the scope of sales included within AMP and suggested revisions to § 447.504(b)(4) to add that an exemption to the exclusion when the conditions of FDA restrict sales of a product solely to certain entities that would not otherwise be deemed a Retail Community Pharmacy.

Response: As we have discussed in earlier responses, we are not finalizing the provision at § 447.504(b)(4). As to the commenters concerns that the proposed language at § 447.504(b)(4) is not clear and that manufacturers may have doubts as to which sales or prices are to be included and which are to be excluded, we believe that the changes we made to the regulatory text at § 447.504(b) and (c), as described in detail in the earlier responses, clarify which manufacturer COD sales (sales to entities that meet the definition of retail community pharmacy at section 1927(k)(10) of the Act or wholesaler as defined at section 1927(k)(11) of the Act) are to be included in the determination of AMP. To that end, the definition of wholesaler would include only those entities that engage in wholesale distribution of prescription drugs to retail community pharmacies in accordance with section 1927(k)(11) of the Act.

Furthermore, we are not applying a different standard for certain drugs not generally dispensed to retail community pharmacies (for example, oral drugs with REMS) to permit the inclusion of sales to a specialty, home infusion or home health care pharmacy for those drugs, because, as noted previously, we are not finalizing that manufacturers, when calculating AMP, include entities that conduct business as retail community pharmacies. Instead, we are

specifying that to the extent a pharmacy, whether it is a specialty, home infusion, or home health care pharmacy, meets the definition of retail community pharmacy at section 1927(k)(10) of the Act, that those sales be included in the calculation of the manufacturer's AMP.

Comment: One commenter stated that CMS's belief that specialty pharmacies, home infusion pharmacies and home health care providers are entities that conduct business as wholesalers or retail community pharmacies is flawed and indicated that a more accurate and reasonable interpretation of this phrase is simply a congressional acknowledgement to the potential for new business models to emerge in the healthcare marketplace. Furthermore, the commenter emphasized that by using the word ''means'' rather than ''such as'' or ''including'' when defining retail community pharmacies, Congress strictly limited the universe of retail community pharmacies in a way that excludes specialty pharmacies, home infusion pharmacies, and home health care providers.

Response: As noted previously in response to comments, we have decided not to finalize our proposal at § 447.504(b)(4). Rather, as we have discussed previously, sales of CODs to only those entities which actually qualify as wholesalers or retail community pharmacies should be included in the AMP calculation. As previously discussed, this may include specialty pharmacies, home health care pharmacies, and home infusion pharmacies but only to the extent that such entities qualify as retail community pharmacies as set forth in section 1927(k)(10) of the Act.

By making these changes in the final rule, we recognize that there are other entities that may meet the definition of a retail community pharmacy or wholesaler, which will affect which manufacturer sales shall be included in AMP. The effect of this final change to the regulations text on whether manufacturer sales of oral drugs dispensed by specialty pharmacies will depend upon whether such pharmacies meet the definition of retail community pharmacy at section 1927(k)(10) of the Act.

Comment: One commenter supported CMS's proposal not to define specialty pharmacy because the specialty pharmacy class of trade is so dynamic and fast evolving, and any regulatory definition would likely be obsolete shortly after it were finalized. The commenter indicated that manufacturers should be permitted to document reasonable assumptions regarding the criteria they use to determine whether an entity qualifies as a specialty pharmacy. Another commenter noted that it is appropriate and necessary to include specialty pharmacy sales in AMP and that it is practical and more logical to include specialty pharmacies as entities that conduct business as retail community pharmacies because these pharmacies are generally not traditional brick and mortar locations, but can distribute products through many different routes, including the mail.

Conversely, several commenters requested that CMS provide additional guidance and define specialty pharmacy. One commenter noted that most state boards of pharmacy do not have a separate regulatory category for specialty pharmacy; and while there is no common definition of specialty pharmacy that can be used to normalize classifications across the industry, if manufacturers are to include specialty pharmacy sales in AMP, CMS has to provide an appropriate definition to ensure consistent treatment across AMP calculations for all manufacturers and all products. Another commenter noted that the term ''specialty pharmacy'' is a term of art in the industry and is characterized by a pharmacy (mail or retail) that serves a very small patient population with chronic, rare and/or life threatening conditions and can dispense medications through the mail, as well as retail and provides patients with the tools to care for themselves at home when clinically appropriate. The commenter further contended that patient support is also provided 24 hours a day, 7 days a week via home visits or telephone consultation with health professional.

One commenter noted that third party data companies that collate and provide information on sales channels segregate retail and mail order pharmacies but do not have a separate category for specialty pharmacies; instead, specialty pharmacies are generally included with mail order pharmacies. The commenter stated that without a consistent and specific definition of specialty pharmacy applied to all industry stakeholders, the inclusion of these transactions in AMP would be inconsistent. Furthermore, the commenter stated that CMS cannot override a statutory directive to exclude mail order pharmacies with a regulatory directive to include a subset of pharmacies that are mail order in nature. Another commenter provided the Utilization Review Accreditation Commission's (URAC) definition of specialty pharmacy and noted that because of their complexities, specialty pharmaceuticals flow through a variety of distribution channels, and these channels may vary according to a product's administration requirements, a payer's benefit design, and a provider's service availability. Additionally, manufacturers may control distribution through select distributors due to limited production capacity and special handling requirements.

Response: We are not further defining the term specialty pharmacy for the purposes of this final rule, since, as we found, there is no standard set of characteristics associated with specialty pharmacies. Rather, as discussed previously, specialty pharmacies may be determined to meet the statutory definition of retail community pharmacy or not qualify as a retail community pharmacy because the pharmacy dispenses prescriptions primarily through the mail. Consistent with section 1927(k)(10) of the Act, specialty pharmacies that dispense prescription medications to patients primarily through the mail would not qualify as a retail community pharmacy. We note that other forms of home delivery that specialty pharmacies may use, such as delivery by a home health aide, delivery by a pharmacy employee or delivery by a courier service, which may be an additional service offered by any type of pharmacy when specialized packaging and handling of the drug is required, would not necessarily qualify the specialty pharmacy as a pharmacy that primarily dispenses prescription medications through the mail. As discussed previously in this section, we are not finalizing our proposal to include sales to entities conducting business as wholesalers or retail community pharmacies. Furthermore, and as discussed previously, to the extent that these pharmacies actually qualify as retail community pharmacies, sales to them should be included in AMP.

Comment: One commenter stated that it should be sufficient for manufacturers to query specialty and chain pharmacy customers no more frequently than annually about the percentage of their overall purchases that are going to retail and non-retail operations and to use the information to allocate sales to the appropriate class of trade. The commenter recognized that CMS may be hesitant to allow the use of such data given that AMPs are drug specific and calculated monthly, but the administrative burden of routinely tracking NDC-specific data would be inordinate for the manufacturer's pharmacy customers.

Response: We are not mandating that manufacturers query specialty and

chain pharmacies to determine the overall percentage of purchases that are mail order or retail or non-retail. We believe, based on comments received regarding the contracted versus non-contracted sales, that a manufacturer often has documentation (such as chargeback data), that will assist in verifying that drugs sold to wholesalers were subsequently sold to excluded entities, such as a mail order pharmacy. When this information is known, the manufacturer must appropriately exclude those sales, rebates, discounts or other financial transactions that are excluded by statute from its determination of AMP. In addition, as we have previously discussed, we have decided not to finalize the buildup methodology requirement, and will continue to allow manufacturers to make reasonable assumptions, provided those assumptions are consistent with the requirements and intent of section 1927 of the Act and federal regulations.

Comment: One commenter noted that a specialty pharmacy can be both a re-seller and a retail community pharmacy, and for each entity, manufacturers will have no way of distinguishing whether the transactions by the pharmacy were made in its role as a re-seller or as a retail community pharmacy. Therefore, the commenter requested clarification as to whether manufacturers would be required to allocate sales to specialty pharmacies depending on the type of business they conduct and noted that it would be very difficult to distinguish whether the transactions by the pharmacy were made in its role as a re-seller or as a retail community pharmacy.

Response: The manufacturer should consider all sales to a wholesaler or retail community pharmacy for inclusion in AMP, in accordance with the requirements of § 447.504(b) and section 1927(k)(1) of the Act. Therefore, if the specialty pharmacy referenced in this comment, be it a re-seller or retail community pharmacy, meets the definition of a retail community pharmacy at section 1927(k)(10) of the Act or wholesaler at section 1927(k)(11) of the Act, the sales to this entity would, in all likelihood, be included in the determination of AMP.

Therefore, for the reasons discussed previously in this section, we have decided not to finalize § 447.504(b)(4). To the extent that home health care, home infusion, or specialty pharmacies qualify as retail community pharmacies in light of the statutory definition of retail community pharmacy, sales to such entities should be included in AMP; however, where they do not qualify as retail community pharmacies, manufacturers should not include such sales in AMP.

6. Sales Excluded From the Determination of AMP

Section 1927(k)(1)(B) of the Act excludes a number of prices, sales, discounts, rebates, payments and other financial transactions from AMP. Section II.C.6.a. includes a discussion of which prices, sales, nominal price sales, applicable discounts, rebates, payments, or other financial transactions we proposed to exclude from the determination of AMP at proposed § 447.504(c), as well as a summary the issues raised in the comments we received and our responses. These proposed exclusions from the determination of AMP are discussed in more detail in the proposed rule (77 FR 5330 through 5334).

a. Prices to Other Federal Programs Including TRICARE (§ 447.504(c)(1) Through (3))

We proposed that prices to federal programs, including the Indian Health Service (IHS), the Department of Veterans Affairs (DVA), a state home receiving funds under 38 U.S.C. 741, the Department of Defense (DoD), the Public Health Service (PHS), 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), the FSS of the General Services Administration (GSA); or any depot prices (including TRICARE) and single award contract prices of any agency of the federal government should be excluded from AMP (77 FR 5331, 5361). We received the following comments concerning the prices to other federal programs including TRICARE.

Comment: Many commenters requested that CMS clarify whether all TRICARE transactions, including sales transactions, are excluded from AMP or is the proposed rule only limited to the refund paid to DoD for TRICARE utilization as was the policy under the DRA regulation. A few commenters noted that it would be logical to include the sales of goods that are dispensed to TRICARE beneficiaries, since those sales are to retail community pharmacies and to exclude the refunds paid to TRICARE for management activities as those are excluded by statute. The commenters indicated that this approach would resolve operational problems that they would face if they were required to exclude TRICARE sales from AMP, namely the job of estimating TRICARE utilization when that data delivery routinely occurs long after monthly and quarterly AMP must be filed. Some commenters suggested that CMS clarify that in AMP, TRICARE ''prices'' are the rebates (or ''refunds'') manufacturers pay quarterly to the DoD. If CMS requires the exclusion of drugs sold directly and indirectly to pharmacies when later reimbursed by TRICARE, a commenter requested that manufacturers be able to smooth the excluded units and remove an allocated percent each month and to devise a reasonable methodology for placing a dollar value on the units removed from the wholesaler and pharmacy sales. One commenter agreed with the CMS's position that TRICARE Retail Pharmacy Program prices should be excluded from AMP calculations because these discounts are not shared with retail pharmacies and do not impact the purchasing costs of retail pharmacies.

Response: We appreciate the comments and in light of section 1927(k)(1)(A) of the Act, we agree with commenters that manufacturer sales to retail community pharmacies or wholesalers that distribute drugs to retail community pharmacies that are later reimbursed by TRICARE as a third party payer are included in the calculation of AMP. However, the rebates or refunds manufacturers pay to TRICARE as a third party payer are excluded from AMP, because such rebates or refunds do not typically adjust the prices paid to manufacturers by retail community pharmacies or wholesalers for drugs distributed to retail community pharmacies.

Therefore, for the reasons discussed in this section and the proposed rule that prices available to federal programs do not reflect prices paid by retail community pharmacies or wholesalers for drugs distributed to retail community pharmacies (77 FR 5331), we are finalizing the provisions in § 447.504(c)(1) through (3) as proposed (77 FR 5331 and 5361).

b. Sales Outside the 50 States, the District of Columbia and Territories (§ 447.504(c)(4) and § 447.505(c)(18))

The proposed definition of ''states'' in § 447.502 was expanded to mean the 50 states, the District of Columbia and the territories (the Commonwealth of Puerto Rico, the Virgin Islands, Guam, the Northern Mariana Islands and American Samoa). We also proposed to add a definition of ''United States'' that would mean the 50 states, the District of Columbia and the territories (the Commonwealth of Puerto Rico, the Virgin Islands, Guam, the Northern Mariana Islands and American Samoa) (77 FR 5326). Therefore, in proposed § 447.504(c)(4), we proposed that sales to entities outside the 50 states, the

District of Columbia and the territories are not within the scope of the definition of sales to retail community pharmacy, and that drugs sold to entities outside the 50 states, the District of Columbia and the territories would not be considered eligible sales within the definition of AMP (77 FR 5331). Please note that in some instances the comments we received referenced both AMP and best price in the context of our proposal to exclude sales outside of the United States. Therefore, where appropriate, we have included in the summaries reference to both AMP and best price. We received the following comments concerning our proposal in § 447.504(c)(4) to exclude from AMP calculations those sales outside of the United States (which as discussed previously we have defined to be include 50 states, the District of Columbia and the territories):

Comment: Many commenters expressed opposition to the inclusion of sales to territories in the calculation of AMP and best price because of the enormous burden and compliance concerns that such an expansion would pose. The commenters stated that in many cases the related but distinct foreign entities do not participate in the MDR program and are not signatories to the National rebate agreement. A few commenters stated that class of trade assignments will be difficult to make because manufacturers are generally unfamiliar with the dispensaries and other providers in the territories. One commenter believed that CMS should retain its current treatment of sales to the territories in the calculation of AMP and best price because drugs sold to customers in the territories may have different WAC prices than drugs sold in the United States due to government imposed territory specific statutory caps.

Response: As discussed in more detail in the discussion of the definitions of states and United States at section II.B.25. of this final rule, we have reconsidered the definitions of states and United States and believe that the revised definitions of states and United States in this final rule are more consistent with section 1101(a)(1) of the Act. We recognize the potential complexities that this change in definition creates for both the territories and the manufacturers and, as discussed previously at section II.B.25. of this final rule, we have decided to delay the inclusion of the territories in the definitions of states and United States until 1 year after the effective date of the final rule. This will allow the territories and the manufacturers an additional year to implement the revised definitions of states and United States. This means that any changes drug manufacturers need to make to their government pricing systems to account for sales to the territories in their AMP and best price calculations would not be required until the territories are included in the definitions and this additional year will allow for the needed time to make this transition. We expect to provide additional guidance to manufacturers regarding the inclusion of territory sales within their calculation of AMP and best price, including additional guidance regarding the treatment of sales to territories that have government imposed statutory caps.

Comment: Several commenters urged CMS to limit a manufacturer's responsibility to that of paying rebates to the territories only, and not to require manufacturers to include sales to territories in their calculation of AMP and best price. Instead their calculation of AMP and best price would be based on the geographic sales to the 50 states and the District of Columbia, which are the only sales that the MDR program has previously included. One commenter stated that AMP and best price cannot be calculated based on prices in an economy with pharmaceutical price controls and that the Congress only intended the statute to apply in the 50 states and the District of Columbia.

Response: We disagree with the suggestion that we limit manufacturers' responsibility to rebate liability only, and that we allow manufacturers to continue to exclude all sales of CODs in the territories from their AMP and best price calculations. As discussed previously in this section, because sections 1927(c)(1)(C) and 1927(k)(1)(A) of the Act define best price and AMP to reflect certain prices paid in the United States, and section 1101(a) of the Act defines United States, for purposes of these provisions, to include the territories, we believe that manufacturers should be responsible for including territories in their rebate calculations.

Comment: Several commenters believed that deeply discounted commercial prices to the territories may need to be terminated to avoid an impact on a manufacturer's best price. Furthermore, the commenters stated that expansion of the AMP and best price calculations to include prices to the territories is inappropriate because the discounted prices may be subject to regulation and would distort AMP and best price calculations. Specifically, a few commenters indicated that Puerto Rico, through pricing regulations, retains the power to set the maximum sales price for medicinal products at the distributor and pharmacy level. Furthermore, many commenters indicated that including the territories in best price could have the unintended effect of disrupting commercial arrangements that benefit the territories because manufacturers have been required to engage in aggressive discounting to enter these markets, but they would have to reconsider this practice if these discounted prices were to affect their best price. One commenter noted that historically the extension of rebates and inclusion of more drug sales in the best price calculation has led to higher prices for other consumers, such as safety net providers. A few commenters stated that any value of the proposed expansion of the MDR program to territories could be severely undercut by the changes manufacturers would make in the pricing practices currently used in the territories and CMS should specify in the final rule that sales to the territories are not included in best price.

Response: We recognize that manufacturers may have to evaluate their current business practices in regards to sales to territories. However, as discussed previously in this section, the statute requires that manufacturers calculate best price and AMP based on certain prices in the United States. Given the definition of United States in section 1101(a) of the Act, we believe that it would be inappropriate to establish a separate definition of United States for purposes of calculating rebates. Therefore, effective with the definition of ''United States'' which we are finalizing, manufacturers should treat prices paid by entities located in one of the territories in the same manner in which they treat prices paid by entities located within one of the 50 states and District of Columbia. That is, manufacturers should calculate AMP consistent with section 1927(k)(1) of the Act which provides, in part, that AMP include the average price paid to the manufacturer for the drug in the United States, which as discussed previously includes the territories.

Comment: Some commenters encouraged CMS to adopt the same practice established for manufacturers for purposes of non-FAMP, which is to require manufacturers to include such sales in their AMP and best price only if the manufacturer treats the territories as part of the United States for financial accounting purposes.

Response: We disagree with the commenter's suggestion. We believe that, in light of the definition of AMP at section 1927(k)(1) of the Act, manufacturers should calculate AMP based on the average price paid to the

manufacturer in the United States, which we have defined to include the territories. Manufacturers are required to comply with this definition, regardless of how they treat the territories for financial accounting purposes.

Comment: Many commenters indicated that the inclusion of sales to the territories in the AMP and best price calculations may have unintended consequences for Medicare Part B because manufacturers have traditionally excluded prices to the territories from the calculation of ASP because they have been excluded from best price. If manufacturers are now required to include prices to territories in AMP and best price, the commenter indicated that CMS must address whether those prices must also be included in ASP. If sales to the territories are treated differently in AMP and ASP, the commenters noted that this could lead to inappropriate substitution of AMP for ASP.

Response: We understand that changes to how manufacturers calculate AMP could have potential implications for ASP and Medicare payment. However, we believe given the small percentage of sales in the territories to total sales throughout the United States, the impact on the manufacturer's AMP and ASP will be minimal. However, we will keep the commenters' concerns in mind as we move forward with our revised AMP policy and may consider issuing additional guidance or rulemaking, if necessary.

Comment: Several commenters expressed specific concern about including sales to territories in the calculation of AMP if the buildup model were to be finalized because obtaining the necessary data from territories would be even more challenging than obtaining such data for sales within the 50 states and the District of Columbia. One commenter stated that the integrity of data from foreign entities is unknown and the inclusion of these transactions could skew both the AMP used to pay retail pharmacies in the states and the rebate amount paid on the majority of Medicaid utilization.

Response: As discussed previously in this section, we have decided not to adopt a buildup methodology requirement and therefore, we believe concerns raised by these commenters have been addressed.

Therefore, after considering the comments received and for the reasons we previously discussed in this section, we are finalizing § 447.504(c)(4), as proposed.

c. Hospitals and Hospital Pharmacy Sales (§ 447.504(c)(5))

Section 1927(k)(1)(B)(i)(IV) of the Act specifically excludes from the determination of AMP, payments received from and rebates or discounts provided to hospitals. Therefore, we proposed at § 447.504(c)(5) that direct and indirect sales to hospitals are excluded from AMP calculations (77 FR 5362). We stated in the preamble discussion that such sales include direct and indirect sales where the drug is used in either the inpatient setting or the outpatient setting (77 FR 5331). We received no comments specific to the exclusion of sales to hospitals; however, as discussed earlier in this section, commenters did note that CMS has not been consistent in the use of terminology in the determination of AMP section of the regulatory text. Therefore, based on these general comments discussed earlier in this section, as well as the statutory requirement to exclude hospital transactions from the determination of AMP we have revised § 447.504(c)(5) to include the phrase ''Sales to hospitals'' rather than ''Direct and indirect sales to hospitals,'' as we proposed. This change to the regulatory text is not meant to be substantive nor meant to change the meaning of the text.

d. Sales to Health Maintenance Organizations (HMOs) (Including MCOs) (§ 447.504(c)(6))

We proposed at proposed § 447.504(c)(6) that sales to HMOs and MCOs, including sales and associated rebates and discounts to HMO/MCO operated pharmacies, are excluded from the determination of AMP (77 FR 5331, 5362) and received the following comment concerning our proposal.

Comment: A commenter expressed support for the proposal to exclude from AMP manufacturer rebates to MCOs, while including in AMP all sales to retail community pharmacies, regardless of whether the pharmacies are later paid by MCOs.

Response: We appreciate the support.

Therefore, consistent with section 1927(k)(1)(B)(i)(IV) of the Act and the exclusion of payments received from and rebates or discounts provided to MCOs and HMOs, we are finalizing § 447.504(c)(6) as it was proposed.

e. Long-Term Care Facility Pharmacies (Proposed § 447.504(c)(7))

We proposed at proposed § 447.504(c)(7) that consistent with the exclusions from AMP at section 1927(k)(1)(B)(i)(IV) of the Act, sales and associated rebates and discounts to long-term care providers, including nursing facility pharmacies, nursing home pharmacies, long-term care facilities, long-term care facilities 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, be excluded from the determination of AMP (77 FR 5331, 5362). We further note that the exclusion of such nursing home and long-term care facility pharmacies is consistent with the entities specifically excluded from the definition of retail community pharmacy at section 1927(k)(10) of the Act. We received the following comment concerning our proposal to exclude sales to long-term care facility pharmacies.

Comment: One commenter requested that CMS provide guidance regarding what type of documentation qualifies as ''adequate'' in regards to the exclusion of sales to contract pharmacies from AMP.

Response: If a long-term care facility contracts with a pharmacy to provide drugs to its population, manufacturers may exclude those sales from AMP because the manufacturer has documented knowledge of the arrangement to support the exclusion. Otherwise, the manufacturer may make reasonable assumptions provided those assumptions are consistent with the requirements and intent of section 1927 of the Act and federal regulations.

Therefore, in regards to the exclusion of sales to long-term care facility pharmacies, for the reasons discussed in this section, and in compliance with sections 1927(k)(1)(B)(i)(IV) and 1927(k)(10) of the Act, we are finalizing § 447.504(c)(7), as proposed.

f. Mail Order Pharmacies (§ 447.504(c)(8))

We proposed at proposed § 447.504(c)(8) that sales to mail order pharmacies are excluded from the determination of AMP (77 FR 5331, 5362) consistent with sections 1927(k)(1)(B)(i)(IV) and 1927(k)(10) of the Act, which exclude such pharmacies from the definition of AMP and retail community pharmacies. We received the following comment on our proposal:

Comment: One commenter stated that CMS should clarify that drugs dispensed at a PBM's mail order facility are delivered primarily through the mail and therefore, should be excluded from the calculation of AMP.

Response: If the PBM's mail order facility is a mail order pharmacy, it is excluded from the definitions of retail

community pharmacy, as well as AMP. Therefore, sales to these mail order pharmacies shall be excluded from the calculation of AMP. Please see section II.C.6.o. for further discussion on PBMs including their mail order facilities.

Therefore, in regards to the exclusion of sales to mail order pharmacies from the AMP calculation, we are finalizing § 447.504(c)(8) as proposed because such sales are excluded from the definition of AMP in section 1927(k)(1)(B)(i)(IV) of the Act and the definition of retail community pharmacies in section 1927(k)(10) of the Act.

g. Clinics and Other Outpatient Facilities (§ 447.504(c)(9))

As discussed in the proposed rule, we proposed at proposed § 447.504(c)(9) to exclude sales and associated rebates and discounts to clinics and outpatient facilities from the determination of AMP (77 FR 5331 and 5362). We received no comments pertaining to this provision and because section 1927(k)(1)(B)(i)(IV) of the Act specifically excludes clinics from the calculation of AMP, we are finalizing § 447.504(c)(9) as proposed.

h. Government Pharmacies (§ 447.504(c)(10))

We proposed at proposed § 447.504(c)(10) to exclude sales to government pharmacies from the determination of AMP (77 FR 5331 through 5332 and 5362) since government pharmacies are specifically excluded from the definition of retail community pharmacies as defined at section 1927(k)(10) of the Act. We received no comments pertaining to this provision. Because section 1927(k)(1)(A) of the Act specifies that AMP shall include sales to wholesalers for drugs distributed to retail community pharmacies and retail community pharmacies that purchase drugs directly from the manufacturer; and because government pharmacies are excluded from the definition of retail community pharmacies as defined at section 1927(k)(10) of the Act, we are finalizing § 447.504(c)(10) as proposed.

i. Sales to Charitable and Not-For-Profit Pharmacies (§ 447.504(c)(11) and (12))

We proposed to exclude sales to charitable and not-for-profit pharmacies from the determination of AMP (77 FR 5332) because such pharmacies are specifically excluded from the definition of retail community pharmacies as defined at section 1927(k)(10) of the Act. We received the following comments concerning sales to charitable and not-for-profit pharmacies:

Comment: Several commenters noted that the proposed rule did not provide any guidance as to the lengths CMS expects manufacturers to go to determine if a pharmacy customer is a tax exempt organization or how to identify such charitable or not-for-profit pharmacies. Therefore, the commenters indicated that CMS should stipulate that manufacturers are entitled to presume their pharmacy customers are for-profit unless they are asked in writing by a particular pharmacy to extend discounts based on the entity's 501(c) non-profit status and are provided with copies of the documentation the pharmacy has from the IRS substantiating that status. The commenters indicated that if a not-for-profit pharmacy is not receiving pricing discounted from that which would otherwise be available to it in the commercial marketplace, including sales to such an entity in the calculation of AMP should have no meaningful negative or downward impact on AMP values. One commenter expressed opposition to the exclusion from AMP of sales to charitable and not-for-profit pharmacies due to the extreme challenges that manufacturers will face in maintaining an accurate and up-to-date list of such pharmacies. Furthermore, the commenter also indicated that systems will require significant upgrades to track entities and properly treat these transactions in AMP calculations.

Response: Section 1927(k)(10) of the Act specifically excludes charitable and not-for-profit pharmacies from the definition of retail community pharmacy and in light of that exclusion, such sales, as well as applicable rebates, discounts, or other transactions to charitable and not-for-profit pharmacies are to be excluded from determination of AMP consistent with section 1927(k)(1) of the Act. The IRS has an on-line search tool called Exempt Organization Select Check that is publically accessible on the IRS Web site at *http://www.irs.gov/Charities-&-Non-Profits/Exempt-Organizations-Select-Check* and is updated monthly. Therefore, manufacturers would not be required to contact all pharmacies to determine their status. Using this readily available information, manufacturers may make certain reasonable assumptions, in the absence of specific guidance, in their determinations of whether or not their pharmacy customer is a charitable or not-for-profit pharmacy, provided those assumptions are consistent with the requirements and intent of section 1927 of the Act and federal regulations.

Therefore, in regards to the exclusion of sales to charitable and not-for-profit pharmacies, we are finalizing the provisions in § 447.504(c)(11) and (12) as proposed since section 1927(k)(10) of the Act specifically excludes charitable and not-for-profit pharmacies from the definition of retail community pharmacy and in light of that exclusion, such sales, as well as applicable rebates, discounts, or other transactions to charitable and not-for-profit pharmacies are excluded from the determination of AMP as specified at section 1927(k)(1) of the Act.

j. Insurers (§ 447.504(c)(13))

Section 1927(k)(1)(B)(i)(IV) of the Act specifically excludes payments received from and rebates or discounts provided to insurers from the determination of AMP. Therefore, at proposed § 447.504(c)(13), we proposed to exclude from the determination of AMP sales to payments received from, and any rebates, discounts, or payments that are provided directly to insurers and that are not passed on to retail community pharmacies (77 FR 5332). We received the following comments concerning insurers.

Comment: One commenter noted that the proposed rule was not clear on the treatment of sales to pharmacies when the pharmacy is later paid by a federal health plan (for example, Medicare, Medicaid, TRICARE, SPAPs, and ADAPs) that operates in a similar manner as an insurer. The commenter requested that CMS clarify that sales of covered drugs to retail community pharmacies are included in AMP, regardless of whether a rebate is later provided to a health plan, and that this rule applies consistently whether the payer is a commercial or government organization functioning as an insurer.

Response: As discussed in the proposed rule (77 FR 5332), except for specific exclusions specified in section 1927(k)(1)(B) of the Act, manufacturer sales of CODs to retail community pharmacies and wholesalers for drugs distributed to retail community pharmacies are included in AMP, regardless of whether a separate rebate is later provided to a health plan. Section 447.504(c)(13) provides that rebates paid by manufacturers directly to insurers are excluded from AMP, regardless of whether the insurer is a commercial or governmental organization. As discussed in the section on prices to other federal programs for the purposes of the AMP calculations, programs such as Medicare, TRICARE, SPAPs, and ADAPs should be treated in the same manner as Medicaid. That is, consistent with section 1927(k)(1)(A) of the Act, rebates or refunds for these other federal

programs are excluded given that they are not prices paid to the manufacturer by wholesalers or retail community pharmacies, as those terms are defined in sections 1927(k)(11) and 1927(k)(10) of the Act. Furthermore, a manufacturer's sales of drugs to retail community pharmacies and wholesalers for drugs distributed to retail community pharmacies that are eventually reimbursed by programs such as Medicaid, SPAPs, and Medicare Part D, are included in the determination of AMP, but the rebates or refunds paid to these programs are to be excluded from the determination of AMP. Further discussion around the exclusion of rebates and refunds made to government programs is provided in this section.

Comment: One commenter noted that many insurers are now partnering with retail community pharmacies to dispense products to their beneficiaries (such as Safeway contracting with Express Scripts to dispense products to Express Script members). The commenter asked if it is CMS's intention that manufacturers back out these transactions and payments from their retail sales within their AMP calculations. The commenter requested that CMS keep in mind the complications this would add to manufacturers' AMP calculations.

Response: Regardless of the arrangement the retail community pharmacy (in this example, Safeway) has with an insurer, manufacturer rebates or discounts provided directly to the insurer would be excluded from AMP (under section 1927(k)(1)(B)(i)(IV) of the Act) while sales to the pharmacy would be included in AMP to the extent that the pharmacy qualifies as a retail community pharmacy, as defined in section 1927(k)(10) of the Act.

Therefore, in regards to the exclusion of sales, associated rebates, discounts, or other price concessions paid directly to insurers, we are finalizing § 447.504(c)(13) as proposed since it is consistent with the exclusion provisions in section 1927(k)(1)(B)(i)(IV) of the Act regarding payments received from and rebates or discounts provided to insurers.

k. Administrative Fees, Including Bona Fide Service Fees, as Well as the Treatment of Group Purchasing Organizations (GPOs) (§ 447.504(c)(14))

We proposed at proposed § 447.504(c)(14) that bona fide service fees paid by manufacturers to wholesalers, retail community pharmacies, or any other entity that conducts business as a wholesaler or retail community pharmacy should be excluded from the calculation of AMP (77 FR 5332, 5362). Furthermore, we proposed that such fees include, but are not limited to, inventory management fees, product stocking allowances, and fees associated with administrative agreements and patient care programs (such as medication compliance programs and patient education programs), including bona fide service fees paid to GPOs. We also proposed that to the extent that fees to GPOs meet the definition of ''bona fide service fee,'' such fees should be excluded from the determination of AMP and are not considered price concessions (77 FR 5332, 5362). We received the following comments regarding the exclusion of bona fide service fees.

Comment: One commenter noted that proposed § 447.504(c)(14) tracks the statutory text calling for the exclusion of bona fide service fees in all respects except one; it has omitted reference to ''distribution service fees.'' The commenter requested that CMS correct this oversight in the final rule.

Response: We agree and in this final rule are revising § 447.504(c)(14) to cross-reference to the definition of bona fide service fees in the § 447.502 instead of relisting all the examples in § 447.504(c)(14). The definition of bona fide service fees in § 447.502 includes distribution service fees.

Comment: We received several comments that disagreed with the proposed rule's exclusion of GPO bona fide service fees from AMP. Commenters noted that it seems illogical to exclude a bona fide service fee paid to GPOs from AMP and best price but not apply the exclusion to other entity types such as PBMs and insurers that, like GPOs, are outside the supply chain in that they do not purchase prescription drugs from manufacturers. One commenter stated that the proposed rule goes beyond the statute by excluding bona fide service fees paid by manufacturers to GPOs since these fees do not affect the price a retail community pharmacy pays for a drug, nor are they passed on to a retail community pharmacy.

Response: Any fees for services outside of the supply chain are typically excluded from the manufacturer's AMP as such fees do not affect prices paid to the manufacturer for the COD itself as required by section 1927(k)(1) of the Act. Furthermore, to the extent manufacturer fees paid to GPOs do not represent discounts, rebates, payments or other financial transactions that are received by, paid by or passed through to, retail community pharmacies in accordance with section 1927(k)(1)(B)(ii) of the Act such fees are excluded from AMP.

Comment: A few commenters believe that including PBM bona fide service fees would result in a lower AMP, which would not be an accurate reflection of the prices retail community pharmacies pay for prescription drugs. The commenter stated that they do not believe all these transactions (which include entities conducting business as a wholesaler or retail community pharmacy, secondary manufacturer for authorized generics and a wide spectrum of entities that dispense drugs subject to the AMP calculation for 5i drugs not generally dispensed through a retail community pharmacy) should be included in the calculation of AMP; however, when sales to any other entities (entities that do not conduct business as either retail community pharmacies or wholesalers) are included in AMP, any bona fide service fees paid to such entities should be excluded.

Response: It was not our intent to require manufacturers to include in the calculation of AMP service fees paid to PBMs. Section 1927(k)(1)(B)(i)(IV) of the Act excludes such fees from AMP calculations for drugs dispensed by retail community pharmacies (regardless of whether the fees meet the bona fide service definition). For 5i drugs that are not generally dispensed by retail community pharmacies, section 1927(k)(1)(B)(i)(IV) of the Act requires manufacturers to calculate an AMP for such drugs by including payments received from, and rebates or discounts provided to a list of entities, including PBMs. However, given the language in this provision, we do not believe that service fees paid by the manufacturer to PBMs represent the types of payments, or discounts or rebates that section 1927(k)(1)(B)(i)(IV) of the Act requires that manufacturers include when calculating AMP for such 5i drugs. We discuss this further in section II.C.7.d. of this final rule.

Comment: Several commenters stated that CMS should revise the current exception at § 447.504(c)(14) by replacing ''to wholesalers, retail community pharmacy, or any other entity that conducts business as a wholesaler or retail community pharmacy'' with ''to any AMP-eligible entity,'' before the phrase ''including but not limited to inventory management fees'' to broaden the application of bona fide service fee exception to include additional customer types. One commenter recommended that to the extent sales to entities other than retail community pharmacies and wholesalers are used to calculate AMP or best price, bona fide

service fees to these entities should be excluded.

Response: As provided in the previous response, a manufacturer's AMP for a COD should exclude any bona fide service fees paid to wholesalers and retail community pharmacies in accordance with section 1927(k)(1)(B)(i)(II) of the Act. The revised AMP definition at section 1927(k)(1)(B)(i)(IV) of the Act requires manufacturers to calculate an AMP for 5i drugs that are not generally dispensed through retail community pharmacies by including payments received from, and rebates or discounts provided to a list of entities that do not conduct business as wholesalers or retail community pharmacies. We do not believe inventory management fees paid by the manufacturer to the entities listed in section 1927(k)(1)(B)(i)(IV) of the Act represent the type of payments, discounts or rebates that this provision requires that manufacturers must include when calculating AMP for such 5i drugs.

As discussed in detail in section II.C.7.d. of this final rule, we have addressed those discounts, rebates and payments included in, and excluded from, the determination of AMP for 5i drugs not generally dispensed through retail community pharmacies (§ 447.504(d) and (e)).

Furthermore, as discussed in the Definitions section (section II.B.4.) of this final rule, based on comments we received, we have replaced the limiting phrase ''to wholesalers or retail community pharmacies'' with ''an entity'' in the definition of bona fide service fee at § 447.502. In response to comments and to be consistent with the definition of AMP and the sales included in and excluded from that definition, as set forth in section 1927(k)(1)(B)(i)(II) of the Act, in this final rule we are revising § 447.504(c)(14) and amending § 447.504(e) to add a new paragraph (5) to clarify that the bona fide service fees, as defined in § 447.502, are excluded from the AMP calculation. We believe these changes provide clarification and consistency to the application of bona fide service fees in the determination of AMP. We further discuss the determination of best price and the effect of bona fide service fees on a manufacturer's determination of best price in section II.D.3. of this final rule.

Comment: One commenter stated that the position taken by CMS in the proposed rule regarding price appreciation credits is improperly vague; is not an accurate interpretation of existing law; is inconsistent with CMS's approach to other fee arrangements (in this proposed rule and the AMP Final Rule); and assumes that the term price appreciation credit is a defined and standardized across the industry. The commenter stated that manufacturers and their direct purchasers enter into a multitude of diverse arrangements that may take into account changes in inventory valuation and the facts and circumstances of each arrangement determine the appropriate price reporting treatment in the AMP, best price, or ASP calculations. Another commenter requested that CMS clarify what is meant by ''price appreciation credits'' as used in the definition of bona fide service fee.

One commenter requested that CMS provide guidance as to how manufacturers should properly value the ''benefit'' that wholesalers may receive by being in possession of inventory that has undergone a price increase as a discount in their calculation. The commenter further noted that manufacturers do not generally issue actual credits to wholesalers for inventory/price appreciation. This commenter provided examples to illustrate their concerns with the operational issues surrounding this obligation.

One commenter agreed that price appreciation credits do not qualify as bona fide service fees and indicated that CMS misrepresented price appreciation credits as retroactive price appreciation credits. The commenter specified that retroactive price appreciation credits do not impact prices to customers and urged CMS to review or remove the incorrect statements regarding retroactive price appreciation credits from the final rule.

Response: We continue to believe that price appreciation credits would likely not meet the definition of bona fide service fee. Based on our experience with the program, it is our understanding that price appreciation credits are not issued for the purposes of payment for any service or offset for a bona fide service performed on behalf of the manufacturer, but rather are issued by the manufacturer to adjust (increase) the wholesaler's purchase price of the drugs in such instances when the drugs were purchased at a certain price and are remaining in the wholesaler's inventory at the time the manufacturer's sale price of the drug increased. In such situations, these credits would amount to a subsequent price adjustment affecting the average price to the manufacturer and should be recognized for purposes of AMP in accordance with § 447.504(f).

Comment: One commenter stated that different manufacturers' treatment of bona fide service fees in their calculations of AMP is an underlying root cause of volatility in the draft FULs that have been released.

Response: While it is possible that inconsistent application of what is included in and excluded from AMPs, such as bona fide service fee treatment may lead to AMP volatility, it is not the sole reason for the AMP volatility. Based on the discussions we have had with manufacturers regarding the variability in monthly AMP reporting, such volatility may be reflective of the trends in sales of drugs in the marketplace. For example, seasonal changes in drug sales can impact the AMP reporting from month-to-month. We further note that with the clarification provided in this section of the final rule (section II.C.) of what manufacturers should include in, and exclude from AMP in this rule, we believe AMPs will become less volatile.

Comment: One commenter noted that there are times when a manufacturer may agree to undertake bona fide services for pharmacies, such as providing stock and inventory management (for example, a distributor or manufacturer provides technology or services to manage and ensure pharmacy on-site inventories and supply, product requirements forecasting and inventory analysis, and/or patient reminder and compliance management). The commenter stated that when these activities are those that the wholesaler or retail community pharmacy must otherwise perform and the services are reasonable and priced at fair market value, then those fees should be excluded from AMP. This commenter recommended changes to § 447.504(c)(14) to specify that the exclusion of bona fide service fees should not be limited only to those paid by manufacturers to wholesalers and retail community pharmacies, but should also include bona fide service fees paid to manufacturers by wholesalers, retail community pharmacies, or any other entity that conducts business as a wholesaler or retail community pharmacy.

Response: We do not agree with the commenter that § 447.504(c)(14) needs to be changed to exclude from AMP service fee payments made by a wholesaler or retail community pharmacy to the manufacturer. Such fees that are paid by the wholesaler or retail community pharmacy to the manufacturer are excluded from AMP because these fees do not represent the average price paid to the manufacturer for a COD in accordance with the definition of AMP in section 1927(k)(1)

of the Act but rather payments for services rendered by the manufacturer.

After consideration of comments received and for the reasons discussed in this section, we have revised § 447.504(c)(14) to specify that bona fide service fees, as defined in § 447.502, paid by manufacturers to wholesalers or retail community pharmacies are excluded from AMP.

l. Customary Prompt Pay Discounts (§ 447.504(c)(15))

We proposed at proposed § 447.504(c)(15) that, consistent with section 1927(k)(1)(B)(i)(I) of the Act, customary prompt pay discounts extended to wholesalers should be excluded from the determination of AMP (77 FR 5332, 5362). We received the following comments regarding customary prompt pay discounts:

Comment: A few commenters noted that the statute contemplates that some sales are made directly to retail community pharmacies, and not to wholesalers, and as such, commenters urged CMS to clarify in the final rule that to the extent customary prompt pay discounts are offered to retail community pharmacies which purchase directly from the manufacturer, such discounts should also be excluded from the AMP calculation.

Response: We disagree. Section 1927(k)(1)(B)(i)(I) of the Act only excludes from the calculation of AMP customary prompt pay discounts extended to wholesalers. In accordance with section 1927(k)(1)(B)(ii) of the Act, if a manufacturer extends a customary prompt pay discount to a retail community pharmacy that purchases drugs directly from the manufacturer, such discount is included in the determination of AMP.

Comment: A few commenters expressed support for the exclusion of customary prompt pay discounts to wholesalers and encouraged CMS to finalize this proposal.

Response: We appreciate the support for the provision.

Therefore, after considering the comments and for the reasons we explained, we are finalizing § 447.504(c)(15) as proposed (77 FR 5362).

m. Returned Goods (§ 447.504(c)(16))

In the proposed rule, we proposed to incorporate the statutory requirement found at section 1927(k)(1)(B)(i)(III) of the Act at § 447.504(c)(16) which requires that reimbursement by manufacturers for recalled, damaged, expired, or otherwise unsalable returned goods, including (but not limited to) reimbursement for the cost of the goods and any reimbursement of costs associated with return goods handling and processing, reverse logistics and drug destruction be excluded from AMP. We further proposed that such reimbursement would be excluded only to the extent it covers only the costs associated with the returned goods, handling, and processing (77 FR 5332, 5362). We did not define the terms recalled, damaged, expired or unsalable, but we did request comments regarding whether we should define these terms or further define how these industry standards for these terms should be set. We also requested examples of what would qualify as unsalable. We received the following comments concerning our proposal.

Comment: Several commenters expressed support for CMS's continued exclusion of returned goods from AMP. One commenter agreed that the proposed limit on what may be excluded from AMP is a reasonable safeguard to prevent price concessions from being disguised as reimbursement for returns, and indicated that manufacturers should be able to conclude that this standard has been met where the manufacturer reimburses the returning party under a return goods policy that the manufacturer has established in good faith. Another commenter supported CMS's decision not to define returned goods or the other terms used in the statute because such terms are self-explanatory within the standard industry practice.

Response: We appreciate the support for this proposed policy and our decisions not to further define recalled, damaged, expired, or unsalable goods. As discussed in the proposed rule, we believe that these terms are self-explanatory within the standard industry practice (77 FR 5332).

Comment: Several commenters stated that the proposed rule refers to the ''good faith'' standard but does not elaborate on it and asked CMS to readopt the good faith standard from the AMP final rule. Another commenter noted that the proposed rule adds that ''the returned goods themselves'' can be excluded from AMP ''when returned in good faith.'' However, the commenter indicated that CMS did not explain whether or how this is a distinct exclusion from that which CMS is incorporating from the statutory definition of AMP, or whether the good faith requirement applies to all return transactions. The commenter further stated that CMS should clarify that manufacturers may use their own written and established company policies and procedures to define returns made in good faith and incorporate this standard at § 447.504(c)(16) by including the following sentence: ''Goods returned under manufacturer policies established in good faith.''

Response: While we stated in the preamble to the proposed rule that returned goods can be excluded from AMP when ''returned in good faith,'' we did not propose, nor have we included in this final regulation this standard as part of § 447.504(c)(16). We believe the proposed exclusion from AMP of reimbursement for returned goods is consistent with section 1927(k)(1)(B)(i)(III) of the Act as the exclusion shall only include reimbursement for recalled, damaged, expired, or otherwise unsalable returned goods, including (but not limited to) reimbursement for the costs of goods and the costs associated with return goods handling and processing, reverse logistics, and drug destruction but only to the extent the payment covers only those costs. We believe proposed § 447.504(c)(16) as proposed clarifies that the exclusion of reimbursement for returns designed to adjust prices or disguise price concessions would not be a return made in good faith because the reimbursement would cover more than the costs of goods and goods handling and processing, reverse logistics, and drug destruction. Therefore, we are adopting § 447.504(c)(16) as proposed. We further note that manufacturers typically have established internal policies regarding returned purchases and to the extent that the reimbursement by the manufacturer for returned goods is consistent with the requirements of section 1927 of the Act and federal regulations, such reimbursement made by the manufacturer shall be excluded from AMP.

Comment: A commenter explained that while a returned product may not technically be within the manufacturer's return policy, there may be extenuating circumstances whereby the manufacturer will accept the returned product and provide credit accordingly. The commenter stated that they believe that the intent is that returned goods not intended to manipulate pricing, provide discounts or any other incentive should be excluded from AMP and best price. Therefore, the commenter asked that CMS clarify the language in the final rule to state the clear intent of these terms. Additionally, the commenter noted that manufacturers may accept returned goods within 3 to 6 months of the expiration date and while they are not technically expired when returned, received and destroyed, the commenter requested confirmation that these

returned goods, not intended to manipulate pricing, may continue to be excluded from AMP and best price.

Response: We are not establishing additional standards as there are a number of business-related reasons for how manufacturers process and accept returns. To the extent a return is made consistent with the statute and the criteria established in the final rule at § 447.504(c)(16), it may be excluded from the AMP calculation.

We recognize that there may be extenuating circumstances that precipitate the need for products to be returned. If such a return does not manipulate prices, the manufacturer would exclude those return-related prices from the AMP calculation for the cost of goods and any costs associated with the return, consistent with section 1927(k)(1)(B)(i)(III) of the Act. Furthermore, if a manufacturer allows for goods to be returned within 3 to 6 months of the expiration date, we would agree that such returns, when not intended to manipulate pricing, may be excluded from AMP and best price.

Comment: Some commenters indicated that while they support excluding reimbursement for returned goods from AMP, they disagree with CMS's proposal to limit the reimbursement for returned goods to the ''cost of the goods.'' The commenters explained that in many cases the manufacturer is unable to determine the cost of the returned goods to customers because they may receive returns from indirect customers or the product is returned long after it was purchased. Therefore, it would be administratively burdensome for the manufacturer to determine the price paid for a particular unit or product by a particular customer months or even years later. The commenters suggested that CMS exclude from AMP reimbursement by the manufacturer for recalled, damaged, expired, or otherwise unsalable returned goods, where such reimbursement is provided under terms of a returned goods policy that the manufacturer has established in good faith. The commenter urged CMS to clarify the regulatory text in the final rule.

Response: As discussed in our previous response, to the extent a return is consistent with the statute and the criteria established at § 447.504(c)(16), it may be excluded from the AMP calculation. We understand that manufacturers may not be able to determine the purchase price of the returned goods because they are received from indirect customers, or the product is returned several months or even years after the initial purchase. However, we believe manufacturers have company records that record the price allowance for such goods when returned as part of their accounting procedures. Using such records, manufacturers may make reasonable assumptions when establishing the value of such goods to be excluded from AMP.

Comment: In response to CMS's request for comments on what would be considered an unsalable product, a few commenters urged CMS to consider short-dated products as unsalable products and therefore, exclude from AMP any reimbursement or credit received by retail community pharmacies or wholesalers for these products. The commenters explained that short-dated products are those within 6 months of their expiration dates that a pharmacy is either unwilling to purchase from the wholesaler or that the pharmacy purchased but believes it will be unable to dispense before the expiration date. A few commenters indicated that unsalable products also include those that a manufacturer had requested be returned for a variety of reasons meant to maintain product integrity and integrity of the distribution chain. The commenters indicated that standard industry practices and manufacturer policies should govern the determination of what is unsalable and urged CMS to adopt that standard. Another commenter explained that pharmacies often return short-dated products to ensure these products are not dispensed to patients and therefore, these products should be considered unsalable to minimize patients receiving or storing products that are about to expire. One commenter noted that it is important for CMS to recognize that what is ''unsalable'' can vary by product based on each product's shelf life. Another commenter stated that they do not believe a specific definition of ''unsalable'' is required and manufacturers should be permitted to rely upon prevailing business standards and their own good faith return policies to determine circumstances where products are unsalable.

Response: We appreciate the comments concerning what would be considered an unsalable product and agree that standard industry practices and manufacturer policies should govern the determination of what is unsalable, provided such practices are not inconsistent with section 1927 of the Act and federal regulations. It is not possible for us to generate a ''one size fits all'' standard as to what is unsalable given the varying and unpredictable characteristics of drug products (for example, potency, shelf life, or packaging). That is, what is ''unsalable'' can vary by the product and manufacturers should be permitted to rely upon prevailing business standards to determine circumstances when their products are unsalable.

Comment: A few commenters requested that CMS clarify that a manufacturer's issuance of replacement product for a returned good, rather than a refund or credit, remains excluded from AMP. The commenters noted that CMS adopted this policy under the DRA and believe there is nothing in the Affordable Care Act to prohibit the same approach now. The proposed rule does not address replacement product specifically, so the commenters requested that CMS make this clarification in the final rule.

Response: The definition of AMP at section 1927(k) of the Act for CODs is defined as the average price paid to the manufacturer for the drug in the United States by wholesalers for drugs distributed to retail community pharmacies and retail community pharmacies that purchase directly from the manufacturer. Therefore, we agree with the commenter that when a manufacturer issues a replacement product for a returned good and does not receive payment for the replacement drug, there is no price paid to be included in the manufacturer's calculation of AMP.

As a result of comments received and for the reasons we explained in this section, in this final rule we are adopting § 447.504(c)(16) as proposed to specify that reimbursement for recalled, damaged, expired or otherwise unsalable returned goods, including (but not limited to) reimbursement for the costs of goods and any reimbursement of costs associated with return goods handling and processing, reverse logistics, and drug destruction but only to the extent that such payment covers only those costs are excluded from AMP.

n. Medicare Coverage Gap Discount (§ 447.504(c)(17))

We proposed that discounts, rebates or other price concessions provided under the Medicare coverage gap discount program should be excluded from AMP (77 FR 5333, 5362) consistent with section 1927(k)(1)(B)(i)(V) of the Act which requires the calculation of AMP exclude discounts provided by manufacturers under section 1860D–14A of the Act. We received no comments pertaining to this provision, and in compliance with section 1927(k)(1)(B)(i)(V) of the Act, we are finalizing § 447.504(c)(17) as proposed.

o. PBM Sales and Price Concessions (§ 447.504(c)(18))

We proposed at § 447.504(c)(18) to exclude from the calculation of AMP, sales to PBMs including their mail order pharmacy's purchases (77 FR 5333, 5362) consistent with section 1927(k)(1)(B)(i)(IV) of the Act which excludes payments received from, and rebates or discounts provided to pharmacy benefit managers (PBMs) and mail order pharmacies (77 FR 5333). We received the following comments concerning PBM and PBM mail order sales and price concessions:

Comment: One commenter noted several concerns with the proposed language regarding exclusion of payments received from, and rebates or discounts provided to, PBMs from the determination of AMP. The commenter was concerned that the statute requires the exclusion of transactions with PBMs and mail order pharmacies irrespective of whether the mail order pharmacies are owned by or affiliated with PBMs and therefore, they should be treated separately for AMP purposes, and the sale to each should be excluded as provided in the statute. The commenter also stated that in the preamble CMS noted that the statute requires the exclusion of payments received from, and rebates or discounts provided to PBMs, but proposed § 447.504(c)(18) simply requires the exclusion of ''sales'' to PBMs. The commenter further noted that PBMs generally negotiate and receive rebates on behalf of their health plan clients that purchase the drugs, and so the sale would not be to the PBM. Thus, limiting the exclusion to ''sales'' to PBMs would improperly include these PBM rebates in AMP. Therefore, the commenter recommended that the language in the regulatory text be revised to align with the statutory exclusion of rebates and other discounts paid to PBMs.

Response: Consistent with the exclusions listed in the definition of AMP at section 1927(k)(1)(B)(i)(IV) of the Act, we agree with the commenter that mail order pharmacy sales are excluded from AMP irrespective of whether the pharmacy is owned by a PBM and as such, agree that it is not necessary to address the specific situation where a mail order pharmacy is owned by a PBM. Therefore, we are revising § 447.504(c)(18) to refer only to PBMs and remove the reference to mail order pharmacy purchasing given that mail order pharmacies are already excluded from AMP under section 1927(k)(1)(B)(i)(IV) of the Act. We have also removed the reference to ''sales'' at proposed § 447.504(c)(18) and replaced it with payments received from and rebates and discounts provided to PBMs to be consistent with section 1927(k)(1)(B)(i)(IV) of the Act which provides that ''payments received from, and rebates or discounts provided to pharmacy benefit managers . . .'' are excluded from AMP. We made this change because we agree with the commenter that it is not likely manufacturers will sell directly to PBMs unless the sale is for its pharmacy line of business (for example, mail order pharmacy). In such cases, when the sale is to the PBM for its pharmacy line of business, the manufacturer will need to determine if such sales would be included or excluded, based upon section 1927(k)(1)(B) of the Act and the definition of retail community pharmacy in accordance with section 1927(k)(10) of the Act.

Comment: One commenter noted that the preamble language of the proposed rule limited the exclusion of sales to PBMs, including their mail order pharmacies, ''to the extent that no part of the rebates, discounts, or payments are received by, paid by or passed through to retail community pharmacies'' but stated that the statute did not condition the exclusion on the payments not being passed through to retail community pharmacies. It was not clear what CMS intended with this limitation and the commenter expressed concern that it could potentially be misconstrued or interpreted so broadly to mean that simply because the PBM and retail community pharmacy are part of the same corporate enterprise, discounts obtained by the PBM are viewed as ''passed through'' to the retail community pharmacy. The commenter recommended that CMS exclude all sales to corporate enterprises that own both excluded entities, such as PBMs and mail order pharmacies, and retail community pharmacies as this is the only way to ensure that their transactions do not influence AMP in a way that would not be reflective of prices available to unaffiliated retail community pharmacies.

Response: We disagree with the commenter's suggestion that all sales to corporate enterprises that own both excluded entities, such as PBMs and mail order pharmacies, and included entities, such as retail community pharmacies should be excluded from AMP. Such an action is contrary to the statutory definition of AMP at section 1927(k)(1) of the Act which requires manufacturer sales of CODs to retail community pharmacies and wholesalers to be included in AMP. We further note that the AMP definition at section 1927(k)(1)(B) of the Act does not provide for the exclusion of retail community pharmacy or wholesaler sales when those sales are provided to a retail community pharmacy or wholesaler that is part of a corporate enterprise that may also own an entity with sales that have been excluded from AMP (for example, PBMs). In addition, section 1927(k)(1)(B)(ii) of the Act provides, in part, that notwithstanding the exclusions in section 1927(k)(1)(B)(i) of the Act, any other discounts, rebates, or payments that are passed through to retail community pharmacies should be included in AMP. Therefore, we disagree with the commenter's approach to excluding all corporate entity sales from AMP because doing so would result in excluding sales that should be included in the determination of AMP consistent with section 1927(k)(1) of the Act.

Comment: A few commenters requested specific direction regarding how manufacturers are to treat rebates paid to an AMP-ineligible entity that owns an AMP-eligible entity, such as a PBM that owns a retail community pharmacy, or an insurer that owns a specialty pharmacy. A few of the commenters asked if is it reasonable for manufacturers to assume that rebates paid to the PBM are passed down to the retail community pharmacy, and therefore, should be included in the manufacturer's calculations, or are manufacturers required to obtain documentation specifically indicating that the rebates paid to PBMs are passed down to the retail community pharmacy before such rebates can be deducted from their AMP calculation. If it is the latter, a few commenters asked if such a requirement to obtain documentation would also apply to best price calculations. Additionally, the commenters asked if CMS would expect similar treatment of rebate payments to PBMs that own specialty pharmacies. One commenter requested that CMS clarify that manufacturers can and should make reasonable assumptions regarding the treatment of PBM owned retail community pharmacy and specialty pharmacy utilization. Another commenter supported the approach where the transaction would be treated as a sale to an AMP-eligible entity since the fact of ownership does not change the characterization of the subsidiary as an AMP-eligible entity and the sales and discounts to the AMP-eligible entity should be included in the AMP calculation.

Response: Section 1927(k)(1)(B)(i)(IV) of the Act specifies that payments received from, and rebates or discounts provided to PBMs are excluded from AMP. However, if a PBM owns an entity

that meets the definition of a retail community pharmacy or wholesaler, manufacturer sales to the retail community pharmacy or wholesaler are included in AMP as required by section 1927(k)(1) of the Act. If a manufacturer knows the PBM is passing the price concessions or discounts on to the retail community pharmacy or wholesaler, the manufacturer should include the price concessions in its AMP. We recommend that manufacturers maintain the documentation that supports the inclusion of this price concession. Otherwise, the manufacturer may make reasonable assumptions that PBM discounts or price concessions are not passed on, and exclude such price concessions from the determination of AMP. As discussed in the Determination of Best Price section of this final rule (section II.D.2.), PBM discounts are excluded, but only to the extent such discounts are not designed to adjust prices at the retail level.

Therefore, for the reasons we discussed in this section, we are finalizing § 447.504(c)(18) to refer only to payments received from, and rebates and discounts provided to PBMs instead of sales to PBMs.

p. Treatment of Medicaid Rebates in AMP (§ 447.504(c)(19))

We proposed to exclude rebates under the national rebate agreement or a CMS-authorized state supplemental rebate agreement paid to state Medicaid agencies from the determination of AMP (77 FR 5333) consistent with section 1927(k)(1)(A) of the Act. In addition, we have excluded such rebates because section 1927(k)(1)(B)(ii) of the Act requires inclusion of other discounts and rebates when such rebates are received by, paid by, or passed through to retail community pharmacies. Medicaid rebates are paid by manufacturers directly to the states and are not passed through to retail community pharmacies. We received no comments pertaining to this provision and for the reason stated previously, we are finalizing § 447.504(c)(19) as proposed.

q. Sales to Hospices (§ 447.504(c)(20))

We proposed to exclude inpatient and outpatient hospice sales from the determination of AMP (77 FR 5333) since the definition of AMP at section 1927(k)(1) of the Act includes only those sales from the manufacturer to a retail community pharmacy as defined at section 1927(k)(10) of the Act or a wholesaler as defined at section 1927(k)(11) of the Act. We received no comments pertaining to this provision and for the reasons specified previously, we are finalizing § 447.504(c)(20) as proposed.

r. Sales to Prisons (§ 447.504(c)(21))

We proposed to exclude sales to prisons from the determination of AMP (77 FR 5333) since the definition of AMP at section 1927(k)(1) of the Act includes only sales from the manufacturer to a retail community pharmacy as defined at section 1927(k)(10) of the Act or a wholesaler as defined at section 1927(k)(11) of the Act. Prisons do not dispense medications to the general public and therefore do not meet the statutory definition of retail community pharmacy. Nor is a prison engaged in the wholesale distribution of drugs to retail community pharmacies. We received no comments pertaining to this provision and for the reasons stated previously, we are finalizing § 447.504(c)(21) as proposed.

s. Direct Sales to Physicians (§ 447.504(c)(22))

We proposed that direct sales to physicians be excluded from the determination of AMP (77 FR 5333) since the definition of AMP at section 1927(k)(1) of the Act includes only sales from the manufacturer to a retail community pharmacy as defined at section 1927(k)(10) of the Act or a wholesaler as defined at section 1927(k)(11) of the Act and sales to a physician does not meet either of these statutory definitions. We received one comment pertaining to sales to physicians in the context of AMP for 5i drugs not generally dispensed through retail community pharmacies.

Comment: One commenter indicated that there are discrepancies in the regulatory language of § 447.504(c) and (d) and provided as an example that § 447.504(c) excludes ''direct sales to physicians'' from the determination of AMP while § 447.504(d) includes ''Sales to Physicians'' to AMP for 5i drugs not generally dispensed through retail community pharmacies. To avoid confusion, the commenter recommended that where CMS intends to include in AMP for 5i drugs not generally dispensed through retail community pharmacies transactions excluded from AMP, CMS should revise the inclusions at § 447.504(d) to match the precise language in § 447.504(c).

Response: We agree that there may have been some ambiguity between the language in § 447.504(c) and (d), and we have made revisions to the regulatory text at § 447.504(c) and (d), where applicable, to align these sections and address the concerns of the commenter, to the extent that such revisions are consistent with section 1927(k) of the Act. Therefore, we have revised § 447.504(c)(22) to specify that it is ''Sales to physicians'' that are excluded from the calculation of AMP and have retained at § 447.504(d)(1) that it is ''Sales to physicians'' that are included in the calculation of AMP for 5i drugs not generally dispensed through retail community pharmacies.

Therefore, for the reasons noted, we are finalizing § 447.504(c)(22) to specify that it is ''Sales to physicians'' that are excluded from the calculation of AMP.

t. Direct Sales to Patients (§ 447.504(c)(23))

We proposed that direct sales to patients be excluded from the determination of AMP (77 FR 5333) since the definition of AMP at section 1927(k)(1) of the Act includes only sales from the manufacturer to a retail community pharmacy as defined at section 1927(k)(10) of the Act or a wholesaler as defined at section 1927(k)(11) of the Act and direct sales to patients do not meet either of these statutory definitions. We received the following comments concerning direct sales to patients:

Comment: We received a few comments in support of our proposal to exclude direct sales to patients from the determination of AMP for all drugs (including 5i drugs not generally dispensed through retail community pharmacies). One commenter noted that patients are not within the list of purchasers included in AMP-eligible entities (including the expanded list of AMP-eligible entities for 5i drugs not generally dispensed through retail community pharmacies) and transactions with, and benefits provided to, patients should be irrelevant to both calculations.

Response: We appreciate the support for this proposal that direct patient sales be excluded from a manufacturer's determination of AMP. Further discussion regarding the exclusion of patient sales from AMP for 5i drugs not generally dispensed through retail community pharmacies is discussed in section II.C.7.d. of this final rule.

Therefore, because AMP is defined, in part, as the average price paid to manufacturers by wholesalers and retail community pharmacies and patients are not included in the definitions of retail community pharmacy at section 1927(k)(10) of the Act or wholesaler at section 1927(k)(11) of the Act, we are finalizing § 447.504(c)(23), as proposed.

u. Free Goods (§ 447.504(c)(24))

We proposed that when a drug or any other item is given away, but not

contingent on any purchase requirement, there is no sale. Therefore, the transaction would be excluded from the determination of AMP (77 FR 5333) because there is no price paid to the manufacturer for the drug consistent with the definition of AMP at section 1927(k)(1) of the Act. We received no comments pertaining to this proposed provision and for the reasons noted, we are finalizing § 447.504(c)(24) as proposed.

v. Manufacturer Coupons, Voucher Programs, Manufacturer-Sponsored Drug Discount Card Programs, Manufacturer-Sponsored Patient Refund/Rebate Programs, and Copayment and Patient Assistance Programs (§ 447.504(c)(25) Through (29))

We proposed that five categories of discounts or benefits to patients are to be excluded from the determination of AMP (77 FR 5333 through 5334, 5362). Because such discounts or benefits are not passed through to retail community pharmacies, we proposed in accordance with section 1927(k)(1)(B)(ii) of the Act that: (1) Manufacturer coupons to a consumer redeemed by the manufacturer, agent, pharmacy, or another entity acting on behalf of the manufacturer should be excluded from AMP, 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; (2) manufacturer vouchers should be excluded from the determination of AMP; (3) prices negotiated under manufacturer-sponsored drug discount programs should be excluded from the determination of AMP; (4) goods provided free of charge under manufacturer-sponsored patient refund or rebate programs should be excluded from the determination of AMP; and (5) goods provided free of charge under manufacturer copayment assistance programs and patient assistance programs should be excluded from the determination of AMP (77 FR 5362). As discussed in the preamble, such discounts or benefits are excluded only to the extent that the full value of the discount/coupon is passed on to the customer, and the pharmacy, agent or other entity does not receive any price concession (77 FR 5333 through 5334).

(1) Comments Regarding Manufacturer-Sponsored Patient Assistance Programs

We have grouped the comments and responses for these five categories together as many of the comments we received pertained to more than one of the categories and thus they are interrelated. We received the following comments concerning these programs that provide discounts or benefits for patients:

Comment: A few commenters expressed support for CMS's exclusion of discounts or benefits provided under patient assistance programs from the determination of AMP, as it is consistent with the view that patients are not a type of customer that is eligible for consideration in the AMP calculation. One commenter stated that since manufacturer discount (patient assistance) programs that assist customers are not designed to provide discounts to retail community pharmacies, discounts or benefits provided under such programs should be excluded from AMP without caveats or conditions.

Response: We agree because we believe the discount or benefits provided under these programs generally do not affect the prices paid by wholesalers or retail community pharmacies and therefore, should be excluded from AMP in accordance with section 1927(k)(1) of the Act.

Comment: One commenter noted that proposed regulatory text for these five categories in AMP and best price is not consistent with the discussion of each in the preamble. The commenter provided a detailed chart outlining the differences between AMP exclusions in the proposed rule preamble and in the proposed rule regulatory text.

For Patient Refund/Rebate Programs, the commenter stated that the inconsistency between the preamble and the regulatory text makes the regulatory text read like it only involves free goods, but in the preamble it reads like payments to reimburse some or all of a patient's out-of-pocket costs. Furthermore, the commenter noted that the language describing the copayment and Patient Assistance Programs (PAPs) in the regulatory text leaves out part of the details described in the preamble and stated that CMS should clarify that discounts or benefits provided under manufacturer-sponsored copayment and PAPs are excluded from AMP even if they do not involve goods provided free of charge (as long as the program benefits are provided entirely to the patient).

Similarly, the commenter noted that the proposed regulatory text for manufacturer coupons excludes coupons ''but only to the extent the full value is passed on to the consumer and the pharmacy, agent, or other entity [that redeems the coupon] does not receive any price concession,'' but does not specify that the pharmacy must not receive price concessions in describing the manufacturer vouchers, drug discount card programs or patient refund/rebate programs. By contrast the preamble does specify that the pharmacy not receive price concessions in discussing all four categories of programs. With regard to Voucher Programs and Drug Discount Card Programs, the commenter noted that the preamble provides details not included in the regulatory text regarding the qualifications for discounts or benefits provided under vouchers and Drug Discount Card Programs to be excluded from AMP.

The commenter recommended that CMS clear up the discrepancies in the final rule and suggested that CMS adopt a simple provision specifying that ''discounts or benefits to patients are excluded from AMP and best price.'' The commenter explained that because patients are not AMP-eligible or best price-eligible customers, one general exclusion is appropriate and further complexity should be avoided. However, the commenter stated that if CMS wished to adopt a more complex approach with multiple exclusions related to patient discounts, then the commenter encouraged CMS to specify in the regulatory text all of the conditions that must be satisfied to make discounts or benefits provided under a particular program excluded and to describe them consistently in the final rule's regulatory text and preamble. Furthermore, CMS should define these programs so that manufacturers can be sure what conditions for exclusion apply to a particular arrangement, otherwise a manufacturer may have difficulty determining under which rules a certain arrangement should be evaluated. Additionally, the commenter requested that CMS clarify the circumstances in which a discount, rebate, or price concession is ''received'' by a retail community pharmacy. The commenter stated that a benefit provided to a patient at the pharmacy counter is not ''received by'' the pharmacy even though it may be temporarily channeled through the pharmacy and therefore is excluded from AMP and best price.

Response: We appreciate these comments and have reviewed the proposed regulatory text for these provisions. We do not agree with the commenter's recommendation to adopt one general provision specifying that discounts or benefits to patients are excluded from AMP and best price because there are variations and nuances about how each program is treated within AMP and best price; thus, each should be addressed in its respective provision regarding

exclusions. However, we do agree that there are some discrepancies between what was proposed in the preamble language and the regulatory text and believe that, as suggested by the commenter, revisions are needed to the regulatory text to more fully describe all of the conditions that must be satisfied to make discounts or benefits provided under a particular program excluded as discussed in the proposed rule (77 FR 5330 through 5338). Therefore, we are making revisions to the AMP and best price sections of the final rule in response to these comments.

First, we are finalizing proposed § 447.504(c)(25) which pertains to manufacturer coupons as it was proposed, except we are adding AMP eligible before the term ''entity'' to clarify to which types of entities we are referring since similar changes are being made to proposed § 447.504(c)(26) through (29), as described in detail in this section.

Second, we removed reference to Patient Assistance Programs (PAPs) from proposed § 447.504(c)(29) and have grouped them with vouchers at § 447.504(c)(26). We have grouped these types of programs together because they are specifically designed to offer free goods. Additionally, we are clarifying that the voucher or benefit provided by the PAPs or other manufacturer-sponsored program must not be contingent on any other purchase requirement to be consistent in our treatment of free goods within AMP. We recognize that we included some discussion in the proposed rule regarding future purchase contingencies associated with patient assistance programs (77 FR 5333); however, we see no reason that we should establish a different standard for discounts or benefits provided under such programs. As discussed previously, we proposed and are finalizing at § 447.504(c)(24) that AMP shall exclude free goods, not contingent upon any purchase requirement. Therefore, we have included a similar standard with these manufacturer-sponsored programs because we see no reason that manufacturers should treat the free goods provided under these patient assistance and voucher programs any differently from how such goods are treated in § 447.504(c)(24). Furthermore, we are clarifying that for the discount or benefit of the voucher or manufacturer-sponsored program to be excluded from AMP, then the full value of the voucher or benefit of the manufacturer-sponsored program must be passed on to the consumer, and that the retail community pharmacy, its agent, or other AMP eligible entity must not receive any price concession. These changes are designed to provide clarification and consistency in the regulatory text as was requested by the commenters, as well as to ensure manufacturer compliance with section 1927(k)(1)(B)(ii) of the Act, which essentially requires that any price adjustments passed on to retail community pharmacies be included in AMP. Similar changes are being made to the AMP for 5i drugs not generally dispensed through retail community pharmacies exclusions at § 447.504(e)(14), as well as the best price exclusions at § 447.505(c)(12) to ensure consistency in the treatment of these programs.

Third, proposed § 447.504(c)(27), which pertains to discounts or benefits provided under manufacturer-sponsored drug discount card programs, has been revised to add the contingency that the full value of the discount is passed on to the consumer, and the pharmacy, its agent or other AMP-eligible entity does not receive any price concession. We also removed the reference to ''prices negotiated under'' to reduce redundancy in this section of the rule. These changes are being made to provide clarification and consistency in the regulatory text, as was requested by the commenters, as well as to ensure manufacturer compliance with section 1927(k)(1)(B)(ii) of the Act which essentially requires that any other price adjustments passed on to retail community pharmacies shall be included in AMP. Similar changes are being made to the AMP for 5i drugs exclusions at § 447.504(e)(15), as well as the best price exclusions at § 447.505(c)(8) to ensure consistency in the treatment of these programs.

Fourth, we have revised proposed § 447.504(c)(28), in light of the comment about the inconsistency between the proposed regulatory text reference to goods provided free of charge (77 FR 5362) and the preamble reference to full or partial refunds of a patient's out-of-pocket costs (77 FR 5333). Additional discussion regarding this discrepancy and the subsequent revision is provided in this section in the response to other comments. However, we wish to acknowledge here that we agree with the commenters that manufacturer-sponsored patient refund/rebate programs typically offer refunds or discounts, not free goods to patients, and therefore, we have revised § 447.504(c)(28), to remove the language ''provided free of charge.'' Furthermore, we have added to the regulatory text of § 447.504(c)(28), the contingency included in the preamble reference (77 FR 5333) that the manufacturer may exclude the discount or benefit provided under such refund/rebate programs where the manufacturer provides a full or partial refund or rebate to the patient for out-of-pocket costs and the pharmacy, agent, or other AMP-eligible entity does not receive any price concessions. While this condition was discussed in the preamble regarding the exclusion of manufacturer-sponsored patient refund/rebate programs, it was inadvertently omitted from the regulatory text of the proposed rule (77 FR 5333 and 5362).

As indicated from the preamble discussion in the proposed rule (77 FR 5333), it was our intention that this contingency language apply to the exclusion of the discount or benefit provided under manufacturer-sponsored patient refund/rebate programs, but as noted by the commenters the proposed regulatory text did not provide the same level of detail (77 FR 5362). Therefore, we are adding this detailed language to the regulatory text of this final rule to provide clarification about the exclusion of the discount or benefit provided under manufacturer-sponsored patient refund/rebate programs from the determination of AMP to ensure compliance with section 1927(k)(1)(B)(ii) of the Act, which as discussed previously, essentially requires that any price adjustments passed on to retail community pharmacies shall be included in AMP. Similar changes are being made to the AMP for 5i drugs not generally dispensed through retail community pharmacies exclusions at § 447.504(e)(16), as well as the best price exclusions at § 447.505(c)(11) to ensure consistency in the treatment of these programs.

Fifth, § 447.504(c)(29), now pertains solely to discounts or benefits provided under Manufacturer copayment assistance programs because we are moving Patient Assistance Programs to § 447.504(c)(26) as discussed in this section. Proposed section § 447.504(c)(29) was also revised to remove the language ''provided free of charge'' as these types of programs typically offer copayment assistance, which may or may not result in free goods to patients and to include discussion from the preamble discussion in the proposed rule that discounts or benefits provided under such programs may only be excluded from AMP to the extent that the pharmacy, agent, or other AMP eligible entity does not receive any price concession (77 FR 5333 through 5334). Additional discussion regarding this discrepancy and the subsequent revision is provided in this section in the response to other comments.

However, we wish to acknowledge that we agree with the commenters that the language describing the copayment assistance programs in the regulatory text leaves out details described in the preamble regarding Manufacturer copayment assistance programs; specifically that Manufacturer copayment assistance programs typically offer copayment assistance or discounts, not free goods, to patients. Therefore, we have revised proposed § 447.504(c)(29) to remove language concerning goods provided free of charge.

Furthermore, we have added the contingency, consistent with section 1927(k)(1)(B)(ii), that the program benefits are provided entirely to the patient, and that the pharmacy, its agent, or other AMP-eligible entity does not receive any price concessions. As pointed out by the commenter, this condition was discussed in the preamble regarding the exclusion of discounts or benefits provided under Manufacturer copayment assistance programs, but it was inadvertently omitted from the regulatory text of the proposed rule (77 FR 5333 and 5362). As indicated in the preamble discussion in the proposed rule (77 FR 5333 through 5334), it was our intention that this contingency language apply to the exclusion of discounts or benefits provided under Manufacturer copayment assistance programs, but as noted by the commenters the proposed regulatory text did not provide the same level of detail (77 FR 5362). Therefore, we are adding this detailed language to the regulatory text of final rule to provide clarification about the exclusion of discounts or benefits provided under Manufacturer copayment assistance programs from the determination of AMP to ensure manufacturer compliance with section 1927(k)(1)(B)(ii) of the Act, which requires, essentially, that any price adjustments passed on to retail community pharmacies shall be included in AMP. Similar changes are being made to the AMP for 5i drugs not generally dispensed through retail community pharmacies exclusions at § 447.504(e)(17), as well as the best price exclusions at § 447.505(c)(10) to ensure consistency in the treatment of these programs.

In addition, we do not agree with the commenter's request that we define each of these programs, because there is no one industry standard definition for each of these types of programs. Instead we believe that the level of specificity that we have added to the regulatory text provides sufficient detail for manufacturers to be able to determine under which ''program'' their manufacturer specific program should be categorized. Once a manufacturer has made that determination, it will need to determine if the discounts or benefits provided under its program meets the specific regulatory requirements as set forth in § 447.504(c) to be excluded from the determination of AMP.

As to the commenter's request that CMS clarify the circumstances in which a discount, rebate or price concession is ''received'' by a retail community pharmacy, we agree with the commenters assessment that a benefit provided to a patient, even if it is provided at the pharmacy counter, is not a discount, rebate, payment or other financial transactions received by or passed through to the retail community pharmacy that must be included in AMP in accordance with section 1927(k)(1)(B)(ii) of the Act. As stated in this section, once the manufacturer determines under which ''program'' their manufacturer specific program should be categorized, the manufacturer must then determine if the discounts or benefits provided under the program meets the specific regulatory requirements of § 447.504(c) to be excluded from the determination of AMP or best price.

Furthermore, we want to ensure consistent treatment of discounts or benefits provided under manufacturer-sponsored programs that provide free goods or subsidies to patients in the calculation of AMP and best price, such as those described in the AMP exclusions at § 447.504(c)(26), § 447.504(e)(14), as well as the best price exclusions at § 447.505(c)(12).

We intend to issue guidance to provide consistency among manufacturers treatment of the ''any purchase requirement'' of the free goods provision and to ensure that the discounts or benefits provided under programs being excluded from AMP and best price are programs that are designed to benefit or assist only the patient, without any purchase contingencies, rather than designed to increase manufacturer sales or profits.

Comment: One commenter noted that typically after a pharmacy processes a voucher it receives a payment from the manufacturer to make it whole for the product dispensed plus a fee that is tantamount to a dispensing fee. The commenter indicated that this transaction is separate from the discount that is passed on to the patient and should be evaluated independently for inclusion in AMP or best price under the proposed four-part test for bona fide service fee.

Response: We would agree that a fee paid to the retail community pharmacy from the manufacturer for the pharmacy to process a voucher should be considered separately and would likely be a bona fide service fee; however, we would need to know the facts and circumstances surrounding the arrangement to fully evaluate whether the fee is a bona fide service fee in accordance with section 1927(k)(1)(B)(i)(II) of the Act and this final rule.

Comment: A few commenters requested that CMS clarify that if a patient program does generate price concessions to an AMP-eligible entity, such as a service fee to a retail community pharmacy that does not satisfy the bona fide service fee definition, that the appropriate treatment is to include that price concession in AMP but to continue to exclude the cost of the program benefits to the patient from AMP. The commenters requested that CMS clarify in the final rule that the patient remains excluded from the calculation and therefore, the manufacturer program benefits provided to the patient should be excluded as well.

Response: In instances when a retail community pharmacy is receiving a service fee paid by a manufacturer to assist with the administration of a patient program, such fees would be excluded to the extent the fees meet the bona fide service fee definition as being a fee paid by the manufacturer that represents fair market value for a bona fide, itemized service actually performed on behalf of the manufacturer that the manufacturer would otherwise perform in the absence of the service arrangement and that is not passed on in whole or in part to a client of customer of an entity. When the manufacturer is providing a price concession (discount) to a patient under its patient assistance program via a retail community pharmacy, it is typically not a fee to which the bona fide service fee test would be applied, but rather a price concession being provided to the patient as part of the patient assistance program. Since the price concession is passed on to the patient, the patient program's discount is excluded because the pharmacy does not receive the price concession. We note that such determinations about patient programs are based on the facts of each program and the program's compliance with section 1927 of the Act and federal regulations.

Comment: Commenters requested that CMS clarify that vouchers for free goods provided to a patient by a provider are exempt from AMP whether or not the

provider is made whole through payment in cash or in kind.

Response: We agree that vouchers for free goods, which are not contingent upon any purchase requirement, that are provided by a provider to a patient should be excluded from AMP regardless of whether the provider is made whole (reimbursed for the cost of the product) through payment in cash or in kind.

Comment: A few commenters indicated that CMS may have mistakenly limited the exclusion from AMP for copayment assistance to the provision of goods free of charge. The commenters explained that free goods are typically provided to patients under a patient assistance program or through vouchers, whereas copayment assistance programs do not provide free goods, but rather help cover the insured patient's share of the payment for the drug at the point of sale. To avoid confusion, the commenters requested that CMS change § 447.504(c)(29) to remove copayment assistance programs as free goods are not provided under these programs and to clarify that payment assistance provided under a copayment assistance programs is excluded from AMP. One of these commenters also suggested changing the regulatory exclusion for patient refund or rebate programs at §§ 447.504(c)(28) and 447.505(c)(11) to read ''full or partial refunds or rebates to patients under manufacturer-sponsored patient refund/rebate programs.''

Response: We agree with the commenters regarding the differences between copayment assistance programs and patient assistance programs or vouchers. As discussed in earlier responses, we have revised proposed § 447.504(c)(29) to remove mention of patient assistance programs in this provision and focus instead only on manufacturer copayment assistance programs. Furthermore, we have revised proposed § 447.504(c)(26) to include manufacturer-sponsored programs that provide free goods, including but not limited to vouchers and patient assistance programs. In addition, as discussed previously, we have revised proposed § 447.504(c)(28) to remove the reference to goods provided free of charge and to include an exclusion for manufacturer-sponsored patient refund/rebate programs to the extent that the manufacturer provides a full or partial refund or rebate to the patient for out-of-pocket costs and the pharmacy, agent, or other AMP eligible entity does not receive any price concessions. We believe these revisions address the concerns of these commenters as we have established separate categories of manufacturer programs to distinguish between those that provide free goods versus those that provide copayment assistance. In addition, as discussed in the preamble to the proposed rule, these revisions address section 1927(k)(1)(B)(ii) of the Act, which requires, in part, that manufacturers include in AMP, such discounts, rebates, and payments to the extent that they are passed through to retail community pharmacies. As discussed in section II.D., we are making similar changes to the regulatory language of the determination of best price section as well.

Comment: A few commenters requested that CMS specifically confirm that the detailed criteria for identifying patient programs under the AMP Final Rule are no longer applicable if a particular transaction meets the standards of the proposed rule.

Response: The revisions to § 447.504(c)(25) through (29), § 447.504(e)(13) through (17), and § 447.505(c)(8) through (12) in this final rule clarify the criteria for identifying when discounts or benefits provided under patient programs are to be included in or excluded from the determination of AMP and best price. Furthermore, as stated in an earlier response, we want to ensure consistent treatment of manufacturer-sponsored programs that provide free goods or subsidies to patients in the calculation of AMP and best price. The criteria that the commenter referenced from the July 27, 2007 AMP Final Rule (72 FR 39189) was provided as guidance regarding criteria that should be considered when determining which manufacturer-sponsored programs that provide free goods are eligible for exclusion from AMP and best price. This guidance was part of a regulation that was withdrawn. We expect to issue new guidance in the future.

(2) Commenter Regarding State Pharmacy Assistance Programs (SPAPs)

We received comments about other patient assistance programs that are established by entities other than manufacturers. Specifically, we received comments pertaining to SPAPs and have chosen to address the comment in this section because SPAPs can be a form of patient assistance programs.

Comment: Several commenters noted that the proposed rule does not specifically mention SPAP sales or prices in the context of AMP even through it instructs manufacturers that such sales do not set a price point for the determination of best price. Since the discounts enjoyed by SPAPs are not available to retail community pharmacies that dispense prescriptions to SPAP enrollees, the commenters requested that CMS add an SPAP-specific exclusion to the final rule for both retail community pharmacy AMP and AMP for 5i drugs not generally dispensed through retail community pharmacies. The commenters also requested that CMS clarify that SPAP sales through retail community pharmacies are to be included in AMP and only SPAP rebates are to be excluded from AMP. One commenter requested that CMS rectify this oversight by adding rebates paid to SPAPs to the list of exclusions from AMP.

Response: For the purpose of calculating AMP, we agree that rebates paid to SPAPs are to be excluded from the calculation of AMP and AMP for 5i drugs not generally dispensed through retail community pharmacies, because the definition of AMP in section 1927(k)(1) of the Act does not contemplate the inclusion of such rebates. As discussed for manufacturer-sponsored programs, rebates, discounts, or price concessions provided to entities other than retail community pharmacies and wholesalers, as defined in sections 1927(k)(10) and 1927(k)(11) of the Act, should not be included in AMP. Such rebates, discounts, or price concessions do not adjust prices paid to the manufacturer by wholesalers or retail community pharmacies and thus, in accordance with section 1927(k)(1) of the Act, should be excluded by the manufacturer when calculating AMP. Therefore, we are adding § 447.504(c)(30) to clarify that rebates, discounts, or price concessions paid to SPAPs are excluded from the calculation of AMP. We have included a similar provision at § 447.504(e)(10) in the AMP for 5i drugs not generally dispensed through retail community pharmacies as further discussed in section C.II.7.d of this preamble.

Therefore, in response to comments and for the reasons discussed in this section, we are finalizing the provisions pertaining to patient assistance programs as follows:

- Proposed § 447.504(c)(25) pertaining to manufacturer coupons is finalized as proposed, except to add ''AMP eligible'' before the term ''entity'' to clarify to which types of entities we are referring.
- Proposed § 447.504(c)(26) is revised to include a reference to manufacturer-sponsored programs that provide free goods and patient assistance programs, but only to the extent that the voucher or benefit of such a program is not contingent on any other purchase requirement; the full value of the

voucher or benefit of such program is passed on to the consumer; and the pharmacy, agent, or other AMP eligible entity does not receive any price concession.

- Proposed § 447.504(c)(27) is revised to delete the reference to ''prices negotiated under'' and to include a reference to the requirements that the full value of the discount is passed on to the consumer, and that the pharmacy, agent, or other AMP eligible entity does not receive any price concession.
- Proposed § 447.504(c)(28) is revised to delete the reference to ''goods provided free of charge'' and to include a reference to the requirements that the manufacturer provides a full or partial refund or rebate to the patient for out-of-pocket costs, and that the pharmacy, agent, or other AMP eligible entity does not receive any price concession.
- Proposed § 447.504(c)(29) is revised to delete the reference ''to goods provided free of charge'' and ''patient assistance programs'', and to include a reference to the requirements that the program benefits are provided entirely to the patient and that the pharmacy, agent, or other AMP eligible entity does not receive any price concession.
- Adding § 447.504(c)(30) to clarify that rebates, discounts, or price concessions paid to designated SPAPs are excluded from the calculation of AMP.

7. Inhalation, Infusion, Instilled, Implanted, and Injectable Drugs (§ 447.502, § 447.507, and § 447.504(d) Through (e))

We proposed to add a definition of 5i drug in the regulatory text of § 447.502 and we proposed to add new § 447.507 (Identification of 5i drugs) to indicate how 5i drugs are to be identified and how the term ''not generally dispensed'' is to be interpreted for 5i drugs. We also proposed to add § 447.504(d) to specify which sales, associated discounts, rebates, payments, and other financial transactions should be included in the determination of AMP for 5i drugs. These proposed provisions are discussed in more detail at 77 FR 5327, 5334 through 5336, 5359, 5362, and 5363. As discussed in more detail in the definition section of this final rule (section II.B.), we have decided not to finalize the definition of 5i drug that was proposed in the definition section of the proposed rule (77 FR 5359). Instead, we will use the acronym of ''5i drug'' to refer to inhalation, infusion, instilled, implanted, or injectable drugs. We received numerous comments concerning the proposed 5i drug provisions. These comments and responses are detailed later in this section.

a. Identification of 5i Drugs (§ 447.507(a))

At § 447.507(a), we proposed to use FDA's Routes of Administration posted on the CMS Web site to identify 5i drugs (77 FR 5334 and 5363). We received the following comments pertaining to this proposal.

Comment: Several commenters expressed opposition to utilizing FDA SPL Routes of Administration to identify 5i drugs because it would add an unnecessary layer of complexity to an otherwise simple process, be burdensome to manufacturers, and increase the time required to update and maintain their product masters. A few commenters believed that manufacturers should be able to make the 5i determination based on the label of the product itself and that CMS should not mandate consultation with FDA guidance. One commenter stated that FDA's Routes of Administration are not published through formal rulemaking but are updated through sub-regulatory guidance and if CMS finalizes its proposal to require that manufacturers consult FDA's Routes of Administration to determine 5i status, CMS should assume responsibility for notifying manufacturers when FDA's information has been updated or revised. Another commenter noted that CMS does not have oversight of FDA information and cannot ensure that the information being used is current and up to date. The commenter requested that CMS clearly state how it will ensure that information relied on by states for administration of pharmacy benefits will be maintained in a current fashion so that payments and delivery of pharmacy benefits to Medicaid recipients are not affected.

Response: In light of the comments, we decided to revise our proposal regarding using the FDA SPL Routes of Administration file referenced in the proposed rule (77 FR 5334, 5363). The Routes of Administration list (77 FR 5334) which we included in the proposed rule is a list that we established based upon routes of administration identified from the FDA SPL Routes of Administration file. It was our intention that manufacturers should use the Routes of Administration list as a reference tool when determining whether a drug meets the definition of a 5i drug. However, after careful review and consideration of the comments received, we are not finalizing our proposal that manufacturers use this list when identifying 5i drugs.

Furthermore, since manufacturers are knowledgeable as to how their drug is administered, manufacturers will have the flexibility to determine whether their drug is a 5i drug based on reasonable assumptions. They may make such determinations, using resources such as the manufacturer's prescribing information, drug package insert, or the FDA SPL Routes of Administration; however, we will not mandate the use of any specific resource. As discussed previously, manufacturers may continue to make reasonable assumptions in the calculation of AMP, provided such assumptions are consistent with the requirements and intent of section 1927 of the Act and federal regulations, and a written or electronic record outlining these assumptions is maintained.

Additionally, we note that manufacturers are responsible for reporting AMP and AMP for 5i drugs that are not generally dispensed through a retail community pharmacy on a monthly basis. We will provide such information to states to ensure that they have current information regarding such drugs.

Therefore, we are revising proposed § 447.507(a) to specify that manufacturers must identify to CMS each COD that qualifies as a 5i drug, and are removing the specific reference to the list of FDA's Routes of Administration.

Comment: One commenter noted that the routes of administration from FDA SPL file do not always correspond with the 5i administration methods cited in the statute (that is, inhaled, infused, instilled, implanted, or injected). As an example, the commenter cited ''transmucosal'' which is listed on FDA SPL list and found in the proposed rule. FDA defines transmucosal as a drug that is ''administered across the mucosa,'' meaning the drug passes through a mucosal membrane. However, there are some ''transmucosal'' drugs that are tablets that a patient holds on the inside of their cheek and the tablet is absorbed as it dissolves. The commenter noted that a drug administered in this manner does not necessarily fall into one of the five enumerated categories for 5i drugs found in the statute. The commenter believed that due to overlapping meanings of the definitions of certain routes of administration, the use of FDA's list could misguide manufacturers into treating certain types of drugs as 5i when categorizing them as such is inconsistent with the statute. Therefore, the commenter recommended that CMS should affirm that manufacturers are capable of deciding based on the (1) the dictionary

definition of such term, and (2) FDA-approved prescribing information and the product labeling for their product, if their drug is inhaled, infused, instilled, implanted, or injected and thus appropriately classified as a 5i drug.

Response: As previously stated in this section, in light of the comments, we decided not to finalize our proposal to use the FDA SPL Routes of Administration file referenced in the preamble discussion, as well as the regulations text of the proposed rule (77 FR 5334 and 5363). Instead, we are revising proposed § 447.507(a) to specify that manufacturers must identify which CODs qualify as 5i drugs and are removing the specific reference to the list of FDA's Routes of Administration. Additionally, as previously discussed in this section, manufacturers have the flexibility to use reasonable assumptions when determining whether their drug is a 5i drug.

Comment: One commenter noted that errors do occur with FDA posting and database maintenance and believed it would be helpful if the final rule laid out a procedure that manufacturers should follow when such situations arise to minimize any adverse impact on patient access stemming from inappropriate changes in Medicaid coverage and/or payment of the affected product. Additionally, since the technology surrounding drug delivery is evolving and new dosage forms are being developed, the commenter asked that the final rule address the procedures manufacturers should follow to determine whether a novel new product would qualify as a 5i drug.

Response: As discussed in this section, we have reconsidered our proposal regarding using the FDA SPL Routes of Administration file referenced in the preamble discussion of the proposed rule (77 FR 5334) and are revising proposed § 447.507(a) to specify that manufacturers identify which CODs are 5i drug(s). Manufacturers, when identifying 5i drugs, are not required to use any particular FDA file or publication. Therefore, the FDA posting errors and database maintenance issues raised by the commenter should not be an issue affecting a manufacturer's timely identification of 5i drugs. Furthermore, as discussed previously, since manufacturers have the flexibility to use reasonable assumptions when determining whether their drug is a 5i drug, we do not believe it is necessary to specify in this final rule the procedures manufacturers should follow to determine whether a novel new product qualifies as a 5i drug.

Comment: One commenter expressed support for CMS's premise to not require states to identify 5i drugs. However, to achieve consistency in identification of 5i products, the commenter requested that CMS identify such products rather than manufacturers. The commenter stated that whether the manufacturer or CMS identifies the 5i products, they request that the quarterly tape and DDR list the products as a common point of reference. Should CMS finalize the proposed policy without revisions, the commenter requested that CMS establish in this rule a dispute resolution policy. The commenter believed that such a process is necessary since states would be relying on manufacturers to correctly identify 5i drugs.

Response: We disagree that CMS, instead of manufacturers, should identify which CODs are 5i drugs. As previously discussed, manufacturers are knowledgeable about their products and are in the best position to identify which CODs are 5i drugs. We believe that once manufacturers identify those drugs that are 5i in our system, both states and manufacturers that use the DDR system will have access to view this product information on the quarterly rebate files. States should notify CMS if it has specific concerns regarding the identification of a product as 5i in the DDR system.

We do not believe a formal dispute resolution process regarding the identification of 5i drugs is necessary because we decided to reconsider our proposed policy that manufacturers identify 5i drugs using the FDA SPL Routes of Administration file referenced in the proposed rule (77 FR 5334 and 5363).

Comment: One commenter that also supports inclusion of drugs sold to physicians in the AMP calculation of 5i drugs suggested that CMS modify § 447.507(a) to require the collection of NDCs for AMP to be calculated and federal rebates to be available and collected.

Response: The NDC is already collected for each COD in our DDR system (including 5i drugs) when a manufacturer reports its product information to CMS.

Comment: One commenter expressed support of the proposed rule's use of the drug's route of administration to determine if the drug is a 5i drug.

Response: We appreciate this support. However, as discussed in this section, in light of comments received on this proposal, we decided to revise our proposal regarding the Routes of Administration list referenced in the proposed rule (77 FR 5334).

After consideration of the comments and for the reasons discussed in this section, we have revised proposed § 447.507 to remove the reference in § 447.507(a) that manufacturers use the list of FDA's Routes of Administration posted on the CMS Web site, to insert a requirement that manufacturers must identify their 5i drugs to CMS, and to delete the first paragraph in this provision.

b. Determination of 5i Drug's Status as ''Not Generally Dispensed''—the 90/10 Rule (§ 447.507(b)(1))

Section 1927(k)(1)(B)(i)(IV) of the Act provides, in part, that manufacturers are to exclude from the determination of AMP for a COD for a rebate period, payments received from, and rebates or discounts provided, to any other entity that does not conduct business as a wholesaler or retail community pharmacy. Section 202 of the Education, Jobs and Medicaid Funding Act (Pub. L. 111–226), enacted on August 10, 2010 and effective on October 1, 2010, amended this provision to include sales for 5i drugs that are not generally dispensed through retail community pharmacies. This provision was added to ensure that an AMP could be calculated and Medicaid rebates could be collected from manufacturers for 5i drugs that are not generally dispensed through retail community pharmacies, as discussed in the proposed rule (77 FR 5334 through 5336, 5363). To effectuate this provision, we proposed in § 447.507(b)(1) to use a 90 percent standard to determine when a drug is not generally dispensed through a retail community pharmacy. We received the following comments pertaining to this proposal.

Comment: Many commenters expressed opposition to our proposal to consider a 5i drug not generally dispensed through a retail community pharmacy if 90 percent or more of its sales were to entities other than retail community pharmacies and thought it was too stringent and would increase the possibility that products would shift in and out of the AMP calculation for 5i drugs not generally dispensed through retail community pharmacies; create the potential for AMP volatility and instability; inappropriately exclude products that should be viewed as 5i drugs not generally dispensed through retail community pharmacies; and product FULs that are less predictable. Several commenters agreed that there should be a quantitative method to determine when a drug is ''not generally dispensed'' as it would be more

meaningful than a qualitative approach, but the commenters recommended that CMS lower the threshold percentage.

One commenter was troubled by the 90/10 rule for products which barely qualify for AMP treatment because too few transactions would be included in the AMP calculation to generate reliable results and the commenter stated that if the proposed rule were to be finalized as drafted, they would expect the AMPs for some 5i drugs not generally dispensed through retail community pharmacies to be lower than the AMP currently being reported. The commenter also stated that Congress, by amending the statute to provide an alternative AMP calculation, sought to improve the accuracy of AMP calculations, and the proposal to adopt a 90 percent standard would undercut this aim. One commenter believed that CMS's interpretation of ''not generally dispensed'' goes beyond the plain reading of the statute and a lower percentage of such sales would be more appropriate.

Several commenters suggested that CMS establish thresholds at the 80/20, 75/25, 70/30, 65/35, or 51/49 because these levels would minimize fluctuation and promote stability as products tend to consistently be above or below the threshold. A few of these commenters specifically stated that a 75/25 or 70/30 threshold would be a more appropriate interpretation of the statutory language, and would ensure there are an adequate number of sales in the appropriate category to support the calculation of a reasonably accurate AMP. One of these commenters performed an analysis of the proposed threshold and alternative thresholds and found that a 75 percent threshold would minimize fluctuation and promote stability as products tend to consistently be above or below the threshold. The commenter further indicated that its analysis of the proposed 90 percent threshold caused more frequent variation in whether or not a product met the threshold. Another one of the commenters indicated that using the 90/10 threshold would cause many of its 5i drugs to flip-flop between the two AMP calculations on a month-to-month basis. The commenter further indicated that its history showed that a 70–75/30–25 threshold would provide a more consistent pattern.

Other commenters suggested that CMS should allow manufacturers the flexibility to consider qualitative factors when making the determination of whether a 5i drug is not generally dispensed through retail community pharmacies and indicated that CMS should permit manufacturers to make reasonable assumptions on whether a particular product is subject to the AMP calculation for 5i drugs not generally dispensed through retail community pharmacies. The commenters believed that a qualitative approach consisting of documented reasonable assumptions would ensure that more accurate AMPs are calculated for each product, without imposing the significant burden and costs that would result if manufacturers had to obtain potentially incomplete or otherwise inaccurate data to comply with the proposed policy.

Another commenter stated that allowing manufacturers flexibility to make reasonable assumptions for the inclusion of drugs in this quantitative standard, based on objective drug characteristics, could further reduce AMP volatility.

Response: When we proposed the 90 percent threshold, we thought that this measure would be appropriate for determining when a drug is not generally dispensed through a retail community pharmacy because it would ensure that drugs not otherwise included in the AMP calculation would be included and reflected in the AMP for such 5i drugs. However, the comments we received have overwhelmingly brought to light concerns regarding this high threshold leading to AMP volatility and fluctuations, as well as not concerns regarding our interpretation of what it means to be ''not generally dispensed.'' We agree with the commenters that a 90 percent threshold would likely result in a limited amount of the product's overall sales being used by the manufacturer to establish an AMP. Given the comments that raised concerns regarding inclusion of an inadequate amount of overall product sales to establish an AMP and volatility of the AMP, we have reconsidered our proposal and agree with commenters that a 90 percent threshold may not accurately reflect what it means to be not ''generally'' dispensed through retail community pharmacies.

We recognize, in light of the comments, that the 90 percent threshold is overly restrictive and sets a threshold that is indicative of instances when most, if not all, of the sales would be to entities other than retail community pharmacies. However, as discussed in the proposed rule (77 FR 5335), we have concerns about setting a lower threshold, such as 50 percent because half of the manufacturer's sales would have been to retail community pharmacies.

Therefore, to address the concerns of commenters for more flexibility, to reduce volatility of AMP, and to ensure sufficient sales to be included in AMP while at the same time appropriately restricting the inclusion of 5i drugs to those that are not generally dispensed through retail community pharmacies, we have decided to adopt the suggestion of the commenters and establish the threshold at 70 percent. Based on the comments received including the analyses performed by the commenters, we believe that a threshold of 70 percent of sales to entities other than retail community pharmacies is more likely than a 90 percent threshold to allow for an AMP calculation based on a sufficient number of sales, which would promote stability and consistency in the AMP calculation, consistent with section 1927(k) of the Act. Thus, a 5i drug would be considered not generally dispensed through a retail community pharmacy when the manufacturer determined that 70 percent or more of its sales, in units (the choice of ''unit'' is discussed later in this section), are to entities other than retail community pharmacies. However, we will continue to consider this issue and will issue additional guidance or rulemaking, if needed, regarding any concerns with implementation of this standard.

Furthermore, as discussed later in this section, we are permitting manufacturers to make reasonable assumptions, and include a smoothing process to determine if the percent of sales (in units) were sufficient to meet the ''not generally dispensed'' threshold.

Comment: Several commenters requested that CMS clarify whether manufacturers are to determine whether the threshold is based on units or dollars and whether the calculation would be made at the NDC–9 or NDC–11 level. Additionally, the commenter indicated that CMS should provide manufacturers the flexibility as to which data should be used for conducting the ''not generally dispensed determination,'' provided that the methodology is otherwise consistent with the company's business practices.

Response: We agree with the commenters that suggested that the not generally dispensed determination should be based on units, not dollars, and that it should be calculated at the NDC–9 level as this is inclusive of all package sizes. While section 1927(k)(1)(B)(i)(IV) of the Act provides for inclusion of payments, rebates, or discounts, for the 5i drugs that are not generally dispensed through retail community pharmacies, it does not mandate that manufacturers use units, as opposed to pricing data, to determine if a 5i drug is not generally dispensed through retail community pharmacies.

However, we believe that manufacturers use of units will ensure consistency in the data being reported to CMS, and will not cause undue burden on the manufacturers as they are already required to report unit data to CMS in accordance with section 1927(b)(3)(A)(iv) of the Act and the requirements outlined in § 447.510(d)(6). Additionally, we believe that the use of pricing data, instead of units, could lead to distortions based on price fluctuations, as noted in the comments, and would not necessarily allow for making determinations based on whether the drug is dispensed through retail community pharmacies.

Comment: A few commenters recommended that manufacturers be permitted to review data within the last 12-months to make the ''not generally dispensed'' determination, noting that end-customer sales data are not available in time to support a determination for the current period, and that analysis be based on sales units rather than sales dollars to avoid distortions due to price changes over time. Another commenter suggested that CMS should adopt a smoothing approach whereby the manufacturer would apply the ''not generally dispensed'' test based on data from the last 12-months, inclusive of the current reporting period, which would help to even out any seasonal or other temporary changes in the distribution of sales, increasing the consistency of AMP reporting.

Response: We agree with the commenters and have decided to allow the use of a smoothing process, as we believe such a process would permit manufacturers to determine general dispensing patterns of a drug over a period of time, such as a 12-month period, resulting in more consistency in the AMP calculation as there should be a reduction in the number of instances when the AMP methodology would need to be revised to account for different sales required to be included in or excluded from the AMP calculation. While we will not be mandating the use of a smoothing process in regards to the calculation of AMP for such 5i drugs, we believe that a smoothing process could be beneficial to manufacturers who might experience fluctuations in sales throughout the year. We believe that permitting manufacturers the option to use data from a current, yet longer, period of time to make the ''not generally dispensed'' determination is reasonable given that section 1927(k)(1)(B)(i)(IV) of the Act does not specify the use of data from a specific length of time. The provision provides for inclusion of sales for the 5i drugs that are not generally dispensed through retail community pharmacies to help ensure that rebates are collected for these 5i drugs; however, it does not prescribe a specific length of time for the ''not generally dispensed'' determination. Therefore, a manufacturer may consider the use of smoothing process as part of its reasonable assumptions so long as the manufacturer documents those reasonable assumptions and consistently applies them across all products included in the AMP calculation for such 5i drugs.

Comment: One commenter believed that the application of the non-FAMP standard to identify a 5i drug for purposes of performing an alternative AMP calculation is misplaced and goes beyond the plain language of the statute. One commenter noted that the draft Amended Master Agreement (9/7/00 draft) cited by CMS to justify a 90 percent threshold has not been finalized, nor is it available to the general public and is therefore not an authoritative basis for CMS regulatory action. Moreover, the commenter indicated that the language in the Amended Master Agreement relates to a different issue and is designed to enable manufacturers to calculate a non-FAMP where it does not ordinarily distribute through wholesalers.

Response: As previously discussed in this section, we have decided not to adopt the 90 percent threshold and believe that a threshold at 70 percent will provide for more flexibility, reduce volatility of AMP, and ensure sufficient sales to be included in AMP while appropriately restricting the inclusion of 5i drugs to those that are not generally dispensed through retail community pharmacies.

Comment: One commenter expressed support for the Medicare Part B standard because it would be more stable, more transparent, and more reflective of the market for 5i drugs. The commenter believed that by starting with Medicare Part B, the significant majority of 5i products would be captured. To ensure no products are missed, that commenter suggested that CMS could allow manufacturers to employ reasonable assumptions related to unit types, units of measure and/or dosage form that relate to products that are 5i. The commenter disagreed that the lack of an all-inclusive Part B list would result in miscategorization and stated that even under the 90/10 rule there would be no independent all inclusive list to reference and the determination would need to be made by the manufacturer based on their own calculations. The commenter urged CMS to reconsider the Part B qualitative approach.

Response: As discussed in the preamble to the proposed rule (77 FR 5335), we did consider adopting the Medicare Part B guidelines used to determine if a drug is to be classified as self-administered under the physician administered drugs requirement. In accordance with sections 1861(s)(2)(A) and 1861(s)(2)(B) of the Act, the Medicare Benefit Policy Manual, Chapter 15—Covered Medical and Other Services, section 50.2(C), a drug is considered to be ''usually'' self-administered if it is self-administered more than 50 percent of the time. We chose not to adopt the 50 percent standard given that it would result in an AMP calculation for those drugs that have a significant number of units sold to wholesalers for distribution to retail community pharmacies and to retail community pharmacies. Additionally, Congress did not define ''not generally dispensed''; thus, we have used our discretion to establish a standard which manufacturers can use when making determinations for such 5i drugs.

Comment: One commenter suggested a two-step approach for determining whether a 5i drug is not generally dispensed through a retail community pharmacy. Step one—if a manufacturer can determine that at least a minimum percentage of sales of a product were to retail community pharmacies or to wholesalers for distribution to retail community pharmacies then the manufacturer must conclude that the drug is ''generally dispensed'' through retail community pharmacies. Step two—if a manufacturer cannot make this determination, the manufacturer should make and document reasonable assumptions that a 5i drug is, or is not, generally dispensed by retail community pharmacies and should document the basis for the assumption (by factors such as drug's labeling, REMS, patient population, or other relevant characteristics).

Response: We appreciate the comment but have decided to establish a more objective standard for manufacturers to use when making determinations as to whether a 5i drug is not generally dispensed through retail community pharmacies. We agree that manufacturers may make reasonable assumptions, in the absence of guidance and adequate documentation to the contrary, when determining whether prices paid to manufacturers by wholesalers are for drugs distributed to retail community pharmacies or are for drugs distributed to the entities eligible for inclusion in the calculation of AMP

for 5i drugs not generally dispensed through retail community pharmacies, provided those assumptions are consistent with the requirements and intent of section 1927 of the Act and federal regulations. As discussed previously, we believe an objective approach will lead to more consistency among manufacturers when making determinations about whether a 5i drug is not generally dispensed through retail community pharmacies.

Comment: The commenter stated any quantitative approach that requires distinction between retail community pharmacy and non-retail community pharmacy customers is problematic because manufacturers do not have reliable, verifiable data to identify end user customers. The commenter also noted that this approach would generate unnecessary contracting simply for the sake of purchasing traceable sales data.

Response: We want the AMP data reported by manufacturers to be as accurate and reliable as possible; however, we understand that in certain circumstances the manufacturer may not have verifiable data to determine the end customer. Therefore, as discussed previously, manufacturers may make reasonable assumptions, to determine if the percent of sales (in units) were sufficient to meet the ''not generally dispensed'' threshold, provided those assumptions are consistent with the requirements and intent of section 1927 of the Act and federal regulations.

Comment: One commenter believed that if a product is determined to be a 5i drug for the first quarter and it dips just below the threshold for the second quarter, rather than a switch in AMP calculation methodology, the manufacturer should have the discretion to look at other factors, such as purchasing patterns, to determine whether the product has actually switched or whether the dip below the threshold is an anomaly. The commenter also suggested that CMS could add a ''buffer zone'' as to when this analysis would be appropriate—such as when a product dips within 5 percent of the threshold. The commenter also suggested that CMS could provide that only after a certain period of time (perhaps 3 consecutive quarters within the ''buffer'' on the sale side of the threshold) would manufacturers switch to the AMP for 5i drugs. The commenter believed this approach would provide more stability to AMP calculations and, much like the smoothing methodology, account for unusual purchasing patterns.

Response: As discussed previously in this section, we recognize that prices and dispensing patterns fluctuate. Therefore, manufacturers may use a smoothing process that could address the concerns raised about the possibility that the AMP will shift between AMP and AMP for 5i drugs not generally dispensed through retail community pharmacies. Furthermore, manufacturers may use the same principle of making reasonable assumptions, in the absence of guidance and adequate documentation to the contrary, when determining whether prices paid to manufacturers by wholesalers are for drugs distributed to retail community pharmacies or are for drugs distributed to the entities eligible for inclusion in the calculation of AMP for 5i drugs not generally dispensed through retail community pharmacies consistent with section 1927(k)(1)(B)(i)(IV) of the Act. As such, we believe the commenters concerns will be addressed by these two options available to manufacturers.

Comment: The commenter stated that the 5i drugs they manufacture are virtually all, with few exceptions, not generally dispensed at retail community pharmacies. The commenter recommended that CMS permit manufacturers to identify 5i products by mere reference to the method of administration exclusively as noted on a product label and also suggested that CMS require all ASP-eligible products be mandated to use the AMP for 5i drugs not generally dispensed through retail community pharmacies methodology, so that differences in methodologies do not artificially create the perception of pricing differences for the Medicare Part B Program and Medicaid.

Response: While manufacturers may use the product labeling when identifying 5i drugs, we believe that, as discussed previously, manufacturers should use a more objective measure based on sales data, which would allow for a uniform approach when determining whether a 5i drug is, or is not generally dispensed through retail community pharmacies. We believe that leaving the interpretation of this ''not generally dispensed'' phrase to the discretion of each manufacturer may create excessive variability in the calculation of AMP, especially because manufacturers could use varied methodologies to establish that the drug was either dispensed, or ''not generally dispensed'' through retail community pharmacies. Therefore, we have established a 70 percent threshold, but as noted previously, we will continue to consider this standard and will issue additional guidance or rulemaking, if needed.

Furthermore, for the reasons discussed in the proposed rule regarding our consideration of the Part B methodology (77 FR 5335), we have decided not to adopt a requirement to use all ASP-eligible products in determining if a drug should be included in the calculation of AMP for 5i drugs not generally dispensed through retail community pharmacies, because we believe that under this methodology some 5i drugs which are generally dispensed through retail community pharmacies would inappropriately be included in the calculation of AMP for such 5i drugs.

Comment: Several commenters expressed support for our proposal to consider 5i drugs not generally dispensed through a retail community pharmacy if 90 percent or more of its sales were to entities other than retail community pharmacies. Another commenter believed that any substantial decrease to the 90 percent threshold would undermine the basic intentions of the 5i methodology, which is to ensure that drugs meeting the threshold are truly non-retail in nature, and could create unplanned and unexpected methodology changes for many existing drugs, which could alter the resulting AMP levels.

Response: As previously discussed, we are not finalizing the 90/10 rule for determining when a drug is not generally sold through a retail community pharmacy. Rather, after considering the analysis provided by commenters, we have decided to adopt a threshold at 70 percent and allow manufacturers to use a smoothing process for monthly sales from the preceding 12-month period, which will further reduce variability to AMP, ensure sufficient sales are included in AMP, and appropriately restrict the inclusion of 5i drugs to those that are not generally dispensed through retail community pharmacies.

Comment: Another commenter noted that under the proposed process for assessing whether a 5i drug is not generally dispensed through retail community pharmacies, the universe of sales to what the 90 percent benchmark would be applied would include, for example, sales to federal governmental agencies and entities enrolled in the 340B program, which the commenter stated would always be excluded from AMP calculations, regardless of whether the standard or the 5i AMP methodology was used. The commenter believed that the assessment of whether a 5i drug is not generally dispensed through a retail community pharmacy should only be on sales to retail community pharmacies and to those

entities that are functional equivalents to retail community pharmacies, in that they dispense CODs to members of the general public, albeit by different means. Furthermore, the commenter noted that federal agency and 340B program sales should not categorically be included in the non-retail community pharmacy sales to which the 90 percent benchmark would be complied. The commenter recommended that CMS revise its proposed process for assessing whether a 5i drug is not generally dispensed through retail community pharmacies to direct manufacturers, as a threshold matter, to exclude sales that would be AMP-ineligible under either the standard or 5i AMP calculation methodology, and then assess whether, of the remaining sales, if 90 percent were to entities other than retail community pharmacies.

Response: We believe that with this final rule, manufacturers will have a clearer understanding as to which unit sales are associated with drugs generally dispensed through retail community pharmacies versus sales not generally dispensed through retail community pharmacies. That is, the manufacturer should use the definition of retail community pharmacy at section 1927(k)(10) of the Act as established in this rule to determine if the 5i drug met the threshold for not generally dispensed through retail community pharmacies, which does not include sales, such as 340B sales and sales to government pharmacies.

A complete discussion of the sales, discounts, rebates and other financial transactions to be included in or excluded from AMP for 5i drugs is provided in section II.C.7.d., including additional discussion about sales to 340B entities and rebates or discounts provided to government programs.

Comment: A few commenters expressed confusion and requested clarification regarding whether entities conducting business as retail community pharmacies (which were proposed to include specialty, home infusion and home health pharmacies) would be treated as retail community pharmacies for purposes of determining when a drug is ''not generally dispensed'' through a retail community pharmacy, as that would be consistent with the treatment of such entities in the AMP calculation. Conversely, many other commenters requested confirmation that sales to entities that conduct business as retail community pharmacies are not considered sales to retail community pharmacies for the purposes of determining whether a 5i drug is not generally dispensed through a retail community pharmacy.

Another commenter believed it is reasonable to construe the AMP calculation rules and the ''not generally dispensed'' 5i status rules differently. By adopting an approach that includes specialty pharmacy sales in AMP but excludes them from the ''not generally dispensed'' test, the commenter believed that CMS will be doing less harm than if it were to adopt an erroneous interpretation of two statutory provisions rather than one. The commenter recognized that CMS is in a predicament because the current statutory definitions leave some products without sales necessary to calculate AMP, and the commenter cautions CMS not to use flawed reasoning to rectify the problem.

One commenter indicated that if the ''not generally dispensed'' evaluation were extended to include specialty pharmacies, home infusion pharmacies, and home health care providers, the exception that Congress created for 5i drugs would be effectively nullified, particularly if CMS adopts the proposed 90 percent standard. One commenter stated that neither the proposed rule nor the statute require manufacturers to consider sales to entities conducting business as retail community pharmacies under proposed § 447.504(b)(4) in the ''not generally dispensed'' determination.

Response: As discussed earlier in this section, we are not finalizing provisions at proposed § 447.504(b) which provided that manufacturers include within AMP those sales to entities that ''conduct business as wholesalers or retail community pharmacies.'' Rather, as discussed previously, we have defined AMP, in part, to include sales to wholesalers and retail community pharmacies, which may include certain home infusion, home health care, and specialty pharmacies to the extent these pharmacies meet the definition in section 1927(k)(10) of the Act. Therefore, manufacturers, when determining whether 5i drugs met the threshold for ''not generally dispensed'' through retail community pharmacies, will need to determine if these entities meet the definition of retail community pharmacy at section 1927(k)(10) of the Act and then apply the threshold test. Additional discussion as to which entities may be included as retail community pharmacies or wholesalers for purposes of AMP can be found in sections II.C.5 and II.C.7 of this rule.

Comment: One commenter noted that a number of 5i drugs are not covered under Medicare Part B, but are also not generally dispensed through retail community pharmacies. Therefore, the commenter believed that 5i drugs that are generally dispensed through specialty pharmacies should be subject to the 5i AMP calculation as those are not transactions through retail community pharmacies.

Response: We do not believe that we should subject all 5i drugs that are generally dispensed through specialty pharmacies to the calculation of AMP for 5i drugs not generally dispensed through retail community pharmacies, because there may be instances when a specialty pharmacy would meet the statutory definition of retail community pharmacy at section 1927(k)(10) of the Act and those drug sales would be included in the AMP calculation. In those situations where the specialty pharmacy does not meet the statutory definition of a retail community pharmacy at section 1927(k)(10) of the Act, but rather is included as one of the providers listed at section 1927(k)(1)(B)(i)(IV) of the Act (because, for example, it is a mail order pharmacy), then the pharmacy would be included on the non-retail community pharmacy side of the 70/30 equation for determining when a 5i drug is not generally dispensed through a retail community pharmacy.

Comment: A few commenters stated that even though the current proposed rule permits the Affordable Care Act base data AMP revision on a product by product basis, CMS will need to provide further clarification on how to determine which method to use for the 5i products that fluctuate between AMP and AMP calculated for 5i drugs not generally dispensed through retail community pharmacies during the base date AMP period.

Another commenter noted that if a manufacturer calculated the base date AMP believing the drug is (or is not) a 5i drug, and the status of the drug changes for a particular quarter, the calculation of the additional rebate would be based on a comparison of a base date AMP and a current-quarter AMP based on different methodologies. A few commenters expressed concern because it does not appear that manufacturers can maintain both two base date AMPs. Even if they were able to do so, the commenter noted that such an option would require major changes to manufacturer's government pricing systems and CMS's DDR system and it would be impossible to implement because manufacturers do not have data needed to establish the missing baseline information. One commenter noted that because the proposed rule only contemplates a product having one baseline AMP calculated in one way,

the additional rebates due on products could be skewed. The commenter also stated they doubt they would have the end customer tracing data necessary to establish a baseline AMP for 5i drugs not generally dispensed through retail community pharmacies for their older 5i products under the buildup methodology.

Response: As discussed further in the base date AMP comments and responses found in section II.H.3. of this rule, the statutory definition of the base date AMP found at sections 1927(c)(2)(A) and (B) of the Act provides that manufacturers report an AMP for a COD. Further, the statute specifies that for drugs originally marketed before the inception of the rebate program, the base date AMP means the AMP for the 7/1/90 to 9/30/90 quarters, for purposes of computing the URA. For those drugs approved by FDA after October 1, 1990, the base date AMP should be calculated based on the AMP for the first full calendar quarter after the day on which the drug was first marketed. Based on these statutory definitions, we believe that a drug should only have one base date AMP as this section of the statute does not contemplate the calculation of two base date AMPs.

In addition, we believe it will not be necessary for manufacturer establishment of two base date AMPs because a manufacturer may make certain reasonable assumptions when determining AMP and has the option to use a smoothing process for determining when a drug is not generally dispensed through retail community pharmacies. We believe such options will result in more stable AMPs since the calculation methodology for 5i drugs should remain relatively consistent from month-to-month and quarter-to-quarter. The establishment of the base date AMP and the effect of the 5i drug statutory provisions on the base date AMP is further discussed in section II.H.3. of this final rule.

Comment: A few commenters believed that the final rule should exempt 5i products from the establishment of FULs, or if it does not exempt 5i products from the establishment of FULs then the FUL multiplier should be higher than the general multiplier in recognition of the fact that the AMP for these products will be significantly lower due to the inclusion of sales to entities other than retail community pharmacies. The commenters urged CMS to work with the Congress to develop a more workable solution to Medicaid pharmacy reimbursement for both 5i products and products that are neither 5i nor generally dispensed through retail community pharmacies. A few commenters indicated that the inclusion of non-retail pharmacy sales will lower AMPs, and a multiplier of only 175 percent for the FULs will not cover retail community pharmacy acquisition costs for these drugs.

Response: As further discussed in the Upper limits for multiple drugs section (section II.K.) of this final rule, in light of the requirement in section 1927(e)(5) of the Act, we will calculate a FUL for multiple source drugs that are available for purchase by retail community pharmacies on a nationwide basis. Furthermore, in light of the criteria set forth in section 1927(k)(1)(B)(i)(IV) of the Act regarding the calculation of the AMP, we have decided that we will not include 5i drugs that are not generally dispensed through retail community pharmacies in the FUL calculations, nor apply the FUL to 5i drugs that are not generally dispensed through retail community pharmacies.

Comment: One commenter noted that AMP is an essential component of setting the 340B ceiling price calculation and was pleased that CMS addressed the importance of generating an AMP for all CODs, including those characterized as 5i drugs. The commenter requested that CMS keep in mind that AMP data is necessary for HRSA to calculate the 340B price since the percentage of sales required to classify a drug as not generally dispensed through a retail community pharmacy may be too high.

Response: We appreciate the comments and are aware of the role that AMP plays in establishing the 340B ceiling prices. In light of the revisions in this final rule, we believe that an AMP will be generated for most, if not all CODs, including 5i drugs not generally dispensed through retail community pharmacies.

Comment: One commenter requested clarification that, if a drug is determined to be generally dispensed through a retail community pharmacy (because it is dispensed more than 10 percent of the time), the AMP rule (and rebate) applies to those drugs.

Response: If a drug is determined to be generally dispensed through a retail community pharmacy (because it is dispensed through a retail community pharmacy more than 30 percent of the time based upon the revised threshold in this final rule), the manufacturer, in accordance with section 1927(k)(1) of the Act, would use the AMP methodology for calculating the AMP of that drug.

Comment: One commenter stated that if a product is not generally dispensed through a retail community pharmacy but is delivered directly to the consumer after it is supplied to a practitioner, that drug should be available for rebates, determination of best price, and the determination of AMP.

Response: Section 1927(a) of the Act generally requires that manufacturers enter into rebate agreements for federal payment to be made available under the Medicaid program for most CODs. Section 1927(b) of the Act requires that manufacturers entering into such rebate agreements provide rebates for CODs for which payment was made under the state plan.

Therefore, we agree that if the drug in the commenter's example meets the definition of a COD at section 1927(k)(2) of the Act, and the manufacturer of the drug has signed an agreement to participate in the MDR program, then the manufacturer must report the AMP (and/or best price) for the drug and be responsible for paying rebates on the units dispensed of the drug. As discussed previously, manufacturers have the option to make reasonable assumptions, which we expect will allow manufacturers to make AMP and best price calculations consistent with the requirements and intent of section 1927(b) of the Act.

After considering the comments and for the reasons we discussed previously in this section, we have decided to revise proposed § 447.507(b)(1) to remove the references to 90 percent and during the reporting period and to insert references to 70 percent and to note that the determination is based on units at the NDC–9 level.

c. Frequency of Determination of 5i Drug's Status as ''Not Generally Dispensed'' (§ 447.507(b)(2))

At § 447.507(b)(2), we proposed that the determination of a 5i drug's status as not generally dispensed through a retail community pharmacy will be evaluated by a manufacturer on a monthly and quarterly basis (77 FR 5336). We received the following comments on this proposal.

Comment: Several commenters expressed opposition to the requirement that manufacturers determine whether a drug is not generally dispensed through a retail community pharmacy on a monthly and quarterly basis stating that the requirement to reassess the ''not generally dispensed'' determination on such a frequent basis is unnecessary, labor intensive, administratively burdensome, and would increase AMP volatility. Other commenters stated that requiring monthly and quarterly 5i eligibility determinations, for drugs ''not generally dispensed'' through retail community pharmacies, would present

significant calculation issues for manufacturers such as how to estimate lagged price concessions if a drug changes categories from period to period, and how to calculate quarterly AMP for quarters when the drug flips categories between months within the quarter. The commenters recommended that CMS revise its proposal by deleting the requirement that manufacturer perform quarterly assessments. Commenters noted that a monthly or quarterly determination could distort pharmacy reimbursement for states which have adopted or will adopt an AMP-based reimbursement methodology and it could also lead to fluctuation in 340B prices. Additionally, some commenters requested that CMS provide guidance to manufacturers as to how they should calculate the quarterly AMP when a 5i drug may have been calculated using the 5i AMP methodology in 2 of the 3 months in a quarter. One commenter stated that even requiring manufacturers to perform the not generally dispensed assessment on a monthly basis would be problematic because of the potential for drugs with sales to retail community pharmacies that oscillate around 10 percent month-to-month could potentially lead to monthly AMPs in one quarter being calculated based on different methodologies. The commenter recommended that CMS revise its proposed process for assessing whether a 5i drug is not generally dispensed through a retail community pharmacy to require manufacturers only perform the assessment after the first month of each quarter.

Many commenters recommended that CMS allow manufacturers to designate a 5i product not generally dispensed through retail community pharmacies for a minimum period of at least 1 year to reduce burdens on manufacturers, particularly those with large numbers of NDCs, as well as reduce the risk of AMP volatility. Many commenters recommended CMS allow manufacturers to adopt specific procedures when determining whether a 5i drug is not generally dispensed through retail community pharmacies, for example, if the 5i drug's retail distribution percentage is within 5 percent of the not generally dispensed threshold during an annual review, the manufacturer could maintain the current classification of the drug instead of switching to a new AMP calculation.

Response: Since the quarterly AMP is reported as a weighted average of the 3 monthly AMPs, we agree with commenters that it is not necessary to require manufacturers to determine the ''not generally dispensed'' requirement on both a monthly and quarterly basis. Accordingly, we have revised proposed § 447.507(b)(2) to remove the reference to the quarterly determination of the ''not generally dispensed'' requirement.

As to the commenters question regarding how to calculate quarterly AMP for quarters when the drug flips between AMP and AMP for 5i drugs not generally dispensed through retail community pharmacies within the months of that quarter, we note that the quarterly AMP is reported as a weighted average of the 3 monthly AMPs reported by the manufacturer; thus, manufacturers are to calculate the quarterly AMP as a weighted average of the 3 monthly AMPs irrespective of the methodology used to calculate each monthly AMP. We expect to issue operational guidance in the future providing additional instructions clarifying how manufacturers may identify and calculate monthly AMPs for 5i drugs not generally dispensed through retail community pharmacies. Until that guidance is issued, as noted previously, manufacturers may continue to make reasonable assumptions consistent with the requirements and intent of section 1927 of the Act and federal regulations.

As discussed previously, manufacturers may also use a smoothing process, where manufacturers may use a 12-month rolling average of their monthly sales (in units) to determine whether a 5i drug is not generally dispensed through a retail community pharmacy. As previously discussed in this section, we believe that since manufacturers may use data from a longer period of time other than the current month to make this determination and make reasonable assumptions consistent with the requirements and intent of section 1927 of the Act and federal regulations, we believe the monthly determination will not be overly burdensome on manufacturers, as suggested by the commenters.

We do not agree with the commenter's suggestion that CMS allow manufacturers to maintain the current classification of the drug instead of switching to a new AMP calculation if the retail distribution percentage is within 5 percent of the threshold. Again, we believe that the option to use the smoothing process and our decision not to finalize the buildup methodology but instead allow manufacturers to make reasonable assumptions in the calculation of AMP will contribute to more stable AMPs and that once a drug is determined to be generally dispensed, or not generally dispensed through retail community pharmacies, it will not flip-flop between the 5i and AMP methodologies.

Comment: One commenter urged CMS to develop a standard that would allow manufacturers to make the determination of whether a 5i drug is generally dispensed through retail community pharmacies prospectively, when the drug is first marketed, and that will result in the drug having the same 5i status thereafter.

Response: We believe that allowing a manufacturer to make a one-time prospective determination without having actual sales data to support that determination is inconsistent with the requirement that manufacturers report AMP based on data for the reporting period, as required by section 1927(b)(3) of the Act. Therefore, as previously discussed in this section, we have retained the requirement that manufacturers determine on a monthly basis when the 5i drug is not generally dispensed through retail community pharmacies although, manufacturers may make reasonable assumptions regarding this determination.

Comment: One commenter did not think that the proposed rule adequately addressed the issue of the buildup methodology for the calculation of AMP for 5i drugs not generally dispensed through retail community pharmacies. Therefore, if CMS were to adopt the buildup model in the final rule, the commenter believed that CMS must clarify that manufacturers cannot utilize the presumed inclusion policy for the AMP calculation for such 5i drugs.

Response: As discussed in the definition of retail community pharmacy at section II.C.4.f., we have reconsidered our proposed buildup methodology requirement and have decided not to finalize that proposal. We believe it is reasonable that manufacturers presume, using reasonable assumptions, in the absence of guidance and adequate documentation to the contrary, that prices paid to manufacturers by wholesalers are for drugs distributed to retail community pharmacies, consistent with the requirements and intent of section 1927 of the Act and federal regulations.

Comment: One commenter supported the addition in DDR of a flag to designate under which methodology, standard or 5i, that a manufacturer used to calculate AMP for a given quarter. The commenter stated that this flag should be set by the manufacturer at the time AMP data is submitted to DDR, and should be subject to unilateral change by the manufacturer within the 12-quarter window if subsequent information/corrections compel

restatement. The ''flag'' would also allow CMS to identify the appropriate base date AMPs to be used when calculating the URA transmitted to the states.

Response: We agree with the commenter's recommendation regarding the addition of an indicator, such as a flag in DDR, to designate the methodology used to calculate the monthly AMP. This will assist us in identifying which methodology was used to calculate monthly AMP and to be able to track whether there is substantial fluctuation based on the methodology used by a manufacturer to calculate the monthly AMP, as well as assist with the FUL calculation. We have already added an indicator to DDR to assist in identifying which methodology the manufacturer used to calculate AMP for a given month. Furthermore, if a manufacturer discovers that an AMP data change would prompt a change to a 5i drug's AMP methodology, the manufacturer would be permitted to report revisions to monthly AMP within 36 months in accordance with § 447.510(d)(3).

Therefore, for the reasons discussed in this section, we are revising proposed § 447.507(b)(2) to remove the reference to determinations on a ''quarterly'' basis and to insert a requirement that a manufacturer is responsible for determining ''and reporting to CMS'' whether a 5i drug is not generally dispensed through a retail community pharmacy on a monthly basis.

d. The Specific Sales, Discounts, Rebates, Payments and Other Financial Transactions Included In, and Excluded From, the Determination of AMP for 5i Drugs Not Generally Dispensed Through Retail Community Pharmacies (§ 447.504(d) and (e))

In proposed § 447.504(d), we discussed the specific sales, discounts, rebates, payments and other transactions that we proposed to include in the determination of AMP for 5i drugs not generally dispensed through retail community pharmacies. These proposed provisions are discussed at 77 FR 5334 through 5336 of the proposed rule. We received the following comments on this provision.

Comment: A few commenters noted that some provisions of the proposed regulatory text refer to ''Sales, Discounts, Rebates, Payments and Other Transactions'' while other provisions just refer simply to ''sales.'' The commenters stated that CMS intended to include in AMP all transactions involving the enumerated entities, not just sales to those entities. The commenters requested that CMS revise the proposed regulatory language to refer consistently to the types of transactions that it intends to include in AMP.

Response: As discussed in the ''Sales Included in the Determination of AMP'' section (II.C.5) of this final rule, after reviewing the proposed regulatory text of this section, we agree with commenters regarding the need for consistency. Accordingly, we are finalizing changes to § 447.504(d) and (e) so that we are consistent in our reference to AMP, as well as the types of transactions that are included in or excluded from AMP for 5i drugs not generally dispensed through retail community pharmacies. Specifically, we are revising the heading of § 447.504(d) to include sales, nominal price sales, and associated discounts, rebates, payments, or other financial transactions included in AMP for 5i drugs that are not generally dispensed through retail community pharmacies. In the introductory text of § 447.504(d), we specify that AMP for 5i drugs identified in accordance with § 447.507 shall include sales, nominal price sales, and associated discounts, rebates, payments or other financial transactions to all entities specified in paragraph (b) of the section, as well as the sales, nominal price sales, and discounts, rebates, payments or other transactions associated with the sales to the named entities that are specified in in paragraph (d), unless specifically excluded as outlined in paragraph (e) of the section. As specified earlier in the Sales Included in the Determination of AMP section (II.C.5) of this final rule, it is our intention that the addition of the term ''associated'' clarifies that it is the sales themselves, as well as the discounts, rebates, payments, or other financial transactions associated with the enumerated sales that are included in the AMP calculation, unless otherwise specifically excluded.

At § 447.504(e) we similarly are revising the heading to include sales, nominal price sales, and associated discounts, rebates, payments, or other transactions excluded from AMP for 5i drugs that are not generally dispensed through retail community pharmacies. In the introductory text of § 447.504(e), we specify that AMP excludes the following sales, nominal price sales, and associated discounts, rebates, payments, or other financial transactions listed in § 447.504(e)(1) through (17). As stated in this section, it is our intention that the addition of the term ''associated'' clarifies that it is the sales or prices themselves, as well as the discounts, rebates, payment or other financial transactions associated with those prices or sales specified in § 447.504(e) that are excluded from the AMP calculation for 5i drugs that are not generally dispensed through retail community pharmacies.

Comment: One commenter noted an apparent drafting error in the list of sales eligible for inclusion in the 5i AMP calculation at § 447.504(d). As proposed, the 5i AMP calculations at proposed § 447.504(d)(10) included sales to other manufacturers who conduct business as wholesalers or retail community pharmacies. The commenter stated that the language in the statute upon which this inclusion is based calls for the inclusion of sales to manufacturers, or any other entity that does not conduct business as wholesaler or a retail community pharmacy.

Response: We agree with the commenter that as originally proposed, § 447.504(d)(10) was not consistent with section 1927(k)(1)(B)(i)(IV) of the Act, because it referenced sales to other manufacturers who conduct business as wholesalers or retail community pharmacies as included in AMP for 5i drugs. Section 1927(k)(1)(B)(i)(IV) of the Act, however, references payments received from and rebates or discounts provided to manufacturers, or any other entity that does not conduct business as a wholesaler or a retail community pharmacy. This was a drafting error in proposed § 447.504(d)(10) and we are correcting this error in the final rule in § 447.504(d)(10) to replace ''manufacturer'' with ''manufacturer or any other entity'' and further include the term ''not'' before ''conduct business as . . .'', which we believe is consistent with the statute at section 1927(k)(1)(B)(i)(IV) of the Act. We believe this clarifies that sales, nominal price sales, and associated discounts, rebates, payments or other financial transactions associated with sales to manufacturers, or any other entity that does not conduct business as a wholesaler or a retail community pharmacy are included in the determination of the AMP for 5i drugs not generally dispensed through retail community pharmacies.

Comment: One commenter believed that the amendments made to the Affordable Care Act by the Education Jobs and Medicaid Assistance Act (creating the alternate 5i AMP calculation) unintentionally included in AMP for 5i drugs all payments from and discounts and rebates provided to government and 340B purchasers. The commenter requested that CMS address this language and clarify that discounts provided to government and 340B entities are excluded from AMP for 5i drugs. The commenter also believes that

the Education Jobs and Medicaid Assistance Act failed to amend the Affordable Care Act to include in AMP for 5i drugs any prices paid by wholesalers for drugs distributed to entities other than retail community pharmacies. The commenter indicated that as amended the statute precludes the inclusion of prices paid by wholesalers when drugs are sold to non-retail end customers, but at the same time requires inclusion of discounts and rebates provided to these purchasers. The commenter noted that even if direct sales to non-retail customers were included in the calculation, if price concessions were netted against eligible gross sales, because these products are not generally sold to retail customers, it could produce a negative number. Therefore, to prevent skewed results, the commenter requested that CMS address this problem and clarify that AMP for 5i drugs includes identifiable indirect sales to non-retail customers other than government and 340B entities.

Response: We do not believe that by adding the 5i drug provision, the statute should be read to disregard CMS's longstanding position to exclude prices made available only through certain State and Federal government providers and programs from AMP and include those prices in AMP for 5i drugs not generally dispensed through retail community pharmacies.

First, government programs, and charitable and not-for-profit pharmacies are not included in the list of entities identified in section 1927(k)(1)(B)(i)(IV) of the Act, and we do not believe that they qualify as the additional entities (which do not conduct business as wholesalers or retail community pharmacies), which as discussed previously we have defined to include physicians and hospices. Therefore, based upon the comments and our reading of section 1927(k)(1)(B)(i)(IV) of the Act, we are excluding sales to these government, charitable, and not-for-profit pharmacies by adding these pharmacies to the exclusions at § 447.504(e)(18) through (20).

In addition, as we discussed in the proposed rule (77 FR 5328–5331), manufacturers are required to calculate AMP to reflect net sales, which is calculated, in part, based on prices paid and discounts provided to, retail community pharmacies and wholesalers, as defined in sections 1927(k)(10) and 1927(k)(11) of the Act. Manufacturers that provide discounts or rebates to government programs and payers generally do not make these discounts or rebates available to retail community pharmacies or wholesalers that distribute to retail community pharmacies, as those terms are defined in section 1927(k) of the Act. Therefore, the manufacturer's determination of AMP shall exclude the payments received from, as well as the discounts or rebates provided to government programs and payers, because they are not retail community pharmacies or wholesalers that distribute drugs to retail community pharmacies, in accordance with section 1927(k)(1) of the Act. We see no reason that manufacturers should adopt a different policy for 5i drugs not generally dispensed through retail community pharmacies. Prices, including manufacturer rebates and discounts, provided to government programs and payers do not represent the type of payments received from, and rebates or discounts provided to the entities listed at section 1927(k)(1)(B)(i)(IV) of the Act because, as discussed previously, government programs and payers are not included in the list of entities identified in section 1927(k)(1)(A) or 1927(k)(1)(B)(i)(IV) of the Act, and we do not believe that they qualify as the additional entities which do not conduct business as wholesalers or retail community pharmacies. Therefore, we have revised proposed § 447.504(e) to exclude prices provided to government programs, pharmacies, charitable pharmacies, and not-for-profit pharmacies from the determination of AMP for 5i drugs not generally dispensed through retail community pharmacies.

Therefore, we are revising proposed § 447.504(e) to clarify which prices should be excluded from the calculation of AMP for 5i drugs not generally dispensed through retail community pharmacies. Specifically, given our reading of section 1927(k) of the Act, as discussed previously, we have revised proposed § 447.504(e)(1) to provide for the exclusion of any prices on or after October 1, 1992, 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). We have also revised proposed § 447.504(e)(2) to provide for the exclusion of prices charged under the FSS and proposed § 447.504(e)(3) to provide for the exclusion of any depot prices (including TRICARE) and single award contract prices, as defined by the Secretary, of any agency of the federal government.

We are also revising proposed § 447.504(d)(10) to include prices paid by wholesalers when the wholesaler distributes drugs to entities other than retail community pharmacies, by including a reference to ''any entity'' that does not conduct business as a wholesaler. As indicated in the comment, the statute is ambiguous regarding the inclusion of prices in AMP for 5i drugs paid by wholesalers when drugs are distributed by the wholesaler to non-retail community pharmacy customers, such as those entities listed at section 1927(k)(1)(B)(i)(IV) of the Act (for example, hospitals, clinics, and long-term care pharmacies). The term wholesaler is defined at section 1927(k)(11) of the Act to mean a drug wholesaler engaged in the wholesale distribution of prescription drugs to retail community pharmacies. Section 1927(k)(1)(B)(i)(IV) of the Act provides that a manufacturer calculate an AMP for 5i drugs not generally dispensed through retail community pharmacies to include sales to entities that do not conduct business as a wholesaler. Therefore, we have interpreted the phrase ''not conducting business as a wholesaler'' to provide that manufacturers shall include sales to a wholesaler that is engaged in wholesale distribution of prescription drugs to the listed entities in section 1927(k)(1)(B)(i)(IV) of the Act, as implemented in § 447.504(d), to be included in AMP for 5i drugs not generally dispensed through retail community pharmacies. It is our position, in light of these provisions, that the sales that manufacturers should include in AMP for such 5i drugs are the sales to the wholesaler when distributing drugs to those listed entities, because that wholesaler is not conducting business as a wholesaler as defined in section 1927(k)(11) of the Act. Therefore, for the purposes of calculating the AMP for such 5i drugs, sales to wholesalers distributing to the entities at section 1927(k)(1)(B)(i)(IV) of the Act, as implemented in § 447.504(d), shall be included.

Accordingly, as discussed previously, we are revising § 447.504(d)(10) to include a reference to ''manufacturers, or any other entity, that does not conduct business as a wholesaler or a retail community pharmacy'' to clarify that such entities are included in the calculation of AMP for such 5i drugs.

Comment: Many commenters expressed concern that the proposed rule did not detail any exclusion from 5i AMP beyond customary prompt pay discounts. These commenters expressed concern about the proposed rule's lack of a subsection detailing exclusions from the 5i AMP calculation and hoped it was an inadvertent oversight and

believe that it is essential that CMS require manufacturers to exclude federal government sales, TRICARE, SPAPs, rebates, non-contingent free goods, sales to government, not-for-profit, or charitable pharmacies, sales to 340B covered entities, and all forms of patient assistance eligible for exclusion from AMP from 5i AMP as well. Several commenters expected 5i AMP to be extraordinarily low because deeply discounted prices would be included in the calculation. The commenters encouraged CMS to ensure the regulatory instructions for calculating 5i AMPs would provide for exclusions that would lead to 5i AMP values reflective of net pricing actually available to non-retail community pharmacy prescription drug purchases in the commercial marketplace. These commenters hoped this was an inadvertent oversight that would be corrected in the final rule; otherwise, pharmacies and physicians would be underpaid for 5i drugs furnished to Medicaid recipients.

Response: As discussed previously, it was our intention that the sales, rebates, discounts or other financial transactions that were not specifically referenced at proposed § 447.504(d) would remain excluded from the determination of AMP for 5i drugs not generally dispensed through retail community pharmacies. Therefore, we have revised proposed § 447.504(d) to more clearly specify the sales that are included in the determination of AMP for such 5i drugs and redesignated the paragraph on ''Further clarification of AMP calculation'' set forth in proposed § 447.504(e) to § 447.504(f), so that we could add a new § 447.504(e) clarifying which sales, nominal price sales, and associated discounts, rebates, payments, or other transactions are excluded from AMP for 5i drugs not generally dispensed through retail community pharmacies. We added this section to address the concerns expressed by commenters that the proposed rule did not detail any exclusions from AMP for such 5i drugs and to provide the requested clarification to ensure accurate calculation of AMP across all manufacturers, consistent with section 1927(k)(1) of the Act.

The payments from those entities listed in section 1927(k)(1)(B)(i)(IV) of the Act as implemented in § 447.504(d), which include payments by, and discounts or rebates provided to, PBMs, MCOs, HMOs, insurers, hospitals, clinics, mail order pharmacies, long term care providers, manufacturers, or any other entity that does not conduct business as a wholesaler or a retail community pharmacy are included in AMP for 5i drugs not generally dispensed through retail community pharmacies. As discussed previously, we have also identified those sales, rebates, and discounts that should be excluded from the AMP calculation for such 5i drugs, which consistent with our interpretation of section 1927(k)(1) of the Act, shall continue to exclude customary prompt payments to wholesalers; bona fide service fees to retail community pharmacies and wholesalers; reimbursement for recalled, damaged, expired, or otherwise unsalable returned goods; and discounts provided under the Medicare Coverage Gap Discount program. Therefore, we have revised proposed § 447.504(e) to provide that manufacturers shall continue to exclude from AMP calculations for such 5i drugs, those prices, rebates, or discounts provided to federal government payers and programs (such as the 340B program, TRICARE, SPAPs), non-contingent free goods, patient assistance programs, because such prices, rebates, or discounts do not represent the type of prices, discounts and rebates contemplated in section 1927(k)(1)(B)(i)(IV) of the Act.

Comment: Several commenters urged CMS to broaden the application of the bona fide service fee exception in the rule to include the additional customer types that are eligible in the AMP calculation for 5i drugs that are not generally dispensed through retail community pharmacies. A few commenters indicated that not broadening the bona fide service fee exception from AMP for 5i drugs not generally dispensed through retail community pharmacies would greatly increase the potential for ASP to exceed AMP by the threshold amount, thus triggering AMP substitution for ASP. One commenter expressed concern that the differential treatment of bona fide service fees in AMP and ASP could side-step the statutory requirement to use ASP as the reimbursement metric for most prescription drugs covered by Medicare Part B and physicians will be reimbursed at levels below their acquisition cost for products administered to Medicare Part B patients.

Response: Since section 1927(k)(1)(B)(i)(II) of the Act references only bona fide service fees paid by manufacturers to wholesalers or retail community pharmacies as being excluded from AMP, the exclusion of bona fide service fees cannot be expanded to apply to the entities other than wholesalers or retail community pharmacies, for purposes of the calculation of AMP for 5i drugs not generally dispensed through retail community pharmacies. However, we believe that the payments provided by manufacturers for such service fees (including distribution service fees, inventory management fees, product stocking fees, and administrative service and patient care program fees) may be excluded from AMP with regard to such 5i drugs, because such fees do not represent type of payments from, or discounts or rebates provided to, the entities listed in section 1927(k)(1)(B)(i)(IV) of the Act as implemented in § 447.504(d). Therefore, such fees should not be included in the determination of AMP for 5i drugs not generally dispensed through retail community pharmacies.

We further note that because manufacturers should exclude such service fees and bona fide service fees from their AMP calculations, the AMP calculated for such 5i drugs would not be reduced by such fees. Therefore, we believe the commenters' concern about AMP substitution for Medicare's ASP, which would likely occur if the manufacturer included such fees as discounts in AMP, is addressed by the fee exclusion. Furthermore, because these payments are not included in the AMP calculation for such 5i drugs, there is no need to add a specific exclusion of such service fees to the regulatory text.

Comment: One commenter stated that, assuming transactions that are expressly excluded from AMP (at § 447.504(c)), but not specifically included in AMP for 5i drugs not generally dispensed through retail community pharmacies, are also to be excluded from AMP for such 5i drugs (at § 447.504(d)), then the proposed definition of AMP for 5i drugs not generally dispensed through retail community pharmacies creates ambiguity because some exclusions from AMP at § 447.504(c) do not match exactly with the inclusions at § 447.504(d). For example, the commenter noted that § 447.504(c) excludes ''direct sales to physicians'' while § 447.504(d) includes ''Sales to Physicians.'' To avoid confusion, the commenter recommended that where CMS intends to include in AMP for 5i drugs not generally dispensed through retail community pharmacies transactions excluded from AMP, CMS should revise the inclusions at § 447.504(d) to match the precise language in § 447.504(c).

Response: We agree that there may have been some ambiguity between the language in § 447.504(c) and (d), and we have made revisions to the regulatory text at § 447.504(c) and (d), where applicable, to align these sections and address the concerns of the commenter

based upon section 1927(k) of the Act, as discussed in the prior comments and responses. Section 447.504(d)(1) includes a reference to ''Sales to physicians,'' which we have included in the AMP for 5i drug not generally dispensed through retail community pharmacies, because physicians do not conduct business as a retail community pharmacy or wholesaler as provided in section 1927(k)(1)(B)(i)(IV) of the Act. Additionally, as discussed earlier in this section, we have revised § 447.504(c)(22) to specify that ''sales to physicians'' (as opposed to direct sales to physicians) should be excluded from the calculation of AMP. In the proposed rule, we proposed to include sales to hospices in the calculation of AMP for 5i drugs that are not generally dispensed through retail community pharmacies, because they do not conduct business as a retail community pharmacy or wholesaler (77 FR 5336). However, we did not specify inpatient and outpatient hospice sales in the regulatory text at proposed § 447.504(d)(9). To address the commenter's concerns with consistency between the two sections (AMP and AMP for 5i drugs not generally dispensed through retail community pharmacies), we have revised proposed § 447.504(d)(9) to specify the inclusion of ''Sales to hospices (inpatient and outpatient)'' to be consistent with the description of such hospice sales in the exclusions from AMP at § 447.504(c)(20). These revisions are designed as a clarification to make these AMP calculation provisions consistent with our reading of the sections 1927(k)(1)(A) and 1927(k)(1)(B)(i)(IV) of the Act.

Comment: A few commenters requested that CMS clarify that indirect sales to hospitals, physicians, etc., are included in the definition of AMP for 5i drugs not generally dispensed through retail community pharmacies. The proposed rule does not explicitly include in AMP for 5i drugs not generally dispensed through retail community pharmacies sales of 5i drugs to wholesalers that are subsequently sold to a doctor or hospital. However, direct sales of 5i drugs to doctors or hospitals will be included in AMP for 5i drugs not generally dispensed through retail community pharmacies. Also chargebacks paid to wholesalers for 5i drugs distributed to these customers will be included in AMP for 5i drugs not generally dispensed through retail community pharmacies as discounts provided to these customers. The commenters indicated that because direct sales and chargebacks generated from wholesaler sales to these customers will be included in AMP for 5i drugs not generally dispensed through retail community pharmacies, sales to wholesalers of 5i drugs resold to these customers should likewise be included. The commenters strongly urged CMS to incorporate within the final rule a detailed section that specifically identifies excluded transactions for the calculation of AMP for 5i drugs not generally sold through retail community pharmacies, comparable to that which is proposed for the AMP calculations.

Response: Section 1927(k)(1)(B)(i)(IV) of the Act provides that ''payments received from, and rebates or discounts provided to, pharmacy benefit managers . . . hospitals . . . or any other entity that does not conduct business as a wholesaler or a retail community pharmacy . . .'' should be included in AMP when the drug is a 5i drug that is not generally dispensed through a retail community pharmacy. Therefore, the AMP for such 5i drugs should include direct sales (sales for those drugs sold directly from the manufacturer to the listed entity, such as PBMs, and hospitals) and indirect sales (sales for those drugs sold through a wholesaler that does not conduct business as a wholesaler, as defined at section 1927(k)(11) of the Act, because it is engaged in the wholesale distribution of the drug to entities other than retail community pharmacies, such as PBMs and hospitals). As discussed previously, we have revised proposed § 447.504(d) to identify which sales and other transactions should be included in the AMP for 5i drugs not generally dispensed through retail community pharmacies.

Comment: One commenter noted that sales to patients were identified as excluded from the AMP calculation and were not identified as being included in the calculation of AMP for 5i drugs not generally dispensed through retail community pharmacies. The commenter requested clarification on whether manufacturers should assume that sales to patients are also excluded from the calculation of AMP for 5i drugs not generally dispensed through retail community pharmacies.

Response: Sales to patients are excluded from AMP for 5i drugs not generally dispensed through retail community pharmacies since patient sales are not included in the definition of AMP at section 1927(k)(1)(A) of the Act and do not represent payments received from, or rebates or discounts provided to, the list of entities listed at section 1927(k)(1)(B)(i)(IV) of the Act, as implemented in § 447.504(d). Therefore, we have added revised § 447.504(e) to add a paragraph to specify that sales to patients are excluded from the calculation of AMP for 5i drugs not generally dispensed through retail community pharmacies.

Comment: A few commenters noted that the broad inclusion of insurers in the calculation of AMP for 5i drugs not generally dispensed through retail community pharmacies could be read to include discounts to entities that are ineligible for best price, such as Medicare Part D plans and SPAPs. The commenters urged CMS to exclude all best price exempt discounts from the calculation of AMP for 5i drugs not generally dispensed through retail community pharmacies to ensure that the resulting AMP figure is not skewed lower by these best price exempt transactions. Furthermore, the commenter stated that this clarification would be consistent with CMS's proposed policy to conform the AMP and best price definitions.

Response: As we have discussed previously, we believe payments received, and discounts and rebates provided to, government programs, including Part D and SPAPs, should be excluded from the determination of AMP for 5i drugs not generally dispensed through retail community pharmacies. As discussed earlier in this section, manufacturers should exclude government programs when determining AMP for such 5i drugs. As discussed previously, we also believe that section 1927(k)(1)(B)(i)(IV) of the Act does not require the inclusion of payments, discounts or rebates, typically provided by manufacturers under government programs. Therefore, manufacturers should exclude Medicare Part D and SPAP government prices, discounts, and rebates when determining AMP for 5i drugs because they do not represent payments received from, and rebates or discounts provided to PBMs, MCOs HMOs, insurers, hospitals, clinics, mail order pharmacies, long term care providers, manufacturers, or any other entity that does not conduct business as a wholesaler or a retail community pharmacy in accordance with section 1927(k)(1)(B)(i)(IV) of the Act.

Therefore, as discussed previously, we have moved the paragraph on ''Further clarification of AMP calculation'' to § 447.504(f) and have created a separate provision to identify those sales, rebates, discounts, and other financial transactions excluded from AMP for 5i drugs not generally dispensed through retail community pharmacies at § 447.504(e)(1) through (21), which include specific exclusions for any prices charged by Part D plans

and any rebates provided to designated SPAPs.

Comment: One commenter noted that while CMS did not specifically list PBMs as an example of an insurer, it is the commenter's belief that based on the proposed definition of insurer that CMS intended for rebates paid to PBMs are to be included in AMP for 5i drugs not generally dispensed through retail community pharmacies. In addition, the commenter requested that CMS provide specific guidance as to whether manufacturers should include rebates paid to PBMs that own specialty and/or retail community pharmacies in the calculation of AMP for such 5i drugs.

Response: Section 1927(k)(1)(B)(i)(IV) of the Act includes both PBMs and insurers in the list of payments, rebates and discounts excluded from AMP, except in the case of 5i drugs that are not generally dispensed through retail community pharmacies. Therefore, in the case of 5i drugs that are not generally dispensed through retail community pharmacies, payments received from, and rebates or discounts provided to PBMs and insurers are to be included in the AMP calculation. Furthermore, based on our interpretation of section 1927(k)(1)(B)(i)(IV) of the Act, all rebates or discounts provided to PBMs and insurers should be included in the AMP for 5i drugs not generally dispensed through retail community pharmacies, regardless of whether the PBM is acting as an insurer or if it owns its own pharmacies. In light of these provisions, we have revised proposed § 447.504(d)(2) to refer to all PBMs without further conditions.

Comment: One commenter believed that sales to prisons (and closed door pharmacies that serve prisons) should be included in AMP for 5i drugs not generally dispensed through retail community pharmacies and indicated that CMS offered no rationale for the exclusion of sales and discounts to prisons (and closed door pharmacies that serve prisons) which operate much like long-term care providers (which are included in AMP for such 5i drugs). The commenter encouraged CMS to clarify the calculation of AMP for 5i drugs not generally dispensed through retail community pharmacies by adding prisons and closed door prison pharmacies.

Response: As stated previously, we do not believe that Congress by adding the 5i drug provision intended that the statute should be read to disregard CMS's longstanding position that manufacturers should exclude prices from AMP that are made available only through certain state and federal government providers and programs and that manufacturers should now include those prices in AMP for 5i drugs not generally dispensed through retail community pharmacies. Consistent with that understanding, we believe that section 1927(k)(1)(B)(i)(IV) of the Act does not require the inclusion of payments, discounts or rebates, typically provided by manufacturers to prisons in AMP for 5i drugs not generally dispensed through retail community pharmacies as prison pharmacies are not included in the list of entities identified in section 1927(k)(1)(B)(i)(IV) of the Act. In addition, we do not believe that they qualify as the other entities, referenced in the statute, that do not conduct business as wholesalers or retail community pharmacies, which as discussed previously we have defined to include physicians and hospices. Therefore, based upon the comments and our reading of section 1927(k)(1)(B)(i)(IV) of the Act, we are not including sales to prison pharmacies in AMP for 5i drugs not generally dispensed through retail community pharmacies.

Comment: One commenter noted that the AMP calculation defined for 5i drugs not generally dispensed through retail community pharmacies would include transactions already proposed for inclusion in the determination of AMP, as well as non-retail customer transactions. The commenter stated that this approach seemed inconsistent with the goal of trying to identify the average retail price for the AMP and an average non-retail price for the non-retail, 5i drugs. (The commenter referred to this as the ''retail community pharmacy plus approach.'') The commenter believed a more logical method would be to utilize the classes of trade relevant to either the retail community pharmacy drugs or the non-retail drugs.

Response: We disagree with this comment. Section 1927(k)(1)(A) of the Act defines AMP based, in part, on prices paid by retail community pharmacies and wholesalers, and section 1927(k)(1)(B) of the Act identifies specific exclusions from AMP. Section 1927(k) of the Act makes a distinction between AMP and AMP for 5i drugs not generally dispensed through retail community pharmacies, by providing that AMPs for such 5i drugs include, rather than exclude, payments made by (and rebates or discounts provided to) the specific entities listed in section 1927(k)(1)(B)(i)(IV) of the Act. Section 1927(k)(1)(B)(i)(IV) of the Act provides for the exclusion of payments received from, and rebates or discounts provided to PBMs, MCOs, HMOs, insurers, hospitals, clinics, mail order pharmacies, long term care providers, manufacturers, or any other entity that does not conduct business as a wholesaler or a retail community pharmacy from AMP, but it includes such payments, rebates, or discounts when the drug is a 5i drug that is not generally dispensed through a retail community pharmacy. Therefore, a manufacturer is required to calculate and report only one AMP for a drug consistent with sections 1927(k)(1)(A) and 1927(k)(1)(B)(i)(IV) of the Act.

For the reasons discussed in this section, we have revised proposed § 447.504(d) and (e) to provide as follows:

- Proposed § 447.504(d) has been revised to more clearly specify the sales, nominal price sales, and associated discounts, rebates, payments, or other financial transactions that are included in the determination of AMP for 5i drugs not generally dispensed through retail community pharmacies.
- The paragraph on ''Further clarification of AMP calculation'' has been moved from proposed § 447.504(e) to § 447.504(f).
- Proposed § 447.504(e) has been revised to specify the sales, nominal price sales, and associated discounts, rebates, payments or other financial transactions excluded from AMP for 5i drugs not generally dispensed through retail community pharmacies at § 447.504(e)(1) through (20).

e. AMP for Oral CODs Not Generally Dispensed Through Retail Community Pharmacies

We received several comments regarding the calculation of AMP for certain oral drugs that meet the definition of a COD, but are not generally dispensed through retail community pharmacies, nor included in the AMP for 5i drugs not generally dispensed at retail community pharmacies.

Comment: Several commenters recommended that CMS address the AMP methodology for other product forms or package configurations that are not generally sold into retail channels but are not 5i drugs as they could benefit from an alternate AMP calculation. These commenters requested guidance as to how to calculate and report AMP for these non-5i drugs with little or no retail sales and does not believe that CMS has adequately addressed this issue in the proposed rule. A few commenters believed that many manufacturers have been utilizing the same methodology for calculating AMP for 5i drugs not

generally dispensed through retail community pharmacies for these non-retail, non-5i drugs and believed that the Congress intended to provide a calculation pathway for all drugs subject to the MDR program when it amended the Affordable Care Act with section 202 of the Education Jobs and Medicaid Assistance Act that created the 5i provision.

Response: We recognize that there may be instances when oral drugs, such as certain REMS drugs, may only be dispensed through non-retail community pharmacy entities such as physician offices or hospital clinics. As discussed earlier in this final rule, we are not finalizing our proposal that manufacturers include entities that conduct business as retail community pharmacies within AMP; however, we understand that entities such as home health care, home infusion and specialty pharmacies may qualify to be included in the definition of retail community pharmacies, in light of the statutory definition of a retail community pharmacy at section 1927(k)(10) of the Act. Therefore, we believe that in such circumstances, there will be AMP sales for those oral drugs at least to the extent that they are sold through those pharmacies that meet the statutory definition of a retail community pharmacy. Additionally, because we are permitting manufacturers to use a presumed inclusion approach when calculating AMP, and to make reasonable assumptions, we believe that an AMP will be generated for such drugs. We will continue to consider this issue and will provide additional guidance or rulemaking, if needed.

Comment: A few commenters recommended that, in the case of drugs with little or no retail sales, that they should default to the AMP calculation for 5i drugs not generally dispensed through retail community apply the AMP calculation methodology to this un-addressed class of products by stating that hospitals (or other applicable entities) are deemed to be ''conducting business as retail community pharmacies'' for a non-5i drug where there is effectively no other option for the general public to purchase that drug, or by creating a new AMP calculation methodology for non-5i drugs that do not have any eligible sales for the AMP methodology. Another commenter recommended that CMS add to the end of regulatory text for § 447.507(a) ''Each drug purchased by a physician's office must have an AMP reported so that federal rebates can be collected.''

Response: Section 1927(k)(1)(B)(i)(IV) of the Act specifically refers to inhalation, infusion, instilled, implanted or injectable drug sales that are not generally dispensed through a retail community pharmacy that would be included in the AMP for 5i drugs not generally dispensed through retail community pharmacies. While the distribution channels for some oral drugs may be very similar to that of the 5i drugs, we do not find a basis for making this exception in the statute. Therefore, when there are any AMP eligible sales, the calculation should be made based on those sales to entities that meet the definition of a retail community pharmacy at section 1927(k)(10) of the Act. As discussed previously in this section, manufacturers have the option to make reasonable assumptions in their AMP calculations, in the absence of guidance, and may make certain presumptions consistent with the requirements and intent of section 1927 of the Act and federal regulations. We believe, in light of this option, manufacturers have some flexibility to calculate AMP for those oral drugs that do not qualify as 5i drugs.

Comment: A commenter recommended the inclusion of non-340B covered entity outpatient clinics, family planning clinics, city/county/state entities and hospitals in the definition of ''entities that conduct business as wholesalers or retail community pharmacies'' as these entities dispense medications to the general public at retail prices and are typically licensed as pharmacies.

Response: Manufacturers must include payments from, and rebates or discounts provided to clinics and hospitals when calculating AMP for 5i drugs not generally dispensed through retail community pharmacies as required by section 1927(k)(1)(B)(i)(IV) of the Act. As discussed earlier in this section, payments from, and discounts or rebates provided to government pharmacies and SPAPs are excluded from AMP for such 5i drugs consistent with our reading of section 1927(k)(1)(B)(i)(IV) of the Act. As discussed previously, manufacturers may continue to make reasonable assumptions when calculating AMP.

Comment: A commenter stated that there is an arguable basis for limited use of sales to certain non-excluded pharmacies to be included in the determination of AMP for those drugs for which AMP could not otherwise be calculated. For example, if greater than 90 percent of the manufacturer's sales for the respective drug were to an entity other than a wholesaler for distribution to an retail community pharmacy or a retail community pharmacy that directly purchases from the manufacturer, then the drug would be classified as not generally dispensed though a retail community pharmacy and to calculate an AMP for rebate purposes, sales to pharmacies on the edge of the definition of retail community pharmacy could be used to provide a more robust pricing measure.

Response: As the commenter did not specifically identify the types of pharmacies ''on the edge'' of the definition of retail community pharmacy, we are unable to specifically address whether the types of pharmacies to which the commenter referred would qualify as a retail community pharmacy. However, when there are any AMP-eligible sales, the calculation should be made based on those sales and, as we have previously stated in this section, manufacturers have the option to make reasonable assumptions in their AMP calculations consistent with the requirements and intent of section 1927 of the Act and federal regulations.

Comment: One commenter noted that many 5i drug products are covered under Medicare Part B and have pricing established by CMS for the Medicare program based on ASP. The commenter noted that since many states already rely on ASP quarterly pricing published by CMS to price these products for their Medicaid programs, the commenter requested that CMS clarify the expected differences between ASP and AMP pricing for these products.

Response: We appreciate the comment, but at this time, we do not have the Medicaid data available to make such a comparison between AMP and ASP for 5i drugs.

8. Further Clarification on the Calculation of AMP (§ 447.504(f)—Proposed § 447.504(e))

We proposed to include proposed § 447.504(e)(1) through (3) to provide further clarification of AMP calculation. As discussed in a previous response in section II.C.7. of this rule, in this final rule we are moving this provision on ''Further clarification of AMP calculation'' from proposed § 447.504(e)(1) through (3) to § 447.504(f)(1) through (3).

a. Chargebacks and Other Discounts (§ 447.504(f)(1)—Proposed § 447.504(e)(1))

We proposed that AMP would include cash discounts, except customary prompt pay discounts extended to wholesalers, free goods that are contingent on any purchase requirement, volume discounts, chargebacks that can be identified with

adequate documentation, incentives, administrative fees, service fees, distribution fees, and any other rebates, discounts or other financial transactions, other than rebates under section 1927 of the Act, which reduce the price received by the manufacturer for drugs distributed to retail community pharmacies (discussed in more detail at 77 FR 5336). We received the following comments concerning chargebacks and other discounts.

Comment: Several commenters noted that CMS has proposed to include certain previously withdrawn regulatory language that may cause further confusion. Specifically, proposed § 447.504(e)(1) provides, in part, that AMP includes incentives, administrative fees, service fees, distribution fees, and any other rebate, discounts or other financial transactions which reduce the price received by the manufacturer for drugs distributed to retail community pharmacies. This appears to be in conflict with the bona fide service fee exclusion and the commenter recommended that CMS withdraw this language.

Another commenter stated that while CMS parenthetically excludes fees that constitute bona fide service fees in the preamble, the proposed regulatory language creates no such exception and implies that administrative, service and distribution fees are in fact discounts. CMS should clarify that all these fees will not be included in AMP as long as they qualify as bona fide service fee or in the case of GPO services meet the anti-kickback safe harbor. Alternatively, CMS could clarify that such fees will be included in AMP to the extent they do not qualify as bona fide service fees or meet the GPO safe harbor.

Response: We agree that there was inconsistency between the language in the preamble and the language in the regulatory text. Therefore, we have amended the discussion proposed § 447.504(e)(1), which is now codified at § 447.504(f)(1), to add the parenthetical containing the words ''other than bona fide service fees'' to be consistent with the preamble discussion. Also, as we discussed previously in this section these manufacturer fees, including bona fide service fees, are excluded from AMP with regard to 5i drugs not generally dispensed through retail community pharmacies because, such fees do not represent the type of payments from, or discounts or rebates provided to, the entities listed in section 1927(k)(1)(B)(i)(IV) of the Act as implemented in § 447.504(d). Therefore, such fees should not be included in the determination of AMP for such 5i drugs. Additionally, to provide consistency between the AMP and best price sections, we are making the same revision to proposed § 447.505(d)(1). As discussed in more detail in the definition of bona fide service fee (section II.B.4. of this final rule), we believe that to adopt a categorical exclusion of administrative fees if they fall within the GPO safe harbor provisions would be inconsistent with our guidance regarding an actual determination as to whether the fee is bona fide or not, therefore we are not providing the requested clarification.

For the reasons discussed in this section, we are finalizing the provisions originally at proposed § 447.504(e)(1), redesignated at § 447.504(f)(1), except as noted, to add the phrase ''other than bona fide service fees.''

b. Quarterly AMP (§ 447.504(f)(2)—Proposed § 447.504(e)(2))

We proposed at § 447.504(e)(2) that quarterly AMP is to be calculated as a weighted average of monthly AMPs in the quarter (discussed in more detail at 77 FR 5336). We received the following comments concerning quarterly AMP provisions.

Comment: One commenter requested that CMS clarify that when the rule calls for quarterly AMP to be calculated as a weighted average of monthly AMPs in that quarter, that the rule means the sum across the 3 months of the quarter of each month's reported AMP multiplied by the reported units of that month divided by the sum of the reported units for the 3 months of the quarter. The commenter noted that other types of weighting are possible and would yield different results. Another commenter noted that the language in the proposed rule seems to raise doubt about how many manufacturers are doing their quarterly calculation. The commenter asked if CMS expects all manufacturers to calculate their quarterly AMP by adding all sales for the quarter and dividing that result by the total number of units in that quarter (for example, month 1 sales + month 2 sales + month 3 sales/month 1 units + month 2 units + month 3 units); or does CMS intend to have the calculation be the 3 monthly AMPs divided by 3 (month 1 AMP + month 2 +AMP + month 3 AMP/3). The commenter asked if it is the latter, does CMS recognize that the AMPs will be artificially inflated by that formula.

Response: While we appreciate the commenter's question, neither of the calculation methods suggested by the commenter are entirely consistent with the calculation method we expect manufacturers to follow. For purposes of the MDR program, a weighted quarterly AMP should equal total sales across the 3 months divided by total units across the 3 months. To complete this calculation, we expect that manufacturers would calculate the sum of the 3 monthly AMPs times monthly units divided by total sum of units across the 3 months or sum [(month 1 AMP X month 1 units) + (month 2 AMP X month 2 units) + (month 3 AMP X month 3 units)]/sum (month 1 units + month 2 units + month 3 units). This methodology, which is designed to show how an average price is calculated, is consistent with section 1927(k)(1) of the Act as it represents the average price paid to the manufacturer for the drug.

Comment: One commenter asked if there has been a study done of averaging monthly AMPs to get the quarterly AMPs versus making the quarterly AMP a separate calculation. The commenter stated that spikes, primarily due to seasonal product sales will cause an ''averaged'' quarterly AMP to be far different from one calculated using the actual quarterly sales dollars and units and indicated this was especially true of multiple package size products. The commenter requested that CMS address this issue in the final rule.

Response: We are not aware of any studies that have been done in this area. We have reviewed monthly AMP submissions from manufacturers and recognize that seasonal product sales can affect the monthly and quarterly AMPs. However, by requiring manufacturers to smooth lagged price concessions we believe the monthly and quarterly AMPs will stabilize. Therefore, we have provided that manufacturer should calculate a weighted AMP, consistent with our reading of section 1927(k)(1) of the Act as it represents the average price paid to the manufacturer for the drug in the United States.

Therefore, for the reasons stated in this section, we are finalizing the provisions pertaining to the calculation of quarterly AMP as proposed, at redesignated § 447.504(f)(2).

c. Manufacturer Adjustments (§ 447.504(f)(3)—Proposed § 447.504(e)(3))

To account for discounts, rebates or other price concessions that may not be available during the rebate reporting period (meaning they are available on a lagged basis), we provided at proposed § 447.504(e)(3) that the manufacturer must adjust the AMP for the applicable rebate period if cumulative discounts, rebates, or other arrangements subsequently adjust the prices actually realized, to the extent that these discounts, rebates or arrangements are

not excluded from the determination of AMP by statute or regulation (77 FR 5336). We received no comments on this provision and for the reasons specified in the proposed rule (77 FR 5336) and this section, are finalizing our proposal at redesignated § 447.504(f)(3).

D. Determination of Best Price (§ 447.505)

1. Definitions of Best Price and Providers

We proposed to codify the definitions for the terms ''best price'' and ''provider'' under proposed § 447.505(a) (77 FR 5336, 5362). Additionally, we proposed to revise the definition of the term ''best price'' at § 447.505(a) so that it is consistent with the definition of best price found in section 1927(c)(1)(C) of the Act (77 FR 5336, 5362). We received no comments regarding our proposal to codify and define ''best price'' and ''providers.'' Therefore, we are including these definitions under § 447.505(a) and finalizing the definition of ''provider'' as proposed. We are also finalizing the definition of best price as proposed, except that we are including a reference to ''an authorized generic drug'' and deleting the phrase ''for any such drug of a manufacturer that is sold under an NDA approved under section 505(c) of the FFDCA,'' to be consistent with the definition of authorized generic drug that we are finalizing at § 447.502. This technical modification is designed to simplify the reference to those drugs sold under an NDA approved under section 505(c) of the FFDCA (for example, authorized generic drugs); it is not designed to substantively change the proposed definition of best price that we are finalizing.

2. Prices Included in Best Price

We proposed the ''Prices included in best price'' section, currently located at § 447.505(c)(1) through (11), be redesignated to proposed § 447.505(b) and that it be revised to remove the list of prices included in best price, so that the definition is consistent with the statute. As discussed in the proposed rule, we believe this revision provides sufficient detail as to the prices included in best price (as discussed in more detail at 77 FR 5336). We received the following comments concerning the proposed redesignation and revisions to the rule to remove the list of prices included in best price:

Comment: Many commenters appreciated CMS's efforts to conform the best price regulatory definition to the statutory definition of best price. However, the commenters were concerned that the proposed language leaves some room for ambiguity regarding the treatment of prices and associated discounts or other price concessions to entities that are not best price-eligible entities as defined by the statute. Specifically, proposed § 447.505(b) provides that best price includes all prices and associated rebates, discounts, or other financial transactions that adjust the price either directly or indirectly unless specifically excluded from best price, but does not expressly limit those prices to the entities listed in paragraph (a), and thus creates ambiguity regarding the treatment of prices and associated discounts or other price concessions to customers, such as patients, that are not included in the statutory definition of best price.

Commenters recommended that CMS revise the proposed language in paragraph (b) to clarify that the prices described in paragraph (b) are eligible for consideration in best price only if they are prices to one of the best price-eligible entities listed in paragraph (a). The commenters suggested that CMS revise paragraph (b) to state, ''Best price for CODs includes all prices and associated rebates, discounts, or other transactions that adjust prices either directly or indirectly, provided to any entity described in paragraph (a), unless such prices are otherwise excluded as provided in paragraph (c) of this section.'' The commenters believed this revision is necessary to ensure that the rule does not unlawfully expand the statutory definition to include prices to entities other than those identified in the statutory definition of best price.

A few commenters stated that to be consistent with the statute and the definition in proposed § 447.505(a), the proposed language at § 447.505(b) should include ''to any wholesaler, retailer, provider, health maintenance organization, nonprofit entity or government entity'' after ''. . . that adjusted prices . . .'' and before ''either directly or indirectly.'' Otherwise, the commenter believed that the proposed language at § 447.505 could be read to include in best price sales to non-entities such as patients.

Response: In accordance with the § 447.505(c), we are finalizing under notice and comment rulemaking, that best price includes prices and associated rebates, discounts, or other price concessions that adjust prices either directly or indirectly. We believe this language, which should be familiar to manufacturers when calculating best price, is designed to require that manufacturers include those adjustments made to an eligible entity but not to require an accumulation of adjustments provided to all entities. Additionally, we do not believe it is necessary to relist the best price-eligible entities already identified in the definition of best price, but agree with the suggestion to further revise proposed § 447.505(b) to clarify that best price includes all prices, applicable discounts, rebates, or other transactions that adjust prices either directly or indirectly to the best price-eligible entities listed in § 447.505(a). In light of the comments, we have decided to include a reference to these best price eligible entities.

Comment: One commenter noted that unlike the AMP final rule, which suggested that manufacturers must ''stack'' price concessions provided to any single best price-eligible entity on a single unit of a product, neither the preamble nor the regulatory text of the proposed rule specifically address stacking. The commenter requested that CMS adopt a policy with regard to the requirement to stack in best price when two different price concessions are provided to two different contracted entities. Specifically, the commenter believed that CMS should adopt a policy where the manufacturer would only be required to combine price concessions on a single unit when it has actual knowledge of, or documentation that reflects that the price concessions will flow to a single entity. Further, the commenter requested guidance as to what degree of relationship that two separate but related entities must have for them to be deemed a ''single entity'' for best price stacking purposes.

Another commenter was concerned that the proposed rule would redefine best price to include within a single price to a particular customer all rebates and payments ''associated'' with that transaction. The commenter believed this to be a vague term which does not clearly state that the associated payment must be provided to the same entity to which the product is sold. The commenter further noted that this would be a significant change to the definition of best price in statute and the national rebate agreement. Therefore, the commenter objected to the definition as it would require manufacturers to include in the best price available to one customer, as a price concession to that customer, a payment made to a completely different entity and the commenter believed this was a significant change to the statutory and contract definition.

Response: A manufacturer is responsible for including all price concessions that adjust the price realized by the manufacturer for the

drug in its determination of best price. If a manufacturer offers multiple price concessions to two entities for the same drug transaction, such as rebates to a PBM where the rebates are designed to adjust prices at the retail or provider level and discounts to a retail community pharmacy's final drug price, all discounts related to that transaction which adjust the price available from the manufacturer should be considered in the manufacturer's final price of that drug when determining the best price to be reported for the drug. We believe this policy is consistent with current § 447.505(e)(3), which requires that if cumulative discounts subsequently adjust the price available from the manufacturer, they should be included in the best price calculation.

Furthermore, the requirement to include all discounts that subsequently adjust the price available from the manufacturer is also consistent with the provisions we are finalizing in this rule at § 447.505(c)(17), which specifies that best price includes PBM rebates, discounts or other financial transactions, including their mail order pharmacy purchases, where such rebates, discounts or price concessions are designed to adjust prices at the retail or provider level. In addition, we are finalizing, as proposed, at § 447.505(d)(3), that manufacturers must adjust the best price if cumulative discounts, rebates, or other arrangements subsequently adjust the prices available from the manufacturer. We do not believe it is necessary to specify the degree of the relationship between two separate but related entities since the manufacturer's price concessions or discounts that are passed on to best price-eligible entities are not predicated upon a relationship existing between the two entities.

We also do not believe it is necessary that this regulation detail every arrangement that may subsequently adjust the prices available from the manufacturer. With the recent introduction of value based purchasing arrangements in the pharmaceutical marketplace, we recognize the value of such arrangements especially when they benefit patients. We are also interested in assuring that states and Medicaid programs have clarity as to how these arrangements might exist in Medicaid. Therefore, since these arrangements are unique, we are considering how to provide more specific guidance on this matter, including how such arrangements affect a manufacturer's best price.

While we are making some minor revisions, as discussed in this section, there are no substantive changes being adopted in this final rule regarding a manufacturer's treatment of financial transactions that subsequently adjust prices to best price-eligible entities.

In response to the comments and for the reasons discussed in this section, we are revising proposed § 447.505(b) to delete the reference to ''associated'' rebate and discounts, and to insert a reference to ''applicable discounts, rebates'' and to the best price-eligible entities listed in § 447.505(a). Specifically, we have revised § 447.505(b) to provide that the best price for CODs includes all prices, including applicable discounts, rebates or other transactions that adjust prices either directly or indirectly to the best price-eligible entities listed in § 447.505(a).

3. AMP Methodology Applied to Best Price

For consistency, we proposed to apply the same methodology to best price that we are applying to AMP, where applicable (77 FR 5336). To do so, we proposed the ''Prices excluded from best price'' section, currently located at § 447.505(d)(1) through (13), be revised and redesignated to § 447.505(c)(1) through (18) (as discussed in more detail at 77 FR 5336). We also proposed in the regulatory text to expand the list of prices excluded from best price to include manufacturer copayment assistant programs (§ 447.505(c)(10)), manufacturer-sponsored patient refund/rebate programs (§ 447.505(c)(11)), manufacturer vouchers (§ 447.505(c)(12)), reimbursement by the manufacturer for recalled, damaged, expired, or otherwise unsalable returned goods (§ 447.505(c)(14)), and sales outside the United States (§ 447.505(c)(18)) to apply the same methodology to best price that is used for the determination of AMP (77 FR 5336, 5363). We also proposed to redesignate § 447.505(e) ''Further clarification of best price'' to proposed § 447.505(d). Because we did not propose changes to the current language of § 447.505(e), the proposed redesignation was only proposed in the regulatory text and not discussed in the preamble (77 FR 5363). Therefore, in this section we address comments regarding the proposed exclusions from best price section (§ 447.505(c)), as well as the proposed further clarification of best price (§ 447.505(d)). Some of these changes were proposed to provide consistency between the AMP and best price sections, while others were retained from the rule finalized with the AMP final rule in 2007. For example, in the preamble to the proposed rule (77 FR 5336), we proposed to expand the list of prices excluded from best price that were not identified previously in regulations to more closely mirror the exclusions from AMP, where applicable, consistent with section 1927(c)(1)(C) of the Act; including vouchers, manufacturer-sponsored patient refund/rebate programs, and sales outside of the United States. In the proposed rule (77 FR 5363), we also proposed to expand the list of prices excluded from best price to include manufacturer copayment assistant programs (§ 447.505(c)(10)) and reimbursement by the manufacturer for recalled, damaged, expired, or otherwise unsalable returned goods (§ 447.505(c)(14). In some instances, commenters generalized their comments so that they were applicable to both AMP and best price. In those cases we have chosen to respond to the comments in the Determination of AMP section (section II.C.) of this final rule and have noted, where applicable, any changes to best price that are being finalized as a result of comments within the AMP section of this final rule. We are therefore not repeating those comments that were specific to both AMP and best price within this section of the final rule. Please note that when referring to AMP in the context of AMP methodology applied to best price, we are referring to AMP in general and are not making any distinctions between AMP for 5i drugs versus AMP for non-5i drugs. We received the following comments related to the best price calculation:

Comment: Some commenters supported CMS's efforts to better align the methods for determining AMP and best price. One of these commenters believed this will streamline and clarify manufacturer's price reporting responsibilities.

Response: We agree that revising the best price provisions to more closely align with AMP will help with streamlining and clarifying manufacturer's price reporting responsibilities.

Comment: Several commenters supported the exclusion of patient transactions from AMP and suggested that we apply these same exclusions to the best price definition. The commenters' stated that patients are not entities and cannot be best price-eligible purchasers and manufacturer-funded benefits to patients are irrelevant to the best price calculations.

Response: We agree that best price excludes direct sales to patients because patients are not one of the entities described in the statutory definition of best price, and therefore, we are adding direct patient sales to the list of sales

excluded from best price at § 447.505(c)(19).

Comment: Several commenters supported CMS's proposal to exclude from best price patient programs (such as manufacturer coupons, vouchers, manufacturer drug discount programs, manufacturer rebate or refund programs and copayment and patient assistance programs) to the same extent as those programs are excluded from AMP, provided that all program benefits go to the patients and no best price-eligible entity receives a discount, rebate or other price concession. The commenters also requested that CMS explicitly confirm that the 2007 AMP final rule prohibition of purchase contingencies to patients when receiving free goods no longer applies and that discounts to patients are excluded from AMP and best price regardless of any purchase contingencies. Another commenter stated that in instances when price concessions go to a best price-eligible entity in relation to a patient transaction, the price concessions do count in best price.

Response: As discussed in this section, in this final rule we are adding § 447.505(c)(19) to list direct patient sales as prices excluded from best price because patients are not one of the entities described in the statutory definition of best price at section 1927(c)(1)(C) of the Act. However, the requirements at section 1927(c)(1)(C)(ii)(I) of the Act further provides that best price shall be inclusive of free goods that are contingent on any purchase requirement. Since this statutory language does not link the availability of free goods to only those purchases made by the entities listed in section 1927(c)(1)(C)(i) of the Act, a manufacturer that provides a free good that requires a purchase be made to receive the free good would be an included transaction. In other words, if a manufacturer provides a free good directly to the patient and there is a purchase requirement that direct to patient sale would no longer be excluded from the manufacturer's determination of best price.

Therefore, we are revising § 447.505(c)(12) to exclude from the best price calculation manufacturer-sponsored programs that provide free goods, including but not limited to vouchers and patient assistance programs, but only to the extent that the voucher or benefit of such a program is not contingent on any other purchase requirement; the full value of the voucher or benefit of such a program is passed on to the consumer; and the pharmacy, agent, or other entity does not receive any price concession. These revisions ensure that the treatment of these programs are in line with the statutory requirements at section 1927(c)(1)(C)(ii)(I) of the Act and provides consistency between AMP and best price.

Furthermore, as discussed in more detail in the Determination of AMP section of the final rule (II.C.6.v) we have also made the following revisions to best price to accurately reflect the exclusion of patient programs from best price. First, proposed § 447.505(c)(8), which pertains to manufacturer-sponsored drug discount card programs, has been revised to add the contingency that the full value of the discount is passed on to the consumer and the pharmacy, agent or other entity does not receive any price concession. These changes are being made to provide clarification and consistency as was requested by the commenters, as well as to more accurately describe all of the conditions that must be satisfied to make a particular program excluded from AMP and best price, consistent with sections 1927(k) and 1927(c)(1)(C) of the Act, as applicable. Additional discussion of this revision is provided in the Determination of AMP section of this final rule (section II.C.6.v.).

Second, we have revised proposed § 447.505(c)(10) to pertain solely to Manufacturer copayment assistance programs because Patient Assistance Programs have been moved to § 447.505(c)(12), as discussed previously in this section and the Determination of AMP section (II.C.6) of this final rule. We have also revised proposed § 447.505(c)(10) to remove the language ''provided free of charge'' because these types of programs typically offer copayment assistance, which may or may not result in free goods to patients. Additional discussion of this revision is provided in the Determination of AMP section of this final rule (section II.C.6.v.). Furthermore, we have revised proposed § 447.505(c)(10) to add the contingency that the program benefits are provided entirely to the patient, and the pharmacy, agent, or other entity does not receive any price concessions. These changes are being made to provide clarification and consistency, as well as to more accurately describe all of the conditions that must be satisfied to make a particular program excluded from AMP and best price, consistent with sections 1927(k) and 1927(c)(1)(C) of the Act, as applicable.

Third, proposed § 447.505(c)(11), which pertains to manufacturer-sponsored patient refund/rebate programs, has been revised to remove the language ''provided free of charge'' because these types of programs typically offer discounts that may or may not result in patients receiving the drug for free. Additional discussion of this revision is provided in the Determination of AMP section of this final rule (section II.C.6.v.). Furthermore, we have added the contingency that the manufacturer provides a full or partial refund or rebate to the patient for out-of-pocket costs and the pharmacy, agent, or other entity does not receive any price concessions. These changes are being made to provide clarification and consistency, as well as to more accurately describe all of the conditions that must be satisfied to make a particular program excluded from AMP and best price, consistent with sections 1927(k) and 1927(c)(1)(C) of the Act, as applicable. Furthermore, we are finalizing § 447.505(c)(13) to provide that free goods, not contingent upon any purchase requirement, are excluded from best price. Additionally, manufacturers must include the value of the discount, coupon, rebate, or voucher in the determination of best price if the program generates a price concession to a best price-eligible entity. Finally, we are also finalizing § 447.505(c)(9) pertaining to manufacturer coupons, as it was proposed (77 FR 5363), since no comments were received on this proposal and it remains unchanged from the present regulations.

Comment: One commenter requested that CMS clarify the proper treatment of financial transactions with AMP or best price-eligible entities that are generated as part of the administration of excluded patient programs. For example, the commenter requested that CMS confirm that when a pharmacy extends a manufacturer-sponsored discount to a patient, and the manufacturer then reimburses the pharmacy for the exact amount of that patient discount, the reimbursement transactions with the pharmacy should be excluded from AMP and best price because the entire benefit of the discount flows through to the patient and there is no discount to the pharmacy. Similarly, where a manufacturer pays a pharmacy a bona fide service fee for administering a discount program that otherwise can be excluded from AMP and best price, the commenter believed that the fee paid to the pharmacy is also properly excluded from AMP and best price. The commenter requested that CMS expressly address the proper treatment of these specific examples in the final rule.

Response: We agree that when a pharmacy is simply a conduit to passing

a discount through to the beneficiary, those manufacturers-to-pharmacy transactions are excluded from AMP and best price. Furthermore, those fees that meet the requirements of our definition of bona fide service fee at § 447.502 shall be excluded. Further discussion regarding the definition and application of bona fide service fee when determining AMP and best price is found at sections II.B., II.C., and II.D. of this final rule (§§ 447.502, 447.504(c), 447.504(e), and 447.505(c)).

Comment: One commenter noted that CMS does not explicitly provide that discounts to SPAPs or other best price-exempt transactions are excluded from the determination of best price.

Response: When prices paid by certain entities, such as SPAPs, are exempt or excluded from best price, the excluded price shall be inclusive of all associated transactions to those entities such as subsequent discounts and rebates eventually paid for by the manufacturer. However, as discussed in prior response, when there is a contingency arrangement related to the provision of free goods, such transactions are generally included in the best price. We have decided to further clarify the proposed rule regarding prices paid to SPAPs, because we agree with the commenter that our proposed rule was not clear regarding the exclusion of such prices, because SPAPs typically do not pay for drugs directly to manufacturers, but rather act as an insurer that may receive additional price concessions from the manufacturer. Therefore, instead of specifying ''any prices'' provided to designated SPAPs, in this final rule we are revising proposed § 447.505(c)(4) to clarify that ''any prices, rebates or discounts'' provided to designated SPAPs are excluded from best price. As we stated earlier, reference to prices is ''typically'' meant to include associated discounts or rebates which reduce the price available from the manufacturer. We believe this revision further clarifies which specific SPAP transactions are excluded from best price.

Comment: A few commenters requested that CMS explicitly confirm that prices to other manufacturers for products sold for use in clinical trials are not included in best price. The commenters noted that according to the plain language of the statute, a manufacturer is a best price-eligible entity only in the specific, limited case of sales of authorized generics. The commenters believed that a manufacturer that purchases drugs from another manufacturer for use in clinical trials does not satisfy the definition of wholesaler or any other best price-eligible entity, and prices associated with such sales should not be included in best price.

Response: There is no explicit exclusion in section 1927(c) of the Act for drugs used in clinical trials. Therefore, in instances when a manufacturer sells drugs to another manufacturer for use specifically in a clinical trial, those prices are included in a manufacturer's determination of best price, but only to the extent the other manufacturer qualifies as a best-price eligible entity as provided at § 447.505(c). A manufacturer, as defined at section 1927(k)(5) of the Act, is a best price-eligible entity if it meets the definition of a wholesaler at section 1927(k)(11) of the Act. That is, the manufacturer is engaged in wholesale distribution of prescription drugs to retail community pharmacies. We believe in instances when the purchasing manufacturer is using the drug as part of a clinical trial, that manufacturer is likely not engaged in wholesale distribution of prescription drugs to retail community pharmacies, and in such situations, such sales would not be included in best price.

Comment: One commenter supported CMS's conforming exclusion of returns from the best price calculation. The commenter believed returns do not impact the price realized by a customer.

Response: We appreciate the support and note that in this final rule we are finalizing, with some revisions, proposed § 447.505(c)(14) (''Reimbursement by the manufacturer for recalled, damaged, expired, or otherwise unsalable returned goods'') to align with the regulations text found in the AMP section at § 447.504(c)(16) by changing ''it only covers these costs'' to ''such payment covers only these costs.'' We believe this will ensure consistency regarding how manufacturers treat returns in their determinations of AMP and best price.

Comment: Many commenters noted that the best price proposed rule failed to delete language providing that best price is ''net of . . . returned goods.'' The commenters stated that this provision is not consistent with the new language on returns that CMS proposes to add to the best price definition and should be removed. Another commenter urged CMS to clarify that returned goods may be excluded from best price to the extent that the return is made from any best price-eligible customer, not just wholesalers, where the transaction otherwise satisfies the qualitative criteria for exclusion.

Response: We agree, and for the reasons commenters noted, in this final rule, we are amending proposed § 447.505(d)(1) by removing the word ''returns'' to be consistent with the proposed § 447.505(c)(14), which, as specified in this section, is being finalized to specify that reimbursement by the manufacturer for recalled, damaged, expired, or otherwise unsalable returned goods is excluded from best price.

Comment: Several commenters did not agree with the limitation of entities eligible for the bona fide service fee exclusion as it applies to best price and indicated that CMS should expand the bona fide service fee exception to include any best price-eligible entity (and any entity that does not trigger best price consideration). The commenters added that CMS should revise the regulatory text to exclude from best price those bona fide service fees paid to any ''wholesaler, retailer, provider, health maintenance organization, nonprofit entity, or governmental entity in the United States.'' Commenters indicated that without this expansion, fees that are bona fide under the proposed rule's substantive definition would be inappropriately counted as adjusting the price realized by the best price-eligible entity and has the potential to inappropriately increase manufacturers' rebate liabilities on brand drugs since it could require manufacturers to recognize the same fee as a discount in some contexts (when the fee is provided to best price-eligible entities other than wholesalers and retail community pharmacies) but as a legitimate fee in others (when the fee is provided to wholesalers and retail community pharmacies).

A few commenters noted that it seems illogical to exclude a bona fide service fee paid to GPOs from AMP and best price but not apply the exclusion to other entity types such as PBMs and insurers that, like GPOs, are outside the supply chain in that they do not purchase prescription drugs. One commenter stated, in certain instances, the change in definition of bona fide service fee could require manufacturers to stack PBM or MCO service fees with rebates when determining best price. The commenter maintained the likely unintended consequences of this type of stacking requirement would be a reduction in the fees and/or rebates that manufacturers would be willing to offer insurers and their agents for formulary placement, which could lead to increases in insurance premium or brand copayments to the commercially insured public. The commenter also noted that long term care and mail order pharmacies, like retail community pharmacies, do on occasion provide services to manufacturers that deserve

to be treated as compensation for work performed and not discounts on products when best price is determined. The commenter stated that CMS has authority to require the exclusion of fees that satisfy the four-part test for a bona fide service fees from best price regardless of the recipient.

Response: We agree with the commenters and have revised the proposed § 447.505(c)(16), which referenced the exclusion of bona fide service fees to wholesalers, retail community pharmacies, or entities that conduct business as wholesalers or retail community pharmacies. We did not intend to change our current policy in § 447.505(d)(12), which provides for a broad exclusion of bona fide service fees for purposes of the best price calculation. This was an unintended drafting error in the proposed rule. Furthermore, we agree with the commenters that for purposes of best price calculations, we specifically distinguish GPOs from best price-eligible entities when applying the bona fide services fee exclusion for MDR purposes. GPOs may function as negotiators for prices on behalf of pharmacies, hospitals, or physician practices, with GPOs receiving service fees for their services, or they may function as distributors of price concessions from manufacturers to their members after volume sales benchmarks have been attained. To the extent that service fees are paid to a GPO and those fees qualify as bona fide service fees, they should be excluded from best price.

Therefore, we have revised proposed § 447.505(c)(16) to specify that the bona fide service fees, as defined in § 447.502 are excluded from the determination of best price and we have removed the specific references to wholesalers, retail community pharmacies, entities that conduct business as wholesalers or retail community pharmacies, and GPOs. As discussed in the definition of Bona Fide Service Fee in section II.B.4. of this final rule, we are no longer specifically referencing GPOs in the regulatory text because we do not believe it is necessary with the revised definition of bona fide service fee. We believe this revision will maintain CMS's current policy which provides for a broad exclusion of bona fide service fees for purposes of the best price calculation. In addition, we have revised proposed § 447.505(d)(1) by adopting the reference to bona fide service fee in current § 447.505(e)(1). Specifically, we have revised proposed § 447.505(d)(1) by adding the parenthetical reference ''except bona fide service fees'' to clarify that such fees should be excluded from best price calculations.

Therefore, for the reasons discussed in this section, we are finalizing proposed § 447.505(c) and (d), including the following revisions:

- Proposed § 447.505(c)(4) is revised to specify that ''any prices, rebates or discounts'' provided to designated SPAPs are excluded from best price.
- Proposed § 447.505(c)(8) is revised to specify that manufacturer-sponsored drug discount card programs, but only to the extent that the full value of the discount is passed on to the consumer and the pharmacy, agent, or other entity does not receive any price concession are excluded from best price.
- Proposed § 447.505(c)(10) is revised to specify that Manufacturer copayment assistance programs, to the extent that the program benefits are provided entirely to the patient and the pharmacy, agent, or other entity does not receive any price concession are excluded from best price.
- Proposed § 447.505(c)(11) is revised to specify that manufacturer-sponsored patient refund or rebate programs, to the extent that the manufacturer provides a full or partial refund or rebate to the patient for out-of-pocket costs and the pharmacy, agent, or other entity does not receive any price concession are excluded from best price.
- Proposed § 447.505(c)(12) is revised to specify that manufacturer-sponsored programs that provide free goods, including but not limited to vouchers and patient assistance programs, but only to the extent that the voucher or benefit of such a program is not contingent on any other purchase requirement; the full value of the voucher or benefit of such program is passed on to the consumer; and the pharmacy, agent, or entity does not receive any price concession are excluded from best price.
- Proposed § 447.505(c)(14) is revised to replace ''it only covers these costs'' with ''such payment covers only these costs'' to further ensure consistency in how returns are treated in AMP and best price.
- Proposed § 447.505(c)(15) is revised to remove the reference to ''of this subpart'' given the regulatory cite is specified (§ 447.508) within the paragraph.
- Proposed § 447.505(c)(16) is revised to reference bona fide service fees ''as defined at § 447.502,'' and to delete language from the proposed rule describing types of fees (inventory fees, distribution service fees, etc.) because such fees are included in the definition of bona fide service fee at § 447.502.
- We have added direct patient sales to the list of sales excluded from best price at § 447.505(c)(19).
- Proposed § 447.505(d)(1) is revised to delete the reference to ''returns'' and to include ''except bona fide service fees'' after the reference to ''service fees'' and before distribution fees.

4. 340B Expanded List of Covered Entities Exempt From Best Price

In accordance with sections 1927(a)(5)(B) and 1927(c) of the Act, we proposed at § 447.505(c)(2) that manufacturers should exclude from best price the prices charged under the 340B program to a covered entity described in section 1927(a)(5)(B) of the Act and any inpatient prices charged to hospitals described in section 340B(a)(4)(L) of the PHSA (77 FR 5363). In accordance with section 340B(a)(4) of the PHSA, we proposed to clarify how manufacturers are to treat orphan drugs sold to new covered entities described in sections 340B(a)(4)(M), (N), and (O) of the PHSA for best price. These requirements were proposed at new § 447.505(c)(2)(i) and (ii) (see 77 FR 5337 for additional information). We received the following comments concerning these provisions:

Comment: Many commenters opposed our proposal that manufacturers can exclude only drugs purchased under the 340B Drug Pricing Program from their best price calculation. One commenter stated that by narrowing the 340B best price exemption to prices charged ''under the 340B Drug Pricing Program'' and inpatient prices to disproportionate share hospitals (DSH), the proposed rule would depart from the rebate statute's plain language, which expressly exempts ''any prices'' to covered entities. Another commenter noted that the term ''any'' is commonly defined as ''every'' and therefore includes all prices offered, whether at a 340B price or not. Many commenters indicated that CMS should incorporate the plain meaning of the statutory language in the final rule because not allowing manufacturers to exclude these sales from best price would be inconsistent with the Medicaid statute. Commenters also noted that nowhere in the law is the best price exclusion limited to sales under the 340B Drug pricing program.

Another commenter stated that this broad exception to best price has been enshrined in the statute and has governed the intersection of Medicaid and 340B since the 340B program's inception.

Response: We are not finalizing the changes to the best price calculation proposed for § 447.505(c)(2). Instead, in light of the comments and section 1927(c)(1)(C)(i) of the Act, we are

revising proposed § 447.505(c)(2) to provide that any prices charged to 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) shall be excluded from best price. We have considered the numerous comments received regarding our proposed interpretation of what any price means in the context of the best price exemption and we agree with the commenters that as long as the entity meets the definition of a ''covered entity,'' which (consistent with section 1927(a)(5)(B) of the Act) is defined in section 340B(a)(4) of the PHSA to include a requirement that the covered entity meet the requirements described in section 340B(a)(5) of the PHSA, any prices charged by manufacturers and paid for by covered entities, consistent with these provisions, shall be excluded from best price.

Comment: One commenter stated that federally qualified health centers (FQHCs) and other covered entities are by definition safety net health care providers and if a manufacturer is willing to sell drugs to FQHCs at a price lower than the 340B ceiling price (but higher than the nominal price) it should be encouraged to do so without concern that it will set a new best price for the product.

Response: We agree with the commenter that including in best price a price charged by a manufacturer and paid for by the covered entity that is lower than a 340B ceiling price (sub-ceiling prices) should not reset the manufacturer's best price for a COD. We believe that any prices for drugs sold to covered entities (as described in section 340B(a)(4) of the PHSA) may be excluded from best price. This policy is further supported by section 340B(a)(10) of the PHSA which allows manufacturers to charge a price for a drug that is lower than the maximum price that may be charged under 340B(a)(1) of the PHSA.

Comment: Several commenters asked for clarification about whether sub-ceiling prices, particularly those not offered through the 340B Prime Vender Program and inpatient prices offered to hospitals not described in PHSA 340B(a)(4)(L) under the 340B program would be exempt from best price. Specifically, several commenters requested that CMS expressly clarify whether the following prices are considered prices under the 340B program: voluntary ceiling prices on orphan drugs offered to entities newly added to the 340B program by the Affordable Care Act, sub-ceiling discounts offered to covered entities, regardless of whether those discounts are offered through the 340B Prime Vendor program, and prices for commercial sales offered to covered entities that elect to ''carve out'' Medicaid patients and purchase non-340B products for those patients, and inpatient prices to entities other than those described in section 340B(a)(4)(L) of the PHSA.

The commenters noted that without clarity, manufacturers would likely interpret the provision differently and some could be putting themselves at risk for best price restatements and potentially False Claims liability. One of these commenters stated that without effectively explaining in the preamble or regulatory text how to interpret the concept, CMS would place restrictions on the prices excluded from best price that are extended to 340B entities.

Response: As discussed previously, we are removing the phrase ''under the 340B drug pricing program'' from proposed § 447.505(c)(2)(i) in this final rule to be consistent with section 1927(c)(1)(C) of the Act and instead revising proposed § 447.505(c)(2) to provide that any prices charged to 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) shall be excluded from best price. We have taken into consideration the number of comments regarding our proposed interpretation of what any price means in the context of the best price exemption and agree that as long as the entity meets the definition of a covered entity described in section 1927(a)(5)(B) of the Act, which defines such entities in section 340B(a)(4) of the PHSA, any prices charged by manufacturers and paid for by covered entities shall be excluded from best price. Furthermore, we believe that this change clarifies that manufacturers may exclude any prices offered at or below the 340B ceiling price (subceiling prices).

Comment: One commenter would like to understand if the current regulation issued under the Medicare Prescription Drug, Improvement, and Modernization Act (MMA) of 2003 that allows manufacturers to exclude from the calculation of best price any inpatient sales to DSH hospitals still remains in effect and can continue to exclude from best price inpatient drug purchases to disproportionate share hospitals.

Response: Those prices for drugs purchased for inpatient use by DSH hospitals described in section 340B(a)(4)(L) of the PHSA are excluded from best price as long as such hospitals meet the definition of a covered entity as defined in section 340B(a)(4) of the PHSA.

Comment: One commenter believed that, even when a covered entity carves out its Medicaid drugs from the 340B program, CMS should still allow manufacturers to exclude these drug prices from their best price calculation as to do otherwise would be inconsistent with the Medicaid statute. The commenter stated that even if a covered entity chooses to carve out its Medicaid drugs from the 340B program, it should be able to negotiate a discounted price, and by not allowing this practice, it could create reluctance on the part of manufacturers to provide discounted prices to safety net providers. The commenter suggested that this final rule clarify that manufacturers may exclude from their best price calculations their sales to covered entities, even when the entity takes advantage of the Medicaid carve-out option.

Response: As discussed previously, we have revised our proposal to provide that manufacturers should exclude from their determination of best price any drug prices charged to a covered entity as described in section 1927(a)(5)(B) of the Act.

Comment: One commenter stated that the ''Orphan Drug Exclusion'' prevents hospitals from accessing 340B prices on certain orphan drugs and indicated that many manufacturers are not offering 340B prices on orphan drugs to rural and freestanding cancer hospitals based on a concern that such a price would lower their best price. Several commenters urged CMS to clarify in the final rule that manufacturers can sell orphan drugs at 340B prices to 340B hospitals including rural and freestanding cancer hospitals and the newly covered entities added by the Affordable Care Act without affecting their best price. Another commenter stated that the inability to exclude from best price voluntary discounts prices (outside of the 340B program) for orphan drugs to covered entities could deter manufacturers from offering such discounts.

Another commenter stated that because the statutory 340B best price exclusion applies to covered entities and not CODs, the commenter believed the orphan drug exclusion does not impact the best price exclusion. The commenter further stated that a voluntary 340B price on an orphan drug to an entity affected by the orphan drug exclusion is still a price to the 340B covered entities, which is the statutory requirement for best price exclusion.

Response: As discussed in the prior responses, we have revised proposed

§ 447.505(c)(2) to delete the provision limiting the exclusion to prices charged ''under the 340B program.'' The orphan drug exclusion does not affect the best price provision in section 1927(c)(1)(C) of the Act. Therefore, as discussed previously in this section, any prices charged by manufacturers to a covered entity that meets the definition of a covered entity as described in section 1927(a)(5)(B) of the Act, which defines such an entity in section 340B(a)(4) of the PHSA to include a reference to the entity meeting the requirements described in section 340B(a)(5) of the PHSA, should be excluded from best price.

Comment: One commenter noted that while the statute specifically allows manufacturers to exclude from best price sales of inpatient drugs to DSH hospitals, the recent addition of other hospitals to the list of 340B covered entities (children's hospitals, critical access hospitals, rural referral centers, sole community hospitals, and freestanding cancer hospitals) were not included because of a statutory drafting convention. The commenter stated this has led to confusion as to whether manufacturers may exclude from their best price calculations the sale of inpatient drugs to the newly-added hospitals. Another commenter supported the proposal by CMS to limit best price exception to the DSH hospital enrolled in 340B programs, which include children's hospitals, rural hospitals and freestanding cancer hospitals.

Response: As discussed previously in this section, we have revised proposed § 447.505(c)(2) to delete the provision limiting the exclusion to prices charged ''under the 340B program.'' Therefore, any prices charged by manufacturers to an entity that meets the definition of a covered entity, as described in section 1927(a)(5)(B) of the Act, which defines such an entity in section 340B(a)(4) of the PHSA to include a reference to the entity meeting the requirements described in paragraph 340B(a)(5) of the PHSA, should be excluded from best price. With regard to the comment that a DSH hospital can include children's hospitals, rural hospitals, and freestanding cancer hospitals, we recognize that a single provider may qualify for the 340B program under one or more covered entity types. If the covered entity is described at section 340B(a)(4) of the PHSA and meet the requirements at section 340B(a)(5) of the PHSA, any prices to these entities shall be excluded from best price. In cases when a single provider may qualify for more than one 340B hospital covered entity type, HRSA has directed the provider to choose which authority under which it will enroll in the 340B program and would need to abide by the requirements that apply to that hospital covered entity type. (See HRSA guidance regarding meeting the criteria for more than one covered entity type at *http://www.hrsa.gov/opa/eligibilityandregistration/hospitals/disproportionatesharehospitals/index.html).*

Comment: Many commenters stated that the HRSA guidance specifically prohibits manufacturers from conditioning pricing to covered entities on assurance that the entity is in compliance with 340B program requirements and manufacturers should be able to rely on the list of 340B entities (maintained by the Office of Pharmacy Affairs (OPA)) that are participating in the 340B Drug Pricing Program to determine whether an entity participates based on that information. One commenter added that if that covered entity fails to comply with program requirements, it should have no bearing on the manufacturer's exclusion of the 340B price transaction for best price calculation.

Another commenter stated that CMS should clarify that manufacturers can exclude ''prices charged under the 340B Drug Pricing Program'' so long as the covered entity is listed as participating in the program on the 340B Web site for the relevant period.

Many commenters urged CMS not to adopt this proposal because it would place a burden on manufacturers because it unreasonably shifts the responsibility for monitoring covered entity compliance with 340B program requirements from HRSA to manufacturers, which is beyond the scope of CMS's authority.

A few commenters stated that such a shift in in burden on the manufacturers would discourage manufacturers from offering such price concessions to these entities, which runs counter to the general policy behind the 340B Drug Pricing Program.

Another commenter stated that the 340B covered entities may not ''double dip'' (purchase at a 340B price and then submit for reimbursement that would give rise to a manufacturer Medicaid rebate). The covered entities are also prohibited from reselling or transferring any drug purchased at 340B pricing to a patient who is not a patient of the covered entity.

Response: A provider's compliance with the covered entity requirements under the 340B program is not a direct subject of this final rule. We are not requiring that manufacturers enforce HRSA requirements in this final rule, nor are we imposing a requirement for manufacturers to oversee whether a covered entity is compliant and/or conducting business in accordance with the 340B program's requirements in accordance with section 340B(a)(4) and (5) of the PHSA. As previously discussed in this section, we have revised our proposal to note that manufacturers may exclude from best price any prices charged to a covered entity described in section 1927(a)(5)(B) of the Act. This final rule addresses the exclusion from best price and the applicability of this exclusion to entities that qualify as covered entities, as defined at section 1927(a)(5)(B) of the Act.

Manufacturers should be able to determine which entities qualify as covered entities by accessing HRSA's online database of covered entities that is publically accessible on the HRSA Web site at *http://opanet.hrsa.gov/OPA/CESearch.aspx.* Any questions regarding this database and/or the eligibility of certain providers as covered entities under the 340B drug pricing program should be directed to HRSA.

Comment: One commenter encouraged CMS and OPA to discuss how their different policies can be coordinated and made consistent. The commenter recommended that CMS consider retracting its proposal that 340B best price exemption be contingent on the 340B provider compliance, because of HRSA lack of 340B enforcement, the noncompliance of 340B providers, and manufacturers inability to police at 340B program, because they are prohibited from doing so by the current 340B guidance.

Response: CMS and HRSA continue to maintain open communication in regards to the 340B best price exclusion and we do not believe our policies are inconsistent in this regard. As previously stated in this section we would like to clarify that we are not imposing a requirement for manufacturers to oversee whether a covered entity is compliant with the 340B program's requirements. Manufacturers should be able to determine which entities qualify as covered entities by accessing HRSA's online database of covered entities that is publically accessible on the HRSA Web site at *http://opanet.hrsa.gov/OPA/CESearch.aspx.* Any questions that manufacturers may have regarding the qualifications of providers either listed or not listed on this data base should be directed to HRSA. We also note that the issue of HRSA's oversight of the 340B program is beyond the scope of this rule.

Comment: One commenter stated that although the 340B drug pricing program only pertains to drugs administered or dispensed in outpatient setting that are eligible for the 340B price, there are many drugs that are administered or dispensed in an outpatient setting that also have inpatient uses. Because the drug may end up being used in the outpatient setting, the commenter believed that CMS should clarify in the final rule that manufacturers may exclude from best price any sale to a 340B covered entity of any drugs that have both inpatient and outpatient uses by virtue of the purchaser being a covered entity.

Response: We agree with the commenter that manufacturers may exclude from best price any prices charged to a covered entity as described in section 1927(a)(5)(B) of the Act. We are not requiring the manufacturer to keep track of whether the drug is used for inpatient or outpatient purposes. We note that the issue of a covered entity that purchases a 340B COD and subsequently uses that drug in an inpatient setting is an issue that should be raised to HRSA and is beyond the scope of this final rule.

Comment: One commenter requested clarification as to whether or not an orphan drug not sold to a 340B entity and used in an outpatient setting, would qualify the product as a COD, and therefore require that the orphan drug to be included in best price. The commenter also asked CMS to provide guidance on the audit procedures for this or similar situations.

Response: If the orphan drug is sold to an entity that is not a 340B entity as defined at section 340B(a)(4) of the PHSA, then the sale would not be excluded from best price based on the covered entity provisions in section 1927(c)(1)(C)(i)(I) of the Act. Audit procedures related to the requirements of a covered entity under the 340B statute are outside the scope of this final rule.

Therefore, based on the comments received, and for the reasons discussed in this section, we are revising proposed § 447.505(c)(2) to delete the phrase in § 447.505(c)(2)(i) ''under the 340B drug pricing program,'' to delete proposed § 447.505(c)(2)(ii), and to include a reference in § 447.505(c)(2) to provide that any prices charged to 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) shall be excluded from a manufacturer's determination of best price.

5. Medicare Coverage Gap Discount Program (The Discount Program)

The Discount Program established under section1860D–14A of the Act makes manufacturer discounts available to applicable Medicare beneficiaries receiving applicable covered Part D drugs while in the coverage gap. In general, as discussed in the proposed rule (77 FR 5337), the discount on each applicable covered Part D drug is 50 percent of an amount that is equal to the negotiated price. In accordance with the section 1927(c)(1)(C)(i)(VI) of the Act, we proposed that manufacturer discounts attributed to the Discount Program should be excluded from the determination of best price, in proposed § 447.505(c)(6) (77 FR 5337, 5363). We did not receive any comments concerning this best price exemption and therefore, for the reasons stated in this section, we are finalizing the provision as proposed.

In § 447.505(a), we also proposed a definition of ''provider''; and in § 447.505(d)(2) we proposed that best price is to be determined on a unit basis without regard to package size, special packaging, labeling, or identifiers on the dosage form or product or packaging and did not receive any comments on these provisions. Thus, for the reasons discussed in the proposed rule (77 FR 5336–5337), and consistent with section 1927(c)(1)(C) of the Act, we are finalizing those provisions, as proposed.

E. Authorized Generic Drugs (§ 447.506)

We proposed to move the definition of authorized generic drugs from § 447.506(a) to proposed § 447.502 (Definitions) (77 FR 5337), as discussed in the proposed rule.

In proposed § 447.506(a), we proposed to define the term ''Primary manufacturer'' to mean a manufacturer that holds the NDA of the authorized generic drug (77 FR 5337, 5363). We also proposed to define the term ''Secondary manufacturer of an authorized generic drug'' to mean a manufacturer that is authorized by the primary manufacturer to sell the drug but does not hold the NDA. We proposed at proposed § 447.506(b) to specify that sales of an authorized generic should be included in the AMP calculation of the primary manufacturer holding title to the NDA when the drug is sold directly to a wholesaler, or to a secondary manufacturer when that secondary manufacturer is acting as a wholesaler (77 FR 5363). In proposed § 447.506(c), as discussed in the preamble to the proposed rule (77 FR 5337), we proposed to specify that a primary manufacturer holding the NDA must include the best price of an authorized generic drug in its computation of best price for a single source or an 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 the NDA (77 FR 5363). We also proposed to add § 447.506(d), which specifies that a secondary manufacturer must provide a rebate based on its sales of the authorized generic drug (77 FR 5363). The secondary manufacturer must calculate AMP and best price consistent with the requirements in proposed §§ 447.504 and 447.505 (77 FR 5363). We received the following comments:

Comment: A number of commenters expressed support for the definitions of primary and secondary manufacturer of an authorized generic drug as set forth in the proposed rule and agreed with CMS's position on the treatment of authorized generic drugs requiring the primary manufacturer of the brand drug to include in its calculation of AMP all sales of its authorized generic drug sold or licensed to a secondary manufacturer when the secondary manufacturer is acting as a wholesaler. Another commenter supported CMS position taken in the proposed rule that a secondary manufacturer is considered to be ''acting as a wholesaler'' when it engages in the wholesale distribution of prescription drugs to retail community pharmacies and that the transfer price of authorized generic product by a primary manufacturer should be included in the brand drug's AMP when the authorized generic company (secondary manufacturer) is engaged in the distribution of drugs to retail community pharmacies.

However, a few commenters indicated that CMS does not explain when the secondary manufacturer would be viewed as ''acting as a wholesaler.'' A commenter supported CMS's position allowing manufacturer flexibility in determining whether the services performed by another manufacturer qualify that manufacturer to be ''acting as a wholesaler'' for purposes of the AMP calculation and the authorized generic provisions by not limiting the wholesaler definition at § 447.502 to only those entities licensed as wholesalers in the state.

Response: As the commenters noted, we rely on the statutory definition of wholesaler to determine whether the secondary manufacturer is acting as a wholesaler. Therefore, to further understand when a secondary manufacturer is ''acting as a

wholesaler,'' the secondary manufacturer must meet the definition of wholesaler, which is further detailed in Definitions (§ 447.502) section (section II.B.) of this final rule. We believe that primary manufacturers have the responsibility to determine whether a secondary manufacturer is acting as a wholesaler, and that such determination should be made in accordance with the definition of wholesaler in § 447.502, which, as discussed in the definition of wholesaler in section II.B., does not include a requirement that the wholesaler be licensed by a state.

Comment: A few commenters requested clarification regarding the calculation of the primary manufacturer's AMP when a corporate relationship exists between the primary and secondary manufacturer stating that the proposed rule does not specifically address the situation where a corporate relationship exists between these entities. The proposed rule also does not provide guidance on how the AMP should be calculated if the primary manufacturer owns the secondary manufacturer, or if the primary and secondary manufacturers are affiliated under the same corporate ownership and asked how the parties can establish an acceptable transfer price if there is not an arm's length transaction. The commenters further noted that complex corporate structures may warrant additional guidance from CMS regarding the calculation of AMP.

Response: There are many different corporate ownership arrangements that exist among pharmaceutical manufacturers which may impact how their AMPs and best prices are calculated. We do not believe it is necessary at this time to further define arrangements in the context of authorized generic sales and note that manufacturers may make reasonable assumptions. We would not consider the conveyance of the authorized generic drug to the secondary manufacturer to be a sale included in AMP unless the secondary manufacturer qualifies as a wholesaler engaged in the wholesale distribution of the prescription drugs to retail community pharmacies, consistent with the definition of wholesaler at section 1927(k)(11) of the Act. Section 1927(k)(11) of the Act defines wholesaler as a drug wholesaler that is engaged in wholesale distribution of prescription drugs to retail community pharmacies and states that manufacturers are included within that definition to the extent the manufacturer ''acts as a wholesaler.'' In light of sections 1927(k)(1) and 1927(k)(11) of the Act, in the context of authorized generic sales, we proposed at § 447.506(b) to require that the primary manufacturer of an authorized generic include in its calculation of AMP, all sales of its authorized generic drug products sold or licensed directly to a wholesaler or to a secondary manufacturer, acting as a wholesaler, or when the primary manufacturer sells directly to a wholesaler (77 FR 5337, 5362). This would include transfer prices and fees paid by the secondary manufacturer to the primary manufacturer for the authorized generic product. If the secondary manufacturer is not engaged in the wholesale distribution of prescription drugs to retail community pharmacies; for example, it relabels or repackages the drug and sells the repackaged authorized generic to wholesalers (as opposed to engaging in the wholesale distribution to retail community pharmacies) the price of the drug paid by the secondary manufacturer would not be included in the primary manufacturer's AMP. This is consistent with section 1927(k)(1)(C) of the Act, which requires that, in the case of a manufacturer that approves, allows, or otherwise permits any drug of the manufacturer to be sold under an NDA approved under section 505(c) of the FFDCA, AMP shall be inclusive of the average price paid for such drug by wholesalers for drugs distributed to retail community pharmacies, as we discussed in the proposed rule (77 FR 5337).

And finally, we note that as discussed previously, since CMS may not be able to address every arrangement that exists among manufacturers, manufacturers may continue to make reasonable assumptions regarding their AMP and best price calculations, provided their assumptions are consistent with the requirements and intent of section 1927 of the Act and federal regulations.

Comment: Another commenter stated that the proposed rule does not address the case where a single manufacturer sells both an innovator multiple source drug and a second version of the innovator multiple source drug at a lower price point (perhaps using the chemical name or a generic package but both products are sold under the same NDA). The commenter questioned whether AMPs should be blended or calculated separately for the different NDC–9s, if the primary and the secondary manufacturer are the same company.

Response: Section 1927(k)(1)(C) of the Act requires that in the case of a manufacturer that approves, allows, or otherwise permits any drug of the manufacturer to be sold under an NDA approved under section 505(c) of the FFDCA, AMP shall be inclusive of the average price paid for such drug by wholesalers for drugs distributed to retail community pharmacies. When a single manufacturer is selling two versions of a product under the same NDA, section 1927(k)(1)(C) of the Act provides that the AMP be inclusive of the authorized generic product when the manufacturer sells the product to a wholesaler who distributes to the retail community pharmacies. In such cases, the price of the drug would be blended for AMP even if, as noted by the commenter, the manufacturer may have given the drug a different product code.

Comment: A commenter asked whether the best price for both products of the same company should be the lowest price at which either product is offered to a customer or whether the brand and the authorized generic should maintain separate best prices, if the primary and the secondary manufacturer are the same company. The commenter believed pricing should be treated separately, and requested that we provide clarification on these issues.

Response: In the case where both the primary and secondary manufacturer are the same company, selling two versions of the drug marketed under the same NDA, both manufacturers are responsible for determining a best price based on the lowest price available from the manufacturers for the sales of both versions of the drugs sold. In other words, we do not believe the manufacturers in this example should determine a separate best price for each NDC simply because the two manufacturers of the same company identify the same drug using different NDCs.

Comment: A commenter requested that CMS confirm that the primary manufacturer should include the transfer sales price of the authorized generic in the AMP calculation and several commenters noted that there is no obligation for the manufacturer to determine the ultimate purchaser in the secondary manufacturer resales. The commenter also sought confirmation that the primary manufacturer will include in AMP and best price the transfer sales price of all sales of authorized generic drugs to the secondary manufacturer of an authorized generic drug. The commenter showed support for this approach, but noted that there is some confusion in light of the proposed change in definition of primary and secondary manufacturer.

Another commenter believed that CMS should not include the transfer prices paid by the secondary

manufacturer to the primary manufacturer for the authorized generic and requested clarification on this issue. The commenters recommended that the primary manufacturer only report those AMP units related to the branded drug itself and not include any authorized generic units. The commenters noted that primary manufacturers who include the transfer price in AMPs by concluding or presuming that the secondary manufacturer acts as a wholesaler have lower AMPs than companies who do not consider the secondary manufacturer to be a wholesaler. Another commenter believed that including the transfer price will lower AMPs and impact FULs for any product grouping that includes an authorized generic and has the three or more equivalent products required to set a FUL.

Response: When a transfer price is established between a primary manufacturer and secondary manufacturer for the authorized generic drug, the primary manufacturer is responsible for determining whether the transfer price associated with the authorized generic sale to the secondary manufacturer is an AMP or BP eligible sale in accordance with sections 1927(k)(1)(C) and 1927(c)(1)(C) of the Act. As noted earlier, the transfer price for an authorized generic drug should only be included in AMP when the secondary manufacturer is acting as a wholesaler and does not relabel the product and engages in the wholesale distribution of the of prescription drugs to retail community pharmacies. If the secondary manufacturer does not qualify as a wholesaler (for example, the secondary manufacturer relabels the product and then sells it to wholesalers or directly to retail community pharmacies) the sale of the drug to the secondary manufacturer would not be included in the primary manufacturer's AMP. Furthermore, the secondary manufacturer would be responsible for providing rebates (for the relabeled product) consistent with § 447.506.

As for best price, the transfer price paid by the secondary manufacturer (except for those prices specifically excluded from best price in section 1927(c)(1)(C) of the Act) will be included in the primary manufacturer's determination of best price since 1927(c)(1)(C)(ii)(IV) of the Act provides that in the case of a manufacturer that approves, allows, or otherwise permits any other drug of the manufacturer to be sold under a new drug application approved under section 505(c) of the Federal Food Drug, and Cosmetic Act, best price shall be inclusive of the lowest price for such authorized drug available from the manufacturer during the rebate period to any manufacturer, wholesaler, retailer, provider, HMO, nonprofit entity, or governmental entity with the United States.

We further agree with the commenter that if a primary manufacturer automatically presumes that the secondary manufacturer is acting as a wholesaler, it is likely the primary manufacturer's AMP for the drug will be lower which in turn may impact FULs. However, as provided earlier in this response, we believe it is the primary manufacturer's responsibility to determine whether the transfer price associated with the authorized generic sale to the secondary manufacturer is an AMP or best price eligible sale.

Comment: A few commenters encouraged CMS to clarify the language in the proposed rule to stipulate that sales of products to another manufacturer are eligible for inclusion in regular AMP only if the other manufacturer will sell the drug under the primary manufacturer's NDC. Otherwise, the commenter believed the primary manufacturer's reported AMP would underestimate the product's price in the commercial market.

Response: We agree with the commenters that the primary manufacturer should not include the price (be it a transfer price or a sale price) of the authorized generic drug in its AMP when the secondary manufacturer is relabeling the product with its own or a different NDC. In such cases, the secondary manufacturer would not be acting as a wholesaler, as defined at section 1927(k)(11) of the Act. In situations when the secondary manufacturer relabels the product with a different NDC, the secondary manufacturer would be acting as a manufacturer in accordance with the definition of manufacturer at section 1927(k)(5) of the Act. We also believe that AMP units would be reported by the primary manufacturer only when the secondary qualifies as a wholesaler, otherwise there may be double counting of AMP units and potential skewing of the AMP or of the FUL calculations.

Comment: A commenter stated that as proposed, § 447.506(b) does not require the primary manufacturer to trace sales made by the secondary manufacturer to downstream customers for either AMP or best price and that requirements to collect and include AMP or best price for downstream sales by a secondary manufacturer would result in operational difficulties and present significant antitrust risk.

Response: As further discussed in the response to comments in the Determination of AMP section II.C. of the final rule, we have reconsidered our position regarding manufacturer's use of a buildup methodology for AMP calculation purposes and have determined that manufacturers may continue to use a presumed inclusion approach when calculating AMP. Therefore, we do not expect that manufacturers will experience the system implications noted by this commenter when determining AMP for authorized generic drugs. We further believe that since we will continue to allow manufacturers to make reasonable assumptions, we have addressed the commenter's concern with anti-trust risks associated with sharing prices.

Comment: One commenter indicated that under current regulations and CMS guidance, the transfer price of an authorized generic between a primary and secondary manufacturer is adjusted by any fees (such as royalties, license fees, or profit-sharing payments) made by the secondary to the primary manufacturer. In the proposed rule, this is not explicit in the restated best price regulation or in the preamble discussion of best price. The commenter requested clarification that the primary manufacturer's determination of best price should continue to include offsets for fees and other adjustments paid by the secondary to the primary manufacturer.

Response: As noted in the proposed rule, § 447.505(d)(3) specifies that 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 (77 FR 5363). ''Other arrangements'' (such as royalty fees, licensing fees and profit sharing payments) or price adjustment that adjusts the sales price for the authorized generic, and that are not otherwise excluded from best price at § 447.505(c), must be accounted for in the primary manufacturer's calculation of best price for the drug. We do not believe further clarification is needed because the determination of best price at § 447.505(d)(3) requires that best price for a rebate period be subsequently adjusted if other arrangements (in this case, royalty fees) adjust the prices available from the manufacturer.

For the reasons discussed in this section and in the proposed rule, we are finalizing the provisions in proposed § 447.506, Authorized Generic Drugs, as proposed (77 FR 5337 and 5363) with the following revisions:

- In response to comments received, we are adding language at § 447.506(b) to further clarify the reference to ''acting as a wholesaler'' to read ''acting as a wholesaler for drugs distributed to retail

community pharmacies,'' or when the primary manufacturer holding the NDA sells directly to a wholesaler.

- While we proposed in the preamble of the proposed rule (77 FR 5337) that a primary manufacturer holding the NDA must include the best price of an authorized generic in its computation of best price for ''a single source or an innovator multiple source drug during a rebate period to any manufacturer . . . .,'' we inadvertently deleted the reference to ''a single source or'' in proposed § 447.506(c) (77 FR 5363), which was not our intention. Therefore, consistent with the discussion in the preamble (77 FR 5337) and the statute at section 1927(c)(1)(c)(i) of the Act, we are adding ''a single source or'' to § 447.506(c) after ''for'' and before ''innovator.''
- As a technical edit, we are removing the reference to ''of this subpart'' from proposed § 447.506(d) as the reference is not necessary given the regulatory citations.

F. Exclusion From Best Price of Certain Sales at a Nominal Price (§ 447.508)

Section 1927(c)(1)(C)(ii)(III) of the Act excludes from best prices those prices that are merely nominal in amount. Section 1927(c)(1)(D)(i) of the Act identifies certain entities to whom sales at nominal prices of CODs are made from manufacturers for purposes of best price. To update our regulations text to reflect the changes set forth in section 221 of Division F, Title II, of the Omnibus Appropriations Act, 2009, (Pub. L. 111–8), enacted on March 11, 2009, we proposed to revise § 447.508(a) by adding proposed § 447.508(a)(4) and (5) to reflect the two categories of entities added to the list of entities that are eligible for manufacturers to sell drugs at nominal prices and have those sales excluded from best price (77 FR 5364). Specifically, in proposed § 447.508(a)(5), we proposed to add entities that are defined by Internal Revenue Service (IRS) in section 501(c)(3) of the Internal Revenue Code of 1986 (Code) and exempt from tax under section 501(a) of the Code, or are State-owned or operated entities; and are providing the same services to the same type of populations as section 340B(a)(4) entities of the PHSA but not funded as such (77 FR 5337, 5364). In proposed § 447.508(a)(4), we proposed to add a public or nonprofit entity, or a facility at an institution of higher learning whose primary purpose is to provide health care services to students of that institution and family planning services described in section 1001(a) of the PHSA (77 FR 5337, 5364).

We also proposed to add the ''Rule of Construction'' at proposed § 447.508(c) to provide, in accordance with section 1927(c)(1)(D)(iv) of the Act, that nothing in section 1927(c)(1)(D) of the Act should be construed in any way to alter any existing statutory or regulatory prohibition on services for entities described in § 447.508(a), including the prohibition set forth in section 1008 of the PHSA (77 FR 5338, 5364). Additionally, in the proposed rule, we declined to identify any further entities for which manufacturer nominally priced sales would be exempt from best price (77 FR 5338).

We received the following comments concerning the proposed revisions to § 447.508:

Comment: One commenter noted that § 447.508(a)(3) referenced § 440.150 for nursing facilities. The commenter requested that we clarify if we intended to reference § 440.155 instead of § 440.150.

Response: We thank the commenter for noting this technical error, and we are correcting the citation in this final rule so that § 447.508(a)(3) is revised to reference § 440.155.

Comment: Several commenters cited that while the statutory language does not explicitly identify a particular type of health care provider, the Congressional Record (S 2817, March 5, 2009—Colloquy regarding Restoring Nominal drug Prices for Family Planning and University Based Clinics) speaks directly to the purpose of the bill, which is to make low cost oral contraceptives available to family planning clinics, college or university based clinics, and other women's health centers. The commenters also indicated that it was the intent of the Congress as having identified family planning clinics, university clinics and women's health centers which do not receive federal funding to be eligible for discounted drug pricing under section 1927(c)(1)(D)(i)(IV) of the Act.

Response: We agree that the entities described in section 1927(c)(1)(D)(i)(IV) and (V) of the Act do not need to be in receipt of federal funding to qualify for the best price exclusion. We are revising proposed § 447.508(a)(5) to more closely align with the statutory language in section 1927(c)(1)(D)(i)(IV) of the Act. Specifically, by replacing ''is not in receipt of grant funds under that Act'' with ''does not receive funding under a provision of law referred to in such section'' in § 447.508(a)(5)(ii), we have provided that entities that meet the requirements in § 447.508(a)(5) do not need to be in receipt of the grant funds described in section 340B(a)(4) of the PHSA in order exclude from best price manufacturer sales to such entities. In addition, in light of the commenters' concerns, we are revising proposed § 447.508(a)(4), by inserting a comma after ''entity'' and changing the reference to ''facility at an institution of higher learning'' to ''an entity based at an institution'' to comport with section 1927(c)(1)(D)(i)(V) of the Act and clarify that sales at nominal price to public or non-profit entities that are not based at an institution of higher learning and that provide services described in section 1001(a) of the PHSA will be excluded from best price.

Comment: One commenter noted that to be consistent with statutory language, § 447.508(a)(5)(ii) should be changed from ''under that Act'' to ''in such section'' for receipt of grants funds.

Response: We agree and are revising proposed § 447.508(a)(5)(ii) so that it reads ''in such section,'' consistent with the statutory language in section 1927(c)(1)(D)(i)(IV)(bb) of the Act.

Comment: Some commenters noted that section 221 of the Omnibus Appropriations Act, 2009, does not limit or remove the authority previously granted to the Secretary to extend nominal pricing to additional entities. One commenter noted that while the addition of the two new categories of entities is a positive step, CMS should use the authority to extend the nominal price best price exemption to other health care entities such as state and local government providers, outpatient clinics, long-term care facilities, health departments and correctional infirmaries serving indigent, vulnerable populations and that are operated and jointly owned by health systems of which 340B hospitals are a part.

Response: While we agree with the commenter that the Secretary has the statutory authority to expand the nominal price exemption to additional entities, we are choosing not to extend the nominal pricing exemption to entities beyond those entities already identified in the Act at this time.

Comment: One commenter noted that prior to the DRA of 2005, manufacturers had nominal price contracts with entire health systems of which 340B hospitals were just one component. These contracts allowed entire health systems to benefit from deep discounts of the nominal pricing which helped defray the cost of serving indigent patients. The commenter stated that actions of the Congress and the former Secretary to limit the entities eligible for best price exempt nominal pricing have negatively impacted manufacturer's willingness to continue nominal pricing.

Response: We appreciate the commenter's concerns regarding the

impact of the nominal price legislation on manufacturer price contracting practices. As previously discussed in this section, we have revised the list of entities eligible for nominal price sales which may be excluded from a manufacturer's best price calculation; however, although the statutory exclusion categories are broad, at this time, we have decided not to include additional excluded entities.

Comment: One commenter requested clarification regarding proposed § 447.508(a)(4) which contained the phrase ''a public or non-profit entity or facility at an institution of higher learning whose primary purpose is to provide health care services to students of that institution and provide family planning services as described under section 1001(a) of the PHSA, 42 U.S.C., 300.'' Specifically, the commenter asked if this section should be read to mean a ''public or non-profit entity or 'any' facility,'' which presumably could include a for-profit facility. This interpretation would allow a retail pharmacy to be included as a facility and could produce an unfair advantage in local markets.

Response: We have revised the regulations text to align with the statutory language at section 1927(c)(1)(D)(i)(V) of the Act to clarify that an entity based at an institution of higher learning whose primary purpose is to provide health care services to students of that institution, that provides family planning services described at section 1001(a) of the PHSA, are eligible for the best price exemption. An entity based at an institution of higher learning is not required to be a public or non-profit entity to be exempt as long as the primary purpose is to provide health care services to students of that institution that provides a service or services described under section 1001(a) of the PHSA.

Comment: One commenter noted that this rule seems to exclude an institution whose purchases are at nominal price from the best price exemption if it does not also provide family planning services. The commenter asked why CMS would limit the exclusion to certain types of educational systems if the purpose is to expand the 340B exclusion and it appears that all drugs purchased by this type of entity would be excluded from best price.

Response: As discussed previously in this section, proposed § 447.508(a)(4) was written to address section 1927(c)(1)(D)(i)(V) of the Act, as revised by section 221 of the Appropriations Act (Pub. L. 111–8, 2009). Specifically, one of the criteria that entities must meet to qualify for the best price exemption is that it provide a service or services described in section 1001(a) of the PHSA, 42 U.S.C. 300(a). Since this section of the PHSA concerns federal grants for family planning services, to be consistent with the requirements of section 1001(a) of the PHSA, the rule references entities at institutions that provide family planning services.

Comment: One commenter noted that family planning services under section 1001(a) of PHSA includes infertility services and services to adolescents. The commenter asked if CMS will require states to provide assurances that all of these services are provided to secure the best price exemption.

Response: We will not require states to provide assurances that these services are provided as there is no requirement for such assurances in statute.

Comment: One commenter stated that it is clear the manufacturer and the facility benefits from the best price exclusion provision but there is no requirement or assurance that the savings be passed along to the consumer.

Response: While we appreciate the comment, we note that the issue of whether the manufacturers and entities which are eligible to purchase nominal priced CODs pass on their savings to their customers is beyond the scope of this rule.

Comment: Some commenters suggested that CMS develop a list similar to the Medicaid SPAP best price list of specific entities to which sales at a nominal price may be excluded from best price as it would help manufacturers avoid potential confusion identifying such entities. The commenter noted that these lists would require that the entity submit information demonstrating compliance with the standards.

Response: We appreciate the suggestion but we did not propose that entities submit such information and therefore believe it would be difficult for CMS to create and maintain such a list without such an information collection requirement. We believe it is the manufacturer's responsibility to assure that an entity meets the criteria specified to exclude its drug sale from best price.

Comment: One commenter suggested that the CMS establish a mechanism to communicate with states regarding the impact of the changes to § 447.508 with regard to prescription drug rebates.

Response: We see no need at this time to establish a mechanism to communicate with states regarding the impact of the changes to § 447.508 with regard to rebates. As with other aspects of the rebate program, we will provide guidance, as needed, to address any state concerns that may arise as these provisions are implemented.

For the reasons articulated in the response to comments in this section and in the proposed rule, and to implement changes to section 1927 of the Act set forth in section 221 Division F, Title II of the Omnibus Appropriations Act, 2009 (Pub. L. 111–8), enacted March 11, 2009, we are finalizing proposed § 447.508 (Exclusions from best price of certain sales at a nominal price), except for the changes discussed in this section, to exclude the following nominal price drug sales from best price for:

- A covered entity as described in section 340B(a)(4) of the PHSA.
- An ICF/IID providing services as set forth in § 440.150.
- A State-owned or operated nursing facility providing services as set forth in § 440.155.
- A public or non-profit entity, or an entity based at an institution of higher learning whose primary purpose is to provide health care services to students of that institution, that provides family planning services described under section of 1001(a) of PHSA to conform with section 1927(c)(1)(D)(i)(IV) of the Act.
- An entity that is described in section 501(c)(3) of the Internal Revenue Code of 1986 and exempt from tax under section 501(a) of that Act or is state-owned or operated; and, is providing the same services to the same type of population as a covered entity described in section 340B(a)(4) of the PHSA but does not receive funding under a provision of law referred to in such section.

In this final rule, we are also revising proposed paragraph (c) to state that nothing in the section is construed to alter any existing statutory or regulatory prohibition on services for an entity described paragraph (a)(5) of the section, including the prohibition set forth in section 1008 of the PHSA.

G. Medicaid Drug Rebates (§ 447.509)

In proposed § 447.509, we proposed to incorporate provisions of the statute concerning the rebate calculation, including the formulas used to calculate rebates for CODs in the MDR program as specified under section 1927(c) of the Act, the requirements for drugs dispensed by Medicaid MCOs under section 1927(b)(1)(A) of the Act, and the federal offset of rebates under section 1927(b)(1)(B) of the Act (77 FR 5338, 5364).

1. Determination of Rebate Amount (§ 447.509(a)(1) Through (3), (5), and (6))

In proposed § 447.509(a)(1) through (3), we proposed provisions regarding the determination of the basic rebate amount for single source and innovator multiple source drugs, as well as clotting factor products for which a separate furnishing payment is made under section 1842(o)(5) of the Act, and drugs approved exclusively for pediatric indications; the additional rebate for single source and innovator multiple source drugs; and the total rebate amount for single source and innovator multiple source drugs. In proposed § 447.509(a)(5) we proposed a limit on the rebate amount such that in no case will the total rebate amount exceed 100 percent of the AMP of the drug. In proposed § 447.509(a)(6) we proposed provisions regarding the determination of rebates for noninnovator multiple source drugs (77 FR 5338, 5364). The following is a summary of the comments received concerning the proposed provisions in § 447.509(a)(1) through (3), (5), and (6).

Comment: One commenter stated that increasing the rebate percentages that manufacturers are required to provide to Medicaid will only lead to manufacturers raising their prices to cover the higher rebates while pharmacies cannot raise their prices because CMS mandates the reimbursement methodology that state Medicaid agencies pay pharmacies. The commenter further stated that CMS is not mandating what a drug manufacturer can charge by increasing the Medicaid rebate percentages. Another commenter stated that the proposed rebate calculations for participation in Medicaid should be decreased, not increased. The commenter further stated that these rebates are a form of taxation ultimately on the consumer and general public, which will only lead to an increase in the cost of medicine for all consumers.

Response: The rebate calculations we proposed were based on the rebate calculations as specified in section 1927(c) of the Act. Given the amendments to the statute by the Affordable Care Act that change the rebate percentages, in this final rule we are finalizing these rebate percentages in the regulation. In light of section 1927(c) of the Act, as revised by the Affordable Care Act, we are not authorized to decrease the rebate amounts. The suggestion that an increase in Medicaid rebates will result in an increase in medication costs for all consumers is beyond the scope of this rule.

Comment: One commenter asked CMS to specify which of the changes specified in the rule that pertain to rebate calculation, if any, will require manufacturers or states to retroactively revise or recalculate rebate payments or collections back to 2010. Commenters believed this will impact rebate payments and collections and states could potentially have to pay back rebates already collected.

Response: The amendments made by section 2501 of the Affordable Care Act, including the modified rebate percentages, were effective January 1, 2010; however, the provisions in this final rule will be implemented on a prospective basis, as noted in the effective date of this final rule. Therefore, there should be no retroactive adjustments to rebates based upon the provisions finalized in this final rule.

Comment: One commenter commended CMS for implementing the minimum rebate percentage for clotting factors as the reduced rebate percentage is critical to ensuring access to these life-saving products.

Response: We appreciate the comment.

Comment: One commenter stated that they had been informed in an email from CMS that the ''clotting factor indicator'' in the MDR system would only be effective in the quarter after a product has been verified by the Agency. Additionally, the minimum rebate rate of 17.1 percent would be applicable prospectively from that date. The commenter stated that this needlessly delays the change in URA for clotting factors; is inconsistent with the Medicaid rebate statute; and it does not take into account the congressional intent which was to give manufacturers incentive to develop and market these products. The commenter believed that these products should receive the 17.1 percent ''as of the time of their launch into the marketplace, irrespective of when the manufacturer requested the indicator be applied to their product.''

Response: We agree with the comment that these products should receive the 17.1 percent minimum rebate rate and previously addressed this issue in Manufacturer Release #85 (October 26, 2012). In this release, CMS indicated that when a drug is determined as a clotting factor, the clotting factor (CF) indicator is activated (Y/N flag) in MDR and the minimum 17.1 rebate percentage is applicable for those drugs for the most recent of:

- The quarter in which the labeler's Medicaid drug rebate agreement was optionally effective (that is, the earliest date states, at their option, can cover the drug);
- the product's Market Date quarter;
- the product's Purchased Product Date quarter (if applicable); or,
- the first quarter 2010 (that is, the quarter in which the minimum rebate percentage under ACA was effective).

In accordance with section1927(c)(1)(B)(iii)(II)(aa) of the Act, which was effective on January 1, 2010, the 17.1 percent rebate is applicable to products identified by Medicare Part B as clotting factors for such products on the market anytime within or before the first quarter of 2010. If the product was marketed on or after April 1, 2010, then the 17.1 rebate percentage is applied as of the market date quarter. Prior verification by CMS is not needed before the lower 17.1 percent rebate is applied. Therefore, when new products are introduced to the market on or after April 1, 2010, regardless of when CMS confirms such products are clotting factors, the effective date of the application of the 17.1 percent rebate will the product's market date quarter.

Comment: One commenter requested that CMS clarify how manufacturers can identify whether there has been a separate furnishing fee payment authorized under the Medicare Program.

Response: For Medicare Part B, CMS regularly identifies clotting factors for which a separate furnishing payment is made under section 1842(o)(5) of the Act as part of the ASP drug pricing files. We use this Medicare Part B data to identify those clotting factor products in the MDR program. A current list of clotting factor drugs is posted in the Medicaid DDR system for state and manufacturer use. This list is updated regularly; however, we recognize that in some cases, system delays may postpone the inclusion of a newly identified clotting factor products on the DDR list. Therefore, we will update the list as needed and we encourage manufacturers to contact CMS if they have a clotting factor product that does not appear on the list.

Comment: One commenter expressed support for limiting the rebate amount to 100 percent of AMP.

Response: We appreciate the commenter's support and consistent with section 1927(c)(2)(D) of the Act, we are finalizing § 447.509(a)(5) as it was proposed in the proposed rule (77 FR 5338).

After considering the comments, and for the reasons we set forth in this section and in the proposed rule, we are finalizing § 447.509(a)(1) through (3), (5), and (6) as proposed (77 FR 5338, 5364).

2. Treatment of New Formulations (§ 447.509(a)(4))

Section 1927(c)(2)(C) of the Act, as added by section 2501(d) of the Affordable Care Act, establishes a separate formula for calculating the URA for a drug that is a line extension of a single source drug or an innovator multiple source drug that is an oral solid dosage form. For such line extension drugs, section 1927(c)(2)(C) of the Act provides that the rebate amount shall be the amount computed under section 1927 of the Act or, if greater, the product of the AMP for the line extension; the highest additional rebate (calculated as a percentage of the AMP) under section 1927 of the Act for any strength of the original single source drug or innovator multiple source drug; and the total number of units of each dosage form and strength of the line extension product paid for under the state plan in the rebate period. Section 1927(c)(2)(C) of the Act defines a line extension for purposes of the rebate calculation as a new formulation of a drug, such an extended release formulation.

We proposed to include a definition for line extension drug in proposed § 447.502 (77 FR 5323 through 5324, 5360). In proposed § 447.502, we proposed to define a line extension drug as a single source or innovator multiple source drug that is in an oral solid dosage form that has been approved by the FDA as a change to the initial brand name listed drug in that it represents a new version of the previously approved listed drug, such as a new ester, a new salt, or other noncovalent derivative; a new formulation of a previously approved drug; a new combination of two or more drugs; or a new indication for an already marketed drug (77 FR 5323, 5360). We also proposed to include the statutory definition of ''line extension'' at proposed § 447.509(a)(4)(ii) (77 FR 5364). Based on FDA's publicly available drug information and data files, we proposed to use FDA's Chemical Type classification, which classifies drugs when an NDA is approved according to the type of change made to an initial brand name listed drug (77 FR 5339). As we discussed in the proposed rule, the Chemical Type may identify a drug as new or related to the active ingredient of another drug that has already been approved (77 FR 5339). We proposed to use FDA's assigned Chemical Types 2, 3, 4, and 6 to identify line extension drugs and Chemical Type 1 to identify an initial brand name listed drug. These proposed provisions are discussed in more detail in the proposed rule at 77 FR 5339 through 5341. Since the writing of the proposed rule, FDA has changed the assigned numbers and meaning of some of the Chemical Types. The current list of Chemical Types and their meanings can be found on the FDA Web site at *http://www.fda.gov/Drugs/InformationOnDrugs/ucm075234.htm.*

In regard to the proposed definition of line extension, we noted that we did not plan to exclude reformulations of existing products that incorporate abuse deterrent technologies from the definition of line extension, as discussed at 77 FR 5338. We also proposed not to exclude single source or innovator multiple source drugs that receive 3-year exclusivity, pediatric exclusivity, or 7-year orphan drug exclusivity from the definition of line extension (77 FR 5340). We also proposed to exclude a new strength of the initial brand name listed drug from the definition of a line extension drug (77 FR 5338).

Additionally, we proposed to include provisions concerning the rebate calculation for line extension drugs, including the method to calculate the URA for such drugs in proposed § 447.509(a)(4)(i) (77 FR 5340, 5364). For the purpose of calculating the URA under section 1927(c)(2)(C) of the Act, we proposed that both the initial brand name listed drug and the line extension drug have to be an oral solid dosage form (77 FR 5338). We also proposed to provide and update a master list that identifies new initial brand name listed drugs and new line extension drugs quarterly for the initial three quarters from the effective date of the final rule (77 FR 5340).

We received numerous comments regarding our proposal on line extensions. The comments addressed our proposed definition and identification of line extension drugs, including the use of FDA's Chemical Types, both as a general concept as well as why specific Chemical Types should not be included in the definition of a line extension. Other comments included concerns that our definition was too broad and not supported by legislative history, suggestions for alternative methods to identify line extension drugs, general rulemaking concerns, and concerns regarding the operational aspect of calculating the rebate amount for line extension drugs. Many comments addressed the inclusion of abuse deterrent formulations (ADFs) in the definition of line extension and described how the inclusion of ADFs is contrary to policies being promulgated to address the nation's drug abuse crisis.

We also received comments that disagreed with inclusion of drugs that receive certain kinds of exclusivity or drugs that were required to undergo certain types of clinical trials. Some commenters indicated there was a disincentive for manufacturers to proceed with innovative products if our proposals were finalized.

We appreciate the comments that were provided; however, at this time, we have decided not to finalize the proposed definitions of line extension drug at proposed §§ 447.502 and 447.509(a)(4)(ii). We will continue to consider the issues commenters raised on the definition of a line extension drug, as well as the scope of the definition as it applies to ADFs or drugs that received certain types of exclusivity. Additionally, we are not finalizing proposed § 447.509(a)(4)(iii), which proposed the process by which line extension drugs would be identified by the FDA's list of certain Chemical Types. Because we are not utilizing FDA's Chemical Types, we will not provide nor update the master list that identifies new initial brand name listed drugs and new line extension drugs for the initial three quarters from the effective date of the final rule.

Although we are taking into consideration the comments we received on the proposed rule for these topics, we are requesting additional comments on the definition of line extension drug and the identification of new formulations as we may consider addressing these in future rule making. Therefore, at this time, manufacturers are to rely on the statutory definition of line extension at section 1927(c)(2)(C) of the Act, and where appropriate, are permitted to use reasonable assumptions in their determination of whether their drug qualifies as a line extension drug. Furthermore, as discussed later in this section, we are finalizing § 447.509(a)(4)(i), which provides the rebate calculation for line extension drugs, including the method to calculate the URA and UROA for such drugs.

We received the following comments concerning operational aspects of proposed § 447.509(a)(4)(i) and the sharing of manufacturer pricing data regarding the alternative rebate calculation:

a. Line Extension Marketed by Different Manufacturer

Comment: Several commenters stated that there is no benefit derived by a new manufacturer resetting the base date AMP if the initial brand name listed drug was marketed by a different manufacturer since the new

manufacturer is not subject to the initial drug owner's lower base date AMP. Other commenters stated that the language CMS used in the proposed rule regarding the exchanging of data suggests the possibility that a single source drug of one manufacturer could be a line extension of a single source drug or innovator multiple source drug by another manufacturer. They stated that the legislative history suggests that the Congress intended to eliminate a manufacturer's incentive to make slight alterations to its own products and that applying the provision between different manufacturers is inconsistent with the statute. Several other commenters noted that it makes no sense to apply the line extension provisions if the line extension drug is made by a manufacturer that does not own the original product. They stated that it is not logical that the manufacturer of the new formulation is trying to avoid a higher URA since another company owns the original product, and that this situation has no possible connection with the intent of the Affordable Care Act. Several commenters urged CMS to draft the final rule, or clarify the language, to provide that a drug by one manufacturer will not be treated as a line extension of a drug by a different manufacturer unless there is a corporate, contractual, licensing, or financial relationship between the manufacturers.

Many commenters noted that manufacturers will be harmed, unfairly penalized, or have proprietary information compromised by the implementation of the line extension provisions. Several commenters stated that the proposed rule, if finalized, would subject products to higher rebate obligations without consideration of the substantial time and financial resource investments associated with the manufacturing of the line extension product.

Several commenters noted that the provisions would make the rebate calculations more burdensome. Several commenters stated that the proposed rule, if finalized, would require the sharing of information between competing manufacturers. One commenter asked if, in the case of a Chemical Type 6 (new indication) product, the manufacturer would need to compare the AMP of its line extension product to the AMP of the original product if both products are currently being marketed by different manufacturers. The commenter stated that if so, the manufacturer would encounter great difficulty because pricing data are proprietary and confidential.

Another commenter stated that data sharing is problematic from both an operational and legal perspective. Competitors are reluctant to share pricing data with a direct competitor and there were no rules regarding such sharing given in the proposed rule, thereby creating barriers for data sharing. Several other commenters stated that the sharing of pricing information is problematic because such information is confidential. One commenter stated that unless the same labeler owns and markets both the initial reference drug and the line extension drug, the alternative URA should not come into play. Another commenter stated that the line extension company has no control or insight into the pricing of the original product. The commenter stated that it makes little sense to apply the line extension provision if the products are marketed by different manufacturers because it would only penalize the manufacturer of the line extension drug and there would be no concern in this case that the original manufacturer was attempting to ''game the system.''

Several commenters expressed concern regarding the use of a formula that relies on the additional rebate of the original drug of another manufacturer who could manipulate the original price to generate higher rebate liability for the line extension company. Another commenter stated that a line extension manufacturer needs pricing data from the original manufacturer to estimate rebate obligations as part of their financial forecasting when deciding whether or not to market a line extension drug. The commenter stated that the original manufacturer is unlikely to supply such data before the line extension drug goes to market.

One commenter noted that if the line extension drug was manufactured by a different company than the initial product, then the manufacturer would have to obtain pricing data from a competitor to calculate a URA and that this would be unworkable and the proposal must be dropped. Another commenter noted that a line extension company could utilize the initial manufacturer's URA information to their competitive advantage. One commenter suggested that CMS narrow and revise the definition such that a new formulation sold by a distinct, unrelated, and competing manufacturer would not be subject to the alternative URA calculation.

Several commenters noted that CMS did not provide any mechanism for manufacturers to rely on each other's data and only stated that it is the manufacturer's responsibility to obtain pricing information. One commenter noted that the data sharing requirements were not defined in the proposed rule and the cost burden associated with gathering such data was not provided. Additionally, some manufacturers may want even more information from the initial manufacturer to verify the additional rebate amount supplied by the original manufacturer. Another commenter stated that requiring manufacturers to share pricing data may require costly indemnification agreements between manufacturers to cover civil liability.

One commenter stated that manufacturers might have to stop selling a line extension drug if they could not obtain data from the manufacturer of the initial reference drug. They noted that a manufacturer may be unable to divest a line extension drug because a potential buyer would know that it could not obtain the information necessary to comply with the line extension provisions. One commenter envisioned scenarios under which one company would only handle the distribution of an authorized generic of a line extension drug. This commenter was concerned by CMS's assumption that any manufacturer marketing a line extension drug can obtain the pricing data from the manufacturer of the original product.

Response: We understand the challenges of obtaining pricing information from unrelated manufacturers. Therefore, in response to the comments received, we have decided to limit the line extension provision to provide that a drug by one manufacturer will not be treated as a line extension of a drug by a different manufacturer, unless there is a corporate relationship between the manufacturers. This will limit the obligation of manufacturers to collect pricing information from unrelated parties. Manufacturers of line extension drugs that have a corporate relationship with the manufacturer of the initial brand name listed drug are expected to obtain the necessary pricing data to calculate the alternative URA on a quarterly basis. This interpretation is consistent with our understanding of section 1927(c)(2)(C) of the Act and the requirement that manufacturers calculate an alternative URA for new formulations.

Section 1927(c)(2)(C) of the Act provides that the rebate obligation for a line extension drug shall be the amount computed under section 1927 of the Act for the line extension product or if greater, the product of the AMP of the line extension drug, the highest additional rebate (calculated as a

percentage of AMP), and the total number of units paid for under the State plan in the rebate period. We believe there is less of a risk for manufacturers to attempt to circumvent the additional rebate for a line extension drug if there is no relationship between the manufacturer of the initial brand name listed drug and the line extension drug, because an unrelated manufacturer is less likely to benefit from the resetting of the base date AMP for a drug if there is no relationship between the two manufacturers. Therefore, in light of the comments received, a drug marketed by a manufacturer will be treated as a line extension of a drug of another manufacturer only where there is a corporate relationship between the manufacturers. We will note this requirement in the final rule regulation at revised § 447.509(a)(4)(ii). We will issue additional guidance or rulemaking, if needed.

Comment: One commenter asked CMS to clarify which entity, the manufacturer of the initial brand name listed drug or the manufacturer of the line extension drug, is ultimately responsible for the data. Several commenters stated that the exchange of price information raises antitrust issues under the Sherman Antitrust Act of 1890, which CMS recognized in the 2007 AMP final rule when CMS rejected a proposal for the primary manufacturer of an authorized generic to obtain the quarterly AMP from a secondary manufacturer to calculate a blended AMP. They stated that CMS did not address these concerns nor provide assurance that compliance with the rule would not result in heightened exposure to state and federal antitrust laws.

Response: We are persuaded by the comments regarding the concerns associated with sharing of pricing data between competing manufacturers and have changed our position concerning the inclusion of another manufacturer's pricing data in the calculations of the additional rebate for line extension drugs. We also recognize the challenges of obtaining pricing information from non-related manufacturers, based on the comments received. Therefore, we are applying the line extension obligations to drugs that are manufactured by the initial brand name listed drug company and any other companies that have a corporate relationship with the manufacturer of the initial brand name listed drug.

b. Initial Brand Name Listed Drug Not in MDR Program

Comment: Several commenters asked for clarification that if the original manufacturer does not participate in the MDR program, then the initial brand name listed drug should be treated as terminated. A few commenters supported the proposal to exclude drugs that have been terminated from the MDR program and stated that manufacturer should only calculate an alternative URA when the initial brand name listed drug is active in the MDR program and they requested that the regulations text should be changed to reflect this. One of the commenters asked that CMS confirm that the word ''terminated'' in the context of the line extension provisions have the same meaning as it has in monthly AMP (that is a product is terminated in the first month after the last lot expiration). The commenter also asked for clarification that if a Chemical Type 1 (new molecular entity) has been terminated, that all resulting Chemical Type 3 (new formulation) products are absolved from the line extension calculations.

Response: We agree that if no initial brand name listed drug(s) are active in the MDR program, then no alternative URA will be calculated for any line extension drug that used the pricing data of the terminated initial brand name listed drug(s) for the calculation of the alternative URA. During any quarter, if there is an active initial brand name listed drug in the MDR program that may be used for the alternative URA calculation, then such calculation is required for the line extension drug. Additionally, we agree with the commenter that ''terminated'' has the same meaning in the line extension provision as in monthly AMP (that is, a product is terminated in the first month after the last lot expiration). We do not see any reason to adopt a different meaning of termination for line extension drugs. However, we do not believe that the final regulation text needs to be further revised to reflect this understanding.

c. New Strengths

Comment: One commenter stated that some drugs assigned to Chemical Type 3 (new formulation) are multiple strengths and asked for clarification about how these drugs should be treated under line extension rules. Another commenter stated that CMS should not include those drugs assigned to Chemical Type 3 (new formulation) if they are simply a new strength. A few commenters supported exclusions for new strengths and recommended that this exclusion be included in the regulatory definition and not just the preamble. A commenter sought guidance regarding how the exclusion for new strengths would operate, and specifically whether, for example, a new strength of the initial brand would be excluded as a line extension. Another commenter supported limiting the line extension provisions to oral solid dosage forms, excluding new strengths of the initial brand name drug, and clarifying that the provision does not apply if the initial brand is no longer active. They asked for clarification in the regulatory text. Additionally, the commenters asked for clarification if a new strength of an extended release product would be excluded from the line extension definition. Another commenter asked for clarification that new strengths classified as Chemical Type 6 (new indication) should not be treated as line extensions.

Response: We agree with the commenters and do not consider new strengths of the same formulation of the initial brand name listed drug to be a line extension because we believe that if the only change to a drug is the strength, without any change to the formulation of the drug, section 1927(c)(2)(C) of the Act does not contemplate that a new strength is a line extension drug. If the sole difference between a drug and the corresponding initial brand name listed drug is the strength, then the drug will not be considered a line extension drug and will not be subject to the alternative URA calculation for line extension drugs. However, because we are not finalizing a definition of line extension in this final rule, we are not including this exclusion in the final regulatory text.

Additionally, we do not see any reason to exclude a new strength of a line extension drug from being a line extension drug as the drug itself is a new formulation, and note that section 1927(c)(2)(C) of the Act specifically provides that the alternative URA calculation include the highest additional rebate under this section for any strength of the original single source drug or innovator multiple source drug. For the purposes of the alternative URA calculation, the same initial brand name listed drug should be reported to CMS and used in the alternative URA calculation for all strengths of the line extension drug.

d. Authorized Generics

Comment: We received several comments relating to the treatment of authorized generic products under the line extension provisions. A commenter requested modification of the definition to clearly state whether an authorized generic drug can be a line extension drug. Several commenters noted that the manufacturer of the authorized generic drug may not have a contractual

relationship with or rights to data from the original manufacturer. Another commenter noted that CMS should address how the URA calculation can be validated by an authorized generic manufacturer when the product is owned by another manufacturer.

Response: We have decided not to treat authorized generic drugs differently than other drugs because we do not read section 1927(c)(2)(C) of the Act as treating authorized generic products differently. Accordingly, manufacturers are responsible for calculating additional rebates for authorized generic drugs if those drugs qualify as line extensions. As previously discussed, a drug marketed by a manufacturer will be treated as a line extension of a drug of another manufacturer only where there is a corporate relationship between the manufacturers.

e. Calculation of Alternative URA and Federal Offset

Comment: A few commenters supported CMS's proposed methodology for the alternate additional rebate calculation which is consistent with previous guidance. One commenter agreed with CMS's interpretation that the URA for a line extension should be based on the greater of either (1) the standard URA or (2) the alternative URA, where the alternative URA is the product of the line extension AMP and the highest additional rebate for any strength of the original drug.

Response: We appreciate the comments and support and are finalizing the alternative rebate calculation formula in § 447.509(a)(4)(i) as proposed.

Comment: A commenter asked if CMS understands that while trying to correct the issue of resetting base date AMP through the line extension provisions (thus paying an artificially low URA), that it is giving manufacturers another tool to use once they have capped out on their calculations.

Response: We understand that the 100 percent cap will limit the effect of the line extension provisions in some circumstances; however, section 1927(c)(2)(D) of the Act does not exclude line extension drugs from the 100 percent of AMP limit that is applied to all CODs.

Comment: We received numerous comments regarding operational issues that will be encountered when CMS, manufacturers, and states attempt to implement the line extension provisions as detailed in the proposed rule. One commenter stated that CMS did not address all possible scenarios faced by manufacturers when trying to calculate the alternative URA. One commenter stated that manufacturers will require additional time to calculate the URA for line extension drugs because they need time to get the URA of the initial product. Another commenter asked how CMS would ensure that information flows timely so that AMPs and offset amounts are accurately reported to states if a line extension drug is manufactured by a different company.

Several commenters stated if CMS proceeds with requiring manufacturers to make calculations based on data of other parties, we should require that data sharing for line extension calculations be a condition of a manufacturer's participation in the MDR program, impose deadlines for providing data, require that the original manufacturer provide NDC numbers and CPI–U penalty percentages, and that the original manufacturer must certify the data. Several commenters noted that the methodology for AMP calculations used by the original company may be different from the methodology of the line extension drug manufacturer. As many facts of the AMP calculation rely on reasonable assumptions, the resultant AMP comparisons would not be an equivalent comparison.

One commenter noted that CMS will need to amend the certification language to reflect that the alternative URA is a product of another manufacturer's data and the calculations are beyond the control of the certifier. One commenter noted that these provisions would require significant changes in DDR, and such changes have historically taken a long time. The commenter discouraged CMS from adopting new regulations that would require process and system changes related to confirming products with data from FDA databases. If CMS does proceed, they ask that manufacturers be provided with enough time to update their own systems.

Response: After reviewing the public comments and as discussed previously, we are modifying our position regarding the proposed requirement that manufacturers obtain data from other companies. A drug marketed by a manufacturer will be treated as a line extension of a drug of another manufacturer only where there is a corporate relationship between the manufacturers, and an alternative URA calculation will be required for the drug.

We believe that our policy as revised in this final rule will address the concerns and operational burden for both the manufacturer of the initial brand name listed drug and the manufacturer of the line extension drug. We also believe that this process will allay concerns as to the accuracy and consistency of the data since information sharing will only be required between manufacturers that have a corporate relationship. We are currently drafting system requirements for the line extension provision and expect to issue guidance to manufacturers regarding the reporting of rebate information for line extension drugs consistent with the requirements of the statute. We also expect to issue guidance to states regarding the reconciliation and reporting of the UROA for line extension drugs.

We appreciate the comments regarding the possibility that different manufacturers may make different reasonable assumptions in their AMP calculations; however, this final rule sets forth requirements regarding how manufacturers are to calculate AMP. We expect the statute, as well as this final rule, will prevent any significant differences in AMP methodologies between manufacturers.

Comment: A commenter asked how restatements will work in regards to line extensions. Commenters also questioned if an initial product is restated, will the line extension company have to restate and reconcile items such as rebates and PHS pricing.

Response: We do not have oversight over the PHS program so we cannot address PHS pricing in this final rule. However, restatements of pricing information will follow the same process as currently used for restatements of pricing data. Manufacturers do not need to notify CMS if the resubmission falls within the 12-quarter timeframe, as manufacturers have access to DDR to make those changes.

Comment: Several commenters discussed the additional burden that would be placed on CMS to calculate the alternative URAs. Commenters requested that CMS describes more comprehensively in the final rule how the URA for line extension drugs should be calculated and how it will be operationalized. The commenters noted that currently, manufacturers do not have to submit URAs to CMS. Because the URA for line extensions is a comparison between two calculated URAs, the commenters asked if CMS will continue to calculate a URA for both forms and select the higher value, or, if manufacturers will be responsible for URA submission. The commenters also asked if all manufacturers of initial brand name listed drugs will submit their additional rebate-to-AMP ratios for all strengths, or will CMS calculate it. They also asked if CMS will be able to do so and if CMS will be ready to implement on the effective date of the

rule. If not, they asked when and what is the plan for reconciliation. Commenters asked whether DDR will contain a new URA field for manufacturers to report quarterly; whether manufacturers have to report both the standard and the alternative URAs or just the higher value; and if the URA has to be reported by the manufacturer, will it be for all products or just for line extensions.

Response: Under section 1927(b) of the Act, it is the responsibility of the manufacturers to calculate rebates and make payment to states. Although CMS is also calculating the URA, it is only for the convenience of the states to facilitate rebate billing and to verify the manufacturer's calculated rebates. Manufacturers are responsible for and must continue calculating the rebates for their CODs, and this current process applies to the line extension provision as well. Manufacturers will not be responsible for submitting URAs or additional rebate-to-AMP ratios to CMS; however, manufacturers will be responsible for identifying line extension drugs and, on a quarterly basis, the initial brand name listed drug with the highest additional rebate ratio, where there is a corporate relationship between the manufacturer of the line extension drug and the initial brand name listed. We will use this information to calculate the URAs for line extension drugs and provide such URAs to the states. Manufacturers will continue to be responsible for reporting product and pricing data to CMS, calculating the rebates, and making rebate payments to states. This responsibility extends to calculation of URA for line extension drugs and includes the necessity of obtaining necessary information from the manufacturer of the initial brand name listed drug, when the manufacturers have a corporate relationship.

We expect to issue future guidance to manufacturers regarding the additional data fields that will be necessary for CMS to calculate quarterly URAs for line extension drugs. We will also issue guidance to states regarding the reconciliation and reporting of the UROA for line extension drugs.

Comment: Several commenters stated that the statutory change represented an attempt to mitigate the perceived windfall for manufacturers, at the expense of the MDR program; however, any financial gain has already been addressed by the states through the negotiation of state supplemental rebates, prior to the Affordable Care Act. Several commenters noted that the offset amounts created by the additional rebate amounts will go to CMS and not to the states. Another commenter noted that if the provision was retroactive to March 2010, it could cost states significantly. The commenters asked that implementation be postponed for some time after the publication of the final rule to allow states time to plan strategy for restructuring their budgets. They cited budget problems due to reduced rebates due to states having to report offset amounts on the additional FFS and MCO rebates states receive under the Affordable Care Act and also stated that the states may not have control over the preferred drug lists of the MCOs.

Several commenters stated that the states expect a large unit rebate offset amount (UROA) for line extension drugs and that due to changes in the Affordable Care Act states have experienced and/or projected manufacturers reducing or eliminating supplement rebates to the state. A commenter indicated that this loss of supplemental rebates is not included in the proposed rule's Economic Analysis.

Response: The effective date of the line extension and offset provisions, as set forth in section 2503 of the Affordable Care Act, was January 1, 2010. However, the provisions in this final rule will be implemented on a prospective basis. Based on the supplemental rebate data reported to CMS on the Medicaid and Children's Health Insurance Program Budget and Expenditure System (MBES), *http://medicaid.gov/Medicaid-CHIP-Program-Information/By-Topics/Data-and-Systems/MBES/CMS-64-Quarterly-Expense-Report.html,* we do not see any significant impact so far to states' supplemental rebate amounts.

Comment: One commenter expressed concern regarding the effect of implementing the line extension provisions on the federal offset of rebates. The commenter stated that section 2501(a)(2) of the Affordable Care Act specified that amounts received by the state that are attributable to the increase in the minimum rebate percentage are for federal offset. The commenter stated that this would apply only to the increases of 15 percent to 23 percent and 11 percent to 13 percent; the alternative URA provision does not contain increases in the minimum rebate percentage; and the calculation does not make any changes in the minimum rebate percentage. The commenter believed that CMS has no authority to impose the offset; however, the commenter stated that if CMS insists on pursuing the offset, it needs to provide manufacturers with guidance including an example of how the offset is performed. The commenter asked what amount CMS plans to retain without sharing, based on state Federal Medical Assistance Percentage (FMAP), with the states. If the alternative URA is higher for a quarter, what will CMS subtract from that alternative URA to determine the offset, and would it be standard URA (either (a) 23.1 percent of AMP or (b) (AMP − BP) + additional rebate) as calculated for comparison to the alternative URA, or the URA as it would have been calculated prior to the Affordable Care Act (either (a) 15.1 percent of AMP or (b) (AMP − BP) + the additional CPI–U rebate).

Response: We are maintaining our position as discussed in the proposed rule (77 FR 5342) and finalizing § 447.509(c)(3) that the offset will be applied to a line extension drug based on section 1927(b)(1)(C) of the Act which specifically references increases in the rebate percentage effected by amendments made by sections 2501(a)(1), 2501(b), and 2501(d) of the Affordable Care Act for drugs that are line extension drugs. These amendments provided that if the alternative URA is greater than the standard URA, then the offset will be applied to the difference between the alternative URA and the standard URA. As noted in the proposed rule, CMS will be responsible for calculating the offset amount. However, in response to the request for an example of how calculation is performed, we are providing the steps for calculating the URA and UROA for a line extension drug in the example below.

Step 1: Standard URA = Basic Rebate Amount + Additional Rebate Amount.

Step 2: The alternative URA is calculated as the product of the AMP of the line extension that is an oral solid dosage form and the highest additional rebate (calculated as a percentage of AMP) for any strength of the initial brand name listed drug.

Step 3: URA = The greater of (1) standard URA or (2) the alternative URA.

Step 4: Determine if the URA is greater than 100 percent of AMP.

a. If the URA is greater than 100 percent of AMP, then the URA = AMP consistent with section 1927(c)(2)(D) of the Act.

b. If the URA is less than 100 percent of AMP, then use the calculated URA.

Step 5: UROA Calculation = For a drug that is a line extension of a single source drug or innovator multiple source drug that is an oral solid dosage form, if the alternative URA is greater than the standard URA, then the offset will be the difference between the alternative URA and the standard URA and the basic UROA will be based on

the increase in the minimum rebate percentage effected by the Affordable Care Act. If the alternative URA is less than the standard URA, then there is no offset amount for line extension portion, however, the basic UROA still applies.

Below is an example of calculating the URA and UROA for a line extension drug.

Baseline AMP (line extension) = 100.00
AMP (line extension) = 300.00
Best Price (line extension) = 250.00
Baseline CPI–U = 170.00
CPI–U = 200.00

Step 1: Calculate Standard URA = Greater of

a. AMP × 23.1% = 300.00 × 23.1% = 69.30 or

b. AMP—best price = 300.00 − 250.00 = 50.00.

The greater of the two results (69.30 or 50.00) is 69.30.

Basic Rebate Amount for the line extension drug = 69.30.

Additional Rebate Amount calculated under formula in section 1927 of the Act: If the [(Baseline AMP/Baseline CPI–U) × CPI–U] is less than the quarterly AMP, subtract [(Baseline AMP/Baseline CPI–U) × CPI–U] from the quarterly AMP to determine the additional URA. If the [(Baseline AMP/Baseline CPI–U) × CPI–U] is equal to or greater than the quarterly AMP, the additional URA is equal to zero.

[(Baseline AMP/Baseline CPI–U) × CPI–U] = 100/170 × 200 = 0.5882 × 200 = 117.65

117.65 is less than 300.00; then, 117.65 is subtracted from 300.00, 300.00 − 117.65 = 182.35

Additional Rebate Amount under section 1927 of the Act = 182.35

Standard URA = 69.30 + 182.35 = 251.65

Step 2: Calculate the Alternative URA

AMP (line extension) = 300.00
AMP (initial brand name listed drug) strength A = 280.00
AMP (initial brand name listed drug) strength B = 275.00
AMP (initial brand name listed drug) strength C = 270.00
Additional Rebate Amount (initial brand name listed drug) strength A = 200.00
Additional Rebate Amount (initial brand name listed drug) strength B = 125.00
Additional Rebate Amount (initial brand name listed drug) strength C = 110.00
Strength A additional rebate amount ratio = 200/280 = 0.7143
Strength B additional rebate amount ratio = 125/275 = 0.4545
Strength C additional rebate amount ratio = 110/270 = 0.4074
Highest additional rebate ratio (calculated as a percentage of AMP) for any strength of the initial brand name listed drug = 0.7143
Alternative URA = Product of the AMP of the line extension that is an oral solid dosage form and the highest additional rebate ratio (calculated as a percentage of AMP) for any strength of the initial brand name listed drug
Alternative URA = 300 × 0.7143 = 214.29

Step 3: URA of the line extension drug = the greater of

(1) Standard URA = 251.65 or
(2) Alternative URA = 214.29

URA of the line extension drug = 251.65

Step 4: Determine if the URA is greater than 100 percent of AMP.

AMP (line extension) = 300.00 = 100% × 300.00 = 300.00
URA = 251.65
URA is less than 100 percent of AMP; therefore, URA is equal to 251.65

Step 5: UROA calculation

AMP (line extension) = 300.00
Best Price (line extension) = 250.00
Basic UROA = If AMP − BP less than AMP × 23.1% and greater than AMP × 15.1%
AMP − BP = 50
AMP × 23.1% = 69.3
AMP − BP is less than AMP × 23.1% and greater than AMP × 15.1%
Then basic UROA = AMP × 23.1% − (AMP − BP) = 69.3 − 50 = 19.3
Line extension UROA = If the Alternative URA greater than the Standard URA

(1) Standard URA = 251.65 or
(2) Alternative URA = 214.29

Alternative URA is NOT greater than Standard URA, thus no line extension UROA.

UROA for this NDC drug is only the basic UROA portion = 19.3

IF the Alternative URA and the Standard URA values were reversed:

(1) Standard URA = 214.29 or
(2) Alternative URA = 251.65

The alternative URA is greater than the standard URA, and the UROA for this line extension drug is = 251.65 − 214.29 = 37.36. Consistent with CMS's reading of the statutory offset provision, we have calculated the offset amount to reflect the amount attributable to the increase in the percentages affected by the Affordable Care Act amendments. In this scenario, this NDC would have both a basic UROA (19.3) and a line extension UROA (37.36).

f. Miscellaneous

Comment: We received many comments regarding timing issues surrounding the implementation of the line extension provisions. Several commenters stated that if the provision is implemented retroactive to 2010, then states that are receiving supplemental rebates currently will have large accumulated offset amounts. One commenter stated that if CMS applies the statute retroactively, it would unfairly punish manufacturers with additional rebate obligations for drugs introduced long before the Congress considered the line extension issue. The commenter stated that the statutory provision does not authorize retroactive application, and the legislative history implies that the Congress did not intend it. The commenter quoted from the Senate Finance Committee comments, which state ''The Chairman's Mark would treat new formulations of existing brand name drugs as if they were the original product for purposes of calculating Medicaid's additional drug rebate. When a new version of an existing drug is introduced, the additional rebate obligation for that new drug would be calculated on the original drug's baseline AMP, rather than a new baseline.'' (S. Comm. on Finance Chairman's Mark, America's Healthy Future Act of 2009, at 55 (Sept. 2009)). The commenter stated that the Congress had the opportunity to require all existing drugs be classified as either initial or line extension drugs, but the statute speaks only to new versions of existing drugs. Therefore, the commenter concluded that all existing drugs are initial brand name drugs, and only new formulations submitted to FDA after the enactment of the final rule can be line extensions. Rather than attempt to classify existing drugs as either initial or line extension drugs, the commenter stated that CMS should treat all drugs submitted to FDA prior to implementation as initial. Then manufacturers will have proper notice that Chemical Type 3 (new formulation) NDA drugs will be subject to additional rebate. Additionally, CMS will have an easier time identifying line extension drugs using FDA's Chemical Type codes.

A few other commenters objected to the application of the line extension provisions to formulations which existed prior to the enactment of the Affordable Care Act. They stated that if CMS limits the provisions to formulations that are new after the enactment date, then some of the problems with acquisition of information about the original drug will be limited. Another commenter stated that applying the line extension provision to formulations existing prior

to the enactment of the Affordable Care Act would be punitive and problematic. One commenter stated that because of the complexity of the policy and multiple unanswered questions, CMS should apply the provision prospectively to new line extension drugs launched after the enactment of the Affordable Care Act. A few other commenters noted that the application of the provision after the effective date of the final rule would allow manufacturers the opportunity to deal with data sharing needs through contractual agreements. Manufacturers do not have the ability to force another manufacturer to provide pricing data after a deal has been completed. Commenters stated that the implementation of the provision will create a tremendous burden on manufacturers to identify all oral solid drugs that are currently sold that received FDA approval based on the four proposed Chemical Types and to obtain both the baseline AMP and current AMP for the original drug.

One commenter noted that the requirements for line extension drugs should not apply to drugs approved by FDA prior to the effective date of the Affordable Care Act line extension provisions because these requirements were not part of the law when the drugs were approved. They stated that this could be seen as retroactive rulemaking by changing AMP in a period that predates the effective date of the statute. Additionally, since CMS has issued guidance that manufacturers should use reasonable assumptions to implement the provisions prior to the final rule, the specific provisions should apply only after the rule is finalized.

One commenter stated that their reading of the proposed rule is that the line extension provision is not retroactive to 2010 and they request confirmation. They stated that if it was to be implemented retroactively, that states could be subject to a significant liability.

Response: The provisions in this final rule are effective on a prospective basis, as indicated in the effective date section of this final rule. However, in accordance with section 2501(d) of the Affordable Care Act, the statutory line extension provision was effective January 1, 2010. Specifically, section 2501(d) of the Affordable Care Act specifies that the line extension amendments apply to drugs paid for by a state after December 31, 2009, but it failed to specify that it would apply only to those line extension drugs that are approved after that effective date. Section 1927(c)(2)(C) of the Act, as revised by section 2501 of the Affordable Care Act, requires that manufacturers calculate an additional rebate for all drugs that are identified as line extension drugs as of the statutory effective date. Therefore, the date of when a drug comes to market does not have an effect on the determination of the applicability of the line extension provisions to a drug. In accordance with the statutory provisions, the line extension requirements apply to drugs that qualify as line extensions as of the statutory effective date of January 1, 2010; however, as noted previously in this section, the provisions of this final rule are not retroactive. The requirements set forth in this final rule shall be effective on a prospective basis only. Also as previously mentioned, we believe that limiting the line extension alternative rebate calculations to drugs produced by manufacturers that have a corporate relationship will alleviate the concerns about data sharing with competitors.

To summarize, based on the comments received and for the reasons discussed in this section, § 447.509(a)(4) is being finalized as follows:

- We are finalizing proposed § 447.509(a)(4)(i) without modification.
- We are not finalizing the definition of the term line extension proposed in § 447.509(a)(4)(ii).
- We have decided that the alternative rebate is required to be calculated if the manufacturer of the line extension drug also manufactured the initial brand name listed drug or if the manufacturer of the line extension drug has a corporate relationship with the manufacturer of the initial brand name listed drug and are including this requirement in the final regulation at revised § 447.509(a)(4)(ii).
- We are not finalizing our proposal to identify line extension drugs by FDA Chemical Types in § 447.509(a)(4)(iii).

3. Rebates for Drugs Dispensed Through Medicaid Managed Care Organizations (MCOs) (§ 447.509(b))

Effective March 23, 2010, section 1927(b) of the Act, as amended by section 2501(c) of the Affordable Care Act, requires manufacturers that participate in the MDR program to pay rebates for drugs dispensed to individuals enrolled with a Medicaid MCO if the MCO is responsible for coverage of such drugs. Therefore, to address these revisions, we proposed a new § 447.509(b) (77 FR 5341, 5364). In § 447.509(b)(1), we proposed to require participating manufacturers to pay rebates for CODs dispensed to individuals enrolled in Medicaid MCOs if the MCO is contractually required to provide such drugs. In proposed § 447.509(b)(2), we proposed that manufacturers are exempt from the requirement in proposed paragraph (b)(1) if such drugs are dispensed by HMOs, including MCOs that contract under section 1903(m) of the Act, and subject to discounts under section 340B of the PHSA. In § 447.509(b)(3), we proposed that a Medicaid MCO that contractually provides CODs dispensed to Medicaid beneficiaries must submit, within 30 days of the end of each quarter, a report containing specific data, including the MCO identifier, the NDC, the period covered, the product FDA list name, the total units, the total number of prescriptions and the amount reimbursed, for the state to access the rebates authorized by the revisions to sections 1927(b) and 1903(m)(2)(A) of the Act (77 FR 5341 through 5342, 5364). We received the following comments concerning rebates for drugs dispensed to individuals enrolled in MCOs:

a. MCO Reporting Requirements

Comment: Several commenters had concerns with § 447.509(b)(3) of the proposed rule which lists specific data elements MCOs would be required to report to states within 30 days of the end of each quarter to support state collection of rebates from manufacturers. One commenter stated that states have not commonly required MCOs to include the ''Product FDA list name'' in their rebate-related data submissions to date and that this information is not routinely maintained by MCOs for other purposes. The commenter stated that since an efficient means is available for states to generate the product FDA list name, and it would be burdensome and costly for MCOs to develop the capability to provide this information, the commenter recommended that CMS revise § 447.509(b)(3) to strike the ''Product FDA list name.''

Another commenter stated that the reporting of data from the MCOs must be timely and reflect the same required data elements in the same required units as is required for fee-for-service data. The commenter noted that encounter data from MCOs has lacked the robust quality component necessary to sustain rebate challenge. Other commenters appreciate the need to clarify Medicaid MCO reporting requirements to promote consistency, but encouraged CMS to allow more flexibility in reporting content and timing.

One commenter indicated that many states are using their encounter data to develop reports that include information needed for the collection of rebates that meets states' needs and has

successfully supported many states in pursuing their respective outpatient drug rebates. The commenter stated that revising these current reporting requirements to include additional data elements may not significantly increase the effectiveness of these reports, and altering their current encounter-based reporting mechanisms would generate unnecessary administrative expense for both states and Medicaid MCOs. The commenter suggested that those states that are not able to use encounter data might consider a separate file submission for those attributes to minimize administrative expense for both states and Medicaid MCOs.

Response: Given the concerns raised by the commenters about flexibility, we have decided not to finalize proposed § 447.509(b)(3) in the final rule. We will continue to consider the MCO submission requirements and issue additional guidance or rulemaking, if needed, concerning such requirements in the future. We have addressed state reporting requirements regarding MCO utilization data in § 447.511.

Comment: One commenter stated that manufacturers may currently request prescription level data from the states for Medicaid FFS utilization that may be the subject of a rebate payment dispute. The commenter stated that it appears that Medicaid MCOs will not be required to provide prescription level data to the states, so it is unclear how manufacturers would obtain this data in the event that submitted utilization from the Medicaid MCO is the subject of a rebate payment dispute. The commenter requested that CMS indicate that Medicaid MCOs will be required to provide prescription level data to the states and/or to manufacturers in order that manufacturers will have access to this data in the event of rebate payment disputes.

Response: As stated in this section, we have decided to not finalize the MCO reporting requirements at proposed § 447.509(b)(3) in this final rule. Instead, we have chosen to address the requirements for states with regard to the data they report to manufacturers, including the data pertaining to MCO utilization, which are codified in § 447.511 of this final rule. Furthermore, we are not adding the requirement for prescription level data in proposed § 447.509(b)(3) for MCO claims because it is not currently a requirement for FFS claims. However, as with FFS utilization, states will need to have detailed, prescription level information or other mutually agreeable data available for dispute resolution purposes, if requested by a manufacturer in accordance with the state provision of information requirements associated with manufacturer audits at section 1927(b)(2)(B) of the Act.

Comment: A few commenters provided their comments regarding invoice processes. One commenter believed separate MCO utilization rebate invoices will further its ability to confirm the integrity of the data, which in turn will facilitate claims processing and payment. The commenter stated that the MCO invoice should specify the actual MCOs included on the invoice to assist in the validation of the data. Several commenters requested that CMS clarify that Medicaid MCO invoice data must be reported separately for each MCO.

Other commenters requested that CMS require states, when invoicing, to provide MCO data separately from FFS data, or a single invoice for quarterly Medicaid MCO rebates, but to reflect each MCOs data separately on that one invoice. The commenter continued that some states meet this condition, but many others issue separate invoices for each MCO, which is detrimental to efforts to promptly, and accurately, validate the data on these invoices and process the related rebates.

Response: In accordance with section 1927(b)(2)(A) of the Act and as specified in State Release #160 (July 19, 2012), states became responsible for identifying FFS and MCO utilization separately on manufacturer rebate invoices beginning in the second calendar quarter 2012. With regard to the issue of whether states should be required to separately list utilization for each MCO on their rebate invoices, we believe that as long as the state separately identifies MCO data from FFS data, it is up to the states to determine how they will further break down these data.

b. MCO—Reimbursement Rates

Comment: Several commenters stated that when manufacturers provide rebates directly to states, it is inappropriate to assume that previous rebate levels obtained by MCOs through negotiation with the same manufacturers would remain unchanged. The commenters continued by noting that the proposed rules state that plans may be affected by this rule if manufacturers reduce rebate payments to the plans to any extent that these rebates are paid to the states, but these costs would likely be mitigated because it is likely that the MCO rates would be adjusted. A few commenters believe that extension of the Medicaid prescription drug rebate to drugs dispensed to Medicaid MCO members has implications for state assumptions about MCO prescription drug costs as a component of Medicaid managed care rate development and some note that it is unlikely that states will adjust their capitation rates in the future to account for such decreases.

Several commenters recommended that CMS add specific language to the proposed § 447.509(b), or through a statement in formal guidance or regulation, that incorporates the importance of the actuarial soundness requirement from section 1903(m)(2)(A)(xiii)(II) of the Act. The commenters believed that it is essential that actual state and MCO rebate experience be taken into consideration to provide an accurate basis for rate development and avoid any unintended adverse impact such as provider access issues. Other commenters stated that actuarial soundness is at the core of retaining the viability of Medicaid managed care as a sound alternative to Medicaid FFS delivery system and states need to be held accountable. Other commenters noted that manufacturers have responded to the changes under the Affordable Care Act by reducing or eliminating rebates to Medicaid MCOs thus increasing plans' pharmacy expenditures.

Response: Issues regarding MCO payment rates are beyond the scope of this final rule; although, we note that states are responsible for establishing capitation rates in accordance with 42 CFR part 438.We expect actuarially sound capitation rates to address appropriately the cost and utilization experience applicable to MCOs.

c. MCO Pharmacy Reimbursement

Comment: One commenter stated that they understand that the requirements for pharmacy reimbursement spelled out in proposed rule (AAC) apply only to fee-for-service Medicaid. The commenter stated that now that the MDR program applies to Medicaid managed care utilization, states probably will choose to include the pharmacy benefit in such plans because of the perceived value of improved care coordination under ''carve in'' arrangements.

Response: The discussion regarding AAC and the payment of appropriate professional dispensing fees under Medicaid FFS is further discussed in this section. States determine if they will contract with MCOs for Medicaid services and pay capitated rates for such services. CMS and the states allow MCOs the flexibility to reimburse for CODs' ingredient costs and professional dispensing fees at the levels necessary to achieve a network of providers to

ensure access to care for each MCO's Medicaid enrollees. States are responsible for oversight of the MCOs.

d. Manufacturer Rebates

Comment: One commenter stated that CMS should be commended for the level of detail they have provided both in the proposed rule and in associated guidance provided to manufacturers and the states regarding changes to invoice and reconciliation formats for state reporting of MCO units.

Response: We appreciate the commenter's support.

Comment: One commenter opposed the amendment to section 1927(b) of the Act which requires manufacturers to pay rebates for drugs dispensed to individuals enrolled with a Medicaid MCO if the MCO is responsible for coverage of such drugs, and states that this process creates a negative for MCOs and a positive for the government.

Response: While we appreciate the commenter's concerns, section 1927(b)(1)(A) of the Act requires that manufacturers pay rebates for drugs dispensed to Medicaid MCO enrollees if the MCO is responsible for coverage of such drugs. We also note that section 1927(j)(1) of the Act, as amended by section 2501(c) of the Affordable Care Act, does provide for an exception to this requirement if such drugs are both dispensed by a HMO, including Medicaid MCOs that contract under 1903(m) of the Act, and are subject to discounts under section 340B of the PHSA. Therefore, we are finalizing our regulations, in accordance with these statutory provisions.

Comment: One commenter noted that depriving MCOs of rebates negatively impacts small Medicaid plans.

Response: We appreciate the concern; however, as discussed in the previous response, section 1927(b)(1)(A) of the Act requires that manufacturers provide rebates for CODs dispensed to individuals enrolled with Medicaid MCOs unless such drugs are both dispensed by a HMO, including Medicaid MCOs that contract under 1903(m) of the Act, and are subject to discounts under section 340B of the PHSA. The issue of rebates that MCOs may collect directly from drug manufacturers outside of the MDR program is beyond the scope of the final rule.

e. 340B Covered Entities

Comment: Many commenters discussed the application of the MCO rebate provisions and its effect on 340B entities, including several concerns regarding states requiring 340B covered entities, including hospitals, to carve out these claims from Medicaid managed care. These commenters recommended that CMS prohibit states from requiring a 340B covered entity to carve out Medicaid MCO drugs. One of the commenters indicated that states were not given the authority under the law to mandate a carve-in or carve-out for Medicaid, and allowing them to do so thwarts the very purpose of the 340B program. Another commenter stated that they have become increasingly concerned that states do not know how to prevent the collection of rebates on 340B MCO drugs and indicated that some states are evaluating a strategy that would compel covered entities to carve their MCO drugs out of 340B. The commenter continued that federal law does not allow states to take these actions, and such an approach would conflict with congressional intent and the purpose of the 340B program.

The commenters also requested that CMS create a mechanism, preferably a pharmacy-friendly mechanism, which states can use to avoid collecting rebates on 340B MCO drugs. Another commenter continued that if it is necessary to prevent the collection of rebates on 340B MCO drugs, the state should assume responsibility for management and oversight of this policy.

A commenter noted that manufacturers would be exempt from paying rebates on MCO drugs when drugs are dispensed by MCOs and continued that this will have a huge impact on the little revenue that MCOs currently pay a local county. Commenters further claim that passing through the 340B cost to the MCO would be administratively burdensome on pharmacy operations.

Response: While we appreciate the concerns about the imposition of manufacturer rebates on Medicaid MCO pharmacy claims and the exclusion of 340B pharmacy claims, the question of whether states have the authority to mandate that 340B covered entities carve out their Medicaid MCO drugs from their 340B purchases is beyond the scope of the final rule. It is, however, the states' responsibility to collect utilization data for purposes of the MDR program and to ensure that procedures are in place with their MCOs to exclude utilization for drugs subject to 340B discounts.

We will continue to work with states to ensure they comply with this requirement regarding the prevention of duplicate discounts on MCO drugs purchased through the 340B program.

Comment: One commenter indicated that it needs to be made clear that the 340B discounts belong to the covered entities, not to the MCOs and that the MCOs responsibility is simply to exclude the 340B transactions from the data transmitted to the states so that the states will not request rebates from manufacturers for those units. The commenter believed that failure to enforce this concept will undermine the entire Safety Net pharmacy program, significantly reducing revenue and forcing covered entities to subsidize MCO operations.

Response: Given the expansion of the availability of MDRs for drugs dispensed to Medicaid MCO enrollees, states need to ensure that the mechanism to ensure against duplicate discounts or rebates on 340B drugs, consistent with section 1927(a)(5)(C) of the Act, applies to 340B drugs dispensed to Medicaid MCO enrollees. We recognize that covered entities may purchase 340B drugs at a discounted rate; however, it is the state's responsibility to instruct their MCOs to exclude such discounted drugs from its utilization data. While we appreciate the comments regarding the 340B discounts, the issue of whether those discounts belong to the covered entities or MCO is beyond the scope of the final rule.

Comment: One commenter noted that due to the expanding scope of the MDR program, manufacturers are encountering greater challenges to auditing and verifying state rebate claims. The commenter appreciated the additional details that the proposed rule provided regarding manufacturer responsibilities for paying rebates for CODs dispensed to individuals enrolled with Medicaid MCOs but indicated that there were several important issues related to the implementation of the expansion of the 340B Program to Medicaid MCOs that the proposed rule does not address. While the commenter supported the proposed rule's express prohibition of duplicate discounts on 340B units, the commenter stated that CMS should require the states to submit prescription-level information, including pharmacy identifiers and the National Council for Prescription Drug Plans (NCPDP) 340B flag for all FFS and MCO utilization. This would permit manufacturers to see through to the prescription level on the invoice to ensure that manufacturers are calculating and paying rebates appropriately in conformance with all 340B program requirements.

Another commenter stated that it is unclear from the list of data elements to be reported by the state at proposed § 447.511(a) how a state (or a manufacturer) could know whether a drug paid for by a Medicaid MCO had

been dispensed by a 340B provider. The commenter indicated that CMS must require that all Medicaid utilization data that states submit to manufacturers (and all Medicaid claims that pharmacies submit to a state or a Medicaid MCO) contain the ''Pharmacy Identifier'' field, and the ''Submission Clarification Code'' field for identifying 340B drugs (along with other data elements the states must report to manufacturers). One commenter discussed an OIG report published in 2011 that raised concerns with regard to rebate claims associated with drugs purchased under the 340B Program and states' ability to conduct oversight activities related to 340B-purchased drugs. The OIG found that nearly half of states (25 of 51) do not have 340B policies' to govern the prohibition on duplicate discounts. This commenter shares the OIG's concerns and urged CMS to require states to submit prescription-level information for both FFS and MCO utilization.

Response: While we appreciate the issues raised by the commenter, we are not in this final rule establishing a specific requirement with regard to the mechanism that 340B covered entities use to bill states for Medicaid FFS or managed care. While section 1927(a)(5) of the Act provides that states not submit a claim to any manufacturer for a rebate payment for a drug subject to 340B discounts, states have flexibility to use a variety of methods to prevent duplicate discounts. We will continue to monitor this issue and will provide additional guidance to states, if needed. As to the commenter's suggestion to include a 340B identifier on invoices submitted to participating drug manufacturers, we do not believe that such pharmacy level data is needed at this time. We will continue to consider this issue and work with states to ensure that utilization data exclude any claims for 340B drugs.

Comment: A few commenters believed that the burden to prevent rebate collection on 340B MCO drugs is on states and that states should create a mechanism that can exclude the drugs from their rebate requests. One of the commenters requested that CMS adopt requirements to prevent duplicate discounts, as well as work with HRSA to create a regulatory mechanism for states to avoid requesting rebates on the 340B MCO drugs consistent with congressional intent and the 340B statute. The commenter was concerned that in the absence of state guidance, states will either explicitly or implicitly rely on the 340B provider community to solve their problem and while it is true that covered entities have a responsibility to do their part in preventing duplicate discounts for Medicaid FFS drugs, nothing in the Affordable Care Act indicates that the Congress intended for those obligations to extend to Medicaid MCO drugs. The commenter stated that how a risk of duplicate discounts is avoided is a matter that must be resolved between the states and manufacturers. And finally, one commenter noted that CMS should prohibit states from implementing procedures for collecting rebates on drugs dispensed through Medicaid MCOs that unreasonably burden 340B covered entities.

Response: We appreciate the concerns raised by the commenters regarding the responsibility of states to avoid the collection of rebates on 340B MCO drugs. It is the states' responsibility to ensure that procedures are in place with their MCOs to exclude utilization for drugs subject to 340B discounts and we will continue to work with states to ensure they comply with this requirement regarding the prevention of duplicate discounts on MCO drugs purchased through the 340B program.

f. FFS vs. MCO

Comment: One commenter stated that as a condition of having its products covered under Medicaid FFS, each manufacturer enters into an MDR program agreement with the Secretary. The commenter continued that states cannot decline to cover any COD of any manufacturer that participates in the MDR program, although states do have the authority to subject a manufacturer's drug to prior authorization. The commenter continued that CMS has long stated this as a governing principle of the MDR program as to FFS utilization, and nothing in the Affordable Care Act's expansion of rebate liability to MCO utilization exempts that utilization from this coverage mandate. The commenter further stated that CMS should require Medicaid MCOs to cover participating manufacturer drugs to the same extent as required for FFS.

Response: Section 1927(b) of the Act, as revised by section 2501(c) of the Affordable Care Act, does not require that Medicaid MCOs modify their formularies to mirror a state's FFS drug coverage policies, although a state might choose to require this through the contracting process. As previously provided in the State Medicaid Director's Letter #10–019 (September 28, 2010), MCOs may continue to have some flexibility in maintaining formularies of drugs regardless of whether the manufacturers of those drugs participate in the drug rebate program. However, states must assure that Medicaid enrollees have access to state plan services; therefore, CODs not on an MCO's formulary either must be available by the MCO through a prior authorization program or be provided by the state through a state carve-out. State Medicaid agencies may continue to establish requirements regarding MCOs' formularies, consistent with the statutory provisions at section 1927(d)(4) through (5) of the Act.

Comment: One commenter requested clarification regarding the identification of MCO utilization on invoices, as well as the effective date of MCO rebate eligibility.

Response: States should differentiate between Medicaid MCO and FFS data on state invoices. In accordance with section 1927(b)(2) of the Act, we give states the option to send manufacturers separate quarterly invoices for FFS rebates and MCO rebates, or send one quarterly invoice containing both FFS units (FFSU) and MCO units (MCOU). However, as previously stated in Manufacturer Release #84 (July 19, 2012) and State Release #160 (July 19, 2012), regardless of which invoice option is selected, states must include a new Record ID value of either FFSU or MCOU on each invoice to differentiate each record as being either FFS or MCO.

Comment: One commenter stated that one area where manufacturers have concern is regarding the rebate period for when MCO utilization is invoiced. The statute requires that it be calculated as ''the total number of units of each dosage form and strength paid for under the state plan in the rebate period. . .'' The commenter continued that for traditional FFS utilization, payment has typically been determined at or near the date of service; in other words, the utilization is invoiced in the rebate period in which the Medicaid recipient received the drug. The commenter stated that for MCO utilization, the paid date is somewhat less clear since payment is not closely linked to the date of service. The commenter stated that this could mean a lag by one or more rebate periods from the date of service. The commenter stated that CMS should define that for MCO utilization, the paid date is the date of service and should be invoiced for the period in which the date of service occurred. The commenter also stated that MCO utilization that is validated by the state after the original invoice for that rebate period can be included as adjustments in a subsequent invoice for that date of service rebate period. The commenter believed that such a definition more closely matches the practice for FFS claims and would allow manufacturers to more easily validate the invoices as

well as provide enhanced process controls and more accurate financial accruals.

Response: As discussed previously, section 1927(b)(1)(A) of the Act, as revised by section 2501(c) of the Affordable Care Act, requires manufacturers to provide rebates for drugs dispensed to individuals enrolled with a Medicaid MCO if the organization is responsible for coverage of such drugs. Furthermore, section 1927(b)(2)(A) of the Act requires states to include MCO utilization in their quarterly rebate invoices submitted to manufacturers. We agree with the commenter that consistent with these provisions, utilization for MCO reporting should be reported based upon the date dispensed (date of service) within the quarter, as opposed to the claim paid date, since prospective capitation payment has been made to the MCO within that quarter. FFS utilization will continue to be reported based upon the date on which the state paid the claim. We also agree with the commenter that states may make adjustments to an original invoice in subsequent invoices as needed.

g. Effective Date

Comment: Several commenters requested that CMS confirm the effective date and conditions for rebate eligibility, encouraging CMS to state explicitly that rebates are only due on MCO drugs dispensed after March 23, 2010.

Response: As stated in the State Medicaid Director letter dated September 28, 2010, only those Medicaid MCO CODs dispensed on or after March 23, 2010, are subject to manufacturer rebates.

h. Dispensing Fee

Comment: One commenter stated that to achieve the objective of adequate pharmacy reimbursement, CMS must also take steps to ensure that the commercial plans taking on Medicaid managed care business respect the need to guarantee adequate pharmacy reimbursement. The commenter continued that commercial plans move away from the historical model of deeply discounting dispensing fees if their drug cost payments are pegged to acquisition cost levels. The commenter points out that the actual cost of dispensing remains the same regardless of the insurance coverage available to the customer being served.

Response: Medicaid MCOs are not required to adopt a pharmacy reimbursement methodology consistent with an AAC standard as provided in this final rule. Rather, as we previously stated in this section, Medicaid managed care organizations are permitted flexibility to reimburse for COD ingredients costs and professional dispensing fees at the levels necessary to achieve adequate access to a network of providers.

i. Dual Eligible Beneficiaries

Comment: One commenter stated that it is critically important that invoices to manufacturers include the MCO data elements so that manufacturers can validate the data, especially for dual eligible beneficiaries. The commenter stated that it will be important for states to scrub Medicaid MCO data to ensure that it does not include Part D drugs for dual eligible beneficiaries (as Part D drugs for dual eligible beneficiaries must be covered by Medicare Part D, rather than by Medicaid). Likewise, it will also be important for manufacturers to have access to this data to verify that invoices do not include drugs that should not be Medicaid-covered.

Response: We recognize the importance of the data elements to manufacturers. We believe that MCOs have billing edits in place for dual eligible beneficiaries to route pharmacy claims to Medicare Part D, since Medicare Part D is responsible for drug coverage of dual eligible beneficiaries. Therefore, state invoices for rebates should not include units associated with drug claims for dual eligible beneficiaries.

j. Coordinate Medical and Pharmaceutical Benefits

Comment: One commenter stated that several states have recognized the value of allowing Medicaid MCOs to coordinate both the medical and pharmaceutical benefits for Medicaid enrollees and have included the management of prescription drug benefits in MCO contracts.

Response: We appreciate this information.

For the reasons we articulated in the response to comments in this section, we have decided to not finalize the MCO reporting requirements that we proposed in § 447.509(b)(3) in this final rule. We have chosen to address the requirements for states with regard to the data they report to manufacturers, including the data pertaining to MCO utilization, in § 447.511 of this final rule. We have revised § 447.509(b)(1) to replace the words ''pay rebates'' with the words ''provide a rebate'' as this more accurately describes the actions of the manufacturers in this transaction. This edit is technical in nature and is not intended to change the policy being finalized.

In addition, for the reasons discussed in response to comments in this section, we are finalizing the requirements in § 447.509(b)(1) and (2) as proposed (77 FR 5341, 5364), with the exception of minor technical edits to proposed § 447.509(b)(2) to add the words ''are the following'' to end of the sentence after the word ''drugs'' and replaced the period at the end of § 447.509(b)(2)(i) with a semicolon and the word ''and'' to clarify that manufacturers are exempt from providing rebates for drugs that are dispensed by HMOs ''and'' discounted under section 340B. These edits are made to effectuate section 1927(j) of the Act and do not change the policy being finalized.

4. Federal Offset of Rebates (§ 447.509(c))

Section 2501(a)(2) of the Affordable Care Act added section 1927(b)(1)(C) of the Act, which provides that, effective January 1, 2010, the amount of the savings resulting from the increases in the rebate percentages effected by certain provisions of the Affordable Care Act (which are described more fully in the proposed rule (77 FR 5342)) will be remitted to the federal government. These offset amounts are in addition to the amounts applied as a reduction under section 1927(b)(1)(B) of the Act. We proposed to calculate the offset as described in the proposed rule (77 FR 5342). Comments regarding line extension offsets are addressed under the Treatment of New Formulations (§ 447.509(a)(4)) section II.G.2. of this final rule. We received the following comments concerning the federal offset of MDRs:

Comment: Several commenters stated that changes to federal offset of rebates in proposed § 447.509(c), including increased rebates returned to the federal government for line extension products and the increase in the federal minimum rebate may negatively impact state supplemental rebates by reducing the size of the supplemental rebates received.

Response: While a reduction in supplemental rebates is not a direct requirement of this rule, we recognize that the federal offset resulting from section 1927(b)(1)(C) of the Act may have some indirect impact on state supplement rebates. However, based on the supplemental rebate data reported to CMS on the Medicaid and Children's Health Insurance Program Budget and Expenditure System (MBES), *http://medicaid.gov/Medicaid-CHIP-Program-Information/By-Topics/Data-and-Systems/MBES/CMS-64-Quarterly-Expense-Report.html,* we do not see an

impact so far to states' supplemental rebates.

Comment: One commenter asked that CMS clarify whether the intent with the statement for CODs that are dispensed to Medicaid MCO enrollees that, ''in addition, we planned for states to retain the non-federal share of the amount above the revised minimum rebates for brand name drugs'' is to have the states retain the full value of the basic rebate percentage of 23.1 percent for brand name drugs dispensed to Medicaid MCO enrollees.

Response: The offset formula for Medicaid MCO drugs is the same as for FFS drugs.

Therefore, after considering the comments we received, and for the reasons discussed in this section and in the proposed rule, we are finalizing proposed § 447.509(c) (federal offset of rebates), with the following technical edits:

- We are adding the word ''following'' to the introductory sentence of § 447.509(c). This edit is technical in nature and is not intended to change the meaning of the provision but rather provides further clarity.
- We are removing the phrase ''for the following'' from the end of paragraph (c)(1). This edit is technical in nature and is not intended to change the meaning of the provision.
- We are removing the phrase ''for the following'' from the end of paragraph (c)(2). This edit is technical in nature and is not intended to change the meaning of the provision.

H. Requirements for Manufacturers (§ 447.510)

To update our regulations to include references to the AMP rule, we proposed to revise the manufacturer reporting requirements in § 447.510(a)(1), § 447.510(c)(2)(i), and § 447.510(d)(2) to reference § 447.504 (Determination of AMP) (77 FR 5342, 5365).

We also proposed revising § 447.510(g) to clarify that CMS will designate the electronic format in which the product and pricing data is submitted. These proposed provisions are discussed in more detail at 77 FR 5342 through 5343 of the proposed rule. We received no comments on these revisions, and therefore, we are finalizing them as proposed, except we are making a technical edit and removing the reference to ''of this subpart'' from § 447.510(a)(1), (c)(2)(i), and (d)(2) because the reference is unnecessary given the regulatory citation.

We also included proposed § 447.510(a)(2), (a)(3), (a)(4), (d)(1), (d)(4), (d)(5), and (e)(1) through (4) without modification (77 FR 5365 through 5366). We did not receive any comments and are finalizing § 447.510(a)(2), (a)(3), (a)(4), (d)(1), (d)(4), (d)(5) and (e)(1) through (4), except to remove the words ''of this subpart'' from the proposed regulatory text of paragraphs (a)(2) and (4) because the reference is unnecessary given the regulatory citation.

In proposed § 447.510(f), we included the existing language pertaining to recordkeeping requirements, with minor changes to the paragraph formatting structure but no modification to the content of paragraph (f) (77 FR 5366). We did not receive any comments and are finalizing § 447.510(f).

1. Failure To Report Quarterly AMP (§ 447.510(a)(5)) and Failure To Report Monthly AMP and AMP Units (§ 447.510(d)(7))

We proposed, in accordance with the statutory requirements at section 1927(b)(3)(C)(i) of the Act, that a manufacturer that fails to submit and certify a quarterly AMP to CMS for a product by the 30th day after the end of each quarter will be reported to the OIG and be subject to a civil monetary penalty (CMP) for each product not reported on the 31st day (77 FR 5343). We also proposed, in accordance with the statutory requirements at section 1927(b)(3)(C)(i) of the Act, that a manufacturer that fails to submit and certify a monthly AMP and AMP units to CMS for a product by the 30th day after the end of each month will be reported to the OIG and be subject to a CMP for each product not reported on the 31st day (77 FR 5344 through 5345). We also invited public comments on appropriate terms and procedures for suspension and termination from the MDR program (77 FR 5343, 5345). We received the following comments concerning failure to report quarterly and monthly AMP and monthly AMP units:

Comment: Many commenters expressed opposition to the automatic imposition of CMPs for late reporting and believed that CMS should retain the right to evaluate whether to refer cases to the OIG and whether CMPs are warranted on a case by case basis. A few commenters noted that factors outside the manufacturer's control may delay reporting of AMP data. Because manufacturers must rely on an array of complex systems to generate, validate, certify, and submit government pricing metrics and these systems can break down or produce unforeseeable errors that preclude timely reporting; the commenters stated that the imposition of automatic CMPs is unwarranted. A few commenters noted that such delays could include system failures or difficulty accessing the DDR system, which manufacturers use to provide data to CMS. It could also be a malfunction of a manufacturer's own internal pricing systems and the commenters voiced concerns with the proposed regulatory provision that would automatically impose CMPs upon manufacturers where there is any DDR or manufacturer system malfunctions.

A few commenters stated that CMS should value accuracy of AMP over timeliness and not penalize for lateness in cases where manufacturers are making adjustments or corrections to ensure accuracy. One commenter stated that CMS should clarify that no CMPs will be imposed where CMS is the cause for any delay in manufacturer access to the DDR system. Another commenter believed the penalty should be applied only in situations where the manufacturer has a history of noncompliance that suggests repeated late filings are purposeful. One commenter requested that CMS clarify if the CMPs will apply to a manufacturer when pricing is late one time, a couple of times, or for repeat offenders.

Response: Section 1927(b)(3)(A) of the Act requires that manufacturers report AMP data not later than 30 days after the last day of each rebate period and month of a rebate period. CMS's current policy is to refer to the OIG manufacturers that do not report their monthly or quarterly AMP data and/or that report their monthly or quarterly AMP data untimely. The OIG then makes the determination as to whether or not to impose any CMPs. Our intent in adding the language at proposed § 447.510(a)(5) and (d)(7) was to strengthen the overall administration of the MDR program by explicitly stating in regulation that manufacturers would be subject to CMPs when manufacturers do not report quarterly AMP, monthly AMP, and monthly AMP unit data timely.

However, based on the comments received, we now recognize that the proposed language implied the automatic imposition of such CMPs. Since OIG is responsible for decisions concerning the imposition of such CMPs, we have decided that we will not be finalizing these proposed changes at this time. However, given the statutory requirements set forth in section 1927(b)(3)(C) of the Act, we will continue to refer to the OIG manufacturers that do not report their monthly or quarterly AMP data and/or that report their monthly or quarterly

AMP data untimely. As discussed in the OIG's Special Advisory Bulletin (*http://oig.hhs.gov/fraud/docs/alertsandbulletins/2010/SpAdvBulletin_AMP_ASP.pdf*) issued in September 2010, OIG and CMS are working together to identify and penalize noncompliant manufacturers through the CMP process because HHS's past approach of promoting voluntary compliance has not been fully effective. The deadlines for filing quarterly and monthly pricing information are not new so we expect that manufacturers should have established operational procedures and timelines to ensure they are able to report timely. We will work with the manufacturers if there is a problem with the DDR system that prevents a manufacturer from reporting its quarterly or monthly pricing information timely. We agree with the commenters that the pricing data reported to CMS need to be accurate; however, the data also should be reported timely, as both accuracy and timeliness are essential components to ensuring that we are able to use the data effectively to generate the monthly FULs and the quarterly URAs.

Comment: One commenter requested that CMS clarify whether the civil monetary penalties will also be imposed upon manufacturers that fail to submit best price as well as AMP. Furthermore, the commenter requested that CMS clarify whether manufacturers that fail to submit AMP and/or best price timely will be subject to CMPs of $10,000 per day per drug calculation (that is charged $10,000 for failure to report AMP and $10,000 for failure to report best price).

Response: We appreciate the comments but, as noted in this section, we are not finalizing the CMP provision. In accordance with section 1927(b)(3)(A) of the Act, as well as implementing regulations manufacturers are responsible for submitting AMP and best price information on a timely basis.

Comment: A few commenters recommended that CMS replace the word ''will'' with the word ''may'' in proposed § 447.510(a)(5) and (d)(7) to indicate that a manufacturer that fails to submit a quarterly AMP and/or monthly AMP and AMP units to CMS for a product by the 30th day after the end of each reporting period may be subject to civil monetary penalties for each product not reported on the 31st day of $10,000 per day per drug. Another commenter stated that while they support CMS's proposal that CMPs may be imposed against manufacturers for failure to report AMP within 30 days of the end of the quarter or month, the commenter urged CMS to consider adopting a good cause exception which would allow CMS the discretion not to initiate CMPs against manufacturers that failed to meet the reporting deadline, despite good faith efforts to meet them. The commenter explained that there are sometimes unforeseen circumstances that cause a manufacturer that is acting in good faith and working to meet the AMP reporting deadlines to be delayed in reporting its AMP data. The commenter went on to say that price reporting is complex and technically challenging, the tight deadline for price reporting often proves challenging and CMS should recognize that and provide reasonable flexibility.

Response: We appreciate the comments but as we noted in this section, based on comments, we are not finalizing these proposed provisions.

Comment: One commenter noted that, if CMS adopts the proposed buildup methodology for calculating AMP, there will be significant operational challenges associated with the transition, and that the buildup requirements combined with the imposition of automatic CMPs for late filing without an adequate transition would be burdensome. Therefore, the commenter believed that CMS should exercise discretion in determining whether CMPs are warranted, based on specific facts and circumstances, as opposed to automatically levying a significant and burdensome penalty. If CMS was to proceed with the buildup methodology, the commenter stated that it must provide manufacturers with lead time to prepare systems for the transition.

A few commenters noted that if CMS chooses to finalize the buildup methodology proposal for calculating AMP, manufacturers' AMP calculations will be even more dependent on third party data. Another commenter noted that if CMS requires manufacturers to purchase end-user data from third parties to use in AMP calculations, it would substantially reduce manufacturers' control over the AMP calculation process and late submission may be more of an issue. Commenters expressed concerns that in such cases it would not be appropriate to impose CMPs automatically on manufacturers. Another commenter noted that if CMS finalizes a plan to abandon the presumed inclusion while retaining its strict certification requirements, the commenter believed that CMS will essentially guarantee that no manufacturer would be able to comply with program requirements, thus exposing the industry to unnecessary legal liability.

Response: As discussed in more detail in the comments and responses in the Determination of AMP section (section II.C.), we are not finalizing the buildup methodology requirement. Manufacturers will continue to be able to make reasonable assumptions, in the absence of adequate documentation to the contrary, that prices paid to manufacturers by wholesalers are for drugs distributed to retail community pharmacies, provided that those assumptions are consistent with the requirements and intent of section 1927 of the Act and federal regulations. Therefore, we believe this will address the concerns raised by commenters pertaining to a manufacturer's ability to report data timely. While we have chosen not to finalize the proposed CMP provision in this rule, we will continue to notify the OIG when a manufacturer is not meeting its timely reporting obligations. Therefore, as we have noted previously, we will continue to operate under the current policy, which is to refer to the OIG manufacturers that do not report or timely report their data. The OIG will be responsible for deciding whether to impose CMPs.

Comment: A few commenters requested that CMS allow a grace period of 6 to 12 months following publication of the rule to enable manufacturers to incorporate changes before penalties are imposed.

Response: As discussed in prior responses, we have decided not to finalize the CMP proposal; thus, the grace period commenters suggested is not needed.

Comment: Several commenters disagreed with the proposal to impose a penalty of $10,000 per drug per day for late AMP reporting and believe that by imposing the late filing penalty on a per drug basis, as well as per day basis, the proposed rule would disproportionately penalize generic manufacturers because they tend to offer more extensive product lines than branded manufacturers and would therefore be subject to larger fines. Several commenters expressed the belief that the proposal goes beyond what is authorized by the statute and could have a significant and disproportionate effect on generic manufacturers. These commenters indicated that CMS is taking an expansive interpretation of the statutory penalty and by imposing the penalty on a per drug per day basis, CMS exceeds the statutory authority by allowing for a fine which could be significantly in excess of the statutory limit. These commenters requested that CMS revise the proposed rule to more closely track with the statute. One commenter believed this is inconsistent

with the Master Agreement which does not include the ''per drug'' provision contained in the proposed rule. Furthermore, the commenter believed that CMS's foremost concern should be the accuracy of the AMP calculation and that manufacturers should not be penalized in cases where late data corrections or system improvements cause a submission to be late.

Response: As discussed in prior responses, we have decided not to finalize the CMP proposal, including the per drug/per day provision included in the proposed rule.

Comment: One commenter requested clarification as to how CMS will define ''a drug'' for purposes of imposing CMPs, at the NDC–9 or NDC–11 level.

Response: As noted in previous responses, we are not finalizing our proposal; however, we report information to the OIG regarding non-reported or late data at the NDC–9 level.

Comment: Several commenters responded to our request for comments on the appropriate terms and procedures for suspension and termination for manufacturers that do not report quarterly AMP on a timely basis or are otherwise out of compliance with rebate requirements. One commenter stated that they believe that a policy of this type is appropriate and recommended that coverage of products for which the manufacturer has not submitted an AMP within a specified number of quarters should be suspended for up to a specified number of quarters. If, after the specified number of quarters under the suspension, the manufacturer is not compliant, its rebate contract could be terminated. The commenter further suggested that CMS consider a policy whereby manufacturers terminated in this manner could be prohibited from participation in the MDR program for a certain period of time following termination. This warning period would apply to any subsidiaries, parent companies, spin-offs, consolidation, or other type of reorganized companies. The commenter also suggested that CMS consider including a policy whereby states would have authority to suspend coverage of a manufacturer's products when they have not received payment for a certain number of consecutive quarters, or an aggregate number of quarters and believed this policy would provide states with a strong mechanism to enforce the terms of the MDR program. Additionally, the commenter suggested that CMS consider a policy whereby manufacturers of noninnovator multiple source products should be penalized after a certain number of months of non-compliance due to the time-sensitive nature of the FUL calculations.

A few commenters encouraged CMS to provide guidance on administrative appeals process that would allow an opportunity for appeal and reconsideration before sanctions such as suspension or termination apply, but did not provide any substantive comments on the appropriate terms and procedures.

Response: We appreciate the suggestions and recommendations received on this issue and will continue to consider suspension and termination procedures for manufacturers that do not report quarterly pricing information on a timely basis or are otherwise out of compliance with rebate requirements. We are not finalizing any suspension or termination procedures at this time; however, we will consider issuing additional guidance on this issue at a later time.

For the reasons discussed in this section, we have decided not to finalize proposed § 447.510(a)(5) and (d)(7).

2. Reporting Revised Monthly and Quarterly AMP, Best Price, Customary Prompt Pay Discounts, or Nominal Prices (§ 447.510(b)(1) and (d)(3)) and Recalculations Including Good Cause (§ 447.510(b)(2))

We proposed to revise the 12-quarter time limitation set forth in § 447.510(b) (77 FR 5343). Specifically, we proposed at proposed § 447.510(b)(1) That a manufacturer could submit a request to revise its pricing data (that is, AMP, best price, customary prompt pay discount, or nominal price) calculations outside of the 12-quarter filing deadline, if the revision request fell within one of the following categories: (1) The change is a result of a drug category change or a market date change; (2) the change is an initial submission for a product; (3) the change is due to termination of a manufacturer from the MDR Program for failure to submit pricing data and must submit pricing data to reenter the program; (4) the change is due to a technical correction (such as a keying error), that is, not based on any changes in sales transactions or pricing adjustments from such transactions; or (5) the change is to address specific underpayments to states, or potential liability regarding those underpayments, as required by CMS, applicable law or regulations, or an OIG or DOJ investigation (77 FR 5343, 5365). Please note that any reference to pricing data mentioned in this section is intended to refer to AMP, best price, customary prompt pay discounts, or nominal prices.

We also proposed at § 447.510(b)(2) an option for manufacturers to submit a recalculation request outside of the 12-quarter time limit based on good cause, which would permit a manufacturer to revise its methodology for calculating AMP, best price, customary prompt pay discounts, or nominal prices (77 FR 5365). We proposed a good cause option to extend the time limit for a manufacturer to submit a recalculation request, similar to that used in Medicare (77 FR 5343, 5365). These proposed provisions are discussed in more detail at 77 FR 5343 of the proposed rule.

While these two provisions were proposed separately, many of the comments we received pertained to confusion commenters had in distinguishing the difference between what CMS was proposing in the restatement for underpayment exception at § 447.510(b)(1)(v) and the good cause exception at § 447.510(b)(2). Due to the nature of the comments received we have chosen to address both proposed provisions in this section.

We received the following comments concerning reporting revised monthly and quarterly AMP, best price, customary prompt pay discounts, or nominal prices, as well as the option for manufacturers to submit a recalculation request outside of the 12-quarter time limit based on good cause:

Comment: One commenter supported CMS's proposal to allow restatement of Medicaid pricing metrics beyond the 12-quarter window under the five listed criteria and the good cause exception.

Response: We appreciate the comment and support.

Comment: A few of commenters requested clarification regarding what is meant by ''good cause.'' One of the commenters asked if CMS would be approving the good causes and wanted to know what type of notice CMS or manufacturers would be required to provide states when the recalculation request exceeds the 12-quarter rule. One commenter stated that it is unclear how the good cause exception (§ 447.510(b)(2)) differs from the fifth exception (§ 447.510(b)(1)(v)) and requested that CMS provide clarification. The commenter otherwise commended CMS for recognizing the potential need for manufacturers to revise pricing data outside of the 12-quarter period including restatements for good cause and supports this aspect of the proposed rule.

Response: We appreciate the comments and requests for clarification. While both proposed provisions were designed to address specific underpayment liability resulting from an OIG, DOJ, or internal investigation,

proposed § 447.510(b)(1)(v) would allow manufacturers to revise their pricing information and the good cause exception under proposed § 447.510(b)(2) would allow for a recalculation outside of the 12-quarter based on a good cause. Generally, a recalculation of AMP or best price is a result of the manufacturer making changes in methodology for calculating the AMP and/or best price. And although proposed § 447.510(b)(2) (the good cause provision) would primarily address similar circumstances as § 447.510(b)(1)(v) (an underpayment to states and potential liability regarding those underpayments that may extend outside of the 12-quarter time frame), the good cause recalculation option was proposed to provide a broader option where a manufacturer could submit such a request for other good cause reasons that stem specifically from a change in the methodology for calculating AMP and/or best price. While we received comments requesting further clarification on our good cause proposal, we did not receive any comments suggesting what situations CMS should consider as a good cause. Based on concerns raised by the commenters, we have decided not to finalize proposed § 447.510(b)(2) at this time; however, we will continue to consider this option and address it in future rulemaking, if appropriate.

Comment: In regards to proposed § 447.510(b)(1)(v), a few commenters requested that CMS allows revisions in the event of underpayments and overpayments. One commenter stated that CMS needs to clarify what it means by ''underpayment'' and suggested that ''underpayment'' should mean a net rebate underpayment, as determined by calculating the overall effect of a particular error across all of the affected periods and NDC–9s and thus taking into account offsets. Several commenters stated that revisions outside of the 12-quarter period can result in revisions to pricing data that can both increase and decrease liability. The commenters stated that CMS should clarify that these exceptions provide CMS with discretion to accept only the totality of revisions proposed by a manufacturer, inclusive of revisions that decrease liability, assuming that CMS does not otherwise have a legal basis for declining the revisions as impermissible based on the AMP and best price calculation rule. The commenters also stated that CMS should not be able to ''cherry pick'' among revisions outside of the 12-quarter period and only accept those that increase rebate liability. A few commenters indicated that this could be addressed by revising the proposed § 447.510(b)(1)(v) to include overpayments by manufacturers as well as underpayments to states. The commenter stated that CMS should be obligated to accept or reject the submission as a whole.

Another commenter requested that CMS clarify if the resulting liability changes across all of a manufacturer's products for a period or several periods is a net overpayment, but some products have been underpaid, whether the manufacturer is liable for the entire underpayment but may not recoup the overpayment or whether the manufacturer while liable for the underpayment is also able to recoup the overpayment. One commenter urged CMS, when determining if a restatement results in an underpayment to the states, to consider the net impact of any overpayment that may also occur as a result of the restatement. Another commenter appreciated CMS's recognition of manufacturers needs to restate these metrics; shared states' desires to settle past periods for rebate liability; and thought that the provisions in proposed § 447.510(b)(1)(v) accomplish these goals. However, the commenter asked that in determining whether revised pricing metrics would correct an ''underpayment'' to the states, CMS considers the totality of all changes resulting from the revised metrics. The commenter stated that some errors that prompt revisions of these metrics impact multiple drugs, such as with some drugs increasing in rebate liability and other drugs decreasing in rebate liability.

Several commenters indicated that CMS should not be able to selectively accept a subset of data that would maximize the manufacturer's rebate liability, but instead the proposed revisions should be accepted or rejected as a whole (unless part of the proposed revision is incorrect). One commenter stated that when a manufacturer identifies an error in a historic pricing submission, CMS should allow or reject a statement outside of the normal 12-quarter period based on its interest in promoting accuracy and the integrity of data. The commenter stated that if granting a request would improve accuracy, it should be allowed. One commenter supported the development of the good cause exception to the 12-quarter limitation on the manufacturer's right to restate AMP and best price. However, the commenter was concerned about automatic restatement rights beyond the 12-quarter window as a result of CMS or OIG determinations that an underpayment of rebates has occurred. The commenter indicated that CMS has always allowed manufacturers to offset rebate underpayments with identified rebate overpayments and does not see why that should not continue to be the case regardless of the period being restated. One commenter noted that limiting a manufacturer's ability to restate pricing resulting from overpayments would prevent manufacturers from restating 340B prices and refunding 340B entities for overcharges on 340B purchases.

Response: As explained in the final time limitation rule (Medicaid Program; Time Limitation on Price Recalculations and Recordkeeping Requirements Under the Drug Rebate Program, (68 FR 51912 (August 29, 2003)), the 12-quarter time frame for submitting pricing changes was established to improve the administration and efficiency of the MDR program and assist states and manufacturers that would otherwise be required to retain drug utilization and pricing data indefinitely. We proposed to allow revisions outside of the 12-quarter time period, given that there are times when certain circumstances will arise that may require a revision of pricing data, for example, a change in drug category or market date, technical mistakes, or certain investigations for the purposes of rebate program. However, we appreciate the comments that we should not ''cherry pick'' among revision requests outside of the 12-quarter rule and that we should consider allowing pricing changes for both overpayment and underpayment to states.

Since we understand that any change in pricing data could potentially lead to either a net underpayment or overpayment to states, and in light of the comments received, we are revising § 447.510(b)(1)(v) to specify that the change in pricing data outside of the 12-quarter rule would be considered if the change is to address specific rebate adjustments to states by manufacturers, as required by CMS or court order, or under an internal investigation, or an OIG or DOJ investigation. This change we are finalizing in wording is intended to reflect that the change request will be considered in cases where there is an underpayment or an overpayment to the state by the manufacturer that is discovered outside of the 12-quarter filing limit, and the adjustment to pricing data is determined to be required by CMS or court order, or is an internal investigation, or an OIG or DOJ investigation.

We also want to clarify, in response to comments concerning the impact of revisions on multiple drugs, that the exception to allow for a revision outside of the 12-quarter rule applies to each

change request submission as a whole, and that at this time we were not proposing to allow revisions based on a per drug, or partial change request submission, but instead based on the net impact of the submission as whole. Furthermore, we believe that our net impact clarification would not prevent 340B restatements; however, we note that the 340B program is administered by HRSA's OPA, and these issues would need to be addressed by HRSA's OPA.

Comment: One commenter stated that CMS should clarify that it would permit restatements under § 447.510(b)(1)(v) or (b)(2) due to an internal manufacturer pricing review and that an inquiry by a government agency should not be required. The commenter suggested that CMS make revisions so § 447.510(b)(1)(v) reads as follows: ''The change is to address specific net underpayments (that is, underpayments minus overpayments) to states, or any potential liability regarding those net underpayments, as required by CMS, applicable law or regulations, or an OIG or DOJ investigation, or arising from a manufacturer review.''

Response: As discussed earlier in this section, we have decided not to finalize § 447.510(b)(2) as proposed at this time. In regards to § 447.510(b)(1)(v), which we are finalizing that a manufacturer will be permitted to revise its pricing information to address specific rebate adjustments to states or manufacturers, as required by CMS or court order, or per an internal investigation, or an OIG or DOJ investigation. The internal investigation specified in § 447.510(b)(1)(v) is intended to mean a manufacturer's internal investigation.

Comment: One commenter requested that CMS add language to the final rule to clarify the timeline for disputes by incorporating a specific limitation on the number of quarters after payment that manufacturers are able to pay invoices, open disputes, and receive credits. The commenter stated that manufacturers should be expected to resolve and close all disputes within 60 months (5 years) from the original quarter, as states spend a significant amount of time working with manufacturers to resolve disputes going back to 1991, which is well over 20 years ago.

Response: We appreciate the comment; however, we have not proposed any time line for closing disputes. While we may consider such time lines in the future, it is outside the scope of this rule.

Comment: One commenter asked CMS to clarify what entity or agency will have responsibility for auditing the submitted data and how frequently the audits should occur.

Response: We did not propose any provision regarding drug rebate audits; however, in accordance with the statute, CMS and the OIG may conduct verification surveys or audits, as-needed to verify pricing.

Comment: We received several comments regarding the timeframe allowed for manufacturers to restate beyond the 12-quarter time limit. One commenter requested that CMS clarify the timetable and the series of events that a manufacturer should anticipate should the manufacturer, as a result of its internal investigation, wish to address a change in liability that extends beyond the 12-quarter filing deadline. Some commenters supported CMS's contemplated policy of allowing manufacturers to make certain revisions to their pricing data on a retroactive basis without any time limits back to the beginning of the program. The commenters stated that any time limit could pose a problem if a manufacturer discovers an error in reporting that occurred several years in the past, and by not setting a time limit CMS can avoid arbitrarily curtailing manufacturer's ability to address errors.

Another commenter requested that CMS amend the language to specify minimum and maximum timeframes for manufacturer adjustments. The commenter believed it is contrary to the programmatic goals of achieving efficiency, economy, and quality of care to allow indefinite changes to pricing, rebates and other calculations. Conversely, another commenter recommended that CMS extend this period because 12 quarters is often too limiting. The commenter indicated that this is especially true when companies acquire other companies or acquire products and there is a chance that the acquiring company will discover errors in AMP and best price that occurred before the acquisition. The commenter stated that in many cases this can happen outside of the 12-quarter window. The commenter recommended that CMS afford companies flexibility to restate outside the window in those circumstances to address net underpayments.

Response: We appreciate the comments regarding the need for submitting price adjustments outside of the 12-quarter window. However, at this time we are only finalizing the five categories identified in this final rule under § 447.510(b)(1). We will continue to consider other possible scenarios for price submissions outside the 12-quarter window and, if warranted, issue additional guidance or rulemaking. In the event that a manufacturer discovers any discrepancy with their reported product and pricing data to the MDR program that are outside of the 12-quarter filing deadline, the manufacturer should determine if the change satisfies any of the five criteria for a revision under § 447.510(b)(1) and, if applicable, submit a request to change the data to CMS. Over the years we have issued guidance via our program releases (for example, Manufacturer Releases #61 (September 23, 2003), #78 (June 26, 2007), #80 (January 5, 2010)) instructing manufacturers that they should contact CMS through the drug policy resource mailbox (*rxdrugpolicy@cms.hhs.gov*) if they discover any discrepancies in pricing data submissions. Upon receipt of a request, we review the request to determine if it meets the criteria established in § 447.510(b)(1) and may contact the manufacturer to obtain additional information, if needed. After reviewing the request, we will notify the manufacturer of our decision. We did not propose a deadline and thus, at this time we are not establishing a deadline, although we will continue to consider the issue.

Comment: A commenter requested that CMS clarify whether manufacturers will be allowed, in the case of a change in methodology, to restate a quarterly AMP only if each of the 3 months of that quarter are restated within the 36 month timeframe from each month. The commenter provided the following example: if a manufacturer must restate AMP for the third quarter 2009 (due October 30, 2012) but is unable to restate the July 2009 monthly AMP before its due date of August 30, 2012, may the quarterly values due October 30, 2012 still be restated.

Response: In accordance with § 447.510(b) and (d), manufacturers have 36-months or 12-quarters from the month or quarter that the submission was originally due to be filed to update monthly and/or quarterly AMP submissions in the DDR without CMS approval. In addition, a manufacturer should update its quarterly AMP submissions regardless of whether either 1 or 2 months used to calculate the quarterly AMP is outside of the 12-quarter timeframe. As discussed in the proposed rule, we would expect that any revision to pricing data to be consistent across the monthly and quarterly AMP submissions (77 FR 5343). Therefore, as specified in § 447.510(d)(3), a manufacturer should submit a revision request for the monthly AMP that exceeds the 36-month period in accordance with § 447.510(b)(1).

Comment: A commenter encouraged CMS to specifically address the situation in which a change in methodology would affect a manufacturer's base date AMP period, thus requiring a restatement or recalculation outside of the 12-quarter window. The commenter encouraged CMS to also address the protocols for differences in resubmitted data, due to either methodology or incorrect data, under the 12-quarter window. The commenter stated that CMS should consider addressing whether or not a bar of materiality can be considered in the determination of the necessity of a recalculation, or whether or not such a consideration can be requested of CMS by a manufacturer (for example financial impact analysis or a change within a certain number of decimal places to a URA).

Response: Any changes to AMP must follow the applicable requirements of this final rule, without regard to whether the changes affect the base date period. Manufacturers may submit revised pricing data for any reason within the 12-quarter window without regard to the criteria we added in § 447.510(b)(1).

Furthermore, as specified in this section, manufacturers do not need to notify CMS if they have a revision within the 12-quarter timeframe, as they may submit pricing data without prior review or approval by CMS. However, any revision within the 12-quarter timeframe must be consistent with the statute and regulations and manufacturers must retain appropriate records pertaining to the revision. In addition, while we appreciate the comment suggesting that CMS consider a bar of materiality, we did not propose such a standard, and do not believe it would be in the best interest of the MDR program at this time to establish such a materiality standard. Instead, for requests that fall outside the 12-quarter time frame, the manufacturer is responsible for demonstrating that its request satisfies one of the criteria we are finalizing in § 447.510(b)(1).

Comment: One commenter requested, that if CMS finalizes any of the proposed exceptions, it should explain how manufacturers should submit requests to CMS for filing under one of these exceptions. A few commenters requested that CMS clarify that the exception does not create new true-up obligations on manufacturers beyond the 12-quarter period, but instead only provides CMS with the discretion to grant voluntary requests made by manufacturers beyond the deadline.

Response: In accordance with section 1927(b)(3) of the Act and § 447.510(a), manufacturers are required to submit pricing data within the 30 days after the end of the quarter. Section 447.510(b) gives manufacturers 12 quarters to update those prices. Section 447.510(b)(1)(i) through (v) also creates exceptions to this 12-quarter time frame, but is not designed to create additional obligations outside of these statutory and regulatory requirements for the purposes of rebate calculations. Manufacturers are responsible for calculating prices consistent with the statute and regulations that are in effect at the time those calculations are submitted. Because the provisions of this final rule are effective prospectively, manufacturers are not responsible for applying these provisions on a retrospective basis. Furthermore, in this final rule, the exceptions in § 447.510(b) do not create any new true-up obligations for the manufacturers.

Therefore, for the reasons stated in this section, we are finalizing § 447.510(b)(1)(i) through (iv) as proposed. In addition, for the reasons stated in this section and in response to comments, we are finalizing § 447.510(b)(1)(v) to include the change is to address specific rebate adjustments to States by manufacturers, as required by CMS or court order, or under an internal investigation, or an OIG or DOJ investigation. We have decided not to finalize § 447.510(b)(2), and as a result, we are redesignating proposed § 447.510(b)(3) as § 447.510(b)(2) and finalizing it without any additional changes in this final rule.

3. Base Date AMP (§ 447.510(c)(1) Through (4))

We proposed to revise § 447.510(c)(1) and (2) by inserting ''DRA'' before base date AMP where it occurs (77 FR 5343, 5365). We also proposed to correct the regulation by removing the notation ''[OFR: insert publication date of the final rule]'' and replacing it with ''July 17, 2007'' in § 447.510(c)(1). To reflect the changes to AMP as set forth in the Affordable Care Act, we proposed to allow manufacturers to recalculate base date AMP in accordance with the definition of AMP in proposed § 447.504. We further proposed to allow manufacturers the option to report a recalculated base date AMP based on the Affordable Care Act definition of AMP or continue to use their existing base date AMP. We also proposed that manufacturers would have the option to report the Affordable Care Act base date AMP for a period of 4 full calendar quarters beginning with the first full quarter after the publication of the final rule. These proposed provisions, and our reasons for these proposals, are discussed in more detail at 77 FR 5343 through 5344 of the proposed rule. We received the following comments concerning the base date AMP:

Comment: We received many comments in support of CMS's proposal to allow manufacturers to recalculate base date AMP on a product by product basis. One commenter indicated that this provision is critical to maintaining the integrity of the additional rebate set out in § 447.509(a)(2). Another commenter sought clarification that the ability to restate base date AMP is not contingent on a manufacturer having restated base date AMP under the DRA. The commenter noted that the pre-DRA AMP and the Affordable Care Act AMP methodologies are not identical and manufacturers may have made the decision about whether to restate base date AMP after the DRA based on the available resources and market conditions at the time. Similarly, manufacturers should have the same ability to determine whether to restate base date AMP based on the definition of AMP, following the Affordable Care Act amendments regardless of the decisions made in the past.

Response: We agree with the commenters and, as discussed in the proposed rule, believe that it is important for manufacturers to have the option, in light of the Affordable Care Act amendments, to revise their base date AMPs. Manufacturers will have the ability to report an Affordable Care Act base date AMP, as provided in the final rule, on a product by product basis regardless of whether they chose to recalculate and report a DRA base date AMP.

Comment: We received several comments regarding the requirement that the base date AMP recalculation must be based on actual and verifiable pricing records. Many commenters indicated that the requirement to use actual and verifiable pricing records, in combination with the proposed buildup methodology for calculating AMP, would make it impossible for manufacturers to recalculate the Affordable Care Act base date AMP because manufacturers lack the end customer data that would be required to recalculate the base date AMP using the buildup methodology. Several commenters indicated that if CMS were to abandon the presumed inclusion methodology and also require manufacturers to recalculate the base date AMP in accordance with this non-statutory change, this would generally make it impossible for manufacturers to restate the base date AMP because the

data required for such a recalculation would be unavailable.

One commenter recommended that CMS consider the base date AMP impact and the likelihood of manufacturers being able to perform a base date AMP restatement with a buildup methodology. One commenter thought that it is also highly unlikely that manufacturers could reasonably obtain information about sales to Puerto Rico and the other territories, which were formerly exempt from AMP and best price. Another commenter noted that the proposed buildup methodology for calculating AMP departs from historical practice and to restate under the buildup methodology would cause manufacturers to be dependent upon information from third parties that may or may not have retained the information. Furthermore, even if the information were obtained, the commenter believes it would not be verifiable by the manufacturer. Another commenter indicated that the data necessary to recalculate the base date AMP, specifically historical off-contract sales data and customer information that are needed to identify sales to retail community pharmacies, are likely to never have existed. Even if the data do exist, they would be prohibitively expensive to obtain or recreate, which would leave companies in a position of having to pay a penalty based on inconsistent definitions of prices that are not directly related to price increases. The commenter stated that if CMS were to adopt the buildup methodology, CMS should be very clear that the recalculated Affordable Care Act base date AMP must reflect AMP changes made by the Affordable Care Act but need not reflect changes in AMP calculations that are not required by the Affordable Care Act.

Another commenter asked that CMS specify in the final rule that the revised Affordable Care Act base date AMP may be calculated using the presumed inclusion methodology rather than requiring a manufacturer to trace prior non-contracted sales to retail community pharmacies by using third party vendors, if such data were even available. The commenter indicated that it would be impossible for manufacturers to certify that such third party data reflected actual and verifiable pricing records and this would render the recalculation option meaningless.

Response: As discussed in more detail in the comments and responses in the Determination of AMP section (section II.C.) of the final rule, in light of the comments we received, we are modifying our position on requiring manufacturers to calculate AMP using the buildup methodology. Thus, manufacturers will be able to recalculate their base date AMPs using the presumed inclusion methodology. We believe this change will satisfy the concerns raised by commenters pertaining to a manufacturer's ability to obtain the necessary historical data to calculate the Affordable Care Act base date AMP under the buildup methodology.

We also believe that while manufacturers may use a presumed inclusion policy to calculate AMP and base date AMP, they must maintain actual and verifiable documentation that otherwise supports such calculations. Furthermore, we have adopted the same standard we used with the DRA base date AMP calculation and see no reason to change that standard. In addition, we would expect manufacturers to have historical data available to them in light of the recordkeeping requirement established in § 447.510(f).

In regards to the commenter's concern about whether manufacturers could obtain sales information from the territories, it is our position that for any time prior to the inclusion of the territories in the definitions of state and United States, manufacturers are not required to consider such sales to territories given the prospective nature of this rule.

Comment: One commenter noted that when the Affordable Care Act-defined AMP became effective in October 2010, many branded manufacturers saw their AMP increase dramatically, resulting in significant penalties inherent in using a current AMP and a base date AMP created under a different methodology. Moreover, the commenter noted that a significant impact on the calculated 340B ceiling prices may result because manufacturers who experienced a significant CPI–U penalty starting in October 2010 also experienced dramatically lower 340B ceiling prices, even penny pricing, as the CPI–U penalty for the URA was so high that they hit the max URA for AMP, resulting in a 340B ceiling price of AMP minus a URA that equaled AMP, which is effectively zero.

Response: We appreciate the concerns raised by this commenter, and in light of such concerns, we believe it is important to give manufacturers an option to recalculate their base date AMP. Furthermore, we recognize that for the time period between the effective date of the Affordable Care Act definition of AMP (October 1, 2010) and the effective date of this final rule, some manufacturers may have had higher CPI–U penalties as well as lower 340B ceiling prices. We are offering manufacturers the opportunity to recalculate their base date AMP in accordance with the Affordable Care Act definition and report this recalculated base date AMP to CMS. With the ability to report the recalculated base date AMP under the Affordable Care Act definition, manufacturers may see a decrease in their rebate liability as their quarterly AMP and base date AMP will be under the same methodology.

Comment: Many commenters requested, especially in light of the proposed buildup methodology for calculating AMP, that CMS permit manufacturers to use reasonable assumptions in their recalculation of the base date AMP. One commenter urged CMS to clarify the provision that manufacturers are to use ''actual and verifiable pricing records'' by specifying that manufacturers may rely on reasonable assumptions in their recalculations of the base date AMP, where necessary and appropriate to address gaps in historical data under a different AMP calculation framework. The commenter indicated that this would be consistent with CMS's previously expressed goal of making the base date AMP recalculation minimally burdensome on manufacturers. The commenter also stated that manufacturers should not be penalized by paying a higher additional rebate that reflects changes in AMP calculation rules, rather than actual changes in a drug's inflation-adjusted pricing, between the base period and the current period. A few commenters indicated that if manufacturers are not able to use reasonable assumptions then it could make recalculating the base date AMP impossible.

Response: As discussed in more detail in the comments and responses in the Determination of AMP section of the final rule, in light of the comments we received, we have decided not to require manufacturers to calculate AMP using the buildup methodology. Thus, manufacturers will be able to recalculate their base date AMPs using the presumed inclusion methodology and we believe this will satisfy the concerns raised by commenters pertaining to a manufacturer's ability perform a base date AMP recalculation.

Furthermore, as discussed in this section, we believe that while manufacturers may use a presumed inclusion policy to calculate AMP and base date AMP, they must maintain actual and verifiable documentation that otherwise supports such calculations. We have adopted the standard used with the DRA base date AMP calculation and see no reason to change that standard. In addition, we would

expect manufacturers to have historical data available to them in light of the record keeping requirement established in § 447.510(f) for purposes of the rebate program.

Comment: One commenter indicated that CMS should allow manufacturers 12-quarters after the final rule is implemented to submit the recalculated Affordable Care Act base date AMP, which will provide manufacturers with the time necessary to conduct a thorough and accurate review on a product by product basis and is consistent with the 3 years recalculation rule that CMS implemented in 2004. The commenter believed the 12 calendar quarters time period is appropriate because it is consistent with CMS's current policy of requiring manufacturers to report revised pricing information for up to 12-quarters from the quarter in which the pricing data were due.

Response: We disagree with the commenter and believe that 4 full quarters is a sufficient timeframe for manufacturers to recalculate their base date AMP under the Affordable Care Act methodology. As discussed earlier in this section, we decided to provide the same options as we did with the DRA base date AMP after the AMP final rule was published—that is manufacturers are being given the option to submit a revised base date AMP, using the same 4 quarter standard for making those revisions (72 FR 39211). Furthermore, we would expect manufacturers to have historical data available to them in light of the recordkeeping requirement established in § 447.510(f).

Additionally, we see no reason to adopt a 3-year time period for such revisions, given that manufacturers will be responsible for recalculating the Affordable Care Act base date AMP using their historical data. In contrast, manufacturers may need additional time to report revised pricing information because the information they are revising concerns current prices, which may need revision as pricing data are received from various sources. Therefore, we do not believe it is necessary to change the time frame which we established in regulations (72 FR 39243) for the DRA base date AMP change.

Comment: Many commenters indicated that CMS did not discuss how manufacturers should address the base date AMP for 5i drugs in the proposed rule. One commenter noted that, as proposed in the Determination of AMP section of the proposed rule, the same drug could be considered generally dispensed or not generally dispensed through retail community pharmacies in any particular time period based on temporary changes in the distribution of the drug. The commenter indicated that if the base date AMP is calculated using the 5i methodology but the drug subsequently does not qualify for the 5i AMP calculation for a time period, the use of the standard base date AMP might trigger an additional rebate obligation even though the manufacturer did not increase the price of the drug. Therefore, the commenter stated that if CMS provides that a drug's classification can change periodically, it is imperative that manufacturers have the option of establishing the base date AMP under both the 5i and the standard AMP methodologies to match the methodology applicable during a given reporting period. Another commenter suggested that CMS should permit manufacturers to calculate a 5i and a standard base date AMP for those single source or innovator multiple source drugs that a manufacturer expects could flip between the two AMP methodologies, so that the additional rebate for the drug is calculated using a quarterly AMP and a base date AMP that have been calculated using the same methodology. Another commenter suggested that CMS should either permit manufacturers to submit a base date AMP calculated under the two new methodologies now, or submit one now and the other at some point in the future if the product switches. Furthermore, the commenter indicated that it is imperative that CMS clearly articulates in the final rule the processes that manufacturers will need to follow when switching between a 5i and non-5i base date AMP.

One commenter indicated that for single source or innovator multiple source 5i drugs launched after the effective date of this rule, CMS should require manufacturers to calculate and report two distinct base date AMPs (one for each of the methodologies). Additionally, for innovator 5i drugs launched prior to the effective date of the final rule, CMS should allow manufacturers to recalculate and report a distinct base date AMP associated with each methodology. Another commenter noted that manufacturers of innovator drugs pay inflation penalties if their current period AMP exceeds the inflation rate since the establishment of the base date AMP at the time of market introduction. If the base date AMP is based on the 5i AMP method, and it crosses the 10 percent threshold in a quarter, so that the standard AMP applies, the resulting exclusion of discounts and rebates to non-retail customers would create the appearance of a price increase, thereby triggering the additional rebate inflation penalty.

One commenter urged CMS to add a field in DDR for identifying whether the 5i or standard AMP methodology was used in a given quarter for any 5i innovator product so that the appropriate base date AMP could be used to calculate the additional rebate applied. Another commenter indicated that CMS should establish dual base Date AMP records in DDR so that manufacturers can recalculate the base date AMP using both the 5i and the standard AMP methodologies for all 5i products to ensure the appropriate base date AMP is used in the additional rebate calculation.

Response: We recognize the potential problem faced by manufacturers of 5i drugs that may be considered generally dispensed through retail community pharmacies in one quarter and not generally dispensed through retail community pharmacies in another quarter based on changes in the distribution of the drug. We believe that the potential for fluctuation will be minimized, because, as discussed in the Determination of AMP section (section II.C.), of this final rule we have revised our proposed threshold from 90 percent down to 70 percent and are allowing manufacturers to smooth the monthly calculation based upon 12 months of data.

In addition, based on the statutory definition of the base date AMP found at sections 1927(c)(2)(A) through (B) of the Act, manufacturers are responsible for reporting one base date AMP for a COD, whether that base date AMP is calculated using the 5i methodology or not, as the statute references the same methodology. Section 1927(c)(2)(A)(ii)(II) of the Act specifies that for drugs originally marketed before the inception of the rebate program, the base date AMP means the AMP for the 7/1/90 to 9/30/90 quarter. For those drugs approved by FDA after October 1, 1990, section 1927(c)(2)(B) of the Act specifies that the base date AMP should be calculated based on the AMP for the first full calendar quarter after the day on which the drug was first marketed. Based on these statutory provisions, we do not believe that a drug can have two distinct base date AMPs. Therefore, in accordance with these statutory provisions, the base date AMP for a drug, whether it is a 5i or a non-5i drug, shall be based on the sales of the drug for the 7/1/90 to 9/30/90 quarter for drugs approved prior to the inception of the rebate program or the first full calendar quarter after the day on which the drug was first marketed for drugs approved after the October 1, 1990.

For new products that are introduced after the effective date of the final rule, the base date AMP will be calculated in accordance with the current policy on calculating the base date AMP (the AMP for the first full calendar quarter after the day on which the drug was first marketed). That is, if a 5i drug in the first full calendar quarter after the day the drug is first marketed meets the ''not generally dispensed'' threshold, the manufacturer is responsible for calculating the base date AMP using the 5i AMP methodology. If a 5i drug in the first full calendar quarter after the day in which the drug is first marketed does not meet the ''not generally dispensed'' threshold, manufacturer is responsible for calculating the base date AMP using the standard AMP methodology.

Comment: One commenter requested clarification as to whether detailed instructions will be forthcoming explaining what has to be done with products having a market date equal to 09/30/1990; a market date falling between 01/01/1991 and 9/30/1993; a market date falling after 09/30/1993; and whether the DDR system will handle these base date AMP updates or will manufacturers have to manually submit recalculated base date AMPs following OBRA 93 rules. The commenter also asked if the recalculated base date AMP and the generation of prior period adjustments (PPAs) will be allowed to be included in state quarterly URA files, and if so, will states be required to open all the affected quarters and submit supplementary invoices to manufacturers for those fractions of dollar adjustments. Furthermore, the commenter asks if manufacturers should recalculate quarterly URAs to be consistent with recalculated base date AMPs.

A few commenters indicated that CMS should establish an effective date for the base date AMP to provide clarity to manufacturers regarding their additional rebate obligation. One commenter requested clarification that the recalculated Affordable Care Act base date AMP will be effective as of the effective date of the final rule even if a company's recalculated base date AMP is not submitted until after the effective date. Another commenter noted that this would be consistent with CMS's approach regarding base date AMPs that occurred due to the DRA and implemented in the 2007 final rule.

Response: Manufacturers will be able to report the Affordable Care Act base date AMP as of the effective date of the final rule, and manufacturers will have 4 full calendar quarters from that date to report the Affordable Care Act base date AMP. The recalculation of the Affordable Care Act base date AMP set forth in this rulemaking will not result in PPAs for quarters prior to the effective date of this final rule because the Affordable Care Act base date AMP is not designed to be retroactively effective; it should only be used in the calculation of the URA for quarters beginning with the effective date of this final rule. We will be providing operational guidance on how manufacturers may report the Affordable Care Act base date AMP if a manufacturer decides to recalculate its base date AMP.

Comment: One commenter asked if CMS intends for all manufacturers to restate their AMP and best price back to the fourth quarter of 2010, since that is the effective date of the Affordable Care Act.

Response: The provisions of this final rule are effective on a prospective basis. Therefore, we do not expect manufacturers to restate their AMP and best price retroactively as a result of this final rule.

We did not receive any comments on the remaining provisions of § 447.510(c). Therefore, for the reasons stated in this section, we are finalizing the provisions at § 447.510(c)(1) through (4) as proposed, with the exception of the following technical and clarifying edits:

We are making a technical revision to § 447.510(c)(1) by changing ''DRA'' to ''Deficit Reduction Act (DRA)'' since this is the first time the reference to the DRA is used within the regulatory text. We are also making a technical revision to § 447.510(c)(2)(i) by removing the reference to ''of this subpart'' because we believe the reference is unnecessary. And we are adding ''in effect from October 1, 2007 to December 14, 2010'' to the end of the sentence in § 447.510(c)(2)(i) to make clear that the AMP methodology applicable to the DRA base date AMP calculation is the AMP methodology that was finalized in the 2007 AMP final rule rather than the AMP methodology being finalized in this final rule as a result of the Affordable Care Act amendments.

4. Calculation of Monthly AMP (§ 447.510(d)(2))

Given the requirement for a smoothing process for AMP under section 1927(e)(5) of the Act, we proposed in § 447.510(d)(2) that manufacturers would be required to use a 12-month rolling percentage to estimate the value of lagged price concessions in their calculation of the monthly AMP (77 FR 5365). We also proposed that a manufacturer's monthly AMP is to be calculated based on the weighted average of the prices for all the manufacturer's package sizes of each COD sold by the manufacturer during a month (77 FR 5365). These proposals are discussed in more detail in the proposed rule (77 FR 5344).

We received the following comments concerning the calculation of monthly AMP:

Comment: Many commenters expressed general support for our proposal that manufacturers use a smoothing methodology similar to that used to determine the ASP under Medicare Part B. The commenters believed that using a 12-month rolling percentage to estimate the value of lagged price concessions in the calculation of monthly AMP will minimize the monthly AMP fluctuations. One commenter stated that they agree with CMS that the smoothing process will result in more stable AMP calculations on a month-to-month basis and believe the process currently in place, under Manufacturer Release #83 (February 3, 2011), is effective and appropriate and encouraged CMS to finalize its proposal and maintain the policy. Another commenter expressed gratitude to CMS for its proposal to adopt a 12-month rolling percentage smoothing method that is consistent with the ASP smoothing method and further stated that consistency between and among the various metrics, where it can be achieved, is appreciated because it simplifies the applicable systems and reduces the risk of inadvertent errors.

Response: We appreciate the support of these comments and agree with the comments about the importance of using a smoothing process consistent with ASP.

Comment: One commenter expressed support for the use of a 12-month rolling percentage to estimate the value of lagged price concessions but stated that CMS should not subsequently adjust state FMAP to account for such changes, or permit states to use such revisions to recoup monies from pharmacies after reimbursement is made.

Response: We note that the requirement to use the 12-month rolling percentage to estimate the value of lagged price concessions is effective on a prospective basis. Furthermore, the FMAP rate is not based on the State's reimbursement, but rather a different methodology that is beyond the scope if this final rule. Therefore, we do not anticipate that this policy will result in any effect on state FMAP, nor do we expect that this policy will cause states to recoup payments from pharmacies for previously paid claims.

Comment: A few commenters specifically expressed their support of the lagged price concession smoothing methodology in the context of the presumed inclusion methodology for calculating AMP. One commenter expressed concern that the proposed smoothing methodology may be inappropriate if CMS mandates a buildup methodology to calculate AMP because in the buildup methodology the sales data would also be lagged, which would call into question whether an estimation methodology should be used at all or whether it should be modified to reflect the lagged nature of the sales data. The commenter believed that if CMS moves forward with the buildup methodology, stakeholders should be given the opportunity to evaluate this aspect of the methodology further to determines if it remains appropriate or should be revised. Another commenter noted that if CMS were to adopt the buildup methodology as proposed, it would temporarily result in two different AMP methodologies being used in the same year, which could distort the calculation 12-month rolling percentage.

One commenter noted that the ASP calculation uses the presumed inclusion approach and therefore its 12-month rolling average estimation methodology was developed based on a presumed inclusion methodology as well. Since the AMP smoothing methodology is statutorily required to be similar to the ASP methodology, the commenter indicated that it is unclear what effect the 12-month rolling average estimation methodology under a buildup methodology would have on the accuracy of AMP. Therefore, the commenter urged CMS to retain the presumed inclusion approach and permit the smoothing process to work as intended.

Response: As discussed in more detail in the comments and responses in the Determination of AMP section (section II.C.) of this final rule, we have decided not to adopt a requirement that manufacturers calculate AMP using a buildup methodology. Manufacturers will continue to be able to make reasonable presumptions, in the absence of adequate documentation to the contrary, that prices paid to manufacturers by wholesalers are for drugs distributed to retail community pharmacies. Therefore, we believe this will address the concerns raised by commenters pertaining to the application of the lagged price concession smoothing methodology in the context of calculating AMP using a buildup methodology.

Comment: Several commenters stated that as drafted, the proposed AMP smoothing process that was described in Manufacturer Release #83 (February 3, 2011) and restated in the preamble to the proposed rule (77 FR 5344) is not consistent with the ASP smoothing process and should be clarified. These commenters noted that the preamble to the proposed rule provides a formula which uses the terms ''lagged price concessions'' and ''total sales.'' The commenters believed that the language requires clarification as the reference to ''total'' sales and lagged price concessions should be changed to ''AMP-eligible'' sales and lagged price concessions. They believe this would make the AMP smoothing method similar to the ASP method (where ASP-eligible sales and price concessions are used to estimate the lagged price concessions). Furthermore, the commenters stated that CMS should revise the smoothing methodology for lagged price concessions in AMP to include the same level of specificity as is included in the ASP smoothing process; and for consistency, should specify that the numerator of the ratio is limited to AMP-eligible lagged concessions (not total lagged price concessions) and the monthly multiplier is AMP-eligible sales (not total sales). The commenters also believe that the specifics of the lagged price concession calculation should be included in the regulatory language at § 447.510(d)(2)(iii) to ensure consistency across calculations and manufacturers.

Response: We appreciate these comments and note that we intended for the proposed AMP smoothing methodology to be consistent with the ASP smoothing process. Furthermore, we agree with commenters who suggested that the specific details of the lagged price concession calculation should be included in the regulatory text because we believe this will provide clarification and consistency across manufacturers and AMP calculations. Therefore, to provide clarification and ensure that the AMP smoothing methodology provided in this final rule is consistent with the ASP smoothing process we are modifying § 447.510(d)(2) to include the details of the monthly AMP calculation process, including the smoothing of lagged price concessions. Specifically, we have added paragraphs (A) and (B) to § 447.510(d)(2)(iii) which provide the detailed instructions, similar to that of the calculation of lagged price concessions for ASP, for how a manufacturer should calculate the lagged price concessions at the NDC 9 level. We explain that for each NDC–9 with at least 12 months of AMP-eligible sales, after adjusting for sales excluded from AMP, the manufacturer calculates a percentage equal to the sum of the price concessions for the most recent 12-month period (inclusive of the current reporting period) available associated with sales subject to the AMP reporting requirement divided by the total in dollars for the sales subject to the AMP reporting requirement for the same 12-month period. Furthermore, we explain that for each NDC–9 with less than 12 months of AMP-eligible sales, the calculation is performed for the time period equaling the total number of months of AMP-eligible sales. This is consistent with the calculation of lagged price concessions for ASP at § 414.804(a)(3)(i).

We have also added paragraph (iv) and (v) to § 447.510(d)(2) which further clarify the methodology used to calculate lagged price concessions by explaining that the manufacturer multiplies the applicable percentage by the total in dollars for the sales subject to the AMP reporting requirement (after adjusting for sales excluded from AMP) for the month being submitted. The result of this multiplication is then subtracted from the total in dollars for the sales subject to the AMP reporting requirement (after adjusting for sales excluded from AMP) for the month being submitted. The manufacturer uses the result of the calculation described in this section as the numerator and the number of units sold in the month (after adjusting for sales excluded from AMP) as the denominator to calculate the manufacturer's AMP for the NDC for the month being submitted. This is consistent with the calculation of lagged price concessions for ASP at § 414.804(a)(3)(ii) through (iii).

Additionally, we agree with commenters who requested that we include the same level of specificity in regulatory text of the monthly AMP smoothing process as is included in the regulatory text of ASP smoothing process, and therefore, we have also added paragraph (vi) to § 447.510(d)(2) which provides an example of the methodology described in the rule. The example in § 447.510(d)(2)(vi) is modeled from that which is provided in § 414.804(a)(3)(iv), except that it has been modified to conform with the terminology used in the calculation of lagged price concessions for AMP rather than the calculation of lagged price concessions for ASP.

We believe this level of detail in the regulatory text will help ensure consistency across the industry by providing more specificity to the

methodology and reduces the need for interpretation. We also believe that offering an example provides even more stability and uniformity to the calculation of lagged price concessions across the industry. Furthermore, we do not believe these are substantive changes to the calculation or components of the calculation, but rather are simply more precise terminology and clarifying language which serve to make the methodology more detailed and accurate. As stated in this section, the format we adopted in this section is modeled from and similar to that used by Medicare Part B to describe the methodology for calculating lagged price concessions for ASP at § 414.804(a)(3).

Comment: Several commenters opposed the proposed methodology for smoothing AMPs and believe that rather than stabilizing AMP, the current smoothing methodology has resulted in instability and that the problem is created because AMPs swing dramatically as individual ''lagged price concessions'' drop into and out of AMP calculations. Furthermore, the commenters believed the proposed methodology creates an inherent disconnect between current prices available to retail community pharmacies and historical prices which contribute to the discrepancy between AMPs and marketplace acquisition cost. The current methodology assumes that the current sales are subject to the same percentage discounts in the form of lagged price concessions as the average percentage discount due to lagged price concessions over the most recent 12-month period. The commenters believed this is not a valid assumption particularly when off-invoice discounts are being reduced or eliminated and in effect forces the manufacturers to report an AMP calculated with an implied discount that is not in fact being provided and consequently not representative of a price available to any retail community pharmacy or wholesaler. One commenter recommended that CMS revise its methodology to require manufacturers to take into account rebates and other lagged price concessions at the time of the sale on an accrual basis and stated that only lagged-price concessions that cannot be accounted for in this manner should be subject to the current methodology. The commenter stated this would help reduce the variability and help to bring reported AMPs close to pharmacy acquisition costs.

Response: We disagree with the commenter's recommendation that CMS revise its methodology. Section 1927(e)(5) of the Act specifies that we are to implement a smoothing process for AMP that is similar to the smoothing process used in the determination of ASP. The methodology suggested by the commenter is not consistent with the ASP methodology, which is not limited to those lagged price concessions that cannot be accounted for on an accrual basis.

Comment: One commenter requested that CMS issue guidance to manufacturers as to whether they will have the option to include lagged price concessions based on either ''earned'' date or ''paid'' date. The commenter noted that in the preamble to the 2007 AMP final rule, CMS allowed manufacturers to select lagged date based on either earned date or paid date.

Response: We did not require that manufacturers select either the earned or the paid date. Therefore, manufacturers have the flexibility to include lagged price concessions based on either earned date or paid date, provided the manufacturer uses one methodology uniformly.

Comment: One commenter believed that CMS's proposed implementation of the definition of lagged price concessions complicates certain logic associated with the calculation of the base date AMP. As the base date AMP is meant to establish the baseline comparison for subsequent quarterly AMPs, the commenter stated that it is important that the first full quarter AMP be representative of the standard price incentives established by manufacturers. The commenter noted that CMS supports this concept by establishing that the base date AMP is calculated on the first full quarter so that one time price incentives on initial sales do not reduce AMP. Lagged price concessions (such as rebates and chargebacks) that are paid for in the initial month prior to the first full quarter are subsequently taken into consideration for the 12-month rolling average and ultimately affect the base date AMP because the time frames used in each calculation do not coincide. The commenter suggested that CMS specifically state that base date AMP be established on the first full quarter of sales, and that the calculation of the 12-month rolling average starts with that quarter.

Response: We disagree that lagged price concessions that are paid for in the initial month(s) prior to the first full calendar quarter (base date AMP quarter) should not be included in the calculation of lagged price concessions. While we agree that the statute contemplates a base date AMP based on the first full calendar quarter after the market date, we continue to believe that the calculation of the 12-month rolling percentage should start with the month in which the product was first marketed. Section 1927(e)(5) of the Act specifies that we are to establish a smoothing process similar that used in ASP; and the Medicare Part B regulations at § 414.804(a)(3)(i)(B) specifically states that for each NDC with less than 12 months of sales, the smoothing process calculation is to be performed for the time period equaling the total number of months of sales. The process we have established is consistent with the smoothing process used to determine ASP and since the ASP process has not made this type of allowance, we do not believe that we should do so either.

Comment: One commenter stated that the inability to include all post-delivery price adjustments will undermine the effort taken. If these adjustments cannot be followed and appropriately considered in a relative ''present'' time frame the commenter believes they should be excluded from the calculation until such time that the life of the product can be monitored and adjusted for out-of-market price adjustments.

Response: Based on our understanding of the market and discussions with manufacturers, we recognize that manufacturers may not always know of every post sales price adjustment that occurs within the timeframe they are required to report monthly AMPs. Without this information, the monthly AMP calculation is not an accurate reflection of the actual sales, discounts or other price adjustments that impact the monthly AMP calculation. Furthermore, the monthly AMP will have a tendency to fluctuate from month-to-month as the price adjustments become known. Therefore, we believe that manufacturers should establish a process to smooth lagged price concessions because this process helps to prevent fluctuations in AMP from month-to-month, as well as to account for any seasonal variations in sales, discounts and other price adjustments. In addition, manufacturers are permitted to adjust monthly and quarterly AMP in accordance with reporting requirements established in § 447.510. While there may be several reasons for a manufacturer to restate or recalculate the monthly AMP, one example could be because additional data became available that requires a revision to the monthly AMP submission.

Comment: One commenter requested that CMS provide clarification regarding the proposal that monthly AMP is to be ''calculated based on the best data

available to the manufacturer at the time of submission.'' Specifically, the commenter requested that CMS address whether it is acceptable for manufacturers to utilize estimated data (for example, rebate accruals for rebates expected to be earned or paid for the calculation period), in their calculations or whether manufacturers are required to submit calculations solely based on actual paid data. Another commenter commended CMS on its proposal that monthly AMP should be calculated consistent with the proposed smoothing method, based on the best data available to the manufacturer at the time of submission.

Response: Manufacturers are to calculate monthly AMP consistent with the statute and based on the best data available to the manufacturer at the time of submission. In doing so, manufacturers are to estimate the value of lagged price concessions using a 12-month rolling percentage. To the extent that the calculation includes any assumptions, those assumptions need to be reasonable and should be documented.

As defined in proposed § 447.502, a 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.'' Therefore, manufacturers may use the 12-month rolling percentage to estimate lagged price concession data (for example, using actual data on past rebate accruals to estimate rebates expected to be earned or paid for the calculation period) rather than only including estimates of future rebates in their monthly AMP calculation.

Comment: Several commenters requested that CMS clarify its position and provide guidance on whether it is reasonable for manufacturers to smooth lagged AMP-ineligible sales. One commenter pointed out that this process is permitted by CMS in the ASP context and noted that if manufacturers were allowed to smooth AMP–ineligible sales it would increase the stability of AMPs. Another commenter noted that many manufacturers already extend the smoothing logic of lagged price concessions to the excluded indirect sales in AMP, such as chargebacks to hospitals. The commenter explained that this means the component of a ''gross to net'' calculation where sales to excluded classes of trade are subtracted from gross sales to arrive at the net retail community pharmacy sales. The commenter noted that this can be done for reasonable business assumptions, such as seasonable medications, and helps ''smooth'' the reported AMP and FUL in the same way as the lagged rebate price concessions. CMS has not provided much guidance regarding a manufacturer's ability to smooth ineligible sales. Therefore, the commenter recommended that CMS allow manufacturers to make reasonable assumptions and determine whether or not they have business reasons to smooth ineligible sales.

Another commenter believed that manufacturers should be permitted to quantify and back out indirect ineligible sales identified through lagged price concession data (chargebacks and rebates) in AMP to avoid unnecessary volatility across reporting periods, while still ensuring that only eligible sales remain in the calculation. Furthermore, the commenter stated that determining and backing out lagged indirect ineligible sales is an important part of an AMP calculation that employs a presumed inclusion methodology. Another commenter suggested that CMS clarify that manufacturers may also estimate indirect ineligible sales using the method that manufacturers use for their ASP calculation and if the manufacturer does not report ASP for its products, then the manufacturer should be able to use any 12-month rolling average approach that is consistent with the lagged price concession ratio proposed by CMS.

Response: Based on our understanding of the comments and discussions with manufacturers, a lagged ineligible AMP sale would be a sale which is determined to meet one of the AMP exclusions, but similar to price concessions, pricing data on the excluded sale is known on a lagged basis. As discussed in the CY 2007 PFS final rule (71 FR 69671), Medicare Part B allows, but does not require, manufacturers to estimate sales exempted from ASP by using a smoothing process. The Medicare Part B smoothing process for lagged exempt ASP sales permits manufacturers to use a 12-month rolling average ratio methodology to make certain estimates and exclude exempt sales from the ASP calculation where appropriate (71 FR 69671). While we did not propose any requirements regarding the calculation of ineligible sales, we agree that it is reasonable for manufacturers to make reasonable assumptions and use the same or similar methodology used for ASP calculations to smooth lagged ineligible-AMP sales when calculating the monthly AMP.

Therefore, in response to comments and for the reasons discussed in this section, we are finalizing § 447.510(d)(2) with the following modifications:

- We are making a technical revision to § 447.510(d)(2) by removing the reference to ''of this subpart'' as the reference is not necessary given the regulatory cite.
- We have added paragraphs (A) and (B) to § 447.510(d)(2)(iii), as well as paragraphs (iv) and (v) to § 447.510(d)(2) which provide the detailed methodology that manufacturers must use to estimate the AMP-eligible lagged price concessions for drugs with at least 12 months of AMP eligible sales and those with less than 12 months of AMP eligible sales.
- We have also added paragraph (vi) to § 447.510(d)(2) which provides an example of the methodology described in the preceding paragraphs.

5. Manufacturer Reported AMP Units (§ 447.510(d)(6))

Based on the requirements set forth in section 2503(b) of the Affordable Care Act, we proposed that the manufacturer report on a monthly basis, the total number of units that are used to calculate the monthly AMP for each COD no later than 30 days after the last day of each prior month. We also proposed that the monthly units should be of the unit type used in the quarterly and monthly AMP calculation for each NDC to ensure consistency in the calculation as well as the reporting of monthly and quarterly AMP and the AMP units (77 FR 5344 and 5365). These proposals are discussed in more detail at 77 FR 5344. We received the following comments concerning the manufacturer reported AMP units.

Comment: One commenter noted that the AMP unit data is key to the proper calculation of weighted AMPs, and stated that the OIG has repeatedly found unit of measure inconsistencies in manufacturers' calculation of AMPs, and CMS's failure to clearly specify the correct unit of measure to be used by manufacturers in reporting AMP units has almost certainly resulted in inconsistent reporting. The commenter states that the Extreme Details tab of the monthly draft FUL files reveals instances of manufacturers of the same product and same package size reporting different units per package size (UPPS) meaning they have used different package sizes in reporting AMP units as well. The commenter recommended that CMS resolve this problem by adopting NCPDP unit of measure standards—which would also be conforming to the units of measure used in Medicaid claims data.

Response: In accordance with section 1927(b) of the Act and implementing regulations, drug manufacturers participating in the MDR program are required to report and certify pricing data to CMS. It is ultimately the

responsibility of the manufacturer to determine, as part of these requirements, the appropriate unit type and units per package size (UPPS) for each of their products. To assist the drug manufacturers, CMS has issued guidance on the reporting of unit type and UPPS in Manufacturer Release #82 (November 1, 2010). As discussed in the release, the AMP Units should be reported as the total sum of units for all package sizes included in the calculation of the AMP, and should be reported for each product code. We do not agree with the commenter that CMS should adopt the NCPDP standards in calculating rebate liability, because the NCPDP standard units are based on package pricing, whereas the AMP and best price information that manufacturers report is based on unit pricing, without regard to package size. Therefore, we do not believe it is practical or reasonable to use the NCPDP units given the Medicaid statute reporting requirements.

Comment: One commenter noted that CMS has previously indicated that the total AMP-eligible units at the NDC–9 level are to be reported for each NDC–11 in the DDR system and asked CMS to clarify that drug manufacturers should continue to report the same AMP unit values as currently reported to DDR for each NDC–11 within the NDC–9.

Response: The AMP units should include the total sum of all units for all package sizes (11-digit NDC level) included in the calculation of the AMP, and should be reported per the 9-digit NDC level for the monthly reporting period. If a drug is distributed in multiple package sizes, the manufacturer should report the same number of AMP units for all package sizes of the product.

Comment: One commenter was concerned that if manufacturers were not permitted to continuing using presumed inclusion and they must rely on third party data to verify those sales included in AMP, it would be difficult to report and certify monthly AMP units to CMS in a timely fashion.

Response: We believe that our decision not to finalize the buildup methodology requirement and to permit manufacturers to continue using the presumed inclusion approach addresses the concerns raised by the commenter pertaining to a manufacturer's ability to obtain the data necessary to report and certify AMP units using a buildup methodology.

Therefore, for the reasons discussed in this section, we are finalizing the requirements at § 447.510(d)(6) regarding the reporting of AMP units as proposed.

I. Requirements for States (§ 447.511)

Consistent with section 1927(b)(2)(A) of the Act, we proposed a new § 447.511 to clarify the reporting requirements for states (77 FR 5345, 5366). In § 447.511(a), we proposed to list the data that the state must provide to participating drug manufacturers within 60 days of the end of each quarter. In § 447.511(b) we proposed that states must submit this same data to CMS on a quarterly basis. In § 447.511(c), we proposed that states that have participating MCOs, which include CODs in their contracts, must report data pertaining to drugs dispensed through those MCOs separately from the data pertaining to drugs dispensed on a FFS basis. In light of the proposed change in definition to ''State,'' we also proposed that the requirements of § 447.511 would not be effective for the territories until 1 year after the first day of the first full calendar quarter after the publication of the final rule. (The proposed change in definition of ''States'' is discussed in the definition section of this final rule (section II.B.25.)). These proposals are discussed in more detail at 77 FR 5345. We received the following comments concerning the proposed requirements for states:

1. Invoice Submission Deadline

Comment: A few commenters supported the imposition of a deadline for state submission of invoices. The commenters stated that the statute requires states to submit information on drugs utilized not later than 60 days after the end of each rebate period. One of the commenters noted that manufacturers are reliant on these data to calculate and pay rebates owed to the state programs. The commenter believed that manufacturers should not be obligated to pay rebates on data that a state fails to submit in accordance with the statutory deadline, including revisions to prior quarter utilization data and suggested that CMS should impose an absolute deadline for the submission of MCO utilization under the Affordable Care Act.

One commenter believed that the statutory time limit should become effective upon publication of the final rule and that states should be prohibited from submitting any further rebate claims for quarters that precede the specified period. The commenter referenced the preamble to CMS's September 19, 1995 proposed rule, in which CMS indicated that although the statute requires states to meet the 60-day requirement, CMS did not believe that the statute limited manufacturers' liability for rebates if states were unable to report utilization data by the deadline. The commenter indicated that CMS did not provide any explanation or statutory support for this policy, nor did it adopt the policy through formal notice-and-comment rulemaking. However, proposed § 447.511 expressly sets forth the requirement that within 60 days of the end of each quarter, the state must bill participating drug manufacturers an invoice, which includes, at a minimum, certain drug utilization data as specified in the regulations text. The commenter suggested that CMS should clarify that, consistent with the statute, this deadline is a firm obligation for states and that manufacturers are not obliged to pay Medicaid rebates for claims that do not meet the state's reporting requirement.

One commenter stated that a policy establishing a maximum time frame during which a manufacturer is obliged to pay rebates to the states would not only be consistent with the statute, but a firm deadline also would shorten the time between the date the utilization occurs and the date the manufacturer initiates any dispute with the state regarding that utilization. The commenter noted that it is inefficient and burdensome for both manufacturers and states to attempt to substantiate rebate claims to resolve disputes months or even years after the drug is utilized. The commenter stated that manufacturers also frequently use information about past utilization to project their future rebate obligations, and these projections are rendered less accurate when there are delays in reconciling sales data.

Response: We appreciate the concerns raised by the commenters. As we discussed in § 447.509(b) of the proposed rule, we did not include a proposal that absolved manufacturers of liability to pay rebates on invoices that are subsequently submitted with data from earlier periods. In accordance with section 1927(b)(1)(A) of the Act, manufacturers are responsible for providing rebate payments based, in part, on state utilization data. We did not propose a deadline for the submission of utilization data but in accordance with section 1927(b)(2) of the Act, states are required to submit utilization data in a standard reporting format to manufacturers within a 60-day timeframe. The statute does not absolve manufacturers of responsibility to provide rebates where states provide such information outside of that 60-day window. Section 1927(b)(1)(A) of the Act includes a broad requirement that manufacturers provide rebates for CODs

for which payment was made under the state plan.

Section 1927(b)(2)(B) of the Act, in turn, contemplates the provision of rebates regardless of when the state data is revised or adjusted following audit of such data. It provides that manufacturers shall provide adjustments to rebates to the extent that the state provides information per an audit (without any indication as to when that audit takes place) to the extent that information indicates that utilization is greater or less than information previously submitted. Accordingly, consistent with these provisions, manufacturers are responsible for complying with the requirements to pay rebates based on utilization data even when the state may be late in providing that data. Although we recognize that utilization data is a critical element for manufacturers to calculate rebates, we will not absolve manufacturers for liability of late state submissions.

Comment: One commenter stated that CMS should clarify that the 60-day time limit includes any revision to prior quarter utilization data. The commenter indicated that CMS had previously recognized the need to establish a maximum time frame during which the manufacturer is bound to pay its rebate obligations because, otherwise, manufacturers could be responsible for rebates years after drugs were dispensed and it may be difficult for manufacturers to substantiate those rebate claims if they subsequently dispute those claims. The commenter stated that the potential for significantly delayed reporting from the states is exacerbated by the expansion of the MDR program to Medicaid MCOs, with many states still not having reported any MCO utilization 2 years after the Affordable Care Act's enactment. The commenter suggested that CMS should impose a deadline of 120 days from the publication of a final rule for the submission of MCO utilization data and suggested that CMS should specify a 120-day deadline for states to submit timely information to CMS and clarify that this deadline applies to states' revision or correction of data previously submitted to CMS.

Response: While we appreciate the concern regarding the importance of timely invoice submission by the states, we did not propose any deadlines for states to submit prior quarter adjustments to manufacturers. The MCO reporting requirements are consistent with the FFS reporting requirements. We recognize the need for states to submit information on a timely basis, and thus, we may consider issuing guidance regarding such deadlines in the future, if needed.

Further, while we recognize that states and MCOs may have initially encountered systems issues regarding timely submission of MCO utilization, we are not planning to set a specific deadline beyond the deadlines already established in section 1927(b)(2)(A) of the Act which states, in part, that MCO invoice submissions are subject to the same 60-day deadline as for Medicaid FFS.

Comment: One commenter urged CMS to consider penalties for states that do not comply with the parameters for submitting reports to CMS that are set forth in the proposed rule.

Response: While we appreciate the concern regarding the importance of timely invoice submission, the statute does not provide for penalties to states that do not comply with submission deadlines. However, the OIG has and continues to review state compliance with various aspects of the MDR program requirements.

2. MCOs and 340B

Comment: One commenter stated that CMS should prohibit states from implementing procedures for collecting rebates on drugs dispensed through Medicaid MCOs that unreasonably burden 340B covered entities. The commenter stated that the proposed rule provides no direction either to MCOs or to states as to how drugs acquired under the 340B Program should be identified so as to prevent the manufacturer from being subject to a duplicate discount. The commenter requested that CMS, through regulation, establish mechanisms that a state can use to separate 340B claims from other MCO claims and suggested that a state-based exclusion file for MCOs, similar to the exclusion file that HRSA maintains for FFS claims would meet the requirement. While the commenter understood that FQHCs, along with other covered entities, share responsibility for 340B compliance, it is unreasonable to expect covered entities to bear the entire burden. A few commenters noted that states must create a mechanism with which they can exclude MCO drugs from their requests, if the drugs are dispensed by MCOs and are discounted under the 340B program.

One commenter stated that to assist in preventing violations of the double-discounting prohibition, CMS should emphasize to the states that they are responsible for ensuring that the utilization information that is reported on rebate invoices does not include drugs purchased under the 340B program. In addition, CMS should require that all Medicaid utilization data that the states submit to manufacturers, including both FFS and MCO utilization data, contain the ''pharmacy identifier'' field so that manufacturers have the ability to verify that the data has been properly screened for duplicate discounts. The utilization data must also include the 340B identification data element developed by NCPDP. The commenter noted that states will only be able to meet these reporting obligations by requiring that pharmacies or other providers that dispense or administer drugs to Medicaid FFS or MCO enrollees include all these same data elements on their claims to the state or to a Medicaid MCO.

Response: We appreciate the concerns raised by the commenter and recognize the importance of preventing duplicate discounts on drugs purchased through the 340B program and dispensed to Medicaid MCO enrollees. As stated, in part, in section 1927(a)(5)(C) of the Act, the state shall provide a means for the covered entity to indicate that a drug is subject to the 340B program and not submit a claim for a rebate payment for such drug. States are encouraged to include such language in their MCO contracts so that 340B claims can be identified as to avoid including such claims in their rebate requests to manufacturers. We will continue to work with states and will consider addressing the issue in future guidance or rulemaking, if needed. As to the commenter's suggestion to include a 340B identifier on invoices submitted to participating drug manufacturers, we disagree and see no need for such an identifier given that, as discussed previously, the utilization data should not include drugs purchased under the 340B program. Therefore, we do not see a need for including a 340B identifier in the list of data items submitted by states to manufacturers.

Comment: One commenter stated that many states have yet to submit any MCO utilization to manufacturers for payment. The commenter requested that CMS impose a fixed deadline for the submission of MCO claims of no more than 180 days after publication of the final rule and utilization submitted after that deadline should not be eligible for rebates. Another commenter stated that CMS should improve reporting for Medicaid MCOs because accurate and timely validation, processing, and payment of Medicaid MCO rebates are problematic for manufacturers to achieve due to delays by states in submissions of claims, incomplete data, and no common reporting formats.

One commenter stated that the Medicaid statute requires states to report to manufacturers on CODs utilized not later than 60 days after the end of each rebate period and the commenter noted that the Affordable Care Act extended this reporting requirement to include information reported by each Medicaid MCO, without altering the statutory 60-day time limit. The commenter stated that CMS should clarify that even though states that have participating Medicaid MCOs are required to report the drug utilization data for Medicaid MCOs separately, the same statutory deadline of within 60 days of the end of each quarter applies to those reports as well.

One commenter stated that the proposed rule implements the requirement that a state promptly transmit a copy of the drug utilization data reported to manufacturers to CMS but the proposed rule does not clearly specify a timeframe for that submission. The commenter also noted that the proposed rule does not address whether, to the extent that the data initially submitted to the manufacturer and CMS subsequently are revised, the state is obligated to revise the data previously submitted to CMS and in a timely matter. The commenter stated that CMS should require states to provide prompt updates to correct the utilization data previously submitted to CMS.

Response: As discussed previously in this section, in accordance with section 1927(b)(2)(A) of the Act, states are responsible for ensuring that utilization information is submitted no later than 60 days after the end of each rebate period to invoice manufacturers for rebates. The extension of manufacturer rebates to drugs covered by Medicaid MCOs did not change these state submission requirements. Further, as discussed previously in this section, the statute does not absolve manufacturers of their obligation to pay rebates for CODs in the event that the state submits an invoice to the manufacturer beyond the 60-day deadline; therefore, we are not providing an exemption for manufacturers from such obligations in this rule. While we recognize that states and MCOs may have encountered systems issues in complying with the new data requirements for the MCO rebate provisions, we are committed to working with states to resolve these issues in a timely manner. We will consider issuing additional guidance, or rulemaking, if necessary, to address the compliance of states to provide timely reports.

3. Branded Prescription Drug Fee

Comment: One commenter stated that data submitted by states to CMS often are revised after the fact to reflect the resolution of disputes with manufacturers as well as to correct errors. The commenter stated that CMS relies on these data to calculate Medicaid sales figures for use in the Affordable Care Act's branded prescription drug fee, and states' failure to correct these data with CMS where they have corrected the data with manufacturers can lead to inaccurate calculations of a manufacturer's Medicaid sales.

Response: CMS appreciates the comments and expects that states provide utilization corrections to manufacturers and CMS consistent with their obligations to submit utilization reports to the Secretary. The issue regarding branded prescription drug fee is beyond the scope of the final rule. However, more details on the branded prescription drug program can be found on Medicaid.gov at *http://www.medicaid.gov/Medicaid-CHIP-Program-Information/By-Topics/Benefits/Prescription-Drugs/Branded-Prescription-Drug.html.*

4. Miscellaneous Comments

Comment: One commenter stated that the proposed rule did not expressly expand upon a state Medicaid agency's obligation or authority to require providers to report NDCs or J-codes for the ''Top 20'' multiple source drugs and single source drugs in connection with submitting claims to the agency for these drugs. However, the proposed rule did expand upon the information that the state Medicaid agency must report to drug manufacturers. The commenter was concerned that a state Medicaid agency may use this expanded reporting obligation as authority for collecting additional information from Medicaid providers and recommended that CMS clarify in the final rule that state Medicaid agencies do not have the authority to collect duplicate data or require providers to report additional drug codes or other data beyond what is required by federal regulation.

Response: In accordance with section 1927(a)(7) of the Act and § 447.520, states are required to have their providers identify physician administered CODs using NDCs for the state to be able to bill manufacturers for rebates for such drugs. In accordance with these provisions, states may request that providers report information necessary to properly identify and report such utilization data.

Therefore, after considering the comments and for the reasons discussed in this section and in the proposed rule, we are finalizing § 447.511 (Requirements for States) as we proposed (77 FR 5366), except to make a grammatical edit to the last sentence to delete the word ''This'' and replace it with ''These'' as the data being referenced in this sentence is plural. Furthermore, given the delayed effective date for the inclusion of the territories in the definition of ''States'' to 1 year after the effective date of the final rule, we are finalizing our proposal to delay the applicability of the requirements of § 447.511 to the territories by 1 year; however, we inadvertently indicated in our proposal that the delay would be 1 year after the publication of the final rule, but we intend it to be 1 year after the effective date of the final rule.

J. Drugs: Aggregate Upper Limits of Payment (§ 447.512)

In the ''Medicaid Program; Withdrawal of Determination of Average Manufacturer Price, Multiple Source Drug Definition, and Upper Limits for Multiple Source Drugs'' final rule (75 FR 69591), we made conforming amendments to § 447.512 (Drugs: Aggregate upper limits of payment) to remove references to § 447.514 (Upper limits for multiple source drugs) as this section (§ 447.514) was removed from regulation. In the proposed rule, we proposed regulatory amendments to add references to § 447.514 (Upper limits for multiple source drugs) in § 447.512 (Drugs: Aggregate upper limits of payment) (77 FR 5345). At § 447.512(b)(1), we proposed to replace the term ''EAC'' with the term ''AAC'' to conform with our proposal to replace ''estimated acquisition cost'' with ''actual acquisition cost.'' As discussed in the proposed rule, we believe that using AAC to determine the drug ingredient cost is more reflective of actual prices paid rather than EAC, which is often based on published compendia pricing, which does not reflect actual prices that providers pay for acquiring drugs (77 FR 5345). Further, we proposed to add the word ''professional'' to the description of dispensing fee in this section. These proposed provisions are discussed in more detail at 77 FR 5345 of the proposed rule. We received many comments regarding the need for adequate Medicaid pharmacy reimbursement, both ingredient costs and professional dispensing fees. Those comments and our responses are discussed later in this section.

1. Cost To Acquire and Dispense

Comment: One commenter stated that a reasonable professional dispensing fee is needed to stay in operation and pay those that choose a career in helping the public. Several commenters stated that Medicaid should ensure that a pharmacy provider is reimbursed for products that they acquire and dispense at least at the amount that it cost them to acquire and dispense the products. Another commenter stated that reimbursement should be based on the true acquisition cost plus a fee that is adequate to cover dispensing costs, and believes that $6.50 for 30 days and $10 for 100 or more days (maintenance drugs) would be fair to the pharmacy providers. Another commenter stated that total reimbursement for pharmacies must recognize the total cost of doing business to provide prescription drugs and pharmacy services to Medicaid patients. Another commenter stated that some independent pharmacies servicing acute care/special needs Medicaid patients will not be able to continue servicing these patients with reimbursement as outlined in the proposed rule. Several commenters noted that increasing demands on a pharmacy provider for professional interventions, technology, and safety, including employing adequate staff, as well as the pharmacy provider's responsibility for customer service and documentation must be compensated respectively by increased dispensing fees to meet these demands and to alleviate patient risk.

Response: Payment to Medicaid pharmacy providers must be consistent with efficiency, economy, and quality of care while assuring sufficient beneficiary access, consistent with section 1902(a)(30)(A) of the Act, and we believe the total reimbursement should take into account the pharmacy's cost to acquire the drug and the pharmacist's professional services and costs to dispense the drug product to a Medicaid beneficiary. We do not anticipate that the aggregate upper limit, as finalized at § 447.512(b), will limit pharmacy participation or compromise a Medicaid beneficiary's access to pharmacy coverage or services.

In addition, as discussed in Section II.M. of this final rule, we are revising the proposed § 447.518(d) to require states to consider both the ingredient cost reimbursement and the professional dispensing fee reimbursement when proposing changes to either or both of these components of the reimbursement for Medicaid covered drugs to ensure that total reimbursement to the pharmacy provider is in accordance with requirements of section 1902(a)(30)(A) of the Act.

Comment: One commenter requested that CMS remember the importance of a multiplier (a percentage markup to AAC), as part of any formula concerning pharmacy reimbursement which uses acquisition cost as a benchmark for setting rates.

Response: As we stated in the proposed rule (77 FR 5321 and 5350), we realize that states may have difficulty determining the actual price of each drug at the time it was purchased; however, given how CMS has defined AAC and clarified why we defined the term, we disagree that the use of a multiplier (that is, the addition of a percentage markup to AAC) should always be used by a state as part of any formula concerning pharmacy reimbursement which uses acquisition cost as a benchmark for setting rates.

2. Profit Margin

Comment: Several commenters stated that providers need to be treated fairly and enjoy a modest profit. A few commenters stated that the state should be allowed to include a specific allowable profit margin above the cost of the product and the cost to dispense it—and that not including a profit margin requires 100 percent efficiency to simply break even financially. Another commenter stated that it is necessary to make a decent profit on his services—costs and fixed overhead need to be taken into account—and the services that are rendered by the community pharmacy vs. the big chains, especially acting as a liaison for Medicaid beneficiaries with their doctors, are important. Several commenters stated that a ''no allowance for profit'' would not ensure adequate participation of pharmacies as Medicaid providers especially in light of the planned expansion of Medicaid in 2014, which could lead to store closings/limited access. One commenter stated that they understood that Alabama's AAC based reimbursement does not account for pharmacy profit—requiring pharmacies to participate for free in the Medicaid program which will, at best, shift cost to the private sector, and at worst, cause pharmacies to drop out of the Medicaid program, especially as Medicaid is set to dramatically expand in 2014. Several commenters stated that the proposed rule, absent clarifications would take the unprecedented step of prohibiting states from paying pharmacies a level of reimbursement sufficient for pharmacies to earn a profit since it appears that both ingredient cost and professional dispensing fee would only cover costs, and does not contemplate the need for reasonable margins.

Response: As discussed previously, states are responsible for setting payment rates consistent with section 1902(a)(30)(A) of the Act. Those rates, as discussed in 77 FR 5345 should provide payment for ingredient costs, as well as professional dispensing fees. We believe that a change to AAC is more consistent with the statutory provisions at section 1902(a)(30)(A) of the Act as AAC requires states to calculate reimbursement prices based on the prices actually paid by pharmacy providers. Further, we afford the states the flexibility to adjust their professional dispensing fees, when necessary, to assure sufficient access in accordance with the requirements of section 1902(a)(30)(A) of the Act. We have not identified profit in the definition of professional dispensing fee given that the definition in the proposed rule was not designed to revise our longstanding definition of dispensing fee. That definition, which was established in 2007 (72 FR 39240), was designed to address those costs associated with transferring possession of the drug from the pharmacy to the Medicaid beneficiary (consistent with the definition of such fees used in other rules, such as § 423.100). In accordance with the definition of professional dispensing fee, which we are finalizing in § 447.502, states should consider pharmacy costs, including the 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 lists review activities, measurement or mixing of the COD, filling the container, beneficiary counseling, 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. After evaluating these factors, the states are responsible for establishing, and if necessary, revising, their professional dispensing fee to ensure that the Medicaid pharmacy providers are adequately reimbursed in accordance with the requirements of section 1902(a)(30)(A) of the Act. We believe that this flexibility should allow states to establish sufficient fees to cover costs and ensure adequate participation.

3. Adequacy Over Time

Comment: Several commenters stated that CMS should add provisions to the final rule to ensure that the combined level of ingredient cost and professional dispensing fee is adequate over time.

The commenters stated that these provisions should recognize the need to build reasonable margins into pharmacy reimbursement formulas, require surveys that determine AAC or update professional dispensing fees to be conducted using methodologies that have been thoroughly vetted through a public comment process that includes a public comment process, establish rules defining requirements for timely adjustments to ingredient cost formulas when market prices change, and mandate the use of stratified professional dispensing fees that account for the differential costs associated with providing pharmacy services in varied settings. The commenters stated that Oregon already reduced the initial dispensing fees that were set based on surveys when the state changed to AAC.

Response: We agree with the need to ensure that both the ingredient cost and professional dispensing fee is adequate and, in this final rule, we are revising proposed § 447.518(d) to require states to consider both the ingredient cost reimbursement and the professional dispensing fee reimbursement when proposing changes to either or both of these components of the reimbursement for Medicaid covered drugs to ensure that total reimbursement to the pharmacy provider is in accordance with requirements of section 1902(a)(30)(A) of the Act.

4. Need for Appeals Process/ Adjustments

Comment: Many commenters stated that there needs to be a process in place for adjustments to AAC to allow for price increases or to address other price issues, such as efficiency or sensitivity to pricing changes and updates, disputes, and discrepancies, where a provider cannot purchase a drug product at the acquisition cost established. Another commenter stated that AAC pharmacy reimbursement, such as in Oregon and Alabama, has shown the commenter that states respond rapidly to price decreases but not price increases and this sluggishness penalizes pharmacies for price increases. Another commenter stated that the final rule should define the requirements for timely adjustments to AAC pricing. One commenter recommended that states should have flexibility in determining AAC, and to address inflation and other price changes between surveys. Several other commenters stated that the final rule should require that states adopt and use procedures to supplement survey data with rapid response plans so that AACs are adjusted timely when market changes cause dramatic price increases.

Response: This final rule is not designed to mandate state payment rates. We set aggregate upper limit requirements, and as we stated in the proposed rule, states have the flexibility to establish an AAC reimbursement in their state plan based on several different pricing benchmarks, for example, the NADAC files, a state survey of retail pharmacy providers, or AMP-based pricing (77 FR 5350). States have the responsibility to ensure that Medicaid pharmacy providers are adequately reimbursed and to establish payment rates in their state plan consistent with such requirements. States have the authority to conduct retail pharmacy surveys without CMS approval; however, if they decide to use data collected from those surveys to revise the methodologies they have established in their state plan to make payments to pharmacies, the state needs to demonstrate that the methodology provides adequate reimbursement consistent with the dictates of section 1902(a)(30)(A) of the Act. Furthermore, states would need to submit a SPA outlining those methodologies for CMS approval and comply with applicable public notice requirements. States also have flexibility to establish a methodology that allows for states to supplement survey data to reflect market changes, although we did not propose requirements for a rapid response plan in our proposed rule.

To the extent that entities have concerns with prices established under a state's AAC methodology, those concerns should be raised to the state, especially given that states are responsible for setting payment rates and complying with a public notice process when setting those rates.

5. Pharmacy Reimbursement and Access

Comment: Several other commenters stated that numerous studies have shown that Medicaid dispensing fees have been below the cost of dispensing and commenters were concerned with current attempts by states to further decrease professional dispensing fees. A few commenters stated that cuts to pharmacy will lead to pharmacy closure, and one commenter stated that reimbursement below the pharmacist's cost should be illegal. Another commenter stated that unless changes in drug costs are tied in some meaningful way to changes in dispensing costs, access can become a problem, including pharmacies being forced out of the Medicaid program. Another commenter stated that CMS should effectuate adequate oversight in both the fee-for-service and managed care context to ensure adequate reimbursement to provide necessary services regardless of how a Medicaid beneficiary's services are delivered.

Another commenter noted that extra services and expenses associated with services provided to Medicaid clients, including pickup and delivery services, make it possible for clients to remain living independently and not be institutionalized, which would add dramatic cost to the Medicaid program. Another commenter stated that increasing the professional dispensing fee will save money in health care by reducing medication related adverse events.

Several commenters stated that CMS must require that states can only use AAC if they increase their dispensing fees to reflect pharmacy's cost to dispense. Another commenter stated that the use of the new AMP-based FULs or any version of AAC should be limited to those states than can provide evidence of adequate professional dispensing fees based on services rendered. Another commenter stated that unless dispensing fees are raised at or prior to the time that AMP-based FULs are finalized, pharmacies will be reimbursed at less than their total cost. Another commenter was concerned that a move to require states to use AAC for brand drugs without a requirement that dispensing fees be increased will negatively impact patient access.

Response: We appreciate the comments and note that states are responsible for calculating reimbursement for prescribed drugs. As discussed previously, states have the flexibility to determine reimbursement for specific drugs depending on their approved state plan, and retain the flexibility to establish a professional dispensing fee that covers pharmacy costs. To ensure adequate reimbursement to Medicaid pharmacy providers, we are revising proposed § 447.518(d) as explained previously.

We have no reason to believe that pharmacies will be forced to leave the Medicaid program or that patient care will suffer as a result of the revised requirements in § 447.512(b), and note that several states are already paying based on an AAC methodology without causing pharmacies to leave the Medicaid program or other adverse effects on patient care. However, we will continue to monitor the issue. Furthermore, as discussed in section II.K. of this final rule, and in our proposed rule (77 FR 5345 through 5347), the FUL is designed as an aggregate upper limit. Therefore, states have the discretion to adjust

reimbursement on a drug-by-drug basis to the extent that such an adjustment is consistent with the state plan.

Comment: One commenter stated that pharmacies are currently only able to serve Medicaid patients by utilizing the margins built into drug costs because most states have been unwilling or unable to pay adequate dispensing fees.

Response: This final rule is designed to address ingredient costs as well as professional dispensing fees to ensure adequate reimbursement. As discussed in more detail in section II.M. of this final rule, we are revising proposed § 447.518(d), based on comments we received, to specify that when states are proposing changes to either the ingredient cost reimbursement or the professional dispensing fee reimbursement, they are required to ensure that total reimbursement to the pharmacy provider complies with requirements of section 1902(a)(30)(A) of the Act.

6. AAC and Drug Shortage Issues

Comment: One commenter stated that there may be instances where the commenter cannot purchase a drug product at the cost basis determined by the Medicaid program. The commenter believed this is already a problem for some of the generic drugs that are in short supply, and will only get worse with a cost-based product reimbursement that is not well monitored and updated. Another commenter noted that there have been situations in the past year, due to drug shortages and other factors, where his acquisition cost for the drug exceeded the reimbursement and he could not dispense it.

Response: In accordance with section 1902(a)(30)(A) of the Act, states have the responsibility to provide pharmacy providers with adequate reimbursement, and likewise, to ensure that states and the federal government receive the cost savings benefits of market changes. To the extent that entities have concerns with reimbursement, those issues should be raised to the state, especially given that states are responsible for setting payment rates that are sufficient to enlist enough providers so that care and services, including drugs, are available to Medicaid beneficiaries, consistent with the requirements of section 1902(a)(30)(A) of the Act.

7. Claim/Aggregate Level

Comment: One commenter requested clarification about § 447.512(b) regarding whether states are required to implement an AAC and professional dispensing fee at the individual claim level or are states required to prove that they are under the AAC and professional dispensing fee in the aggregate. The commenter was concerned that a move to AAC and professional dispensing fee at the claims level could increase pharmacy program costs to the state. The commenter supported the aggregate model for AAC reimbursement, as long as reliable AAC data are available to the state. Another commenter stated that the use of aggregate upper payment limits allows states some flexibility in implementation; however, the range of variance of pricing for drugs in a product group should be available to states to allow them the transparency necessary to develop an AAC model linked to the professional dispensing fee that can be fair and supported.

Response: In accordance with § 447.512(b) of this final rule, payments for covered drug products must not exceed, in the aggregate, payment levels that the agency has determined by applying the lower of the AAC and professional dispensing fee or usual and customary (U&C) charges to the general public. We agree that these aggregate upper limits allow states some flexibility in setting payment rates. As discussed previously, states have the flexibility to determine reimbursement for specific drugs and are responsible for calculating payments consistent with section 1902(a)(30)(A) of the Act.

8. Application of AAC to Specific Entities/Products

Comment: One commenter asked if MCOs are required to abide by the AAC definition when reimbursing Medicaid pharmacies. Several commenters stated that if MCOs are required to abide by the AAC definition, all safeguards should be in place (for establishing/changing ingredient cost and professional dispensing fee) that will ensure adequate pharmacy reimbursement for Medicaid managed care patients.

Response: In accordance the requirements of section 1932 of the Act, MCOs may continue to establish their own reimbursement methodologies, in accordance with their contractual arrangement with the state agency, including payment to pharmacy providers for ingredient cost and professional dispensing fees; therefore, the provisions of this final rule related to pharmacy payment at AAC do not apply.

Comment: One commenter requested clarification on how the AAC and professional dispensing fee methodology will work in the context of specialty drugs. Another commenter stated that physician-administered drugs should be reimbursed at AAC too, and that states should collect rebates on these drugs.

Response: The requirements for Medicaid pharmacy reimbursement we are finalizing § 447.512(b) are designed to apply to payment rates established by states for prescription drugs. States have the flexibility for determining separate reimbursement rates for specialty and physician-administered drugs. We agree that states are required to collect rebates on physician-administered drugs when such drugs are billed separately.

9. Differential Reimbursement for Classes of Trade

Comment: One commenter expressed that a state may want to create a differential reimbursement between independent and chain pharmacies or rural and urban pharmacies (relating to establishment of AAC) to meet particular access issues or concerns.

Response: We have not required that states create a differential reimbursement methodology based on pharmacy type; however, the states retain the option to adjust the reimbursement for provider type or services rendered such as special packaging or delivery.

10. Method for Determining AAC

Comment: One commenter stated that if CMS insists on the use of AAC, it is critical that a state be allowed to maintain flexibility in the method they elect to determine AAC. Another commenter stated that each state should be allowed to demonstrate that its process for determining AAC is consistent with the proposed definition, and that the state should be able to use processes other than pharmacy invoices to determine AAC. The commenter was opposed to renaming and revising EAC to AAC if it limits states to only one method for determining AAC, such as pharmacy pricing surveys, as the commenter's Medicaid state agency currently uses drug pricing information provided by drug manufacturers to determine acquisition cost. The commenter added that guidance should be revised to allow payment based on an average of AACs from a number of sources, including pharmacies, wholesalers, manufacturers, etc. and noted that if CMS does not allow this flexibility, reimbursement expenditures could increase.

Response: We recognize that there are a variety of sources which states may use to establish payments consistent with the AAC requirements in § 447.512(b). This final rule does not limit states to one method or only using pharmacy invoices to determine AAC;

however, in accordance with the requirement in § 447.518(d) of this final rule, states must provide adequate data, such as a state or national survey of retail pharmacy providers or other reliable data other than a survey when proposing any change to its ingredient cost or dispensing fee reimbursement.

11. Method for Determining Professional Dispensing Fee

Comment: One commenter recommended that the state should have the flexibility to determine what are in the components of the dispensing fee. Another commenter encouraged CMS to provide guidance to states on re-evaluating their dispensing fees, specifically with regard to operational costs, costs unique to each state, and a reasonable profit. A few commenters noted general categories of items/expenses that should be considered when determining a professional dispensing fee, including all fixed and variable costs and all overhead expenses, prescription department payroll/personnel expenses, direct prescription department costs, and pharmacy-wide expense items. Other commenters submitted specific areas to be considered when establishing the professional dispensing fee, which included consulting with prescribers, disease management, unique handling fees, unit dose packaging/dispensing, shipping, overhead for factor replacement products, special monitoring and reporting of lab values for certain drug products and adjustments for medical inflation. One commenter also noted that adequate reimbursement for additional services provided such as compliance packaging and review of medication regimens need to be addressed, as the cost effectiveness of these services is well documented. Several commenters stated that it is not reasonable for states to be permitted to set a single professional dispensing fee for all pharmacies that fill a Medicaid prescription, and stated that CMS should require that professional dispensing fees be stratified so that each type of pharmacy, such as long term care (LTC) pharmacies, are paid appropriately for the type of professional dispensing services it provides. The commenters stated that the higher costs of packaging, dispensing, and delivery borne by both home infusion and LTC pharmacies, as opposed to retail community pharmacies, should be reflected in the professional dispensing fee. Another commenter stated that Alaskan pharmacies, because of their remote location, face significant freight charges that ultimately increase their cost of doing business in the state.

Response: In accordance with the definition of professional dispensing fee that we are finalizing at § 447.502, states should calculate their professional dispensing fees to include those costs which are associated with ensuring that possession of the appropriate COD is transferred to a Medicaid beneficiary. The states retain the flexibility to establish, and if necessary, revise, their professional dispensing fee to ensure that the Medicaid pharmacy providers are adequately reimbursed in accordance with the requirements of section 1902(a)(30)(A) of the Act.

Comment: One commenter requested that CMS implement a unique Medicaid reimbursement for blood clotting factor as the dispensing of this product requires enhanced services and activities that vary greatly from those performed by a typical retail pharmacy. Another commenter stated that they are not suggesting that state Medicaid offices must necessarily adopt the current Medicare per unit furnishing fee of $0.18 for the coverage of professional, management and distribution cost of the clotting factor, but rather recognize, as Medicare has, that such professional dispensing fees should be unique from the typical professional dispensing fee for common prescriptions. One commenter stated that the professional dispensing fee for many states is $5.00–$10.00, resulting in significant loss to all pharmacies that provide clotting factor to Medicaid patients.

Response: While we appreciate the comment regarding blood clotting factors, we do not think it is necessary for states to implement a specific dispensing fee for providing clotting factors. The regulatory provisions applicable to Medicare Part B and the MDR program are different and the furnishing fee payment allowed for Medicare Part B is not applicable to Medicaid. We recognize that there are other services that may be offered to a Medicaid patient when clotting factor is dispensed. We encourage states to accurately reflect those services in their Medicaid state plan under the appropriate service category and establish appropriate payment rates for such services.

Comment: One commenter stated that states could be negatively impacted if increasing volume or efficiencies reduce dispensing costs and they have no methodology to reduce dispensing fee payments.

Response: We are not mandating a specific formula or methodology which the state must use when calculating their professional dispensing fees because we believe that each state should maintain the flexibility to establish and, if necessary, revise its professional dispensing fee in accordance with the requirements in this final rule.

12. State Choice To Implement AAC

Comment: Several commenters stated that a state should be able to choose not to use AAC at all in pharmacy reimbursement. One of these commenters stated that many states have used EAC for years and already have predictable and reliable EAC metrics in place. The commenter stated that, with this proposal, CMS is forcing states to engage in multiple reimbursement methodology changes simultaneously.

Response: As we previously stated in this section, we no longer believe that the EAC is an appropriate measure of the pharmacy provider's acquisition cost because it was based traditionally on published compendia pricing which did not include discounts and price concessions which adjusted the prices actually charged in the marketplace. The OIG previously published reports focusing on the relationship between reimbursement for Medicaid CODs and compendia pricing (OIG Audit reports—A–06–00–00023, A–06–01–00053, A–06–02–00041). Based on these reports, we believe it is necessary for states to have a more accurate reference price as the basis for Medicaid reimbursement for prescription drugs. We believe that AAC will provide states with a more accurate reference price to base ingredient cost reimbursement, as it reflects prices actually paid by providers to acquire drugs. While we agree that EAC may have been predictable, we do not believe it was an accurate standard for determining pharmacy reimbursement rates.

13. Maintain SMAC

Comment: One commenter stated that a state should be able to maintain a state maximum allowable cost (SMAC) program, which monitors prices currently available in the marketplace, thereby complying with the definition of AAC.

Response: We agree that states should have flexibility for establishing reimbursement rates, which could include a SMAC program; however, the pricing methodologies need to be consistent with § 447.512(b) of this final rule.

14. State Budget Pressures

Comment: Several commenters expressed concern that the states should be encouraged or even required, to

objectively determine fees regardless of state budget pressures and/or allocations. Another commenter noted that the state of California has already suggested that additional cuts based solely on budgetary constraints would be applied to the survey findings for AAC and professional dispensing fee, which runs counter to a cost-based methodology.

Response: States retain the flexibility to establish reimbursement methodologies consistent with the requirements of this final rule. Comments about state budget pressures are outside the scope of this rule but we will review any SPAs to determine whether states' proposed payments rates are consistent with section 1902(a)(30)(A) of the Act.

15. Burden for Territories

Comment: One commenter stated that to have full participation in the CMS MDR program, a specific territory will need to take certain measures such as: develop a data bank or reference to determine AAC for pharmacy claims reimbursement to community pharmacies, and a study for the determination and validation of professional dispensing fees.

Response: We agree with the commenter that territories will need to take certain measures to determine their AAC reimbursement model. As noted in our response to comments on the definitions of states and United States, we are committed to working with all of the territories that participate in the MDR program to ensure their compliance with all applicable requirements.

Therefore, after considering the comments and for the reasons discussed in this section and in the proposed rule, we are finalizing the provisions in proposed § 447.512 Drugs: Aggregate upper limits of payment, with minor changes to remove the words ''of this subpart'' from the proposed regulatory text at § 447.512(a), (b), and (c)(1) as the reference is not necessary given the regulatory citations. This minor editorial change is not intended to change the meaning or intent of this regulatory text.

K. Upper Limits for Multiple Source Drugs (§ 447.514)

Section 2503(a) of the Affordable Care Act revised the definition of multiple source drug established in section 1927(k)(7)(A) of the Act. As discussed in the proposed rule, we proposed that the definition of ''multiple source drug'' be included in § 447.502 ''Definitions'' (77 FR 5345). In accordance with section 1927(e)(4) of the Act, we proposed in § 447.514(a)(1) that a FUL be calculated for each multiple source drug for which the FDA has rated three or more products therapeutically and pharmaceutically equivalent (77 FR 5346, 5366). We also proposed that the FUL will be calculated, in accordance with section 1927(e)(4) of the Act, using only therapeutically and pharmaceutically equivalent drugs (77 FR 5346, 5366). Additionally, we proposed to calculate the FUL as an aggregate upper limit at 175 percent of the weighted average of monthly AMPs, to use the most recently reported monthly AMPs and AMP units, and to eliminate single source drugs from the FUL calculation (77 FR 5346). We also considered various approaches, but did not propose a specific methodology for smoothing the FULs (77 FR 5349). These proposed provisions are discussed in more detail in the proposed rule (77 FR 5345 through 5350).

We received comments concerning our proposed upper limit for multiple source drugs section which include comments pertaining to the proposed upper limits calculation methodology, the impact of terminated drug products, the impact of the proposed buildup methodology for calculating AMP, and national availability. The comments and our responses are as follows:

1. Methodology

Comment: One commenter stated that in the proposed rule, CMS does not present any situation in which a FUL would be calculated at more than 175 percent of the weighted AMP, and another commenter was disappointed by the absence in the proposed rule of a process to determine when a higher multiplier would be used. Several commenters stated that CMS uses the 175 percent markup as a maximum instead of a minimum and encouraged CMS to consider offering itself more flexibility in using a markup higher than 175 percent. One commenter noted that if this rule is finalized, it would eliminate CMS's ability to set the FUL above 175 percent of the average weighted AMPs. Another commenter noted that CMS proposed the 175 percent markup as a result of its own data analysis and a GAO report that indicated ''using a factor of 175 percent of weighted monthly AMPs should yield adequate reimbursement for pharmacy providers, while achieving cost savings for the Medicaid program compared to pre-DRA FUL.'' The commenter noted that CMS's reasoning that 175 percent of AMP should be adequate reimbursement may be logical but it does not include a sound basis for CMS to limit its flexibility to raise the FULs when needed. The commenter further noted that CMS may never have to use the discretion given in the statute; however, a regulation that merely recognized the existence of that discretion, (without implementing) would not prevent CMS from setting FULs at a 175 percent markup.

Another commenter stated, referring to the draft AMP-based FULs, that a large number of generic drugs are so low cost that even with a 175 percent markup and a traditional dispensing fee, the reimbursement will fall short of a retail pharmacy's cost to dispense, and suggested that either a minimum FUL value or a higher percentage markup should be applied to these drug groups. Several commenters stated that the multiplier should be set at a level that will incentivize generic utilization given the overall cost savings to the system with increased use of generic drug products. One commenter stated that flexibility to set the FULs at levels greater than 175 percent of the weighted average of AMP should ensure adequate pharmacy reimbursement and limit the extreme volatility in monthly weighted AMPs and FULs.

Another commenter noted that the FULs multiplier needs flexibility to ensure that any FUL is set at the NADAC value, given that NADAC values will not be used by states if they are higher than the FUL. Yet, another commenter noted that CMS may be able to use the monthly survey data it is planning to publish for the NADAC to identify FULs that are too low. The commenter noted that CMS's proposal to limit the FUL to 175 percent of the weighted average of AMP may be inadequate if a substantial number of FULs yield a reimbursement lower than the NADAC or other state AAC based payment reimbursement.

Several commenters stated that Congress provided CMS with broad authority to increase the multiplier in certain justifiable cases, and commenters cited examples when the multiplier should be increased, including for certain specialty drug products, drugs subject to shortages, drugs that experience market inflation or plummet as a result of discounts. One commenter stated that initially, CMS may need to increase the multiplier for calculating all FULs on a frequent basis, and then if FULs begin to more closely approximate acquisition cost over time, there still may be cases (listed previously) where a higher multiplier should still be used.

Response: As stated in the proposed rule (77 FR 5349), we believed that calculating the FULs using a fixed mark-up of 175 percent would result in

Medicaid payments for multiple source drugs that are adequate to meet the costs incurred by retail community pharmacies to acquire drugs. However, in response to comments, we conducted an analysis of the NADAC files, which found that about 40 percent of the individual FUL values calculated using the 175 percent multiplier are lower than the corresponding NADACs each month. The NADAC and FUL data can be found by visiting *http://www.medicaid.gov/Medicaid-CHIP-Program-Information/By-Topics/Benefits/Prescription-Drugs/Pharmacy-Pricing.html* and *http://www.medicaid.gov/Medicaid-CHIP-Program-Information/By-Topics/Benefits/Prescription-Drugs/Federal-Upper-Limits.html* respectively. We recognize that the FUL may be higher or lower than the NADAC, as the FUL is calculated using AMPs which are based on prices paid to manufacturers by retail community pharmacies and wholesalers distributing drugs to retail community pharmacies. The NADAC file, in contrast, is based on a monthly nationwide survey of invoice prices for CODs purchased by retail community pharmacies. Further information on the methodology for calculating the NADAC can be found at *http://medicaid.gov/medicaid-chip-program-information/by-topics/benefits/prescription-drugs/ful-nadac-downloads/nadacmethodology.pdf.* Where the FUL value calculated using the 175 percent multiplier is below the corresponding NADAC file value, we agree with the commenter that the FUL using that multiplier is potentially too low to ensure adequate reimbursement for at least some of the drugs within that FUL group. We believe that in such instances, the FUL would not ensure that pharmacies are reimbursed for their acquisition costs, potentially jeopardizing access to certain drug products.

In light of these concerns, we agree with the commenters about the need for some flexibility in establishing the FUL multiplier. Therefore, upon consideration of the comments and as a result of our ongoing analysis of the draft FULs in comparison with the monthly NADAC pricing files, we agree with the suggestion to establish a revised process using a higher multiplier to calculate the FULs for certain multiple source drugs. Specifically, in this final rule, we are making an exception to calculate the FUL at an amount equal to 175 percent of the weighted average of the most recently reported monthly AMPs for pharmaceutically and therapeutically equivalent multiple source drugs, except where that amount is less than the average retail community pharmacies' acquisition cost for such drug products as determined by the most current national survey of such costs. In situations where the FUL is less than the average retail community pharmacies' acquisition cost, we will establish the FUL using a higher multiplier so that the FUL amount would equal the most current average retail community pharmacies' acquisition cost as determined by the most current national survey of such costs. This revised process by which a higher multiplier is used, is codified in § 447.514(b)(1) and (2) of this final rule. To implement this revision when we calculate the FULs each month, we intend to use the most current monthly NADAC pricing file values, as we believe that such values represent the best data available to estimate the average retail community pharmacies' acquisition cost. We may consider using other values in the future if such data become available and issuing additional rulemaking, if needed.

We note that, as discussed previously and in the proposed rule (77 FR 5347), this final rule is not designed to mandate state payment rates. Therefore, states have the discretion to adjust reimbursement on a drug-by-drug basis using pricing benchmarks, such as the NADAC pricing file, or other reliable data, to adjust reimbursement, as long as such payments are consistent with the state plan.

Comment: Several commenters stated that the 175 percent multiplier should be increased for 5i drugs as commenters believed that inclusion of non-retail pharmacy sales will lower AMPs and a multiplier of only 175 percent will not cover retail community pharmacies' acquisition cost for these drugs.

Response: In light of the criteria set forth in section 1927(k)(1)(B)(i)(IV) of the Act for the dispensing of 5i drugs, we have decided that we will not include 5i drugs that are not generally dispensed through retail community pharmacies in the FUL calculations, or apply the FUL to 5i drugs that are not generally dispensed through retail community pharmacies.

Comment: One commenter stated that a multiplier higher than 175 percent should be set where the independent pharmacies and small chains have higher acquisition costs than publicly traded chain pharmacies. One commenter added that despite aggressive efforts to negotiate and obtain lower prices, small business community pharmacy providers purchase generic drugs at a relative premium. The commenter noted than an OIG report found that independent pharmacies purchase multiple source drugs at a higher price than chain pharmacies or big box pharmacies.

Response: The FUL is calculated using AMPs, which are based on prices paid by retail community pharmacies and wholesalers distributing drugs to retail community pharmacies, which are defined in section 1927(k)(10) of the Act to include independent, chain, supermarket and mass merchandiser pharmacies that are licensed by the state and distribute medications to the general public at retail prices. Further, the NADAC pricing file, which we intend to use in the revised process for using a multiplier higher than 175 percent of the weighted average of the most recently reported monthly AMPs for pharmaceutically and therapeutically equivalent multiple source drugs to calculate the FUL, includes a statistically reliable representation of acquisition data from a random sample of pharmacies selected from all 50 states and the District of Columbia. Pharmacy entities surveyed include independent and chain retail community pharmacies in the United States. Thus, in light of this, we do not see a need at this time to calculate a separate FUL using a higher multiplier for independent or small chain pharmacies. For more information about the methodology for calculating the NADAC, please see *http://medicaid.gov/medicaid-chip-program-information/by-topics/benefits/prescription-drugs/ful-nadac-downloads/nadacmethodology.pdf.*

Comment: One commenter agreed with the proposal to use the most recently reported monthly AMP and utilization data to calculate the FUL.

Response: We appreciate the comment and believe that using the most recently reported AMP and utilization data is consistent with the statute.

Comment: Several commenters stated that CMS did not adequately describe in the proposed rule or the draft FUL files the methodology implemented for the draft AMP-based FULs including calculation of the weighted AMPs and criteria for establishment of the FUL groups. One of the commenters requested that CMS communicate the criteria for calculating the FULs so that stakeholders can provide comprehensive and meaningful input before the final rule is issued.

Response: We disagree with the commenters that we did not adequately describe in the proposed rule the methodology that would be used for calculating the FULs. As discussed in

the proposed rule, sections 1927(e)(4) and (5) of the Act outline the requirements for calculating the FUL (77 FR 5346–5349). Effective October 1, 2010, section 1927(e)(5) of the Act was revised to require that the Secretary calculate FULs as no less than 175 percent of the weighted average (determined on the basis of manufacturer utilization) of the most recently reported monthly AMPs for pharmaceutically and therapeutically equivalent multiple source drug products that are available for purchase by retail community pharmacies on a nationwide basis. In accordance with these provisions, in the proposed rule (77 FR 5345 through 5347), we described the methodology that we intended to use to calculate the FULs. We proposed that, in accordance with section 1927(k)(7) of the Act, at least two therapeutically equivalent (''A'' rated) formulations must be listed in the FDA's Orange book for the drug to be defined as a multiple source drug. We also proposed that, in accordance with section 1927(e)(4) of the Act, a FUL would be calculated for each multiple source drug for which the FDA has rated at least three products therapeutically and pharmaceutically equivalent (77 FR 5346).

In accordance with section 1927(e)(5) of the Act, as revised by section 2503(a) of the Affordable Care Act, we further proposed that the specific FUL will be calculated using a multiplier equal to 175 percent of the weighted average of the most recently reported monthly AMPs for therapeutically and pharmaceutically equivalent multiple source drugs (77 FR 5349, 5366). We proposed that the weighted average will be determined on the basis of manufacturer reported utilization of the most recently reported innovator and noninnovator pharmaceutically and therapeutically equivalent multiple source drugs available for purchase by retail community pharmacies on a nationwide basis (77 FR 5346). We also proposed that the determination of the weighted average will not include utilization from single source drugs (77 FR 5346). We proposed to use the most recently reported monthly AMP and utilization data submitted by the manufacturer in the calculation of the weighted AMP (77 FR 5346). We also proposed to calculate the FUL based on the nine-digit NDC, which is specific to the product code, combining all package sizes of a drug into the same computation of AMP (77 FR 5346). We proposed to exclude the AMP of a terminated NDC in calculating the FUL beginning with the first day of the month after the termination date reported by the manufacturer to CMS, and to calculate the FUL using a multiplier of 175 percent of the weighted average of the most recently reported monthly AMPs using manufacturer submitted utilization data (77 FR 5346, 5366). The proposals put forth in the proposed rule (77 FR 5345 through 5347, 5366) regarding the FUL calculation were detailed for stakeholders to consider and comment upon accordingly. We have established a revised process by which a multiplier higher than 175 percent will be used to calculate the FUL, by comparing the FUL established using the 175 percent multiplier to the average retail community pharmacies' acquisition cost and, where necessary, using a higher percentage markup to ensure that the FUL is not lower than such average retail community pharmacies' acquisition costs. As discussed previously in this section, we have not revised our proposed methodology to base the FUL calculation on the weighted average of the most recently reported monthly AMPs for pharmaceutically and therapeutically multiple source drug products.

2. Calculation Requirements—Therapeutic Equivalent Criteria and Authorized Generic Pricing

Comment: One commenter recommended that CMS clarify how it will consider authorized generic drugs in the determination of whether three drug products are pharmaceutically and therapeutically equivalent, providing examples for consideration and clarification. Another commenter stated that CMS's methodology does not conform to the statutory requirement because authorized generic drugs are not rated by the FDA as therapeutically and pharmaceutically equivalent to the branded drug and the authorized generic drug is not listed in FDA's Orange Book. The commenter further asked if CMS counts the authorized generic drug as one of the three drug products required to calculate a FUL during the 180 day time frame when the first generic drug receives exclusivity since there are only two competitors—the brand manufacturer and the manufacturer that holds the ANDA. The commenter added that CMS should revise its methodology to ensure that authorized generic drugs will not be included in the three equivalent drug product standard required to calculate a FUL. The commenter further stated that congressional intent was to ensure that a FUL is calculated when there are a sufficient number of competitors in the marketplace.

Response: In accordance with section 1927(e)(4) of the Act, the Secretary is required to calculate a FUL for each multiple source drug for which the FDA has rated three or more drug products therapeutically and pharmaceutically equivalent. Therefore, when the FDA has determined three or more drugs to be therapeutically and pharmaceutically equivalent, we will calculate a FUL for those drugs provided that they meet the other requirements of section 1927(e)(5) of the Act. An authorized generic drug, found by the FDA to be therapeutically and pharmaceutically equivalent to the reference listed drug, will be used in the calculation of the FUL. The FDA's ''Approved Drug Products with Therapeutic Equivalence Evaluations'' (Orange Book) will be reviewed to determine if drugs have been A-rated by the FDA or not. Consistent with section 1927(e)(4) of the Act, we will calculate the FUL using both innovator multiple source and noninnovator therapeutically and pharmaceutically equivalent multiple source drugs. As stated in the preamble to the proposed rule, any other formulations of the drug listed in the FDA Orange Book that are not therapeutically and pharmaceutically equivalent to the reference listed drug will not be used in the calculation of the FUL (77 FR 5346).

Comment: For authorized generic drugs and the calculation of FULs, a few commenters stated that the transfer price between the primary and secondary manufacturer is not a market price and should not be included in AMP. The commenters further stated that these lower AMPs will impact FULs for any product grouping that includes an authorized generic drug, and has three or more equivalent products required to set a FUL. One of the commenters stated that this scenario is inconsistent with congressional intent to provide adequate reimbursement to pharmacies for multiple source drugs.

Response: In accordance with section 1927(k)(1)(C) of the Act, in the case of a manufacturer that approves, allows, or otherwise permits any drug of the manufacturer to be sold under an NDA approved under section 505(c) of the FFDCA, the AMP shall be inclusive of the average price paid for such drug by wholesalers for drugs distributed to the retail community pharmacies. Additionally, section 1927(e)(4) of the Act requires that we calculate a FUL for each multiple source drug for which the FDA has rated three or more products therapeutically and pharmaceutically equivalent. Further, section 1927(e)(5) of the Act states, in part, that the FUL shall be calculated using the weighted average of the most recently reported

monthly AMPs for pharmaceutically and therapeutically equivalent multiple source drugs available for purchase by retail community pharmacies on a nationwide basis. Therefore, to the extent that an authorized generic drug meets the criteria necessary for the calculation of a FUL, its weighted AMP shall be included in the FUL calculation in accordance with the statute. However, we also note that our decision to use a revised process to increase the multiplier used in the FUL calculation, as discussed previously, should alleviate the concerns raised by the commenters about the adequacy of Medicaid reimbursement to pharmacies.

3. Non-Therapeutically Equivalent and B-Rated Drugs—Application/Calculation of the FUL

Comment: Several commenters expressed support for CMS's proposal that FULs will only derive from and be applied to A-rated drugs that are pharmaceutically and therapeutically equivalent to the reference listed drug. Several commenters stated that it is appropriate not to apply a FUL to a drug product that is not therapeutically equivalent, that is, a B-rated drug, to a reference listed drug. Another commenter stated that in the proposed rule, CMS does not explain the rationale for why FULs might be applied to drugs that are not therapeutically equivalent and how this would be consistent with the statute.

Response: As noted in the proposed rule, we would not apply the FUL to a drug that is not therapeutically equivalent to the reference listed drug nor would we use a drug that is not-therapeutically or pharmaceutically equivalent to calculate a FUL for the product group (77 FR 5346). To clarify, and as discussed previously, we will only apply the FUL to drugs which are rated by the FDA as therapeutically and pharmaceutically equivalent.

Comment: Several commenters stated that B-rated products typically compete in different markets characterized by different pricing than that applicable to the A-rated drugs, and, therefore, should not have a FUL applied. One commenter suggested that CMS should establish a mechanism which will prevent the improper calculation of FULs based on non-A rated products, as well as a mechanism to ensure that the FUL does not apply to those drugs. One commenter stated that CMS should codify both that B-rated generics are not counted when determining whether there are three sources of supply of a multiple source drug, and that the FULs do not apply to these B-rated drugs. Commenters stated that CMS is calculating draft FULs using non-A rated products and that each of the draft FUL releases included FULs on both B-rated drugs and drugs which have not been rated at all.

Response: In accordance with section 1927(e)(4) of the Act, the FUL is only calculated for each multiple source drug for which the FDA has rated three or more products therapeutically and pharmaceutically equivalent. Section 1927(e)(4) of the Act also requires that only these therapeutically and pharmaceutically equivalent products shall be used when calculating the FUL. Therefore, we agree with the commenter that B-rated drugs should not be included in the calculation of the FUL; however, we disagree with the comments suggesting that we are calculating draft FULs using non-A rated products. We have also decided that B-rated drugs should not be subject to the FULs because, as discussed more fully in the proposed rule (77 FR 5346), B-rated drugs are not therapeutically equivalent to the reference drug or other pharmaceutically equivalent products within the group. Therefore, we would not apply the FUL to a B-rated drug product, nor would we use a B-rated drug in the calculation of the FUL.

In the draft FUL reimbursement files, which are available on the Medicaid.gov Web site at *http://www.medicaid.gov/Medicaid-CHIP-Program-Information/By-Topics/Benefits/Prescription-Drugs/Federal-Upper-Limits.html,* we include a comprehensive list of NDC–11s by FUL product group which have the same ingredient, strength, dose, and route of administration. These groups may or may not contain both A-rated and B-rated drug products. That is, these groups may or may not contain drugs that have not been found by the FDA to be therapeutically and pharmaceutically equivalent in addition to those that have been found to be therapeutically and pharmaceutically equivalent. However, as noted previously in this section, B-rated drug products are not used in the calculation of the FUL and the FUL is not applied to B-rated drug products. We have also included this same information in the Draft FULs Methodology and Data Elements Guide posted on the Medicaid.gov Web site at *http://www.medicaid.gov/medicaid-chip-program-information/by-topics/benefits/prescription-drugs/downloads/methodologyguide-amp-basedfulnew.pdf.*

Comment: One commenter was concerned that if the FUL does not apply to all drugs, (and it only applies to A-rated drugs), states may have to determine that some drugs in a FUL product group might have a FUL applied, while others may not, and that this change could result in intensive manual review and correction.

Response: We appreciate the comment; however, for the reasons discussed previously, we have retained the provision in this final rule that the FULs will not apply to non-therapeutically equivalent drug products. The draft FUL files, which can be found on the Medicaid.gov Web site at *http://www.medicaid.gov/Medicaid-CHIP-Program-Information/By-Topics/Benefits/Prescription-Drugs/Federal-Upper-Limits.html,* are designed such that they can be sorted and the user can easily identify drugs to which a FUL applies.

4. Unit Type/UPPS Issues

Comment: One commenter expressed concern that CMS did not propose a solution to the unit of measure issues that are confounding CMS efforts to set FULs in the proposed rule.

Response: It is ultimately the responsibility of the manufacturer to determine the appropriate Unit Type and Units per Package Size (UPPS) for each of their products. We issued guidance to manufacturers on November 1, 2010, to remind manufacturers of their reporting obligations concerning unit type and UPPS in Manufacturer Release #82 (November 1, 2010), which is posted on the Medicaid.gov Web site at *http://www.medicaid.gov/Medicaid-CHIP-Program-Information/By-Topics/Benefits/Prescription-Drugs/Downloads/Rx-Releases/MFR-Releases/mfr-rel-082.pdf.* In accordance with section 1927(b) of the Act, manufacturers are required to submit monthly and quarterly drug product pricing data which includes (but is not limited to drug unit type and UPPS) via the DDR system. Manufacturers are also responsible for submitting corrections to submitted drug product pricing data, if necessary. In the case where various drug manufacturers have not reported the same unit type for their drug products in a product group, which is comprised of drug products with the same ingredient, strength, route of administration and dosage form, we do not calculate a FUL for that product group. We routinely review the manufacturer reported data to identify FUL product groups that do not have the same unit type reported, and we do not calculate a FUL for those product groups. Furthermore, we contact drug manufacturers if we have questions about the accuracy of their unit type submission, and, when necessary, inform them that we have determined that their reported unit type does not

appear to be consistent with the issued guidance and that their review of the reported unit type is necessary.

5. Calculation of the FUL and Single Source (S) Drugs

Comment: One commenter was concerned that some manufacturers may not change a drug product's category from a single source to an innovator multiple source drug upon introduction of another competitor/therapeutically equivalent drug product and suggested that CMS should revise its methodology to ensure that any branded product for which a therapeutically and pharmaceutically equivalent generic is listed in the FDA Orange Book will be included in the relevant product group and in the calculation of the FUL, even if the manufacturer continues to incorrectly report the product as a single source drug.

Response: In accordance with section 1927(e)(4) of the Act, CMS is required to calculate FULs for multiple source drugs. Single source drugs, in accordance with section 1927(k)(7) of the Act, are not multiple source drugs. Accordingly, we have decided not to include single source drugs in the FUL calculation. In addition, drug manufacturers are required to report and certify drug category product data when submitting drug product data for their CODs to CMS. We have issued guidance to drug manufacturers regarding such reporting, in Manufacturer Release #82 (November 1, 2010), which can be found on the Medicaid.gov Web site at *http://www.medicaid.gov/Medicaid-CHIP-Program-Information/By-Topics/Benefits/Prescription-Drugs/Downloads/Rx-Releases/MFR-Releases/mfr-rel-082.pdf.* In that guidance, we remind manufacturers of their reporting obligations and recommended that they review their reported drug category for accuracy. In light of these requirements, we see no reason to disregard the manufacturers' submissions and calculate the FULs using drugs which manufacturers have reported and certified to CMS as single source products.

6. FUL and Calculation/Application to 5i Drugs

Comment: One commenter stated that since the statute requires that FULs be based on a formula of no less than 175 percent of the weighted AMPs for equivalent multiple source drug products that are ''available for purchase by retail community pharmacies on a nationwide basis,'' they believe that calculating FULs for 5i drugs would be inappropriate. The idea of a product being ''available for purchase by retail community pharmacies,'' not ''generally dispensed through retail community pharmacies'' suggests that the Congress never intended for FULs to be calculated for 5i drugs. Several commenters stated that FULs should be determined using prices paid by retail community pharmacies, and therefore when AMPs are calculated for 5i drugs which are not generally dispensed through a retail community pharmacy, these AMPs should not be used to determine FULs. The commenters added that since these drugs would clearly not be available in retail community pharmacies, their AMPs should not be used to set FULs under the requirements of the Affordable Care Act.

A few commenters stated that CMS's proposal does not appear to exempt 5i drugs from the calculation of a FUL, and noted that such an exemption is necessary in that the alternative AMP calculation for such drugs consists of non-retail community pharmacy transactions. One commenter stated that calculating FULs based on weighted AMPs which include these transactions (such as physicians, PBMs, HMO, hospitals, clinics, outpatient facilities, mail order, LTC, and hospice transactions) include sales and discounts not available to retail community pharmacies, and will likely result in below cost reimbursement, and run afoul of Congressional intent. Several commenters requested that CMS exempt 5i drugs from the calculation of FULs for the above reasons.

Several commenters noted that the FUL for infusion and injectable drugs should be calculated using a percent of the AMP that is higher than 175 percent. One commenter noted that the FUL should be increased due to the non-retail pharmacy drug sources that are included in the AMP calculation. The commenter noted that the proposed FUL calculation would result in insufficient reimbursement for infusion and injectable drugs due to the inclusion of sales, rebates, discounts and other financial transactions for very large and very small buyers within the alternate calculation of AMP for infusion drugs. The commenter noted that CMS should ensure that the reimbursement levels resulting from the proposed rule will be sufficient for home infusion therapy pharmacies to provide infusion and injectable drugs to Medicaid beneficiaries. Several commenters recommended that CMS should reach out to the infusion community to develop a more appropriate percentage to be used to calculate the FUL for injectable and infusion drugs. Another commenter stated that there should be a tiered structure for calculating FULs based on buying power; thus, CMS should ensure that even small buyers receive reasonable reimbursement that reflects their acquisition costs.

Response: In light of the requirement in section 1927(e)(5) of the Act, we will calculate a FUL for multiple source drugs that are available for purchase by retail community pharmacies and, as noted earlier in this section, given the criteria set forth in section 1927(k)(1)(B)(i)(IV) of the Act regarding the calculation of the AMP, we have decided that we will not include 5i drugs that are not generally dispensed through retail community pharmacies in the FUL calculations, nor apply the FUL to 5i drugs that are not generally dispensed through retail community pharmacies.

7. NDC–9 vs. NDC–11

Comment: One commenter noted that the currently reported AMP is based on the NDC–9 level and is specific to the product code, combining all package sizes of the drug into the same computation of AMP. However, the commenter believed that basing reimbursement on the specific package size, that is, the NDC–11 level, will yield a more accurate measurement of acquisition cost.

Response: For each drug product in the rebate program, the drug manufacturers calculate the AMP at the NDC–9 level which is reflective of the specific drug product, that is, the ingredient, route, strength, and dosage. The drug manufacturers report and certify the same AMP calculated at the NDC–9 level for all package sizes (NDC–11) of that same drug product. This calculation and reporting process for AMPs, which includes the monthly AMPs used in the calculation of the FUL, is consistent with the rebate calculation requirements in section 1927(c) of the Act, which require that manufacturers calculate rebates for each dosage form and strength, and with the requirements for the reporting of AMP since the start of the program. We note that despite a number of amendments to the drug rebate provisions, including the FUL provisions, Congress did not revise these requirements, and thus, we did not propose to revise the reporting requirements in regulation. We will, therefore, continue to base our calculations of the FUL on AMPs at the NDC–9 level.

8. FUL and Terminated Drugs

Comment: Several commenters stated that if a terminated product reduces the number of therapeutically equivalent or A-rated products to two, then CMS

should immediately suspend the FUL and not wait for several months for the product's AMP to be omitted from the FUL calculation. Several commenters were concerned that drug manufacturers' reporting terminated NDCs will affect the availability determination for multiple source products because CMS proposes to disregard only the AMPs of terminated NDCs in assessing nationwide availability, assuming the AMPs of all non-terminated NDCs should be included. Several other commenters stated that Orange Book listings are tied to notifications from the manufacturer that a drug is no longer marketed. Several commenters also stated that supplies of many multiple source products will sell out before the product's NDC is discontinued in the Orange Book. Another commenter was concerned that drug manufacturers have no incentive to terminate NDC numbers but prefer to keep NDCs as assets for use at a later date. One commenter stated that drug pricing compendia continue to list terminated NDCs for a period of 2 years to provide for dispensing and claims reversal. Yet another commenter stated that drug manufacturers generally do not terminate the NDC of drugs in short supply, and CMS has not stated in the proposed rule that it will include only drugs for which a certain level of AMP units are reported, and even if there were a threshold of AMP units used, that statistic would not indicate availability to retail community pharmacies on a nationwide basis.

Response: As we stated in the proposed rule (77 FR 5347), based on our reading of section 1927(e)(5) of the Act, which requires the FUL to be calculated using the weighted average of the most recently reported AMPs for A-rated multiple source drugs that are available for purchase by retail community pharmacies on a nationwide basis, the AMP of a terminated NDC will not be used to calculate the FUL, beginning with the first day of the month after the termination date reported by the manufacturer to CMS. In the case where there are fewer than three therapeutically and pharmaceutically equivalent drug products for a monthly reporting period, a FUL would not be calculated for that multiple source drug product.

In addition, manufacturers are required to report and certify data regarding the termination date of a product to the CMS MDR program via the DDR system. We use the data reported and certified by the manufacturer to determine the termination date of the drug product. We also rely, in part, on the reported monthly AMP and AMP unit data from drug manufacturers to determine the availability of three therapeutically and pharmaceutically equivalent multiple source drugs before we calculate a FUL.

Comment: A few commenters were concerned that since CMS requires that a drug manufacturer report a monthly AMP for a product until the first month after the expiration date of the last lot sold, it may appear that there is availability, even when supplies of many multiple source products may sell out long before the product's last-lot expiration date.

Response: For purposes of drug manufacturer monthly reporting and the calculation of the FUL, in the case where a drug product does not have any utilization prior to the drug product's actual termination date, the drug manufacturer is responsible for reporting the drug product's AMP, and that drug product's AMP units would be correctly reported as zero. That drug product will not be considered in determining if three therapeutically equivalent multiple source drugs are available to calculate a FUL, consistent with our reading of section 1927(e)(5) of the Act, which provides that when a drug is not available for purchase on a nationwide basis, a FUL should not be calculated for that drug. In addition, that drug would not be included in the FUL calculation.

Comment: One commenter was concerned that CMS has directed manufacturers to carry forward the last reported positive AMP if they have no product sales in a given month and stated that some manufacturers may understand this instruction to require they carry forward the last reported positive AMP units too.

Response: When a manufacturer has had no product sales in a given month, the manufacturer should not carry forward the last reported positive AMP units. Instead, in this instance, the manufacturer should report to us via the DDR system an AMP based on the most recent prior month's positive AMP and an AMP units value of zero. We previously issued guidance concerning such reporting in Manufacturer Release #80 (January 5, 2010), which can be found on Medicaid.gov at *http://www.medicaid.gov/Medicaid-CHIP-Program-Information/By-Topics/Benefits/Prescription-Drugs/Downloads/Rx-Releases/MFR-Releases/mfr-rel-080.pdf.* This guidance instructs manufacturers to report the most recent prior month's positive AMP if a calculated monthly AMP is zero or negative. Further, in Manufacturer Release #86 (May 2, 2013), we issued guidance to drug manufacturers that AMP units should be entered in the DDR system as a number equal to or greater than zero and should reflect the AMP units for applicable time period (that is, for the month for which the manufacturer is reporting the monthly AMP). Manufacturer Release #86 (May 2, 2013) can be found on Medicaid.gov at *http://www.medicaid.gov/Medicaid-CHIP-Program-Information/By-topics/Benefits/Prescription-Drugs/Downloads/Rx-Releases/MFR-Releases/mfr-rel-086.pdf.* Additionally, since the DDR system will not accept a negative value for the AMP units, in the event that there is a negative AMP units value, manufacturers should enter a zero and not enter a previous month's AMP unit value.

9. FUL and Presumed Inclusion Method of Calculating AMP

Comment: Several commenters stated that changing the default rule will result in lower AMPs, which in turn, will result in lower FULs, and will increase the variability in AMPs and FULs. One commenter stated that under the buildup method, AMPs for multiple source products will be lower than the AMPs CMS has relied upon to justify its conclusion that FULs set at 175 percent of weighted AMPs will be sufficient to ensure adequate pharmacy reimbursement. One commenter expressed that a stable AMP (under presumed inclusion) yields a more predictable FUL. A commenter noted that an AMP calculated based on the presumed inclusion method would include a buffer that would help prevent periodic variability and price fluctuations. Another commenter stated that market driven fluctuations in the purchasing patterns of the relatively small number of identifiable purchasing retail customers will have a larger impact on the resulting AMP and FUL. Another commenter noted that in a buildup approach, generic manufacturers may have a larger number of sales (than brand manufacturers) that are identifiable as retail because of agreements with retail pharmacies, such as chain retail stores; and would have more lower priced products included in their AMP calculation. Then as another commenter noted, the generic manufacturers' generated AMPs would be lower, and as a result the calculated FUL could also be lower due to the volume and weighting of the retail AMPs; and ultimately could result in inconsistent and varying FULs from quarter-to-quarter.

One commenter stated that the FULs would not be negatively impacted by continuing the presumed inclusion

policy and that the policy would not hurt pharmacies that serve Medicaid beneficiaries because it would not result in reduced FULs. The commenter referred to the preamble of the proposed rule (77 FR 5348), which states that CMS and the Government Accountability Office (GAO) compared various FUL methodologies and found the FULs under the Affordable Care Act are higher than other possible reimbursement metrics. The commenter noted that because this analysis was based on 2009 data that was calculated and reported under the presumed inclusion policy, the FULs were not artificially lowered by that policy.

Finally, several commenters stated that without the presumed inclusion model, a lag in data availability would occur as manufacturers would not be able to count any sale until they are able to trace data over time, which would reduce the number of identifiable AMP-eligible units in some periods, and would result in an AMP that would be calculated likely using both a lower net price numerator and a lower units denominator. The commenters noted that this would yield variable measurements that would increase what they see as already unacceptable levels of period-to-period volatility in AMPs, weighted AMPs, and FULs.

Response: As discussed in detail in the Determination of AMP section (II.C.) of this final rule, we have decided not to require that manufacturers adopt the buildup methodology requirement. The use of presumed inclusion is consistent with the longstanding practice that permits manufacturers to presume that sales to wholesalers are for drugs distributed to retail community pharmacies, but to exclude sales to non-retail customers that specifically could be identified, such as by using chargeback data. We understand based on the comments, that the implementation of a buildup methodology could increase period-to-period volatility in AMPs, weighted AMPs and FULs while proving administratively burdensome to manufacturers. We believe that our decision not to require that manufacturers use the buildup methodology will allay the concerns raised by the commenters pertaining to the impact of that methodology on the FULs.

10. Fluctuation in AMP/FULs

Comment: A few commenters appreciated CMS involving stakeholders, through the rulemaking process, in the implementation of AMP, but expressed significant concerns with the AMP calculation and/or reporting of AMP values and the calculation of the FUL. One commenter stated that until drug manufacturers are calculating and reporting AMP and AMP units in a manner that is consistent with both the statute and with one another, the weighted AMPs CMS uses to calculate FULs will continue to vary wildly from month-to-month and fail to reflect pharmacy acquisition costs. Specifically, the commenters' expressed concerns regarding inconsistencies in the unit of measure, particularly related to reporting of AMP units; inconsistencies in the methodology for smoothing of lagged price concessions, inconsistencies in the method of using a presumed inclusion policy for calculating AMP, treatment of authorized generics, as well as inadequate guidance on bona fide service fees, and the treatment of specialty and home infusion pharmacies.

Response: In accordance with section 1927(b) of the Act, drug manufacturers participating in the MDR program are required to report pricing data to CMS. To assist the drug manufacturers, and to encourage consistency in their data reporting, CMS has issued guidance on the correct reporting of unit type and UPPS, in Manufacturer Release #82 (November 1, 2010), as well as on the calculation and reporting of AMP units and lagged price concessions in Manufacturer Release #83 (February 3, 2011). These releases can be found on the Medicaid.gov Web site at *http://www.medicaid.gov/Medicaid-CHIP-Program-Information/By-Topics/Benefits/Prescription-Drugs/Downloads/Rx-Releases/MFR-Releases/mfr-rel-082.pdf* and *http://www.medicaid.gov/Medicaid-CHIP-Program-Information/By-Topics/Benefits/Prescription-Drugs/Downloads/Rx-Releases/MFR-Releases/mfr-rel-083.pdf* respectively. In accordance with section 1927(e)(5) of the Act, the calculation of the FUL is based on the most recently reported monthly AMPs for pharmaceutically and therapeutically equivalent multiple source drugs that are available for purchase by retail community pharmacies on a nationwide basis. In accordance with these provisions, we have used the applicable monthly AMPS, as reported by the manufacturer, to calculate the FULs. We have issued guidance consistent with the statutory standard that the FUL is calculated based on reported monthly AMPs for those multiple source drugs available for purchase on a nationwide basis. We also note that section 2503(d) of the Affordable Care Act provides that amendments to the FUL provisions shall take effect on October 1, 2010, without regard to whether final regulations to carry out the amendments have been issued by that date. Therefore, in light of the effective date, we see no reason to wait an additional period of time after issuance of the final rules for the FUL provisions to take effect.

Comment: One commenter stated that due to a lack of agency guidance, many manufacturers are improperly treating certain service fees that the Congress intended be excluded from AMP calculation in their calculation of AMP as discounts (that is, deducting the amounts of the fees from sales revenue before calculating AMP), which results in artificially low AMPs and FULs.

Response: We have no reason to believe that manufacturers are improperly treating certain service fees as discounts. Manufacturers must calculate AMP in accordance with section 1927(k)(1) of the Act, regardless of whether CMS has issued final rules regarding those provisions.

Comment: One commenter stated that manufacturers continue to report AMPs calculated based on limited sales for products in short supply or on back order.

Response: Manufacturers are required to report AMP based on the average price paid to manufacturers consistent with the requirements found at section 1927(k)(1) of the Act. If a sale did not occur, such as for a back ordered product, then it would not be included in the AMP calculation until the respective month in which the sale occurred.

11. National Availability

Comment: A few commenters noted that a FUL should be calculated for a multiple source drug if it is generally and widely available for purchase by pharmacies throughout the United States. The commenters stated that CMS is required to calculate a FUL for each multiple source drug for which the FDA has rated three or more drug products therapeutically and pharmaceutically equivalent in accordance with section 1927(e)(4) of the Act, and added that the FUL must also be based on the AMP for drug products available for purchase by retail pharmacies on a nationwide basis in accordance with section 1927(e)(5) of the Act. The commenters noted that these requirements must be examined together to establish Medicaid payment policy for outpatient drugs that is consistent with congressional intent. The commenters state that the Congress did not intend for the FUL to be calculated based on only one nationally available multiple source drug product. Doing so would eliminate the

requirement for three or more FDA-rated equivalent drug products. The commenter understood CMS's interpretation of a multiple source drug to mean a drug for which there is at least one FDA-rated equivalent drug product that is sold or marketed in the United States and is available for purchase on a nationwide basis. The commenters believed that this interpretation violates the plain meaning of the statute where the Congress used the plural to state ''drug products that are available on a nationwide basis.'' One commenter stated that this language alone implies that a minimum of two drug products would need to be nationally available for purchase by retail community pharmacies before a FUL could be calculated. Several other commenters noted that they do not believe that the existence of only one other FDA therapeutically and pharmaceutically equivalent drug available indicates that the drug is sold or marketed on a nationwide basis, stating that it is not accurate to assume that all drugs listed in the FDA Orange Book are nationally available and should be included in the calculation of FULs. They noted that there are instances where drugs are not available due to shortages, manufacturing issues, and recalls, or the drug is only available for distribution in part of the country.

Several commenters stated that the proposed rule did not suggest a process to determine national availability. Some commenters suggested that an adequate survey should be used to determine when a drug product is available for purchase by retail pharmacies on a nationwide basis. One commenter proposed a possible test for national availability that is dependent on whether the product is generally and widely available for purchase by all pharmacies in the United States, such as when it is available from the national wholesalers and stated that a drug that is only available in one state or region cannot be nationally available as the statute requires. Another commenter proposed that a product be considered nationally available when it is stocked by two of the three national wholesalers in sufficient quantities to supply most retail community pharmacies. Several commenters encouraged CMS to address national availability by using its contractor under section 1927(f)(1)(A) of the Act to determine product availability to appropriately apply FULs. The commenters noted that despite CMS having a contractor to conduct NADAC surveys, it does not appear that the agency has engaged a contractor to assess product availability. The contractor, when conducting monthly pharmacy surveys to permit CMS distribution of NADAC data to the states, could alert CMS to drug supply issues.

Response: In light of our experience with the implementation of section 1927 of the Act, as well as managing the operation of the MDR program, for any given month, when there are at least three FDA-approved, therapeutically and pharmaceutically equivalent multiple source drug products reported to CMS by their manufacturers with a monthly reported AMP, and AMP units greater than zero for that given month, we believe that the drug is available for purchase by retail community pharmacies on a nationwide basis. A multiple source drug is not eligible to have a FUL calculated unless the FDA has rated three or more drugs therapeutically and pharmaceutically equivalent. To the extent that such a drug product is rated by the FDA to be therapeutically and pharmaceutically equivalent to at least two other drugs, the reported AMP for that drug (which includes sales directly to retail community pharmacies nationwide, as well as sales to wholesalers for distribution to retail community pharmacies nationwide) is eligible for inclusion in the FUL calculation.

We are aware that in cases of shortages, various market forces, which may include supply and demand, or competition in the market by multiple generic manufacturers (or lack thereof) may result in changes in product supply, may cause AMPs to fluctuate, and may affect the prices of drug products paid by retail community pharmacies. However, we believe that our revised process by which a higher multiplier will be used to calculate the FUL will address concerns regarding the calculation of a FUL for such drugs. Specifically, as discussed previously, we will calculate the FUL at an amount equal to 175 percent of the weighted average of the most recently reported monthly AMPs, except where the FUL calculated using the 175 percent multiplier is less than the average retail community pharmacies' acquisition cost, as determined by the most current national survey of such costs incurred by retail community pharmacies. In these instances we will use a higher multiplier to calculate the FUL to equal the average retail community pharmacies' acquisition cost incurred by retail community pharmacies as determined by such survey.

In addition, as noted previously, manufacturers are responsible for reporting drug termination dates timely to CMS via the DDR system and the AMP of such terminated NDCs will not be used to calculate the FUL, beginning with the first day of the month after the termination date is reported to CMS by the manufacturer. We also plan to regularly monitor the availability of drugs by reviewing the FDA drug shortage list for drugs that have a FUL calculated, but are not likely to have enough supply in the market to meet current demand. Further, we plan to monitor weekly pricing changes available to us in the most current national survey of pricing to consider changes to the multiplier used to calculate the FULs, based on average retail community pharmacies' acquisition costs. We also note that CMS currently publishes a monthly and weekly file of NADAC pricing values, which states can use to monitor those changes in average retail community pharmacies' acquisition costs as they apply the FUL aggregate reimbursement. We will not calculate a FUL for a given drug if we determine that there is a lack of availability of that drug to retail community pharmacies on a nationwide basis.

Comment: One commenter stated that draft AMP-based FUL product groups include drug products in short supply or that are completely unavailable, and it is evident that CMS has challenges in its statutory obligation to adopt FULs only where there are at least three therapeutically and pharmaceutically equivalent products that are available nationally. Another commenter stated that CMS has no basis for the position in the proposed rule that all retail community pharmacies would be able to purchase at least one drug product through a market channel of distribution, when a drug product has at least two FDA-approved therapeutically and pharmaceutically equivalent drug products, as drug availability is highly dependent on pharmacies' relationships with suppliers and wholesalers, and thus, what may be available through one wholesaler may not be reflective of the overall market. Yet another commenter noted that availability of the drug product in chain warehouses is not a proxy for national availability as these are generally only available for distribution to specific chain pharmacies, and further noted that certain GPOs only allow their member pharmacies to purchase products from their warehouses. The commenter stated that they believe CMS should adopt a more objective definition of nationally available.

One commenter noted that the shortcomings of CMS's proposal are exemplified in an analysis of NDCs in

commercial compendia and the commenter provided an example. The commenter noted that the existence of an NDC in a national compendium does not show nationwide availability to retail community pharmacies. Several commenters stated that manufacturers may not be able to supply the nation's retail community pharmacies as a manufacturer may only have the production capacity to meet a percentage, such as 10 percent, of the nationwide market demand.

One commenter stated that since the Congress required nationwide availability for three equivalent products, each of the three products should be available for purchase by any pharmacy in the nation. Several commenters also noted that CMS should create a policy to suspend the FUL when the drug product is no longer nationally available. One commenter noted that if an NDC is inactive but remains in the marketplace, CMS could freeze the reimbursement rate at the current FUL until the product is no longer available in the market. A few commenters also recommended that a process be put in place when factors such as environmental or natural disasters that cause material constraints result in decreases in FUL values.

The commenters added that when disruptions occur that limit availability of drug products, the WAC should be used for reimbursement until the constraints are resolved. One commenter stated that CMS should not just assume that all products are available nationwide and then place the burden of this determination on pharmacies, states, manufacturers or others. One commenter stated that CMS is improperly counting repackagers and authorized generic drug products toward the minimum of three FDA-rated equivalent drug products required to calculate a FUL under the Affordable Care Act.

One commenter would like CMS to clarify whether the qualification that drugs are ''available for purchase by retail community pharmacies'' include specialty pharmacies, home infusion centers and home health care centers, and if so, will it only include these providers that conduct business as retail community pharmacies.

Response: Section 1927(e)(4) of the Act requires that the Secretary calculate a FUL for those multiple source drugs for which the FDA has rated three or more products pharmaceutically and therapeutically equivalent. Section 1927(e)(5) of the Act provides that the FUL calculation be based on the weighted average (determined on the basis of utilization) of the most recently reported monthly AMPs for such drug products that are available for purchase by retail community pharmacies on a nationwide basis. Therefore, in accordance with section 1927 of the Act, for any given month, when there are at least three FDA-approved, therapeutically and pharmaceutically equivalent multiple source drug products reported to CMS by their manufacturers with a monthly AMP, and AMP units greater than zero for that given month, we believe that the drug is available for purchase by retail community pharmacies on a nationwide basis. To the extent a multiple source drug product is rated by the FDA to be therapeutically and pharmaceutically equivalent to at least two other drugs, the reported AMP for that drug (which includes sales directly to retail community pharmacies nationwide, as well as sales to wholesalers for drugs distributed to retail community pharmacies in the United States) is eligible for inclusion in the FUL calculation. This is because for a given month reporting period, the fact that there were AMP and AMP units greater than zero reported for that multiple source drug means that the drug was available on the market for purchase by retail community pharmacies in the United States.

We are aware that in cases of shortages, various market forces (supply and demand), or competition in the market by multiple generic manufacturers (or lack thereof) may result in changes in product supply, may cause AMPs to fluctuate, and may affect the prices of drug products paid by retail community pharmacies. These are factors and circumstances over which CMS has no control. However, we believe that the revised process of calculating the FULs using a higher multiplier should operate to ensure beneficiary access to medications given that the FUL calculated using the 175 percent multiplier will be increased under the exception we are finalizing at § 447.514(b)(2), to equal the most current average acquisition cost paid by retail community pharmacies as determined by the most current national survey.

The FUL is designed as an aggregate upper limit. Therefore, states have the flexibility to address price fluctuations due to shortages and other market forces. States have the discretion to adjust reimbursements on a drug-by-drug basis to the extent that such adjustments are consistent with the state plan and the state ensures that the total amount reimbursed to pharmacy providers for all drugs for which there is a FUL does not exceed the aggregate upper limit. We also note to the extent that pharmacy providers have concerns with payment amounts; they should raise those concerns with the state.

Furthermore, as discussed in the above response, we have plans in place to regularly monitor the availability of drugs by reviewing the FDA drug shortage list, as well as to monitor weekly pricing changes available to us in the most current national survey of pricing to consider changes to the multiplier used to calculate the FULs, based on average retail community pharmacies' acquisition costs. We will not calculate a FUL for a drug if we determine that the drug does not meet the criteria to have a FUL calculated.

Comment: Several commenters stated that a drug should only be considered a multiple source drug when there are three or more sources of supply and the drug is generally and widely available for purchase by all retail pharmacies in the United States. One commenter recommended that CMS address availability issues by revising the proposed definition to provide that the drug be accessible from at least three sources of supply in addition to being produced by more than one manufacturer. The commenter further noted that the proposed definition of a multiple source drug does not take into consideration whether or not both sources of the drug are available to all pharmacies. Several commenters stated that a multiple source drug should be considered nationally available when it is generally and widely available for purchase by all pharmacies in the United States, such as when it is available in sufficient quantities for independent pharmacies to buy from national wholesalers. A drug that is only available in one state or region cannot be nationally available as the statute requires. The commenters further stated that a simple listing of the drug in FDA's Orange Book does not mean it is nationally available to all pharmacies. Another commenter asked, per the third prong of the definition of multiple source drug, if ''sold or marketed in the United States'' is intended to refer to availability nationwide or simply in one or a few states. The commenter further noted that this will have important implications for recent regional and national drug shortages and inconsistent supplies at the regional and national level. Further, availability will determine whether a FUL will be calculated for a multiple source drug.

Response: We disagree with the commenters that the test for whether a multiple source drug is sold or marketed in the United States should be that more than one manufacturer's version of the

drug is available to all pharmacies through at least three sources of supply. Section 1927(k)(7)(A) of the Act defines the term multiple source drug, in part, to mean for a rebate period, a COD for which there is at least one other drug product which is sold or marketed in the United States during the period. Therefore, we disagree with the commenter that the basis for the determination of a multiple source drug should be a whether a multiple source drug is available by three suppliers.

In light of our experience with the implementation of section 1927 of the Act and managing the MDR program, a listed drug in the FDA Orange Book is generally one that is sold or marketed in the United States. We disagree with commenters that drugs listed in the FDA's Orange Book are not typically available as multiple source drugs. Additionally, we disagree that a multiple source drug should be considered nationally available when it is generally and widely available for purchase by all pharmacies in all states nationwide and in sufficient quantities for independent pharmacies to buy from national wholesalers. While we recognize the importance of the availability of multiple source drugs, we note that the statutory definition of multiple source drug in section 1927(k)(7) of the Act does not require that such a drug meet any threshold of availability from national wholesalers in a given geographic area relative to another but rather, such drug is sold or marketed in the United States during the given rebate period.

Furthermore, neither provision, that is, section 1927(e)(5) or (k)(7) of the Act references any threshold of relative regional availability before we calculate a FUL for a drug; however, we will continue to monitor the market for the availability of multiple source drugs, as well as pricing trends and we welcome feedback from providers, wholesalers, manufacturers, and states regarding the availability, or shortages, of drug products. We will continue to consider the issue of national availability and will issue additional guidance or rulemaking, if necessary.

12. Data Time Lag—Reporting and Publishing

Comment: One commenter noted concern that AMP values are not reflective of real-time market prices available to retail pharmacies, and stated that given the lag time in calculating and reporting AMPs, the values are outdated by several weeks compared to when they would be used for pharmacy reimbursement. The commenter further stated that the lag in data may be problematic and raised the issue of the adequacy of the FUL multiplier percentage in cases where there is sudden inflation due to market forces, and the availability of products for which reimbursement is based on a previous AMP reported. Another commenter noted that there is a 3-month time lag in the actual sale of a drug product and the release of the FUL files. One commenter noted that CMS should monitor drug shortages as tracked by the FDA, as the states are observing a trend of increased drug prices when there is a drug with limited supply that returns back to the marketplace.

Response: In accordance with section 1927(e)(5) of the Act, the FUL is calculated using the most recently reported monthly AMPs and AMP units for pharmaceutically and therapeutically equivalent multiple source drug products available for purchase by retail community pharmacies on a nationwide basis. The FULs are updated on a monthly basis to reflect the data from the most recent monthly reporting period. We note that section 1927(e)(5) of the Act states that FULs should be calculated using a multiplier of no less than 175 percent, and we do not interpret the statutory language to mean that this multiplier was established to address changes in pricing that may occur between the most recent monthly reporting period and the issuance of the updated FUL. We also note that our decision to use a higher multiplier to increase the FUL if the FUL using the 175 percent multiplier is lower than the average retail community pharmacies' acquisition cost for such drug products, as determined by the most current national survey of such costs should address the concern raised by the commenters regarding the connection between the FULs and real-time prices available to pharmacies. Further, the states have had longstanding processes in place to address and respond to reimbursement issues, and to the extent that pharmacy providers have concerns with payment amounts, including situations where there is a change in pricing due to an increase in provider acquisition cost without a change in reimbursement, the pharmacy providers should raise those concerns with the state.

13. Aggregate Requirement

Comment: One commenter stated that for the least disruption to providers, states should be required to meet the FULs in the aggregate and not on the claim level.

Response: We have calculated the FULs as an aggregate upper limit, which gives states greater flexibility to determine payment rates for individual drugs in accordance with the approved state plan.

Comment: One commenter stated that they will need more information to implement the FULs under the Affordable Care Act as products in the draft FUL files have moved on and off the list, and commenter questioned how these products may be accounted for in an aggregate calculation.

Response: FULs are calculated using the most recently reported monthly pricing and utilization data, consistent with the statute. Where a drug product does not have a FUL calculated for a given time period, the state would reimburse for that drug in accordance with the requirements established in § 447.512(b), and the approved state plan.

Comment: A few commenters also noted that according to the proposed rule, CMS, noting the close alignment between the AMP-based FUL and the Indiana SMAC, has concluded it will never need to exercise its authority under the statute to use a weighted AMP multiplier higher than 175 percent, because using this multiplier will not have an impact on pharmacies. One commenter believed that CMS will need to exercise its authority to use a weighted AMP multiplier higher than 175 percent, citing that most states apply FULs on a drug-by-drug basis and not in the aggregate. Other commenters stated that CMS proposed that the AMP-based FULs would limit generic reimbursement only in the aggregate, rather than on a drug-by-drug basis, but most states currently pay the lower of FUL or a SMAC on a drug-by-drug basis, and that CMS should not publish final FULs until appropriate revision to state plans are complete to correspond with the aggregate test CMS has proposed. If not, the commenters stated that generic ingredient cost reimbursement will be cut much more than suggested by CMS's bar chart in the proposed rule. Commenters added that even for states that do not apply the FUL on a drug-by-drug basis, states are likely to reduce their SMAC on drugs where the FUL is lower.

Several commenters stated that there must be procedures in place for lifting FUL caps on product reimbursement after they have verified pharmacy complaints about access issues. One commenter also noted that when there are cases that applying a markup of 175 percent to the weighted AMP results in a FUL that is considerably low, CMS should have the ability to expeditiously

set an appropriate FUL to ensure appropriate reimbursement for pharmacies and patient access to medications.

Response: We have calculated the FULs as an aggregate upper limit, which gives states flexibility to determine payment rates for individual drugs in accordance with the approved state plan. We believe the commenters' concerns regarding the adequacy of the Affordable Care Act FUL amount to ensure access is addressed by our decision to use a higher multiplier to increase the FUL if the FUL using the 175 percent multiplier is lower than the average retail community pharmacies' acquisition cost for such drug products, as determined by the most current national survey of such costs.

We believe that this option to use a higher multiplier should operate to ensure access given that the FUL calculated using the 175 percent multiplier will be increased under the exception we are finalizing at § 447.514(b)(2), to equal the most current average acquisition cost paid by retail community pharmacies as determined by the most current national survey.

14. Appeals Process

Comment: One commenter stated that CMS should develop and implement a process by which pharmacies could alert the state to situations in which a FUL needs to be lifted or adjusted above the 175 percent multiplier to address supply issues or other issues (including recalls or manufacturing issues) to prevent pharmacies from being paid for ingredient costs at less than market values. The commenter suggests that any such system should include a process through which pharmacies paid based on a discredited FUL can reverse and re-bill the affected claims. Another commenter believed that CMS has the authority to include an appeals process for the FULs in its regulatory authority, as the Congress did not explicitly limit this authority. Another commenter stated that due to the complexity of issues involved in the calculation of AMP and FULs, a formal appeals process should be in place, to provide a formal response regarding concerns raised. Another commenter stated that without a formal process in place, a formal agency response is entirely discretionary. Another commenter does not believe that CMS should defer appeals of AMP and FULs to the states as CMS is directly responsible for establishing both values and it would be difficult for providers to appeal to numerous states each time CMS updates FULs.

Response: Medicaid pharmacy payments must be consistent with efficiency, economy, and quality of care while assuring sufficient beneficiary access, consistent with section 1902(a)(30)(A) of the Act. CMS is not responsible for calculating AMP and we did not propose a specific process for pharmacies to alert the states or CMS when a FUL needs to be lifted or adjusted. We note that to the extent pharmacy providers have concerns with payment amounts, they should raise those concerns with the state. Further, we believe the revised process by which to calculate a FUL using a multiplier above 175 percent if the FUL using the 175 percent multiplier is lower than the average retail community pharmacies' acquisition cost for such drug products, as determined by the most current national survey of such costs, incurred by retail community pharmacies, will address the concerns raised by the commenter regarding the possibility that pharmacies will be inadequately reimbursed. We believe that this revised process of calculating the FULs using a higher multiplier should operate to ensure beneficiary access to medications given that the FUL calculated using the 175 percent multiplier will be increased under the exception we are finalizing at § 447.514(b)(2), to equal the most current average acquisition cost paid by retail community pharmacies as determined by the most current national survey.

Comment: Several commenters stated that CMS needs to create a process to suspend the FUL when the agency determines—either on its own or based on an appeal from a state or pharmacists—that there are no longer three nationally available sources of supply of the multiple source drug or it is no longer nationally available.

Response: In accordance with section 1927(e)(5) of the Act, we will not calculate a FUL unless there are at least three pharmaceutically and therapeutically equivalent multiple source drugs available, and all other established criteria are met. If a drug meets the criteria to have a FUL calculated, the FUL would apply to that drug for the period that the FUL was in effect. In the event that there are not three pharmaceutically and therapeutically equivalent multiple source drugs available, a FUL would not be calculated for the drug. We see no reason at this time to establish a process to suspend the FUL in an interim period between monthly updates when there is sufficient data to calculate the FUL.

15. Draft AMP-Based FUL Files

Comment: Several commenters raised issues concerning the draft AMP-based FUL files. The commenters stated that there is a pattern of inconsistency in the monthly files with a drug product having a FUL calculated for 1 month and then the drug is not on the next month's draft AMP-based FUL file. The commenters also noted that the draft AMP-based FULs have revealed significant price swings for some drug products. Another commenter noted that they have observed hundreds of draft AMP-based FULs that experience fluctuations on a monthly basis that do not represent changes in pharmacy acquisition costs. One commenter noted that no less than half of the draft AMP-based FULs changed by at least 10 percent from one release to the next and over a quarter changed by at least 20 percent, and there were several examples of draft AMP-based FULs that increased by more than 100 percent or decreased by more than 50 percent from one month to the next.

Another commenter encouraged CMS to give states an opportunity to review the draft AMP-based FUL files before the agency processes it through a pricing vendor, and noted that state review may prevent overpayment for drugs. The commenter stated that portions of the file could create state challenges as the states seek to utilize the files for reimbursement on a claim or an NDC level. The commenter asked how CMS would address inconsistencies and changes in published AMP-based FULs for drug groups. One commenter claimed that about 20 percent of the NDC's with a reported AMP, (published in November 2011, based on September 2011 monthly reported data), had supply issues, and stated that the existence of an NDC does not demonstrate national availability, including national availability to retail community pharmacies.

Another commenter stated that problems with the draft AMP-based FUL files included the treatment of authorized generic drugs and repackaged drugs (as they are included in the FUL product groups), supply issues, fluctuating prices, and drug products that may have not been placed in the appropriate product groups. Further, several commenters stated that because the repackaged product is competitively distinct from non-repackaged products, CMS should establish product groups for repackaged products separate from the product groups for the non-repackaged products.

Another commenter noted that if a pharmacy was reimbursed for a specific

manufacturer's drugs using the price caps in that same monthly draft AMP-based FUL file, they would lose money on approximately 15 percent of that manufacturer's drugs. Another commenter noted that reimbursement using the draft AMP-based FULs resulted in a decrease of generic ingredient cost reimbursement for several states. Another commenter provided CMS with examples of how the draft AMP-based FULs impacted low, medium, high volume Medicaid pharmacies and stated that, in many cases, these pharmacies lost from one-third to 40 percent of their Medicaid revenues using this reimbursement.

Response: As noted previously, a FUL will not be calculated in the case where a FUL product group does not have at least three pharmaceutically and therapeutically equivalent multiple source drugs with manufacturer reported data based on the reporting requirements established in section 1927 of the Act; therefore, we expect that a FUL group may not have a price calculated every month.

We note that the draft AMP-based FULs can experience price variations, and we note that these changes can and do occur due to changes in supply and demand, including drug shortages or manufacturing issues. The FULs are designed as an aggregate upper limit to give states flexibility to establish payment rates and adjust those rates for individual drugs consistent with those aggregate limits. Furthermore, the revised process we are adopting in this final rule for calculating the FUL, whereby the FUL will not be calculated lower than the average retail community pharmacies' acquisition cost for such drug product, as determined by the most current national survey of such costs incurred by retail community pharmacies should address concerns raised regarding these fluctuations.

We released draft AMP-based FUL files, beginning in September 2011, to give states, pharmacies, and other stakeholders an opportunity to review and provide comment on the FULs and the methodology we use to calculate the FULs, prior to the finalization of the FULs. Once the FULs are issued in final, we do not believe that we should continue to issue draft FUL prices to the states for review on a monthly basis prior to the FULs becoming effective. Section 1927(e)(5) of the Act does not require a process for issuance of draft FULs prior to finalization on a monthly basis.

In accordance with section 1927(e)(5) of the Act, a FUL is calculated where the FDA has rated three or more products therapeutically and pharmaceutically equivalent. To the extent that an authorized generic drug or a repackaged drug is rated by the FDA as therapeutically and pharmaceutically equivalent, we will include those drugs in the calculation of the FUL.

We have taken steps to ensure that there were not any inconsistencies regarding the data in the draft FUL files. For example, we have verified the correct placement of multiple source drugs into the appropriate FUL group; performed internal review of duplicate FUL groupings; and ensured that drugs that have the same ingredient, route of administration, strength, and dosage but different therapeutic equivalence ratings (for example, AB1 and AB2 ratings), are not placed in the same FUL group. We believe that these steps will alleviate some of the fluctuations that may have previously existed in the some of the draft files.

As noted earlier in this section, we believe that our decision to adopt a revised process by which the FUL can be calculated using a multiplier higher than 175 percent of the weighted average of the most recently reported AMPs, so that the FUL will not be lower than the average retail community pharmacies' acquisition cost for such drug product, as determined by the most current national survey of such costs incurred by retail community pharmacies will also address the concerns regarding the adequacy of the draft AMP-based FULs we posted on the Medicaid.gov Web site, as we believe that this option to use a higher multiplier should operate to ensure access given that it is based on actual invoice data.

Comment: A few commenters made suggestions for addressing the fluctuations with the draft AMP-based FUL prices including the use of an aggressive SMAC program that is compliant in the aggregate. The commenters noted that states could meet FULs in the aggregate, but also noted that CMS should provide ample time and guidance for states that do not have a SMAC program to develop one.

Response: We note that the FUL is calculated as an aggregate upper limit, and states have the discretion to adjust reimbursement on a drug-by-drug basis, and may use their SMAC program as a benchmark to do so.

Nearly all states currently have a SMAC program in place; however, we believe that the notification previously issued by CMS that the FULs would not be finalized until this final rule is published, should have provided the few states that do not currently have a SMAC program in place to develop and implement a program to meet the FUL aggregate requirement, if they choose to do so.

16. The FUL and AAC

Comment: Several commenters noted that if the AAC methodology is appropriate for multiple source drugs, there will not be a need for the FULs. One commenter asked about the need for AAC, if the FUL were adequate reimbursement. The commenters stated that it is more logical to use the AAC model for reimbursement for branded products and a more flexible FUL for reimbursement for multiple source drugs. Multiple source drugs comprise 80 percent of all Medicaid prescriptions and comprise less than 20 percent of Medicaid spending. Another commenter noted that the proposed rule had a considerable discussion on the definition of AMP and the use of AMP to develop new FULs, which the commenter noted is a complicated and error-prone process. The commenter stated that if states decide not to change to an AAC-based reimbursement, the adoption of these new FULs as a basis for reimbursement would result in a reduction in pharmacy reimbursement if there is no increase in pharmacy dispensing fees. The commenter noted that there is no guidance to states to evaluate and increase dispensing fees if they do not change to AAC or delay the change to AAC and adopt the new FULs.

A few commenters noted that implementing a defective FUL process with extreme period-to-period volatility will undermine the move to AAC and destroy any confidence that industry providers have in AAC. The commenters requested clarification on whether a state will override an AAC that was based on provider survey data with a lower FUL, and they noted that this ''lesser of'' logic could undermine both the AAC and the FUL. One commenter noted that the comparison of the draft AMP-based FULs to Alabama AAC values showed that a number of draft AMP-based FULs are below the reimbursement benchmark of 175 percent, and the analysis did not take into account that the dispensing fee in Alabama is $10.64, compared with the nation average Medicaid dispensing fee of $4.50. One commenter stated that to ensure the adequacy of AAC amounts when brand drugs have price increases, the procedures should include a mechanism for pharmacies to resubmit claims that were previously under reimbursed. One commenter stated CMS should use an appropriate measure of pharmacy acquisition cost to determine reimbursement and when the weighted

AMP is below that cost, CMS could calculate the FUL at 175 percent of such pharmacy acquisition cost measure.

Response: Payment to Medicaid pharmacy providers must be consistent with efficiency, economy, and quality of care while assuring sufficient beneficiary access, consistent with section 1902(a)(30)(A) of the Act. Section 447.518(d) as finalized requires that when states are proposing changes to either the ingredient cost reimbursement or the professional dispensing fee reimbursement, they must evaluate their proposed changes in accordance with the revised requirements of this final rule, and states must consider both the ingredient cost reimbursement and the professional dispensing fee reimbursement when proposing such changes.

We did not propose that states establish procedures for the resubmission of claims that may have been under-reimbursed, as we believe that a process for pharmacies to re-submit claims is a state function, and these issues should be raised to the state.

Furthermore, in response to comments that CMS consider pharmacy acquisition costs when calculating the FUL, as discussed previously, we have adopted a revised process by which the FUL can be calculated using a multiplier higher than 175 percent of the weighted average of the most recently reported monthly AMPs, when the FUL calculated at 175 percent of the weighted average of the most recently reported monthly AMPs is lower than the average retail community pharmacies' acquisition cost for such drug product, as determined by the most current national survey of such costs incurred by retail community pharmacies. This revised process considers pharmacy acquisition cost to establish a higher multiplier, such that, the resulting FUL is no less than the average retail community pharmacies' acquisition cost.

17. Policy for Misreporting and Posting of FUL

Comment: One commenter noted that there is a need to have a mechanism in place to eliminate obvious gross errors in the final reported FUL values as reported on a monthly basis.

Response: We did not propose a mechanism to eliminate obvious gross errors in the FUL; however, to the extent that a provider believes that a FUL reflects an obvious error, they should contact the state or CMS to report such errors.

18. Brand Medically Necessary (BMN)

Comment: One commenter stated that the BMN section of the proposed rule appears to be in conflict with many state laws and regulations in which brand substitution requirements are already defined, including acceptable language and the use of check off boxes. CMS should more appropriately refer to those laws in the aggregate and allow state regulations to prevail in determining appropriate substitution. To do otherwise imposes a burden on providers. Additionally, this does not take into consideration state regulation or nationally accepted standards and systems already in use for e-prescribing that address this issue.

Response: In our most recent change to this policy, we did allow for a BMN determination to be documented as part of an electronically transmitted prescription, and this policy was not designed to be in conflict with state laws. We did not propose deferring to state law on the e-prescribing issue, but we will continue to consider the issue. See 42 CFR 447.512(c) for further information on e-prescribing and the BMN certification for Medicaid CODs.

Comment: One commenter stated that it was a good step that the language in § 447.512 changed to allow the dispensing of a brand drug if the prescriber indicates that the brand is medically necessary; however, the commenter stated that they would like an electronic check box to be an acceptable way to indicate medical necessity as long as the wording on the check box specifically states that the prescriber certifies that the brand is medically necessary for the patient and further added that any type of electronic indication from the prescriber should be acceptable. Another commenter expressed disappointment that the proposed rule did not address an electronic alternative for prescribers to certify BMN on a prescription. The commenter points out that with e-prescribing and electronic medical records fully implemented in many parts of the country, requiring a handwritten dispense as written (DAW) certification is out of step with modern technology, and the commenter requested that CMS establish an electronic alternative to the handwritten DAW certification requirement.

Response: We do not agree with this characterization of the current regulations, as § 447.512(c) already provides an electronic alternative to the handwritten DAW requirement. We did not propose to modify the language in § 447.512(c) in the proposed rule, nor are we making any changes to that section in this final rule.

19. Implementation/Timeline

Comment: One commenter requested that CMS take into consideration in final rulemaking the establishment of effective dates for the implementation of the AMP-based FULs, and the commenter states that it will take months and additional contractor cost to implement these statutory provisions.

Response: We believe that the notification previously issued by CMS that the FULs would not be finalized until this final rule is published should have provided states sufficient time to plan for the implementation of the Affordable Care Act FULs. Therefore, states are responsible for revising their state plans to be consistent with these final regulations, including the FULs, which we have issued to implement section 1927(e)(4) and (5) of the Act as of the effective date of this final rule.

Comment: A few commenters stated that until the rule is finalized and implemented, CMS will not have the data necessary to calculate FULs as provided in the Affordable Care Act. Consequently, the commenters stated that CMS should defer calculating FULs—draft or final—until the regulations are finalized, and manufacturers have had an opportunity to properly implement calculation methodologies consistent with the statute.

Response: We disagree with the commenters. In accordance with section 1927 of the Act, drug manufacturers participating in the MDR program are required to report valid drug product and pricing data to CMS, including the monthly AMP and AMP unit data for their CODs. Therefore, CMS is in receipt of the data necessary to calculate the FUL based on AMP data, consistent with section 1927(e)(5) of the Act.

Comment: One commenter asked when CMS expected to post finalized FULs.

Response: We expect to finalize the FUL in April 2016 after the final rule is effective.

20. Publication of FULs

Comment: Several commenters stated that using the monthly AMP and monthly utilization (AMP unit) data submitted by the manufacturer to change the reimbursement levels on a monthly basis will create a significant administrative burden for all parties within the product supply channel and will create confusion in the marketplace as parties react monthly to the volatile and unpredictable FULs. The commenters stated that the frequency by

which CMS proposes to update the FULs to the various state Medicaid agencies should be extended to a quarterly basis or greater length of time, and that monthly changes in the FULs could ultimately harm the generic industry.

Response: We disagree with commenters. The FULs may fluctuate from month-to-month, but we see no basis to extend the timeframe for updating the FULs as section 1927(e)(5) of the Act requires that the FUL should be calculated using the most recently reported monthly AMPs and AMP units.

21. Smoothing Process

Comment: Several commenters supported the use of a 12-month rolling percentage to estimate the value of lagged price concessions to smooth out fluctuations in AMP from month-to-month that can negatively affect pharmacy reimbursement, as outlined in Manufacturer Release #83 (February 3, 2011).

Response: We appreciate the comment, and except for some minor clarification, we expect to implement the policy as outlined in the proposed rule (77 FR 5344). These clarifications are discussed in more detail in the Requirements for Manufacturers (section II.H.5.) of this final rule.

Comment: A few commenters stated that the proposed rule did little to reduce the weighted AMP volatility that was evident in the draft AMP-based FULs and could exacerbate it. Another commenter stated that the proposed rule did not offer a solution to the volatility problem. Several commenters stated that the prevalence of extremely low and inordinately high FULs and the high degree of period-to-period variability in draft FULs posted to date clarify that the current methodology being used by CMS does not provide a reliable basis for setting FULs and could negatively impact community pharmacies. Another commenter stated that such volatility in a reimbursement metric would be highly problematic particularly for pharmacies that serve a high proportion of Medicaid beneficiaries.

Response: We share the concerns of the commenters regarding the volatility of certain draft FULs. We contacted a number of manufacturers on this point and based on feedback from manufacturers we believe that this variation in price reflects changes in a supply and demand market, including drug shortages or manufacturing issues.

Comment: Several commenters stated, after review of the draft FULs, that an additional smoothing methodology is necessary. Despite the smoothing requirements for manufacturers, the commenters stated that AMP-based FULs continue to demonstrate great variability. Another commenter thinks that the variability evident in the draft weighted AMPs and FULs published by CMS to date urges strongly for the development of a smoothing methodology for FULs and they disagreed with CMS's decision not to do so. One commenter stated that CMS is correct that any smoothing process would have drawbacks, but the unsmoothed FULs will have challenges as well, particularly for states without a SMAC. Several commenters stated that to provide predictability for Medicaid pharmacy providers and beneficiaries, a 12-month rolling average to determine FULs should be used rather than a single month's calculation. This additional smoothing process would substantially reduce the variability in FULs from month-to-month. This additional smoothing would not change the total reimbursement to pharmacies in a 12-month period, but it would reduce variability. This predictability is important for all pharmacies but particularly those that serve a high percentage of Medicaid patients. One of the commenters provided an example of an approximation of what a FUL may look like using a 12-month rolling average. Another commenter suggested the following proposed smoothing methodologies for FULs (besides the lagged price concession smoothing for AMPs currently in place): excluding outlier monthly weighted AMPs that are less than a certain percentage of the next highest monthly AMP for equivalent products, excluding a monthly AMP if the percent change is greater than a certain percentage when compared to the last manufacturer reported and certified monthly AMP, and increasing the calculated FUL by a certain percentage if the FUL is less than a certain percentage from the last FUL. One commenter stated that merely smoothing the FULs is not the appropriate solution to the fluctuating FULs given that so many of the erratic FULs are also well below 175 percent of the pharmacy acquisition cost. The commenter stated that CMS should exercise their authority to ensure stability and adequacy of the FULs by using a multiplier greater than 175 percent.

Response: Smoothing the pricing data using one of the methodologies discussed in the proposed rule (77 FR 5349) may prevent some month-to-month fluctuations in the FULs; however, as we noted in the proposed rule, implementing any of the smoothing methods would have limitations. Therefore, we do not plan to apply a specific methodology to smooth the FULs at this time. As noted previously in this section, we believe that our revised process by which the FUL will be calculated using a multiplier higher than 175 percent of the weighted average of the most recently reported monthly AMPs, when the FUL calculated at 175 percent of the weighted average of the most recently reported monthly AMPs is lower than the average retail community pharmacies' acquisition cost for such drug product, as determined by the most current national survey of such costs incurred by retail community pharmacies will ensure the FUL is not lower than the average retail community pharmacy average acquisition costs and should address concerns regarding the adequacy of the FULs as a reimbursement metric.

Comment: One commenter stated that there is a proposed smoothing process for reported AMPs; however, since the FUL can vary due to sales mix (units sold) among vendors of the same product, the average weighted AMP can actually change with no change in individual AMP values, so the commenter recommended that there should be a smoothing process for FULs.

Response: We agree with the commenter that the FUL can vary due to units sold; however, the average weighted AMP for a FUL product group (required by section 1927(e)(5) of the Act) is calculated based on a drug product's AMP units weighted against the other drug products in the FUL product group.

Comment: One commenter recommended an additional process be implemented when factors such as drug shortages result in dramatic changes in FUL values. Another commenter stated that CMS has proposed a ''smoothing process'' that may reduce the variability in the FULs, but stated that it may create a new problem in that generic medications are subject to periodic product shortages, and these product shortages create dramatic price increases when they occur. The commenter noted that a smoothing process would mask these dramatic cost increases and would result in substantial underpayment to pharmacies when these cost increases occur.

Response: We understand that variations in pricing do occur in the marketplace for various reasons, including, but not limited to, drug shortages or manufacturing issues. If a drug product is in shortage and lesser amounts of that particular drug product

are sold, that drug product's AMP units would be weighted less against other products in the FUL product group.

In the case where a drug product is not being manufactured, and the drug product has no utilization, it will not be included in the calculation of the FUL. Sections 1927(e)(4) and (5) of the Act do not include any exceptions for calculating a FUL when a drug is in shortage, provided the drug is available on a nationwide basis. Therefore, as discussed previously, a FUL will only be established for those multiple source drugs for which the FDA has rated three or more products therapeutically and pharmaceutically equivalent that are available for purchase by retail community pharmacies on a nationwide basis.

Comment: One commenter states that there are limitations in all of the smoothing methodologies that CMS has proposed, and a more predictable measure should be used to address the wide swings in FULs from month-to-month. The commenter suggested that in lieu of smoothing, CMS establish a threshold for FUL variance. If the absolute value of the change in a grouping's FUL from period to period exceeds the threshold, then no FUL should be calculated for the ensuing month.

Response: We did not propose a threshold option for determining whether to calculate a FUL based on a change in the FUL amount from a previous month in this final rule, but we will continue to consider this issue as we gain more experience with the FUL program.

Comment: A few commenters believed that CMS should not use AMP revisions to adjust FULs for the 12-month time period, should not subsequently adjust a state's FMAP to account for such changes, and should not permit states to use such revisions to recoup monies from pharmacies after reimbursement is made.

Response: At this time we are not planning to use any AMP revisions to adjust past FULs as section 1927(e)(5) of the Act requires that the FULs must be calculated based on the most recently reported AMPs. CMS does not read the section 1927(e)(5) of the Act to require, or contemplate, that FUL adjustments should be made based on subsequent AMP calculations or to require an adjustment to the state FMAP to account for such changes.

Further, the states have had longstanding processes in place to address and respond to reimbursement issues, and to the extent that pharmacy providers have concerns with payment amounts, the pharmacy providers should raise those concerns with the state.

Therefore, after considering the comments and for the reasons articulated in this section and in the proposed rule, we are finalizing proposed § 447.514 (Upper limits for multiple source drugs), except for the following revisions:

- Proposed § 447.514(a)(1) is revised to remove the third instance of the word ''therapeutically,'' which appeared prior to the word ''equivalent'' in the last sentence, given the earlier reference, in the same sentence, to the phrase ''pharmaceutically and therapeutically equivalent.'' This was a technical error in the proposed rule that we are correcting and is not intended to change the general meaning of this provision.
- We are adding a period to the end of the sentence in § 447.514(a)(1) as it was omitted from the proposed regulatory text.
- Section 447.514(b) is revised to create two paragraphs.
- Paragraph (b)(1) includes the language from the proposed § 447.514(b), except that it is revised to replace the phrase ''drug entity'' with the phrase ''pharmaceutically and therapeutically equivalent multiple source drug product,'' and is not intended to change the general meaning of this provision; rather, this terminology more closely matches the statutory language in section 1927(e)(4) of the Act.
- Paragraph (b)(2) addresses the exceptions process.

L. Upper Limits for Drugs Furnished as Part of Services (§ 447.516)

In proposed § 447.516, we included, without any modification, the existing upper limit provision (77 FR 5367), which we had previously finalized in the AMP final rule (72 FR 39244). We received no comments on this section and are finalizing the provision in § 447.516 (Upper limits for drugs furnished as part of services).

M. State Plan Requirements, Findings, and Assurances (§ 447.518)

In the ''Medicaid Program; Withdrawal of Determination of Average Manufacturer Price, Multiple Source Drug Definition, and Upper Limits for Multiple Source Drugs'' final rule (75 FR 69591) we made conforming amendments to § 447.518 (''State plan requirements, findings, and assurances) to remove reference to § 447.514 (''Upper limits for multiple source drugs'') as this section was removed from regulation. In the proposed rule, we proposed regulatory amendments to add back in references to § 447.514 ''Upper limits for multiple source drugs'' to § 447.518 ''State plan requirements, findings, and assurances'' (77 FR 5350). In addition, to conform with the proposed change from ''estimated acquisition cost'' to ''actual acquisition cost,'' we proposed in § 447.518(d) to require states to provide data to support proposed changes in reimbursement using AAC and specified that this supporting data could include, but is not limited to, a state or national survey of retail community pharmacy providers, or other reliable data which reflects the pharmacy's price to acquire a drug (77 FR 5350, 5367). We also proposed to add a new requirement that states must describe their payment methodology for drugs dispensed by a covered entity described in section 1927(a)(5)(B) of the Act, a contract pharmacy under contract with a covered entity described in section 1927(a)(5)(B) of the Act, and an Indian Health Service, tribal and urban Indian pharmacy. These provisions are discussed in more detail at 77 FR 5350 through 5351 of the proposed rule. Furthermore, we invited comments on the practicality of requiring each state to conduct a survey, the frequency of such a survey, and how closely we would expect the state to conform to the survey results in the reimbursement rates they propose in their SPA, including the use of acquisition cost averaging, AMPs as a basis for reimbursement, including the application of an appropriate markup factor or other methods of determining the ingredient cost (77 FR 5350). We received the following comments concerning proposed § 447.518 (the state plan, requirements, findings, and assurances).

1. Pharmacy Reimbursement Using AAC

The following comments pertain to pharmacy reimbursement using AAC.

a. Support for Proposal—The SPA Review Process and Change of Reimbursement

Comment: One commenter was pleased that CMS has committed to ensuring that through the SPA process, no state will be allowed to reduce drug reimbursement to the required AAC without assessing the costs of dispensing and increasing the professional dispensing fee accordingly. One commenter supported CMS's proposal to require states to reconsider their dispensing fee methodology and to include this methodology in any SPAs that are submitted to CMS proposing revised drug cost payment. Many commenters supported CMS's proposal that states need to provide adequate data when proposing changes to the

ingredient cost or professional dispensing fee.

Response: As discussed in section II.J. of this final rule, in light of the comments, we are revising § 447.518(d) in this final rule to require states to consider both the ingredient cost reimbursement and the professional dispensing fee reimbursement when proposing changes to either or both of these components of the reimbursement for Medicaid covered drugs to ensure that total reimbursement to the pharmacy provider is in accordance with requirements of section 1902(a)(30)(A) of the Act. Also, states must provide adequate data such as a state or national survey of retail pharmacy providers, or other reliable data other than a survey, to support any proposed changes to either or both of the components of the reimbursement methodology. States must submit to CMS the proposed change in reimbursement and the supporting data through a SPA through the formal review process.

b. CMS Oversight—State Requirements for SPAs

Comment: One commenter encouraged CMS to implement robust SPA oversight to ensure that pharmacy reimbursement is adequate. Several commenters stated that the SPA approval process should be overseen such that once a state adopts AAC, they cannot unilaterally reduce the professional dispensing fee without a cost of dispensing survey. Several commenters stated that CMS should require states to increase the dispensing fee as a condition of approving a SPA (for AAC) to ensure fair and accurate reimbursement for pharmacies, and this should be made clear in the final rule so future Administrations will comply/share this view. Another commenter stated that failure to increase dispensing fees as a condition to approving a SPA will arbitrarily reduce reimbursement to pharmacies and threaten the economic viability and ability to continue providing the services currently offered to meet the distinct needs of the Medicaid population. Several commenters stated that prior to initiating any changes in ingredient cost or professional dispensing fee, including implementing an AAC model for reimbursement, a state must have an approved SPA with supporting data.

Response: We agree that the total reimbursement should consider not only the pharmacy's cost to acquire the drug, but also the pharmacist's professional services in dispensing the drug; however, we do not agree that states must conduct surveys to revise dispensing fees. Rather, they have the option to submit data, other than a survey, which demonstrates that the total reimbursement to the pharmacy provider is in accordance with requirements of section 1902(a)(30)(A) of the Act. In light of the comments, we have revised proposed § 447.518(d), to provide that states must consider both ingredient costs and professional dispensing fees to assure compliance with section 1902(a)(30)(A) of the Act, and provide data to support any proposed changes to either or both of the components of the reimbursement methodology. In accordance with 42 CFR 430.20, states may submit a SPA for reimbursement changes as late as the last day of a quarter to maintain an effective date no earlier than the first date of that quarter.

Comment: Several commenters stated that the SPA approval process for professional dispensing fees should require states to include a profit margin to receive CMS approval.

Response: As we have explained in the Drugs: Aggregate upper limits of payment (§ 447.512) section (section II.J.), we have not separately identified profit in the definition of professional dispensing fee. Therefore, we will not require that states include a profit margin in their calculation of dispensing fee to receive CMS approval of any SPA revising such fees.

c. Timing—State Must Have an Approved SPA With Supporting Data Prior To Implementing Changes

Comment: Several commenters stated that CMS should require states to have an approved SPA before initiating any changes in either component of reimbursement, including transitioning from old FULs to new FULs.

Response: States are required to implement pharmacy reimbursement limits, in the aggregate, in accordance with §§ 447.512 and 447.514 as of the effective date of this final rule. However, when a state implements changes to its approved state plan prior to the CMS approval of those changes, and the SPA is subsequently disapproved, the state is responsible for the financial impact of those changes. As noted earlier in this section, we realize that states may need to revise their Medicaid state plans to accommodate the Affordable Care Act FULs provisions of this final rule, and we have decided to allow them 4 quarters from the effective date of this rule to submit a SPA to comply with the FUL provisions. In accordance with § 430.20, states may submit a SPA for reimbursement changes as late as the last day of a quarter to maintain an effective date no earlier than the first date of that quarter.

d. SPAs and Approvals for Different Classes of Trade/Pharmacies

Comment: Several commenters stated that the requirements for approval of SPAs regarding reimbursement should also extend to different classes of pharmacies as different pharmacies have different costs of purchasing, as well as different costs of dispensing. Other commenters stated that CMS should reject SPAs that tier dispensing fees based on pharmacy types, such as chain vs. non-chain, because this is unfair, anti-competitive, and based on false assumptions that chain pharmacies consistently purchase and dispense prescription medications at lower prices than independent pharmacies. The commenter further stated that national cost of dispensing studies have revealed no consistent differentials in dispensing costs for chain versus independent pharmacies.

Response: We do not agree that we should reject SPAs that propose to tier dispensing fees based on pharmacy types. We believe that states are in a better position to assess adequate fees for their pharmacies and decide if tiered fees are appropriate for such providers. The state retains the flexibility to establish, and if necessary, revise, its professional dispensing fees to ensure that the Medicaid pharmacy providers are adequately reimbursed in accordance with the requirements of section 1902(a)(30)(A) of the Act. In addition, states retain the option to adjust the professional dispensing fee for provider type or services rendered such as special packaging or delivery.

e. Supporting Changes to Pharmacy Reimbursement

Comment: One commenter claims that too often states have proposed, and CMS has indiscriminately approved, devastating Medicaid reimbursement reductions without requiring the submission of data.

Response: We disagree with the commenter that CMS has indiscriminately approved Medicaid reimbursement reductions without submission of data. States have had the flexibility of establishing their pharmacy reimbursement methodology; however, states have had to support their proposed changes in reimbursement to ensure that the Medicaid pharmacy providers are adequately reimbursed consistent with the requirements of section 1902(a)(30)(A) of the Act.

f. Determining the Professional Dispensing Fee—Data/Surveys

Comment: Many commenters stated that the process for determining the professional dispensing fee must be an open and transparent process that covers all aspects of doing business within that state. One commenter stated that the professional dispensing fee should be determined using well-designed surveys that address all costs, overhead, and delivery to pharmacy customers in varied settings, and that CMS should require states to adhere to rigorous standards when conducting state surveys to determine the professional dispensing fee. Several commenters stated that cost of dispensing surveys should reflect the added costs associated with entities which serve patients with special needs, such as frail, elderly, and disabled residents, and that CMS should require this in the final rule. Several commenters stated that there have been both statewide and nationwide attempts to assess cost of dispensing and the metrics utilized in those studies have been validated and could be included or at least referenced in the final rule and that there are a number of costs that should be included to ensure some degree of uniformity across states. One commenter recommended that CMS should provide a list of ''including, but not limited to'' items that comprise the core of the cost of dispensing survey—this would allow transparent additions by the state for state specific items such as unique regulatory requirements, levies, and taxes.

Another commenter stated that the cost of dispensing survey should be conducted at least annually and that this should be included in the final rule. Another commenter noted that annual surveys are necessary as a pharmacy's cost to dispense will have some regional variation and will change periodically due to the costs of regulatory compliance and patient needs. Another commenter stated that cost of dispensing studies need to be repeated on a timely basis and utilize the results in pharmacy reimbursement, as pharmacy costs change over time as drug costs do, yet rate changes for dispensing costs have not occurred with similar frequency, and many times come under negative pressure, as in the case of Oregon, whenever budgets are tight. Many commenters stated that if a survey is not done annually to support the dispensing fee, then an annual adjustment must be made. Commenters suggested that adjustments should be made on a standard such as the one used to adjust Medicare Part D co-pays and state payments, or the medical care component of the CPI for urban areas.

Response: We agree that to the extent that a state is conducting a cost of dispensing study, it should be a transparent, comprehensive, and well-designed tool that addresses a pharmacy provider's cost to dispense the drug product to a Medicaid beneficiary. States retain the flexibility to set professional dispensing fees, including creating a differential reimbursement per provider delivery type. We disagree that they should be required to use any specific methodology or study to do so, because we believe that states are in the best position to establish fees based on data reflective of the cost of dispensing drugs in their state.

Comment: One commenter stated that states should be required to base professional dispensing fees on a recent survey conducted in the region or state. Another commenter requested clarification on whether CMS will accept a cost of dispensing survey from a neighboring state or a national cost of dispensing survey. One commenter stated that the professional dispensing fee should be set on actual provider invoice cost. The commenter stated that asking each state to conduct a cost of dispensing survey each time the pharmacy rate methodology changes is a large administrative burden. Another commenter expressed that the states may not have enough information to know what the fair professional dispensing fee is, as no data or survey has been conducted.

Response: As noted previously in this section, states have the flexibility to set professional dispensing fees, including using national or regional data from another state and we do not require that a state use a specific standard or methodology such as a survey to do so. States are not required to conduct cost studies or use an inflation update where cost studies are not conducted; however, states should ensure that pharmacy providers are compensated in accordance with the requirements in section 1902(a)(30)(A) of the Act.

g. Determining AAC—Data/Surveys/Benchmarks

Comment: Several commenters supported CMS's proposed change from EAC to AAC, providing that reliable and accurate data on acquisition cost and all associated discounts can be obtained from pharmacies. A few commenters stated that the proposed rule fails to lay out the requirements to ensure the accuracy of surveys to assess AAC and also the appropriateness of reimbursement rates derived from survey data. Another commenter stated that a pharmacy survey may only yield an invoice price, which could be an inaccurate pricing point, and states should be careful to use a term that accurately describes the information actually collected in the survey. One commenter stated that to ensure that AAC is reliable and sustainable; AAC should only be reported for retail pharmacy prices, and should not include discounts, rebates, allowances and any other price concessions not available to retail community pharmacies. Several commenters were concerned about the state's ability to secure a timely AAC benchmark that takes off-invoice rebates and incentives into consideration. Another commenter stated that given these shortcomings of the AAC model, AAC should be stated as a derivative with a confidence interval that will assure the smallest of the providers will not be disadvantaged, and added that access to medications should not be compromised by a price setting process.

Response: We appreciate the comments on AAC. We agree with the commenter that reliable and accurate data should be used to establish an AAC model of reimbursement. We have cited examples in the proposed rule (77 FR 5350) that the states can use to develop or support an AAC. States retain the flexibility to establish an AAC reimbursement based on several different pricing benchmarks, but they have the responsibility to ensure that Medicaid pharmacy providers are adequately reimbursed in accordance with the requirements of section 1902(a)(30)(A) of the Act.

Off-invoice rebates and incentives are pricing concessions that are generally extended to pharmacy providers on a case-by-case basis under specific contracting arrangements with wholesalers, and CMS does not require states to include these pricing concessions in a survey of pharmacy prices. Further, we believe that survey prices that do not reflect off-invoice rebates and incentives tend to benefit pharmacy providers. In accordance with the requirements in § 447.518(d) of this final rule, states must provide data to support any changes to reimbursement, and have the proposed changes reviewed under the formal SPA review process. Under this process, states are responsible to ensure that total reimbursement to the pharmacy provider is in accordance with requirements of section 1902 (a)(30)(A) of the Act. States must also provide public notice of that change, in accordance with § 447.205, before it can be implemented. Therefore, the state's proposed methodology to establish an

AAC model of reimbursement, including how/if the state is including any rebates or discounts afforded to pharmacy providers in calculating an AAC, should be part of this public notice and SPA review process. In light of this public process, providers may raise any concerns regarding the accuracy of the data to the state once the details of the proposal are made public.

Comment: A few commenters stated that strong confidentiality and liability protections should be in place for pharmacies that submit invoices. To protect the ability of chain pharmacies to negotiate drug prices, it is critical that individual company invoice data are not revealed.

Response: The issue of liability protections for pharmacy pricing invoices is beyond the scope of this rulemaking.

Comment: One commenter understood CMS's basis for defining the term AAC, and the need to pay pharmacies accurately for the cost of drug products, but believed that the benchmarks suggested in the proposed rule are not reliable for meeting this goal. The commenter stated that the NADAC's reliability, accuracy, timeliness, and sustainability have not been established, and the commenter stated that AMP is not a price paid in the marketplace. Several commenters stated that there is no reliable measure of AAC currently available on a nationwide basis, and while CMS indicates it will publish the NADAC, it has not been published to date. The commenter stated that before mandating AAC, CMS should publish NADAC for a period of time, collect comments, and implement refinements.

Another commenter recognized the need for alternative metrics for pharmacy acquisition costs to support state Medicaid reimbursement rates. The commenter is concerned that industry stakeholders do not yet have the necessary information or guidance to make the change to AAC-based reimbursement in a responsible and practical manner. Therefore the commenter stated that any new type of pricing data requires further review before it can serve as the basis for reimbursement.

Another commenter stated that CMS should forego requiring states to adopt ingredient cost payment based upon survey-derived measures of AAC as the accuracy of these unpublished and untested measures of AAC could have an unpredictable impact on pharmacy reimbursement. Another commenter expressed concern about encouraging states, without more specific guidance, to conduct and implement an AAC which could create inadequate reimbursement, with risk to access and patient care. One commenter stated that some states may believe that the NADAC doesn't represent cost to pharmacies in their state if they have a disproportionate share of independent pharmacies in their state. One commenter stated that CMS and state Medicaid programs should first issue draft ingredient cost for comment before implementing AAC, as this transparency is essential for pharmacy provider feedback.

Response: We note that this final rule is not designed to mandate state payment rates. CMS sets aggregate upper limit requirements in accordance with the methodology established in §§ 447.512 and 447.514, and as we stated in the proposed rule, states have the authority to establish an AAC reimbursement in their state plan based on several different pricing benchmarks, for example, the NADAC file, a state survey of retail pharmacy providers, or AMP-based pricing (77 FR 5350). States have the responsibility to ensure that Medicaid pharmacy providers are adequately reimbursed in accordance with the requirements of section 1902(a)(30)(A) of the Act, consistent with the state plan.

We disagree with the commenters about the reliability of the data which states may use to calculate ingredient costs. A notification for the retail price survey collection was placed in the **Federal Register** on September 30, 2011 for public comment as part of the PRA process (76 FR 60845). The public was given notice in July 2011 that, consistent with section 1927(f) of the Act, and as noted on the Medicaid.gov Web site on July 8, 2011, CMS contracted with an outside vendor for a monthly survey of retail community pharmacy prescription drug prices. We expected that state Medicaid agencies would be able to use this information to compare their own pricing methodologies and payments to those derived from this survey of retail prices.

On a monthly basis, our contracted vendor collects acquisition cost data from a random sample of pharmacies selected from all 50 states and the District of Columbia. Pharmacy entities surveyed include independent and chain retail community pharmacies. A national pharmacy compendia file containing information on retail pharmacies throughout the country is used to determine the pool of pharmacies eligible for each survey. The Methodology for Calculating the NADAC, found at *http://www.medicaid.gov/medicaid-chip-program-information/by-topics/benefits/prescription-drugs/ful-nadac-downloads/nadacmethodology.pdf* discusses the actual data collection, survey process, and quality assurance measures in place for calculating a NADAC.

The draft NADAC files and the draft Methodology for Calculating the NADAC were made available on the Medicaid.gov Web site as of October 2012, and were finalized in November 2013. Further information on the survey of retail prices can be found at *http://www.medicaid.gov/medicaid-chip-program-information/by-topics/benefits/prescription-drugs/survey-of-retail-prices.html.* The NADAC pricing files can be found at *http://www.medicaid.gov/medicaid-chip-program-information/by-topics/benefits/prescription-drugs/pharmacy-pricing.html.*

We also disagree with the commenters concerning the reliability of AMP-based prices. In accordance with the requirements of section 1927(b)(3) of the Act and § 447.510, manufacturers are required to submit and certify the accuracy of all of the pricing data they report to CMS, including monthly and quarterly AMP data. As discussed previously in this section, we have reviewed manufacturers' submissions to ensure that manufacturers calculate their AMPs consistently. We also note that while states may use AMP data, which is based on the prices paid by both retail community pharmacies and wholesalers, they are responsible for demonstrating that using AMP-based prices as a reimbursement methodology will ensure that pharmacies are reimbursed at a price that reflects AAC.

Therefore, we believe that we have given the states sufficient time and opportunity to review the NADAC pricing files and AMPs, and we expect that state Medicaid agencies should be able to use this data, if they choose to do so, to establish payment rates consistent with section 1902(a)(30)(A) of the Act.

Comment: Many commenters stated that whatever process is used to determine AAC, it should be open, transparent, updated timely and specific to practice/provider type and location, readily available, and specific to the needs of the pharmacy, pharmacists and patients served, and that those provisions should be added to the final rule. Another commenter stated that the conformity and frequency of surveys to determine AAC should be matched to determine cost of dispensing and professional dispensing fees. The commenter recommended adding provisions to the final rule stipulating that states electing to carry out their

own pharmacy surveys for AAC must conduct them no less frequently than annually. The commenter would prefer to see a requirement for CMS's plan to carry out rolling monthly surveys. Another commenter requested that the final rule also should require states to use survey methodologies that have been thoroughly vetted through well-noticed, open public comment processes similar to those used by CMS for NADAC. One commenter stated that AAC could vary with the different regions in the United States. Several commenters thought that this supporting data should be provided specifically by state surveys. Another commenter thought that a state should be allowed to use a regional survey, which would be more representative of a particular state's demographics and unique market. Several other commenters added that the cost of a regional survey could be shared with a neighboring state.

One commenter stated that CMS should take into account different entities such as specialty pharmacy products, and thus, the surveys should be well-designed to focus effectively on the specifics of the products and the customers involved such as vulnerable populations and those with rare diseases. One commenter stated that specialty products should be excluded from the methodology as they are unique and costly. Another commenter stated that independent pharmacies need special consideration as they do not have the advantage of ordering in large quantities, so it is more difficult for them to make a profit. Another commenter stated that AAC could vary with each pharmacy's contractual prices from their primary wholesaler. Several commenters stated that if CMS uses a survey to determine AAC, the survey should be conducted at the enrolled pharmacy location level, and in the case of chain pharmacies, individual pharmacies, and not retail chain distribution centers are most reflective of drug acquisition cost and should be used in surveying these entities.

Response: We note that this final rule is not designed to mandate state payment rates, and we have not proposed specific requirements regarding state surveys to determine an AAC model of reimbursement for those states that choose to conduct a state survey; however, we agree that to the extent that a state is conducting a survey to establish an AAC model of reimbursement, it should be transparent, comprehensive, and one that will allow the state to provide adequate reimbursement to Medicaid pharmacy providers in accordance with the requirements of section 1902(a)(30)(A) of the Act, and consistent with the state plan.

Comment: One commenter stated that survey-based AACs may not reflect manufacturers' price increases which could result in pharmacies taking a loss when they must dispense at a price less than what they can buy the drug, especially for brand drugs wherein manufacturers raise their prices quite frequently. Another commenter stated that the final rule should include protections against a substantial time lag between the pharmacy's incurring AAC and the calculation of AAC by the Medicaid agency to prevent inadequate reimbursement. Another commenter stated that if a survey does not take place following a price increase, payments to pharmacies will not be sufficient.

Response: States have the flexibility to determine reimbursement for specific drugs and to provide timely updates to their AAC model of reimbursement as necessary to afford pharmacy providers adequate reimbursement, and likewise, to ensure that states and the federal government receive the cost savings benefits of market changes. States have authority to conduct retail pharmacy surveys without CMS approval; however, if they decide to use data collected from those surveys to make payments to pharmacies, they would need to submit a SPA outlining this methodology for approval. While we do not object to a process for adjustments to a state's AAC methodology, states retain the flexibility to set prices. We note that states have had longstanding processes in place to address and respond to reimbursement issues, and to the extent that pharmacy providers have concerns with payment amounts, including situations where there is a change in pricing due to a time lag in the pharmacy provider's acquisition and subsequent reimbursement for the drug, they should raise those concerns with the state.

Comment: One commenter stated that while CMS has published in the **Federal Register** its intent to begin submitting surveys to retail pharmacies to support its NADAC efforts, CMS still has yet to respond to stakeholder comments on its proposed NADAC methodology or publish NADAC data for stakeholder review. The commenter questioned when such data may be made available. Another commenter requested that CMS not implement AAC until a national benchmark is available, as it makes little sense for each state to expend scarce administrative funds for state specific acquisition cost surveys. Another commenter stated that last year, the OIG reported that as of July 2011, a large number of states did not have well-developed plans for prescription drug reimbursement once First DataBank ceases to publish AWP data in September 2011. The commenter continued that the same report showed that a vast majority of states preferred that CMS develop a national benchmark for Medicaid reimbursement for prescription drugs, which CMS has begun to do with its NADAC survey, conducted by Myers & Stauffer, LC.

Another commenter stated that CMS's proposal to use the NADAC survey as a basis to calculate AAC does not currently provide sufficient assurances that it will lead to accurate or adequate reimbursements for the more complex and costly specialty pharmacy products. The commenter expressed concerns that CMS and the states are unsure even how to identify specialty pharmacies, which do not typically receive a separate license for state pharmacy purposes. The commenter added that it is unclear that the NADAC survey will provide adequate data to accurately calculate AAC for specialty pharmacies.

Response: As we explained previously in this section, since the publication of the proposed rule, we have finalized the NADAC pricing files and the NADAC methodology documents. Information pertaining to the NADAC and our response to comments can be found on the Medicaid.gov Web site at *http://www.medicaid.gov/Medicaid-CHIP-Program-Information/By-Topics/Benefits/Prescription-Drugs/Survey-of-Retail-Prices.html.*

We agree with the commenter that the NADAC files may not address the more complex and costly specialty pharmacy products. In regard to specialty pharmacies that have products primarily delivered through the mail, these pharmacies are not included in the NADAC survey at this time. However, specialty drug products purchased through retail community pharmacies are included in the NADAC files. If states choose to use the NADAC pricing files in their reimbursement methodologies, they will be responsible for determining AAC for specialty drugs dispensed through specialty pharmacies.

Comment: Several commenters stated that in the case of AMP, a transition to the buildup methodology has the potential to cause future AMPs to depart radically from their historical trends, and buildup AMPs should not be used as a benchmark for AAC.

Response: As discussed in more detail in the comments and responses in the Determination of AMP section (section

II.C.) of this final rule, we are not requiring manufacturers to use a buildup methodology to calculate AMP. Therefore, we believe this will satisfy the concerns raised by the commenter pertaining to the impact of a buildup methodology on AMPs as a benchmark for AAC.

Comment: We received many comments on the use of published compendia pricing, that is, AWP and WAC, and how these reference prices may help states to establish/maintain an AAC model of reimbursement. A few commenters opined that the states should not engage in time consuming costly re-survey efforts to adjust AAC when a brand manufacturer has a price increase nor should they be allowed to wait for new survey results if they are committed to a monthly survey process. Instead, the commenters recommended that states should contract with a drug pricing compendium to get real time updates. Other commenters requested that CMS provide for the continued use of pricing compendia benchmarks to determine AAC for single source products, referencing the October 2011 OIG report. Another commenter stated that their analysis of the relationship between acquisition cost and WAC is consistent with the OIG study, and compared WAC with AAC as collected by the state of Alabama for single source drugs and consistently found a strong correlation between the two benchmarks. Several commenters recommended the use of WAC, or WAC plus or minus a percentage, to determine AAC for single source drugs and multiple source drugs without a FUL because they claim WAC is currently used by many state Medicaid programs, readily available from commercial vendors, and updated on a daily basis.

Another commenter stated that an analysis of historical ingredient cost survey results available to many states establish that WAC is reasonable, and noted that WAC and AWP will likely still play a role in pharmacy reimbursement as there will be occasions where a drug product will not have an AAC. In these cases, the commenter suggested the use of WAC plus an appropriate multiplier to take into account the wholesaler's markup before a drug product is sold to a pharmacy. Another commenter stated that if AAC is not available, there must be an acceptable surrogate for interim pricing, and suggests that using an escalator such as the medical care component of the CPI for urban areas would provide a methodology for an EAC when AAC is not immediately available. One commenter stated that, at a minimum, WAC should be used until an AMP is submitted to CMS, similar to the current Part B methodology, which states that during the initial period when the prices for a drug are not sufficiently available from a manufacturer, the Secretary can base reimbursement off of the WAC. One commenter recommended that states should have the option of using WAC as an alternative to determine their reimbursement for single source drugs as some states may not believe the NADAC is appropriate for their state and may not have the resources to contract for their own AAC survey.

One commenter stated that several states currently base ingredient cost reimbursement on manufacturer reported (published compendia) data, and the commenter believed this is not the appropriate source for acquisition cost data. The commenter stated that pharmacies, not manufacturers, are in the best position to monitor and report the prices at which pharmacies acquire drugs, as wholesalers could be providing discounts or reselling to pharmacies at a premium.

Response: We note that this final rule is not designed to mandate state payment rates. We set aggregate upper limit requirements, and states have the authority to develop and support an AAC model of reimbursement. Reimbursement based on publish compendia pricing, such as the AWP or WAC, often fail to represent accurate purchase prices, especially given that they do not necessarily include the discounts and price concessions available in the marketplace. However, the state may use WAC to develop and support an AAC model of reimbursement, if the state can provide data to support a model of reimbursement using the WAC prices consistent with § 447.512(b) of this final rule.

We note that, in establishing NADAC file pricing, the WAC is used to update brand drug prices, and on a weekly basis, the NADACs for brand drugs are reviewed and adjusted if necessary based on changes in published prices. The NADAC pricing files, including the weekly changes to the NADAC files can be found at *http://www.medicaid.gov/medicaid-chip-program-information/by-topics/benefits/prescription-drugs/pharmacy-pricing.html.* Changes in published prices are measured as the relative percentage difference between the new published price and the previous published price. Therefore, if the published price for a drug increases by 5 percent, then the NADAC for that drug is also increased by 5 percent. The pricing change is then validated with survey data obtained from the next monthly survey, and adjusted, if necessary, according to those survey prices. The relationship between changes in published brand drug prices and changes in actual brand drug prices obtained from surveys are tracked and monitored to ensure that a consistent correlation continues to exist.

2. Reimbursement Based on AMP

The following comments pertain to pharmacy reimbursement based on AMP:

a. Comments Opposed to AMP as a Reimbursement Methodology

Comment: One commenter stated that the Affordable Care Act does not authorize the use of AMPs for single source drug reimbursement since the AMP data are confidential and proprietary and may not be disclosed. The commenter indicated that using AMP as a reimbursement metric is inappropriate since AMP is based on actual sales data and it is not and has never been a measure of pharmacies' drug acquisition costs. The commenter recommended that in the final rule, CMS retract this suggestion.

Response: We recognize that AMP is defined, in part, as the average price paid to the manufacturer for drugs in the United States by wholesalers for drugs distributed to retail community pharmacies and retail community pharmacies that purchase drugs directly from the manufacturer, and is therefore an indirect measure of pharmacy drug acquisition costs; however, we believe AMP-based pricing could be used by states as a method for setting reimbursement where a state can demonstrate that by adjusting AMP it will ensure that pharmacies are reimbursed at a price that reflects AAC. States would also need to address any confidentiality concerns in their SPA submission if the state chooses to use AMP-based prices for reimbursement.

AMP, which is addressed in detail in section II.C., is based on actual sales data and reported and certified by drug manufacturers on a monthly and quarterly basis. As discussed in the proposed rule (77 FR 5350), states that consider using AMP-based pricing as a reimbursement metric could determine the relationship between AMP and wholesaler markup, to cover the cost of distribution and other service charges by the wholesaler, to determine a reasonable reimbursement that would appropriately compensate pharmacies in accordance with the requirements of this final rule. As specified previously in this section, states are responsible for submitting SPAs with adequate data to

support any revisions to their current payment methodologies.

Comment: One commenter believed most manufacturers are sending in information incorrectly to CMS that results in AMP pricing that is flawed. The commenter believed the regulations are too confusing and the final results are AMPs that are below acquisition cost for both independent and chain pharmacies.

Response: In accordance with the requirements of section 1927(b)(3) of the Act and § 447.510, manufacturers are required to submit and certify the accuracy of all of the pricing data they report to CMS, including monthly and quarterly AMP data. We believe that the provisions in the Determination of AMP section (section II.C.) of this final rule, which pertain to the manufacturers' calculation of AMP, provide the needed clarity to ensure that manufacturers calculate their AMPs consistently. As discussed previously in this section, states which use AMP-based prices as a reimbursement methodology must ensure that pharmacies are reimbursed at a price that reflects AAC and is consistent with section 1902(a)(30) of the Act.

b. Confidentiality

Comment: One commenter stated that CMS has no statutory authority to make public individual AMPs for brand name or multiple source drugs. Thus, there should be no ability for states to use AMPs to set Medicaid reimbursement. Another commenter noted that AMP will likely not be an acceptable reimbursement metric for providers since AMP is not a publicly available price that is available to providers. AMP is always in arrears, and it is subject to retroactive restatement.

Another commenter stated that AMP data is confidential and proprietary and it is unclear how states could use AMP data to set publicly-available payment rates without disclosing proprietary information. The commenter stated that by law, the AMP data for individual single source drugs may not be disclosed. The commenter stated that not only would using AMP as a pharmacy reimbursement metric make it more difficult to establish an accurate AAC, but it would also contravene the statute. The commenter continued that the Federal Trade Commission and the CBO have both cautioned that disclosing confidential price information could have adverse effects, ultimately leading to higher prescription costs.

Response: In accordance with requirements of section 1927(b)(3)(D) of the Act, we have made AMP available through the DDR system for states only. Section 1927(b)(3)(D)(i) of the Act states, in part, that AMP may be disclosed as the Secretary determines it to be necessary to carry out section 1927 of the Act. Further, section 1927(b)(3)(D)(iv) of the Act permits disclosure of AMP data to states to carry out Title XIX; however, we remind states that such information is confidential and should not be disclosed in a form which discloses the identity of a specific manufacturer or wholesaler, or the prices charged for drugs by the manufacturer or wholesaler, except for certain exceptions. We believe that these provisions, when read together, permit states to use AMP-based pricing for purposes of pharmacy reimbursement; however, we further note that any disclosure concerning AMP must be addressed by the state during the SPA submission process. During the SPA process, the state must demonstrate how such disclosure of the AMP-based prices are consistent with the confidentiality requirements set forth by the statute and other applicable federal regulations and statutory requirements, including the requirement in section 1902(a)(30)(A) of the Act that payments be consistent with efficiency, economy and quality of care and sufficient to assure access.

c. CMS Appeals Process

Comment: One commenter recommended that CMS provide a formal appeals and resolution forum as this would provide an opportunity for stakeholders impacted by AMP to raise questions and receive timely consideration and resolution regarding their concerns involving AMP as a price paid in the market. The commenter further believed that AMP is not a price paid in the market and should not serve as a basis for AAC.

Response: Stakeholders should work directly with states in regard to their decision to use AMP-based pricing as a state reimbursement methodology since the states are responsible for determining the reimbursement methodology and providing public notice of any changes in reimbursement consistent with § 447.205. Further, we will continue to work with manufacturers to ensure that manufacturers are in compliance with their obligation to accurately report and certify pricing information.

Comment: Several commenters raised concerns regarding to use AMP in payment methodologies when CMS simultaneously proposes the use of a buildup methodology for calculating AMP, which commenters stated will almost certainly generate lower AMPs going forward and also cause greater fluctuation in those figures month-to-month. A few commenters also stated that AMP values do not reflect real time market prices and is not a price paid in the market to pharmacies; therefore, AMP is not a good reimbursement metric for AAC reimbursement to pharmacies. One commenter referenced OIG publication, ''Review of Drug Costs to Medicaid Pharmacies and Their Relation to Benchmark Prices,'' A–06–11–00002 (October 18, 2011), which reports that AMP had the least consistent relationship with pharmacy invoice prices and was not as consistent as the relationship between invoice prices and AWPs and WACs.

Response: As discussed in the OIG Report (A–06–11–00002), we recognize that AMP, along with AWP and WAC, were found to have pricing fluctuations and none of the benchmarks had consistent relationships with invoice prices for multiple source drugs without FULs. We disagree with the commenter regarding the option that states may calculate a reimbursement methodology using AMP-based prices. Manufacturers are required to report and certify monthly and quarterly AMP, calculated in accordance with the requirements of section 1927(k) of the Act. We recognize that AMPs are reported based on prior month's data, and that states will need to address that time lag in any SPA using AMP-based pricing while setting their reimbursement methodologies. We note that states have had longstanding processes in place to address and respond to reimbursement issues, and to the extent that pharmacy providers have concerns with payment amounts, they should address those concerns to the state, especially given that in accordance with § 447.205, public notice is required prior to any changes in the methods and standards for setting payment rates.

Comment: One commenter requested further clarification regarding how restatements of AMP would affect, if at all, AAC reimbursements; whether AAC would be based on monthly or quarterly AMP; how frequently would AAC change as a result of AMP changes; and how states would compare the AAC to a provider's U&C charges, and whether that comparison would consider that the AAC may be based on a calculation that contains lagged data. Another commenter requested that CMS provide guidance as to how states can apply AMP to drug prices and to further clarify whether CMS means AMP or weighted AMP.

Response: The questions regarding how states may choose to use AMP-based prices in their reimbursement

formulas should be addressed by the states in determining their respective reimbursement methodology. States must provide notice and opportunity for comment before implementing reimbursement changes, as required in the public notice provisions in § 447.205. We further note that this notice and comment opportunity will allow the stakeholders to raise any such concerns with the state.

d. Miscellaneous

Comment: One commenter stated that CMS should require states to demonstrate that both their brand name drug reimbursement, as well as the maximum allowable cost (MAC) lists for generics are justified based on state-based data and not permit states to make reductions in these MAC lists without justification to CMS. The commenter added that states should be required to demonstrate that their MAC methodology is based on community pharmacies costs of purchasing prescription drugs and also include a process by which such values are changed in a timely manner so that they are more transparent to the pharmacy.

Response: Provisions addressing the use of maximum allowable cost (MAC) lists are not addressed in this final rule.

Along with a SPA submission, states must also provide public notice of that change in accordance with § 447.205 prior to proposing any changes; therefore, the public notice process shall address any transparency concerns. States are not limited in regard to conducting retail pharmacy surveys and CMS is not finalizing any such requirement in this final rule. We further emphasize that states must establish rates that ensure beneficiary access in accordance with the requirements of section 1902(a)(30) of the Act. We also note that to the extent that pharmacies have concerns regarding the adequacy of the payment rates, they should present these concerns to the state.

Comment: One commenter believed that it is essential that AMP-based Medicaid reimbursement and the resulting FUL represent an accurate determination of retail pharmacy AAC since the reimbursement methodology may extend beyond Medicaid to private and commercial payers who may elect to adopt AMP as a pricing and reimbursement benchmark.

Response: Concerns regarding private and commercial payers are beyond the scope of this rulemaking. Private payers are not bound by regulations to use reimbursement methodologies established for the Medicaid program and we are not setting payment rates for such payers in this final rule.

3. Reimbursement for 340B Entities, IHS, Tribal, and Urban Indian Organization Pharmacies

The following comments pertain to pharmacy reimbursement for 340B entities, IHS, Tribal, and Urban Indian Organization Pharmacies.

a. IHS, Tribal, and Urban Indian Organizations (I/T/U)

Comment: Some commenters expressed specific concerns regarding the adequacy of any proposed changes to Medicaid reimbursements to I/T/U pharmacies. Commenters wanted to ensure that any changes made will not negatively impact their ability to deliver pharmaceutical services. For instance, one commenter noted that I/T/U pharmacies are generally smaller and located in remote areas where they serve a critical need for tribal communities. The commenter further noted that I/T/U pharmacies are more reliant on Medicaid reimbursement for dispensing CODs to cover higher overhead costs. Another commenter noted that a decrease in the reimbursement rates could result in some of these pharmacies having to close, which would threaten access to prescription drugs and pharmaceutical services for American Indians and Alaska Natives (AI/ANs) who live in some of the poorest and most remote areas of the country. The commenters also expressed concern about potentially losing the encounter rates by which some states reimburse I/T/U pharmacies. Specifically, the commenters feared that if states are allowed to impose AAC reimbursement methodologies on the pharmacy, it could cause the encounter rates to be lost, preventing the I/T/U pharmacies from using reimbursements at the encounter rates to subsidize all costs, including clinical care associated with the dispensing of outpatient drugs to AI/ANs within the I/T/U delivery health system. One commenter suggested that if I/T/U pharmacies are included in this proposed rule, CMS should create a mechanism that protects the interest of federal beneficiaries, AI/ANs, from arbitrary and capricious state action.

Response: We recognize there are unique aspects of dispensing CODs to AI/ANs by I/T/U pharmacies and understand the various concerns expressed through the regulatory comment process. The encounter rate is approved by the Office of Management and Budget (OMB) and published in the **Federal Register** every year. It is intended to be an all-inclusive average of all provider costs incurred by I/T/Us for the delivery of care for their patients. It is a uniform amount reimbursed to all I/T/Us by the state for the delivery of any service provided to any patient seen by the facility, irrespective of the nature of the care provided. Unlike AAC, which is defined in § 447.502, the encounter rate is more reflective of services provided and is not granular to the extent of identifying the ingredient cost of a drug. Therefore, if a state pays I/T/Us at the encounter rate, it will satisfy the requirements in § 447.518(a)(2), which specifies that the state's payments must be in accordance with the definition of AAC. We have determined that the encounter rate is one model that states may use to reimburse I/T/U pharmacies, given that the rates are designed to address provider costs. It was not our intent in the proposed rule to change the state's authority to reimburse I/T/U pharmacies using the encounter rate, and we believe that nothing in this final rule prevents states from using the encounter rate as a model to reimburse I/T/U pharmacies. We believe that as designed, the current CMS SPA review and approval process which requires states to obtain the advice and input from I/T/Us before making changes to Medicaid reimbursements to I/T/U pharmacies, before CMS approval of the SPA, provides sufficient oversight and input regarding states establishing such pharmacy rates.

b. Tribal Consultation

Comment: Several commenters expressed uncertainty about how CMS considers comments received during the Tribal consultation process. Commenters urged that CMS consult with tribes before changes in Medicaid pharmacy reimbursement for CODs with regard to I/T/U pharmacies are finalized. The commenters also stated the Tribal consultation process is a way to assure that the full effects of the proposed rule are well understood and is addressed in a way that is supportive of the Indian health programs.

Response: We agree that the Tribal consultation process is valuable in helping us to finalize policies and support Indian health programs. We obtained the advice and input of Tribal officials during the Tribal Technical Advisory Group (TTAG) face-to-face meeting in Washington, DC on February 23, 2012; and under Executive Order 13175 and the CMS HHS Tribal Consultation Policy (November 2011), we consulted with Tribal officials during an All Tribes' Call on March 16, 2012 and through the regulatory review process. In determining our final

policies and regulations, we considered all comments received before the close of the comment period (including comments received through Tribal consultations).

c. 340B Oversight

Comment: One commenter expressed concern about the role that drug manufacturers play in the oversight audits of 340B covered entities. The commenter further noted that 340B oversight is a governmental function that is the responsibility of OPA at HRSA.

Response: Currently, oversight of the 340B program is the responsibility of OPA at HRSA and beyond the scope of this rulemaking.

d. Orphan Drugs

Comment: Commenters expressed concern about the inability of certain 340B covered entities; that is, critical access hospitals, cancer centers, rural referral centers, and sole community hospitals, to purchase orphan drugs through the 340B program, stating that this is a hardship. They recommended that CMS change this policy so they can continue to provide valuable services to the underserved and underinsured populations they serve. Another commenter noted that it would be difficult for a manufacturer to determine if a drug that is sold through the 340B program is used as an orphan drug.

Response: This exclusion relating to orphan drugs under the 340B program is governed by section 340B(e) of the PHSA and is beyond the scope of this rulemaking.

e. Inpatient Drugs

Comment: Some commenters noted concern with the fact that the 340B program does not allow 340B covered entities to purchase 340B drugs for inpatient use. Commenters indicated that this is a hardship and asked CMS to reverse this policy.

Response: Currently, oversight of the 340B program is the responsibility of OPA at HRSA and is beyond the scope of this rulemaking.

f. Professional Dispensing Fee

Comment: Several commenters stated that CMS should provide guidance to states regarding dispensing fees paid to 340B covered entities. A few commenters expressed the view that the proposed rule, if properly implemented, would not only require states to present a rationale for their reimbursement policies, but also provide a vehicle for federal oversight and enforcement. One commenter noted that the state dispensing fees paid to 340B covered entities generally are inadequate, and asked CMS to use its authority under the existing regulation and under the proposed rule to approve the reimbursement methodology in a state's Medicaid state plan, to correct those deficiencies. Several commenters supported the requirement for states to formalize the 340B reimbursement methodology as part of their state plan, but recommended that the final rule specifically require states to document, as a condition of approval of their state plan, that their professional dispensing fee appropriately and fairly reimburses FQHCs (and other covered entities) for their cost in dispensing drugs to Medicaid beneficiaries. The commenter questioned whether current policy does, in fact, result in reasonable, cost-based reimbursement for 340B covered entities.

Response: We agree with the commenters that states must express the rationale for the reimbursement methodologies in their state plans as discussed in § 447.418(d).

We agree that there may be unique circumstances for 340B covered entities that states should consider when establishing their professional dispensing fees for these providers and that states must express the rationale for the reimbursement methodologies being proposed in their state plans. We also believe that it is important the providers are reimbursed adequately for the provision of care to beneficiaries. Therefore, we will require states to substantiate how their dispensing fee reimbursement to pharmacy providers, including 340B providers, is consistent with section 1902(a)(30)(A) of the Act. We note that states may decide to use different professional dispensing fee rates for different entities and providers. While we do not mandate any specific professional dispensing fee methodologies that states must use, states are required to provide data which indicates that the methodology is consistent with the regulation and ensures access.

g. Actual Acquisition Costs (AAC)

Comment: Several commenters supported CMS's proposal to pay 340B providers at their cost for 340B drugs as part of the implementation of AAC. One commenter recommended that CMS should require, as a condition of approval of a state's Medicaid plan, documentation that 340B covered entities are reimbursed fairly for services to Medicaid beneficiaries.

Response: In this final rule, we are revising § 447.518 by adding paragraph (a)(2) to specify that the state's payment methodology must be in accordance with the definition of AAC in § 447.502 of this final rule. We appreciate the commenter's support for our proposal that 340B covered entities be reimbursed for 340B drugs using methodologies consistent with our shift to AAC. We believe that our shift to AAC and the professional dispensing fee, including the new regulatory requirement at § 447.518(d) that states must provide adequate data which reflect the pharmacy's AAC as a basis to support any proposed change in ingredient cost reimbursement, address the concerns raised by the commenter regarding state's assurances of adequate reimbursement for 340B drugs.

The formula for calculating the 340B ceiling price is generally defined in section 340B(a)(1) of the PHSA as AMP minus the URA, and these data are available for states in DDR. AMP minus URA is then calculated by the Package Size to ultimately determine the 340B ceiling price paid. We are aware that 340B entities are often able to negotiate discounts below the statutory 340B ceiling price for 340B drugs. However, in consideration of the fact that information regarding these discounts (or subceiling prices) for 340B drugs may not be accessible to states, where states are unable to determine the prices at which 340B providers actually acquired their drugs, we would consider a methodology that reimburses at the statutory 340B ceiling price for the ingredient cost component of reimbursement in addition to an adequate professional dispensing fee to be compliant with the AAC payment criteria. We believe that if states reimburse 340B providers for the ingredient cost at their actual purchase price, then those providers must be adequately reimbursed a professional dispensing fee that is representative of the cost to dispense the drug. Specifically, the dispensing fee should not be earmarked as an offset for ingredient cost reimbursements set at AAC. Instead, it should reflect the pharmacist's professional services and costs associated with ensuring that possession of the appropriate COD is transferred to a beneficiary.

Additionally, we continue to encourage states to develop clear reimbursement policies for 340B covered entities in their state plans which detail measures that ensure that reimbursements will reflect the ingredient costs at their AAC and that providers will be reimbursed a professional dispensing fee. States will be required to submit SPAs consistent with the regulations, including those requirements in §§ 447.502 and 447.512 finalized in this rulemaking, detailing

how 340B covered entities are reimbursed for their 340B drugs, to the extent their approved state plans do not already include this information. State Medicaid agencies are encouraged to work with the covered entities in their states when setting appropriate reimbursement rates for both the ingredient cost and dispensing fees.

Comment: One commenter stated that it is unclear whether 340B prices would be included in the data underlying a state's pharmacy reimbursement system under the proposal to base Medicaid FFS reimbursement on a drug's AAC rather than its EAC. Another commenter stated that paying at the 340B price or AAC, whichever is higher, would be appropriate because many entities pay distributing fees to their wholesalers that effectively increase acquisition cost to above the 340B price.

Response: In this final rule, we are requiring states to establish their AAC-based pharmacy reimbursement methodologies such that pharmacy providers are reimbursed the ingredient cost reflective of the cost of a drug, as well as a professional dispensing fee, which is incurred at the point of sale or service. We encourage states to determine the existence of, or develop, clear reimbursement policies for 340B covered entities in their state plans.

Comment: One commenter noted that it is premature to require states to include 340B payment methodology in their Medicaid plan until HRSA shares 340B prices with states. The commenter stated that it would be illegal and irresponsible to presume to create policy outlining a state's payment methodology for 340B drugs without having the requisite pricing information from HRSA. The commenter continued that to determine the AAC paid by 340B entities, states would need to manually review invoice prices paid by each 340B entity on a regular basis which would be a burdensome and costly process. Until HRSA has provided the necessary tools to calculate pricing, the commenter recommended that CMS allow states to reimburse 340B entities based on the ceiling price, not the AAC.

Response: We understand that it may be burdensome and costly to review invoice prices paid by each 340B entity on a regular basis but states have a responsibility to set rates that reflect the acquisition costs of providers and are consistent with section 1902(a)(30)(A) of the Act. We would consider a methodology that reimburses at the statutory 340B ceiling price to be compliant with the AAC payment criteria in the event that the state is unable to establish or obtain data reflective of 340B providers' acquisition costs. The 340B ceiling prices are known to the states based on their access to the AMP and the URAs through the DDR system. The formula for calculating the 340B ceiling price is generally defined in section 340B(a)(1) of the PHSA as AMP minus the URA, and these data are available for states in DDR. AMP minus URA is then calculated by the Package Size to ultimately determine the 340B ceiling price paid. While these data will establish the ceiling price paid by 340B entities, as we noted earlier, in Manufacturer Release #85 (October 26, 2012), states should be aware and consider that these covered entities may have additional costs associated with dispensing these drugs compared to a retail pharmacy and also consider those dispensing costs when looking at overall payment to these covered entities. In accordance with section 1902(a)(30)(A) of the Act, a state must establish payments that are consistent with efficiency, economy and quality of care and are sufficient to enlist enough providers so that care and services are available. Thus, it is the responsibility of individual states to develop methodologies that ensure that pharmacy providers, including 340B entities, are reimbursed adequately for their provision of pharmacy services which include dispensing CODs.

Comment: One commenter noted that shifting to an AAC-based reimbursement would cause a hospital to reassess the value of the 340B program, as this change in policy would likely create significant administrative burden and extra cost. The commenter stated that one particular hospital fulfills the intent of the 340B program by reinvesting savings from pharmaceutical drugs back into the institution so more underinsured and uninsured receive the pharmaceutical treatments they need.

Response: We recognize the important role that 340B covered entities play in the provision of services to Medicaid patients and as key safety net providers. Further, we believe that 340B covered entities recognize the benefits of participating in the 340B program, which by definition, offers them access to CODs at federally-discounted prices.

Reimbursing providers based on the ingredient cost representative of the cost of the drug alone and a dispensing fee representative of the cost to dispense the drug to the patient is in keeping with section 1902(a)(30)(A) of the Act. We do not expect the implementation of AAC-based reimbursement would result in unrealistic administrative burdens being placed on the covered entities. Instead, we believe that states establishing a methodology that provides reimbursement based on costs would not lead to a reduced commitment by 340B covered entities, in part, because this shift to an AAC-based reimbursement model will ensure that 340B covered entities are provided with payment for their drugs consistent with Medicaid requirements.

h. Medicaid Carve-Out

Comment: One commenter stated that if CMS finalizes its proposal that states must move to an actual acquisition based reimbursement methodology, it is essential that CMS ensure 340B covered entities retain the flexibility to carve Medicaid in or out of their 340B programs. The commenter also noted that it is their understanding that some states are requiring that 340B providers carve out their Medicaid MCO drugs from their 340B programs so that the state may collect rebates on the MCO drugs used by 340B entities. The commenter stated that states were not given the authority under the statute to mandate a carve-in or carve-out for Medicaid and allowing them to do so thwarts the very purpose of the 340B program. The commenter further noted that few states have or are considering to ''double down'' on their restrictive reimbursement of FQHC's and other 340B covered entities by eliminating the ''carve-out'' option while at the same time allowing 340B covered entities to recoup only their 340B acquisition cost and the state's minimal dispensing fee. This could force FQHCs to close down its pharmacy. Another commenter opposed a policy that would require hospitals to carve out Medicaid managed care drugs as the effect would be a devaluation of the 340B program for the hospital by creating a significant administrative burden. The commenter stated that as a result, the intended effect of the 340B program is diluted.

Some commenters indicated that some states are not interpreting the 340B MCO exception in a manner compatible with the intent of the law and one of the commenters recommended that CMS prohibit states from requiring a 340B entity to carve out Medicaid MCO drugs. The commenter further requested that CMS create a mechanism that states can use to avoid collecting rebates on 340B MCO drugs. Another commenter indicated that the impact on their health plan, if they were required to carve-out drug costs, could negatively impact their budget and supported the creation of a pharmacy-friendly mechanism that states can use to prevent the collection of rebates on 340B MCO drugs.

Another commenter urged CMS to publicly reject the path taken by a particular state which enacted a law that prohibits 340B covered entities from carving out Medicaid drugs and requires them to bill and be reimbursed at no more than their 340B acquisition cost plus a dispensing fee that is far too low to cover the costs of serving this population.

Response: We recognize that states are examining the issue of the Medicaid carve-out in the context of the new authority to collect Medicaid rebates for MCO drugs and in the overall scheme of their 340B reimbursement methodologies. As discussed in prior responses, states have the responsibility to set payment rates for all CODs, including 340B drugs. States are also responsible for not submitting claims to manufacturers for rebates for drugs acquired under the 340B program, in accordance with section 1927(a)(5) of the Act.

i. MCO Rebates

Comment: One commenter supported CMS's proposal to explicitly exempt manufacturers from the requirement to pay rebates for CODs dispensed to individuals enrolled in Medicaid MCOs if such drugs are subject to discounts under the 340B program. The commenter appreciated CMS's proposal to require Medicaid MCOs to submit a data report to states within 30 days of the end of each quarter and in turn to require states to submit this information to manufacturers, with data for Medicaid MCO utilization carved out from the data pertaining to FFS utilization. The commenter believed that a more active exchange of information between 340B stakeholders will help ensure the integrity of both the Medicaid and 340B programs.

Response: As stated in this section, we are not finalizing the MCO reporting requirements that we proposed at § 447.509(b)(3). Instead, we will address the requirements for states with regard to the data they report to manufacturers, including the data pertaining to MCO utilization, at § 447.511.

Comment: One commenter stated that currently due to the lack of specific information, it is impossible for a 340B covered entity to manage Medicaid compliance where outpatient drug claims are processed through Medicaid MCOs. The commenter requested that CMS or HRSA's OPA publish Medicaid identifiers that are unique for each MCO that reports reimbursed drug units to states' Medicaid programs. The commenter continued that an official list of MCOs that reimburse Medicaid eligible claims, including each Medicaid Bank Identification Number (BIN) or Processor Control Number (PCN) could be published by CMS or HRSA's OPA. Where a unique MCO–BIN/PCN is unavailable, a unique Group ID would also be necessary. The commenter believed this would allow 340B covered entities to carve out drugs from 340B replenishment based on identification of Medicaid MCO reimbursement. The commenter noted that MCOs pose a significant challenge because claims are not linked to Medicaid Provider numbers and eligibility is frequently determined retroactively.

Response: Specific billing standards regarding BIN or PCNs are outside the scope of this final rule; however, we appreciate the concerns raised by the commenter and recognize the importance of ensuring that manufacturers do not pay rebates on drugs purchased the 340B program and dispensed through Medicaid MCOs. States are responsible for implementing billing requirements to identify 340B claims, which may include such options as HRSA's Medicaid Exclusion File or the NCPDP 340B Telecommunication Standards. We will continue to monitor this issue and decide about additional guidance, if needed.

Comment: One commenter believed that CMS's proposed policy to exclude 340B MCO drugs from the rebate program will have a huge impact on the little revenue that MCOs currently pay a particular county. The commenter believed that passing through the 340B cost to MCOs would be administratively burdensome to pharmacy operations.

Response: Section 1927(j) of the Act states in part that CODs are not subject to rebates if such drugs are dispensed through Medicaid MCOs and subject to 340B discounts. The details of the financial arrangements between MCOs and their 340B providers are beyond the scope of the final rule.

j. OIG Report

Comment: One commenter stated that there is limited transparency in the 340B and the FSS programs and as a result, states do not have access to the 340B prices paid by entities. The commenter cited the June 2011 OIG report—State Medicaid Policies and Oversight Activities Related to 340B-Purchased Drugs, which indicated that states do not have the necessary pricing information to create prepay edits for 340B drugs and recommended that HRSA share 340B ceiling prices with states. The commenter noted that while direct reporting of the ceiling prices through the drug pricing compendia would be helpful to states, it still would not provide the states with the data to determine AAC paid by any 340B covered entity. Commenters stated to determine the AAC for each entity regularly would be burdensome and a manual process for states.

Response: In accordance with the requirements of section 1902(a)(30)(A) of the Act and this final rule, states should determine a reasonable reimbursement that would appropriately compensate pharmacies including 340B covered entities. As stated in Manufacturer Release #85 (October 26, 2012), states should consider that 340B covered entities may have additional costs associated with dispensing drugs compared to a retail pharmacy and also consider those dispensing costs when setting their payment rates in accordance with the principles of AAC in this final rule. In consideration for the fact that information regarding discounts or subceiling prices for 340B drugs may not be accessible or determined by states, where states are unable to determine the prices at which 340B providers actually acquired their drugs, we would consider a methodology that reimburses at the statutory 340B ceiling price for the ingredient cost component of reimbursement in addition to an adequate professional dispensing fee to be compliant with the AAC payment criteria.

In requiring that states establish methodology consistent with AAC, we are not requiring that states determine the AAC for every drug dispensed by every pharmacy in their state. Rather, states can establish an AAC using aggregate data obtained based on surveys or other reliable data sources, and in the case of 340B covered entities, they can use the 340B ceiling price, given that these prices are generally representative of acquisition costs for such entities. Some covered entities (that is, tribal facilities), may be able to purchase CODs under the FSS and seek Medicaid payment. For states to determine AAC in these cases, they can access FSS pricing via the Department of Veterans Affairs Web site at *http://www.va.gov/oal/business/fss/pharmaceuticals.asp* and review files with drug pharmaceutical prices.

k. State Plan Requirements

Comment: One commenter stated that implementing the state plan requirement and the formal review process required for SPAs is an appropriate mechanism for CMS to exercise oversight to ensure that states are capturing the savings that result from the federal discounts available to 340B covered entities and IHS pharmacies. The commenter requested

that CMS extend these requirements to the documentation of the state's mechanism for ensuring compliance with the statutory prohibition on duplicate discounts which protects manufacturers from paying a Medicaid rebate on FFS or MCO utilization that is sourced through a 340B-priced unit. As an additional mechanism to ensure compliance with the statutory prohibition on duplicative discounts, the commenter requested that CMS encourage state Medicaid agencies to cooperate with manufacturer requests for data as needed to evaluate 340B covered entity compliance with this prohibition.

Another commenter noted that claims processing in 340B pharmacies are entirely different from claims processing in outpatient clinics, and each system requires a different mechanism for identifying 340B claims and excluding them from rebate requests. Therefore, the commenter encouraged CMS to require states to describe in SPAs their 340B duplicate discount prevention processes, including how the states require 340B pharmacies to identify 340B claims in the retail setting.

Response: We did not propose and are not finalizing a requirement that state plans include information on a state's activities associated with collecting rebates from manufacturers. However, we believe there are other appropriate mechanisms for identifying these claims, such as HRSA's Medicaid Exclusion File or the use of the NCPDP Telecommunication Standards to identify 340B claims. We will continue to consider the issue and decide about additional guidance, if needed.

Comment: One commenter noted that the proposed rule does not provide a deadline for a state to come into compliance with the 340B requirements proposed in this rule and suggested that the final rule should establish a specific deadline for states to amend their state plan to incorporate the features required under the regulation.

Response: States must submit a SPA to CMS not later than 4 quarters after the effective date of the final rule to revise its payment methodology for CODs. This includes the incorporation of the 340B requirements at § 447.518(a)(1).

Upon the effective date of this final rule, when proposing changes to either the ingredient cost reimbursement or professional dispensing fee reimbursement, states are required to evaluate their proposed changes in accordance with the requirements of this subpart, and states must consider both the ingredient cost reimbursement and the professional dispensing fee reimbursement when proposing such changes to ensure that total reimbursement to the pharmacy provider is in accordance with requirements of section 1902(a)(30)(A) of the Act. States must provide data to support proposed changes in reimbursement through the SPA process. Examples of such supporting data include, but are not limited to, a national or state survey of retail community pharmacy providers, or other reliable data other than a survey to support any proposed changes to either or both of the components of the reimbursement methodology.

l. Dispute Resolution

Comment: One commenter stated that manufacturers employ various back-end checks to attempt to identify 340B claims in Medicaid utilization files and go through Medicaid's dispute resolution process when a rebate is requested on 340B claims.

Response: We appreciate the comment and note that states and manufacturers are responsible for engaging in the process of dispute resolution in the MDR program to resolve duplicate discount issues. We have also provided best practices for states and manufacturers on our Web site at *http://www.medicaid.gov/Medicaid-CHIP-Program-Information/By-Topics/Benefits/Prescription-Drugs/Medicaid-Drug-Rebate-Program-Dispute-Resolution.html.*

Comment: One commenter noted that a national dispute resolution forum would better serve Medicaid programs, 340B entities, and drug manufacturers. The commenter recommended that CMS implement a nation-wide dispute resolution program for drug manufacturers that do not provide 340B prices as required.

Response: We appreciate the comment; however, we did not propose and therefore, are not finalizing, any requirement concerning a national dispute resolution forum and believe that such a forum is beyond the scope of this rule. Manufacturers should continue to contact states and HRSA, if applicable, for issues concerning 340B prices.

m. Shared Savings

Comment: Several commenters requested that CMS consider allowing states to enter into shared savings arrangements with 340B covered entities. The commenter noted that under these arrangements, the states create an incentive for 340B providers to dispense 340B drugs to Medicaid patients, which benefits the state Medicaid programs, Medicaid patients, and the 340B providers. The commenters claim that shared savings arrangements also promote access to care.

Response: We believe that to the extent that covered entities have a higher cost of dispensing these drugs, we recognize that states have the flexibility of establishing a higher dispensing fee for 340B providers. Further, to the extent that covered entities incur costs associated with acquisition of 340B drugs, states can appropriately reflect these costs in establishing their reimbursement methodology for the cost of 340B drugs. We believe it is appropriate to apply the AAC provisions consistently to all Medicaid pharmacy providers including those that acquire drugs through the 340B program. States should consider that certain pharmacy providers may have differing costs to dispense or different acquisition cost for 340B drugs. Further, while care/disease management services cannot be reimbursed through the pharmacy reimbursement methodology, states can chose to pay for such services through other Medicaid service categories.

Comment: One commenter asked CMS to provide guidance to states in developing clear policies with regard to 340B drug purchases, as well as encourage states to develop shared saving programs with 340B providers, such as hemophilia treatment centers. The commenter noted that states should be given the flexibility to negotiate both the drug ingredient cost component and professional dispensing fee in a different manner that what is being done for other drugs; this is especially important for a shared savings program for hemophilia. The commenter continued that while the 340B drug prices can provide significant savings to the state, they need to be assured that it can adequately cover the significant cost of dispensing, distribution, and clinical pharmacy services. Some commenters stated that CMS should provide guidance as to what unique circumstances might support a differential professional dispensing fee and how the magnitude of those fees may be determined because not doing so would likely undermine the states' vision when pursuing shared savings models that benefit the government as well as patients.

Response: As noted in this section, we are requiring states to submit their 340B reimbursement methodologies and professional dispensing fee proposals to CMS through the Medicaid SPA process. We will consider all proposals, including those that may establish a different payment to hemophilia

treatment centers, and review them in accordance with the provisions of this final rule.

n. Duplicate Discounts

Comment: One commenter applauded CMS for recognizing the need to create mechanisms by which 340B entities and states (including their Medicaid MCOs) can satisfy their duties to prevent duplicate discounting.

Response: We appreciate the support.

Comment: One commenter noted that the discussion in the preamble to the proposed rule following Medicaid carve-out is misleading as it states that covered entities are not allowed to seek payment for 340B drugs from Medicaid. The commenter stated that covered entities are allowed to seek payment for 340B drugs if they follow state guidelines that result in the state not seeking rebates from the manufacturers for those 340B drugs dispensed to Medicaid patients. The commenter stated this needs to be clarified so that states and insurers do not develop policies based on erroneous information. Another commenter stated that CMS should adopt requirements to prevent duplicate discounts on Medicaid reimbursed drugs purchased under the 340B program. The commenter stated that they are concerned about the high level of risk that exists for duplicate discounts, which can occur when a COD is purchased at 340B prices and also claimed for a Medicaid rebate. The commenter further recommended that CMS require state Medicaid programs to develop effective systems to assume responsibility for ensuring that drugs purchased at 340B prices are not included on Medicaid rebate invoices, add new pharmacy and 340B identifiers to the list of required data elements for Medicaid rebate claims, provide claims-level Medicaid rebate data in a common format, and apply similarly-effective reporting requirements for drugs purchased by non-pharmacy providers.

One commenter supported transparency of reimbursement rates to all providers, but was particularly concerned with understanding the processes by which states eliminate 340B utilization from their rebate requests so as not to request a duplicate discount.

Several commenters were concerned that the proposed methodology and the information to be reported are not sufficient to prohibit duplicate discounts. The commenter stated that none of the proposed information in the MCO utilization reports would help identify products that were subject to 340B pricing and therefore alert the state that Medicaid rebates should not be sought for these products. The commenter also urged CMS to require that the MCO utilization report contain data that will clearly identify when a product was subject to a discount under the 340B program so that MCOs, CMS, states, and manufacturers can easily and clearly identify 340B priced products and ensure that Medicaid rebates are not requested nor paid for such products.

Response: We want to clarify that 340B covered entities may seek Medicaid reimbursement for 340B drugs dispensed to Medicaid beneficiaries. As noted in the June 2011 OIG report, we recognize that states use a variety of methods to ensure against duplicate discounts, including HRSA's Medicaid exclusion file and the claim identifiers developed by NCPDP. We further note that HRSA's OPA sets forth the guidance that covered entities must follow with regard to compliance with the requirements of the 340B program.

We did not propose any specific requirements in this final rule regarding the submission of claims level data in rebate invoices states send to manufacturers; however, we encourage states and 340B entities to work together to ensure they take necessary measures to prevent duplicate discounts. At this time, we have not finalized requirements concerning the need to include 340B identifiers in the list of required data elements for Medicaid rebate claims since each individual state is responsible for establishing billing instructions necessary to identify 340B claims. In addition, we are not requiring that states include 340B identifiers on rebate invoices given the prohibition on states seeking Medicaid rebates on drugs purchased through the 340B program.

While we encourage states and manufacturers to work cooperatively in verifying these rebate claims, we believe those actions are best handled at the state level and do not plan to add further reporting or auditing mechanisms at the federal level at this time.

Comment: Some commenters asked CMS to take a stronger stance and establish a specific standard or set of requirements that states must follow to avoid requesting a Medicaid rebate on a drug that was purchased under the 340B program. For instance, one commenter suggested that CMS could require Medicaid MCOs to collect individual prescription numbers and pharmacy ID numbers in NCPDP format for 340B drugs dispensed to Medicaid enrollees, and that Medicaid MCOs should make such information available to manufacturers. Another commenter suggested that the NCPDP claim identifier could be a useful tool for preventing duplicate discounts.

One commenter acknowledged that the NCPDP 340B identifier is not in wide use today, but believed it is within CMS's discretion to require participants in the Medicaid pharmacy program to include this identifier. The commenter stated that further data sharing is needed to ensure compliance with the 340B statute so that Medicaid receives the benefit of the 340B prices and that manufacturers are not forced to pay deep discounts twice on the same prescription. The commenter believed that to eliminate the double discounting, states would need patient de-identified, specific, prescription level information, including claim level data for both MCO and Medicaid FFS prescriptions, instead of just the aggregate-level data shared under the proposed rule. These additional data fields would allow for verification that the data has been properly screened for duplicate discounts.

Response: We appreciate the concerns raised by the commenter and recognize the importance of preventing duplicate discounts on drugs purchased through the 340B program. As noted previously in this section, states and manufacturers should continue to work together in verifying claims with potential duplicate discount issues. We did not issue specific requirements concerning such issues, but we will continue to consider these concerns and issue future rules or guidance, if needed.

Comment: One commenter stated that most FQHCs, as well as many other 340B covered entities, do not have in-house pharmacies and instead rely on contract pharmacies, which promote access to pharmacy services, enhance patient care, and makes medication management easier and more effective. The commenter suggested that the final rule should require states to implement a payment methodology, incorporated in the Medicaid state plan, under which FQHCs (and other covered entities) can use a contract pharmacy to dispense 340B drugs to Medicaid patients. The commenter indicated that current HRSA guidance prohibits the use of a contract pharmacy unless the pharmacy has a method in place to prevent a manufacturer from paying a rebate on 340B drugs but states have not been eager to entertain proposals from FQHCs to implement such methods. The commenter requested that CMS should require states to establish methods for preventing duplicate discounts and contract pharmacy arrangements as a matter of patient care.

Response: It is a covered entity's choice whether to use a contract

pharmacy. We encourage states to work with a covered entity that seeks to enter into a contract with a contract pharmacy so the state can be assured that the entity appropriately reports 340B claims.

Therefore, after considering the comments and for the reasons discussed in this section and in the proposed rule, we are finalizing the provisions of § 447.518 State plan requirements, findings and assurances, but making the following revisions in response to comments and for the reasons discussed in detail in this section:

- We are revising § 447.518 by renumbering § 447.518(a) to add a new paragraph (a)(2) to specify that the state's payment methodology described in paragraph (a)(1) must be in accordance with the definition of AAC in § 447.502.
- Because of the renumbering configuration, proposed § 447.518(a)(1), (2), and (3) are being renumbered and finalized as § 447.518(a)(1)(i), (ii), and (iii) respectively.
- We are revising § 447.518(d) to provide that, when states are proposing changes to either the ingredient cost reimbursement or professional dispensing fee reimbursement, they are required to evaluate their proposed changes in accordance with the revised requirements of this subpart, and states must consider both the ingredient cost reimbursement and the professional dispensing fee reimbursement when proposing such changes to ensure that total reimbursement to the pharmacy provider is in accordance with requirements of section 1902 (a)(30)(A) of the Act. States must provide adequate data such as a state or national survey of retail pharmacy providers or other reliable data other than survey data to support any proposed changes to either or both of the components of the reimbursement methodology. States must submit to CMS the proposed change in reimbursement and the supporting data through a SPA through the formal review process.
- We are removing the words ''of this subpart'' from the proposed regulatory text of § 447.518(b) as the reference is not necessary as given the regulatory citations.

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

In the regulatory text of the proposed rule (77 FR 5367), we proposed to retain the current § 447.520 (FFP: Conditions relating to physician-administered drugs) without modification. We received the following comment specific to this section.

Comment: One commenter indicated that the proposed language relating to physician-administered drugs provides that FFP would not be available when a state has not required the submission of NDC codes necessary for rebates. The commenter stated that the requirement does not make sense for drugs administered by 340B entities, since 340B entities are not allowed to invoice these drugs for rebate. The commenter requested that FFP still be available for 340B physician-administered drugs, even without the collection of NDC codes.

Response: The application of the physician-administered drug provisions to 340B entities is beyond the scope of this final rulemaking.

We received no other relevant comments to this section. Accordingly, we are finalizing § 447.520 (FFP: Conditions relating to physician-administered drugs) without modification.

O. Optional Coverage of Investigational Drugs and Other Drugs Not Subject to Rebate (§ 447.522)

We proposed to add § 447.522 to clarify that states may, at their option, provide coverage of investigational drugs and may only pay for and receive FFP for these drugs when they are reimbursed in accordance with FDA final rules 21 CFR part 312 and 316 as amended by the final rules published in the August 13, 2009 **Federal Register**, ''Charging for Investigational Drugs Under an Investigational New Drug Application'' (74 FR 40872), and ''Expanded Access to Investigational Drugs for Treatment Use'' (74 FR 40900), and when the state specifies in their state plan that they are providing this coverage (77 FR 5351 and 5367). We also proposed adding a provision to allow for the coverage of other non-CODs, as there are other items that may also be covered as prescribed drugs or products under section 1905(a)(12) of the Act, such as whole blood products (77 FR 5367). This proposal is discussed in more detail at 77 FR 5351 of the proposed rule. We received the following comments concerning the optional coverage of investigational drugs and other drugs not subject to rebate.

Comment: One commenter stated appreciation for giving states the option to cover investigational drugs but wondered whether this action might deter manufacturers from seeking FDA approval.

Response: We do not believe this will deter manufacturers from seeking FDA approval as Investigational drugs must be approved by FDA under an Investigational NDA for the manufacturer to begin the process of clinical drug trials and otherwise follow the approval process as designated by FDA at 21 CFR parts 312 and 320. When the manufacturer submits an Investigational NDA, it has initiated the process of seeking an NDA from FDA for its drug to be eligible to be marketed to the general public. FDA approval will allow the manufacturer to report the drug to CMS as a COD. Therefore, we do not believe that allowing Medicaid agencies to choose to cover investigational drugs will deter the manufacturer from seeking approval from FDA to market to the general public.

Comment: One commenter stated that it seems contradictory that CMS would allow a state to cover an investigational drug not yet approved by FDA, while limiting the definition of ''CODs'' to medically accepted indications.

Response: We do not agree. States may cover drugs, other than those drugs which meet the definition of CODs under section 1905(a)(12) of the Act. This includes drugs subject to an investigational new drug application (IND) that has been allowed by FDA to proceed. To clarify this point in the regulatory text, we are revising proposed § 447.522(a) to remove ''has been indicated by FDA for human trials'' and replace with ''when such drug is the subject of an investigational new drug application (IND) that has been allowed by FDA to proceed.'' To further clarify this point in the regulatory text, we are also revising proposed § 447.522(d) to specify that Medicaid coverage of other drugs may be provided, at state option if they are not eligible to be covered as CODs in the Medicaid Drug Rebate program. The revisions to proposed sections § 447.522(a) and (d) are technical and clarifying edits that are not intended to change the meaning of the provisions.

Comment: One commenter stated that the cost of investigational drugs should be the responsibility of the manufacturer or the entity conducting the study and not by government programs.

Response: This issue is outside the scope of this rulemaking.

Comment: One commenter urged that this rule be finalized as it gives states flexibility to cover new products and new treatment indication, thus enabling patients with conditions that are unresponsive to currently approved therapy or for which there are no current therapies, crucial access to innovative treatment.

Response: We appreciate this comment.

After considering the comments, and for the reasons we discussed in this section and in the proposed rule, we are finalizing the provisions at § 447.522, with the following revisions that do not change the substance of the proposed language.

- At § 447.522(a) we are replacing ''has been indicated by FDA for human trials'' to ''is the subject of an investigational new drug application (IND) that has been allowed by FDA to proceed'' because the terminology is not technically accurate in its representation of how FDA allows for the use of investigational drugs and is not intended to change the meaning of the provision.
- At § 447.522(c), we are removing reference to 21 CFR part 316 as it is specific to orphan drugs, which at the time that the proposed rule was drafted, was not yet finalized. We are also simplifying the structure of the paragraph. This is not intended to change the meaning of the provision.
- We are not finalizing the proposed language at § 447.522(d) about being listed electronically with FDA given that, as discussed previously in the definition of COD at section II.B. of this final rule, we are not finalizing such a requirement under the definition of COD.
- We are clarifying at § 447.522(d), that Medicaid coverage of other drugs may be provided, at state option if they are not eligible to be covered as CODs in the MDR program.

III. Collection of Information Requirements

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

In the February 2, 2012, proposed rule (77 FR 5318) we solicited public comment on each of these issues for the following information collection requirements (ICRs). Comments were received and have been summarized below along with our response.

Based on internal review and the most current data, we have revised our estimated number of drug manufacturers that participate in the MDR program from 600 to 610. We have also revised our cost estimates by using the most current U.S. Bureau of Labor Statistics' wage estimates. Additional changes are discussed, where applicable, throughout this Collection of Information section.

A. Wage Estimates

To derive average costs, we used data from the U.S. Bureau of Labor Statistics' May 2014 National Occupational Employment and Wage Estimates for all salary estimates (*http://www.bls.gov/oes/current/oes_nat.htm*). In this regard, Table 1 presents the mean hourly wage, the cost of fringe benefits (calculated at 100 percent of salary), and the adjusted hourly wage.

TABLE 1—HOURLY WAGE ESTIMATES

Occupation title	Occupation code	Mean hourly wage ($/hr)	Fringe benefit ($/hr)	Adjusted hourly wage ($/hr)
Business Operations Specialist	13–1199	35.10	35.10	70.20
Computer System Analysts	15–1121	41.98	41.98	83.96
General & Operations Managers	11–1021	56.35	56.35	112.70
Lawyers	23–1011	64.17	64.17	128.34
Operations Research Analysts	15–2031	39.88	39.88	79.76
Training & Development Managers	11–3131	53.38	53.38	106.76

As indicated, we are adjusting our employee hourly wage estimates by a factor of 100 percent. This is necessarily a rough adjustment, both because fringe benefits and overhead costs vary significantly from employer to employer, and because methods of estimating these costs vary widely from study to study. Nonetheless, there is no practical alternative and we believe that doubling the hourly wage to estimate total cost is a reasonably accurate estimation method.

B. ICRs Carried Over From the February 2, 2012, Proposed Rule

1. ICRs Regarding ''Covered Outpatient Drug'' Definition (§ 447.502)

For CMS to be able to verify that reported products meet the definition of ''covered outpatient drug'' in § 447.502, this rule requires that drug manufacturers must report the FDA application number (issued by FDA when the product is approved) and, if applicable, the COD status code as part of their product data information via DDR for each product.

In the proposed rule, drug manufacturers would have been required to submit evidence demonstrating that the product meets the definition of a COD if the product does not have an FDA application number (77 FR 5323). Based on public comments (see section II.B.9. of this final rule) we revised this provision such that this final rule clarifies that drug manufacturers may submit evidence supporting whether the product meets the definition of a COD by way of reporting the COD status for each of their products.

For instance, if the product does not currently have an FDA application number, we will accept the COD status as evidence demonstrating that the product is otherwise a COD. The FDA application number and COD status should not be difficult for the drug manufacturer to determine since the drug manufacturer should already know the FDA application number when the product was approved by FDA, or the reason it qualifies as a COD, if there is no application number.

The requirements and burden to report the FDA application number and, if applicable, the COD status code are approved by OMB under control number 0938–0578 (CMS–367). Although the requirements and burden were set out in the February 2, 2012, proposed rule, the ICR was submitted to OMB for review and approval (April 11,

2014; 79 FR 20209) under our authority in section 2503 of the Affordable Care Act, section 1927(k)(2) of the Act, and section 202 of the Education Jobs and Medicaid Assistance Act. This was noted in that package's Supporting Statement.

2. ICRs Regarding the Identification of 5i Drugs (§ 447.507)

In § 447.507, drug manufacturers are required to identify—for the purpose of calculating AMP—inhalation, infusion, instilled, implanted, and injectable drugs (5i), when not generally dispensed through retail community pharmacies. Using the methodology described at § 447.504 and under section II.C.7. of this final rule, a drug manufacturer is required to identify and determine the AMP of these drugs. We estimate that these requirements apply to approximately 610 drug manufacturers that participate in the MDR program. The burden associated with the initial reporting of the 5i drugs is the time and the effort it takes each drug manufacturer to identify these drugs using reasonable assumptions as described earlier in section II.C.7. of this final rule.

Section II.C.7. of this final rule, sets forth our understanding that each drug manufacturer should be knowledgeable about how its drugs are administered; therefore, we are not finalizing the requirement that drug manufacturers use the Route of Administration list we proposed (77 FR 5334). Instead, drug manufacturers will have the flexibility to determine whether their drug is a 5i drug based on reasonable assumptions and use any resource that they deem appropriate to make their assumptions. While such assumptions must be consistent with the requirements and intent of section 1927 of the Act and with federal regulations, a written or electronic record outlining these assumptions must be maintained by the drug manufacturer. Once the drug manufacturer has established its initial list of 5i drugs, it is required (on a monthly basis) to determine which of those drugs are not generally dispensed through a retail community pharmacy.

The burden for the one-time reporting requirement for all drug manufacturers to identify 5i drugs and the ongoing monthly burden to report whether the 5i drugs are not generally dispensed through a retail community pharmacy to CMS through the DDR system are approved by OMB under control number 0938–0578 (CMS–367). Although the requirements and burden were set out in the February 2, 2012, proposed rule, the ICR was submitted to OMB for review and approval (April 11, 2014; 79 FR 20209) under our authority in section 1927(k) of the Act, as revised by section 2503 of the Affordable Care Act and section 202 of the Education Jobs and Medicaid Assistance Act. This was noted in that package's Supporting Statement.

As noted in section II.C.7. of this final rule, based on comments received, we have revised proposed § 447.507(b)(2) by removing the reference to a quarterly basis. In accordance with § 447.507(b)(1) of this final rule, the drug manufacturer is required to determine whether the percentage of sales for the 5i drugs has met the threshold to be considered not generally dispensed through a retail community pharmacy only on a monthly basis. We estimate that it will take a Computer System Analyst 5 hours at $83.96/hr, a General and Operations Manager 5 hours at $112.70/hr, a Training and Development Manager 10 hours at $106.76/hr, and an Operations Research Analyst 10 hours at $79.76/hr for each drug manufacturer to identify which 5i drugs are not generally dispensed through a retail community pharmacy and report the status to CMS. This equates to an annual burden of 360 additional hours (30 hr/response x 12 responses/year) per drug manufacturer. In aggregate, we estimate 219,600 hours (610 drug manufacturers participating in the MDR program × 360 hr) at a cost of $20,851,020. The requirements and burden estimates will be submitted to OMB for approval under control number 0938–0578 (CMS–367).

We received the following PRA-related comments regarding the identification of 5i drugs. A summary of the comments along with our response follow.

Comment: Several commenters noted that our estimates associated with a drug manufacturer's burden to identify 5i drugs and determine whether such drugs are not generally dispensed through retail community pharmacies were low. In particular, commenters noted that it would take 40 hours per month to perform a manual analysis regarding which drugs are subject to the 5i AMP methodology, which they believe is equivalent approximately to one-fourth of work time of a full-time employee. Another commenter noted that it would cost approximately $150,000 per year for drug manufacturers to identify 5i drugs including those not generally dispensed through retail community pharmacies, which is the cost for one additional full-time employee.

Response: In the proposed rule, we estimated that it would take 20 hours per response with 16 responses per year for each drug manufacturer to identify which 5i drugs are not generally dispensed through a retail community pharmacy. Because we received comments noting that our estimate was low, and we received a specific comment estimating that it would take 40 hours per drug manufacturer to perform the analysis for this requirement, we decided to increase our burden estimate from 20 to 30 hours monthly per response for drug manufacturers to identify which 5i drugs are not generally dispensed through a retail community pharmacy and an additional 1.0 hour per month for drug manufacturers to report this information to CMS. Given the comments received and the need to increase our estimate from 20 hours, we believe this revised estimate is sufficient and appropriate as it is halfway between our original estimate and the specific comment that we received. The requirement and burden estimate for performing this analysis will be submitted to OMB under control number 0938–0578 (CMS–367).

3. ICRs Regarding Medicaid Drug Rebates (§ 447.509)

Under § 447.509(a)(4), drug manufacturers participating in the rebate program that have line extension drugs are required to compute an alternative rebate calculation for certain drugs. To compute the alternative rebate calculation for a line extension drug of a brand name that is an oral solid dosage form, the drug manufacturer must first identify the line extension drug and the initial brand name listed drug that has the highest additional rebate ratio (calculated as a percentage of AMP) for any strength of the initial brand name listed drug. Drug manufacturers also must calculate the URA for the line extension drug on a quarterly basis. However, as discussed in sections II.B. and II.G. of this final rule, at this time we are not finalizing the regulatory definition of a line extension drug. Instead, manufacturers will rely on the statutory definition of line extension at section 1927(c)(2)(C) of the Act and, where appropriate, are permitted to use reasonable assumptions in their determination of whether their drug qualifies as a line extension drug. Additionally, as discussed in section II.G. of this final rule, we are finalizing the requirements of § 447.509(a)(4)(i), which specifies the rebate calculation requirements for line extension drugs, and we are also finalizing revised § 447.509(a)(4)(ii) to require the alternative rebate be calculated if there is a corporate relationship between the manufacturer of the line extension drug and the

manufacturer of the initial brand name listed drug. Therefore, we provide the following estimates regarding the reporting of line extension drugs to CMS for the purposes of calculating rebates for line extension drugs.

We estimate that this requirement affects the approximately 610 drug manufacturers participating in the MDR program. The one-time burden associated with the reporting of the Line Extension Drug Indicator is the time and effort it will take each drug manufacturer to identify whether each drug is a line extension product.

We estimate that it will take a Computer System Analyst 10 hours at $83.96/hr, a General and Operations Manager 5 hours at $112.70/hr, a Training and Development Manager 1 hour at $106.76/hr, and an Operations Research Analyst 10 hours at $79.76/hr (for a one-time total cost of $2,307.46 across all four positions) to complete the reporting of the Line Extension Drug Indicator. The one-time burden for the 610 drug manufacturers participating in the MDR program is estimated to be 15,860 hours (610 drug manufacturers × 1 response) with a cost of $1,407,550.60. The requirements and burden estimates will be submitted to OMB for approval under control number 0938–0578 (CMS–367).

In addition, for the drugs that have been determined to be a line extension product, the burden associated with the quarterly reporting of the initial brand name listed drug and the line extension drug is the time and effort it takes each drug manufacturer to calculate the URA for the line extension drug.

We estimate that it will take a Computer System Analyst 5 hours at $83.96/hr, a General and Operations Manager 5 hours at $112.70/hr, a Training and Development Manager 5 hours at $106.76/hr, and an Operations Research Analyst 5 hours at $79.76/hr to complete the new reporting requirements to calculate the URA for the line extension drug on a quarterly basis. The annual burden for the 610 drug manufacturers participating in the MDR program is estimated to be 48,800 hours (610 drug manufacturers × 20 hr/response × 4 responses/year) with a cost of $4,675,528. The requirements and burden estimates will be submitted to OMB for approval under control number 0938–0578 (CMS–367).

As discussed in the preamble to the proposed rule (77 FR 5319), section 2501(c) of the Affordable Care Act amended section 1903(m) of the Act by specifying new conditions for MCO contracts, including that CODs dispensed to individuals eligible for medical assistance under Title XIX of the Act who are enrolled with a Medicaid MCO shall be subject to the same rebate required by the rebate agreement authorized under section 1927 of the Act.

Section 447.509(b) adds requirements that drug manufacturers pay rebates for drugs dispensed to individuals enrolled in Medicaid MCOs. It also requires that states remit to the federal government the amount of the savings resulting from the increases in the rebate percentages. States are required to report the total quarterly rebate offset amount (on the CMS–64 form) that they are remitting to the federal government for the FFS rebates they currently receive from drug manufacturers and for the Medicaid MCO rebates they will receive from drug manufacturers. The information collection requirements and burden associated with CMS–64 are approved by OMB under control number 0938–1265 (CMS–10529). Since this final rule does not impose any new or revised burden or reporting or recordkeeping requirements concerning CMS–64, a revised PRA package is not applicable.

We received the following PRA-related comments regarding Medicaid drug rebates. A summary of the comments along with our response follow.

Comment: A few commenters from organizations representing states indicated that the cost associated with the collection of Medicaid MCO rebates on states appears to be underestimated. One of the commenters stated that the cost to states for collecting Medicaid MCO rebates could be more than $400,000 annually, but will vary from state to state. Another commenter stated that CMS's estimate of costs associated with the collection of Medicaid MCO rebates was underestimated by approximately $100,000 annually.

Response: As discussed in preamble section II.G.3., we are not finalizing the Medicaid MCO reporting requirements that were proposed under § 447.509(b)(3). Instead, we address the requirements for states with regard to the data they report to drug manufacturers, including the data pertaining to Medicaid MCO utilization, under § 447.511. The ICRs and burden associated with the state invoice and state utilization data reporting associated with Medicaid MCO rebates within the MDR program for the current state Medicaid programs is approved by OMB under control number 0938–0582 (CMS–368 and CMS–R–144).

4. ICRs Regarding Requirements for Manufacturers (§ 447.510)

Consistent with § 447.510, drug manufacturers currently must report (electronically) product and quarterly pricing information to CMS not later than 30 days after the end of the rebate period. Monthly pricing and units are due no later than 30 days after the end of the month. In addition, customary prompt pay discounts and nominal prices must be reported quarterly.

This final rule significantly revises the definitions of AMP and best price. Consequently, drug manufacturers must reconfigure their pricing systems to correctly calculate AMP and best price. In addition, drug manufacturers must submit the total number of units that are used to calculate the monthly AMP. The burden associated with these new requirements is the time and effort it takes a drug manufacturer to reconfigure its pricing systems to correctly calculate AMP and best price before it can submit the required data to CMS.

We estimate that these requirements affect the approximately 610 drug manufacturers in the MDR program. We estimate it will take a Computer System Analyst 400 hours at $83.96/hr, a General and Operations Manager 180 hours at $112.70/hr, a Training and Development Manager 180 hours at $106.76/hr, a Lawyer 40 hours at $128.34/hr, and an Operations Research Analyst 400 hours at $79.76/hr to complete the new requirements concerning the changes to AMP and best price definitions. In aggregate, the one-time total burden for the 610 drug manufacturers participating in the MDR program is estimated to be 732,000 hours (610 drug manufacturers × 1,200 hr/drug manufacturer) at a cost of $67,175,884. The requirements and burden estimates will be submitted to OMB for approval under control number 0938–0578 (CMS–367).

In addition to the one-time burden of reconfiguring pricing systems, based on comments received, we now estimate a one-time start-up cost to include the cost of training drug manufacturer staff on the new, reconfigured pricing systems. To complete this task, we believe it will take a General and Operations Manager 600 hours at $112.70/hr, a Training and Development Manager 1,700 hours at $106.76/hr, and an Operations Research Analyst 1,700 hours at $79.76/hr. In aggregate, the one-time total burden is estimated to be 2,440,000 hours (610 drug manufacturers × 4,000 hr/drug manufacturer) at a cost of $234,669,440. The requirements and burden estimates will be submitted to OMB for approval under control number 0938–0578 (CMS–367). Once the pricing systems have been reconfigured, there should be no additional burden in time or effort other than that which already exists.

Drug manufacturers are required to pay a 17.1 percent rebate on innovator drugs identified as approved by the FDA exclusively for a pediatric indication. There are currently only nine manufacturers that have identified such drugs to CMS within the first 5 years since this statutory requirement became effective. Therefore, we believe very few drug manufacturers will pay the 17.1 percent rebate based on the number of drug manufacturers that have identified such drugs to CMS. We also believe drug manufacturers will be able to easily identify such drugs based upon this final rule's definition of pediatric indication at § 447.502. Therefore, the requirement that drug manufacturers identify such drugs and pay the 17.1 percent rebate on drugs approved exclusively for pediatric indications does not add a measurable burden to drug manufacturers.

In section II.B.9. of this final rule, we discuss that manufacturers of certain drugs may choose to seek an exception to the requirement that drugs approved under an NDA, other than an ANDA, must be reported to the MDR program as single source or innovator multiple source drugs. We indicate that in such cases, for drugs that are reported to the MDR program prior to the effective date of the final rule, the manufacturer will have up to four quarters after the effective date of the final rule to submit, for CMS approval, materials to CMS demonstrating the basis of how the drug may be subject to the narrow exception to classify the drug as a noninnovator multiple source drug. While this exception process is subject to the requirements of the PRA, we believe it would affect relatively few manufacturers. Similarly, it should require very little evaluation or assessment on the manufacturer's part of whether the manufacturer believes the exception applies since the manufacturer should know the approval route under which the drug was approved; and the manufacturer should already have in its possession the necessary documentation to submit the exception request to CMS, if applicable. We are developing an information collection request for OMB review and approval. The public will have an opportunity to both review the information collection and submit comments. We plan to announce the information collection request under the required 60-day and 30-day **Federal Register** notice and comment periods that will be separate from those associated with the information collection requirements discussed in this final rule. The information collection requirements are not effective until approved by OMB.

Under § 447.510(f)(1), a drug manufacturer is required to retain records for 10 years from the date the drug manufacturer reports data to CMS for that rebate period. While this requirement is subject to the PRA, we believe this is a usual and customary business practice as defined in 5 CFR 1320.3(b)(2) and, therefore, the associated burden is exempt from the PRA.

We received the following PRA-related comments regarding requirements for drug manufacturers. A summary of the comments along with our response follow.

Comment: Several commenters expressed concern that the estimates we provided in the proposed rule are not an accurate reflection of the costs that drug manufacturers will incur to develop and test updated systems in order to implement several requirements in the proposed rule, including the determination of AMP, 5i drugs, best price, and general cost of data analysis. A few of those commenters noted in particular that the estimate does not reflect the costs a drug manufacturer would incur in implementing the build-up model for AMP versus the presumed inclusion model.

Response: While we appreciate the comments that noted our estimates are low, we are unable to revise them in the absence of specific data or information. Further, because we are not finalizing the buildup methodology requirement and have retained the longstanding presumed inclusion methodology for drug manufacturers to calculate AMP, we do not need to include costs associated with the buildup model in this final rule.

Comment: Several commenters shared their concern regarding requirements associated with Affordable Care Act changes and shared their thoughts on burden estimates and costs associated with the drug manufacturer requirements to pay rebates in accordance with the changes made by Affordable Care Act including the costs of determining which sales are in and out of AMP, drafting policy decisions and assumptions, systems changes, changing to a buildup approach, and training costs. Specifically, a commenter noted that it would need to hire a team of 10 full-time contracted Information Technology (IT) professionals at a rate higher than the $60/hr that CMS estimated, and that the drug manufacturer would incur the following expenses to implement all of CMS's proposals: $2.65 million for upfront costs; spend 3 months and cost $400,000 for finalizing new AMP and best price calculation methodologies; take 12 months and cost $1 million for updating wholesaler data to implement the new rule, not including the IT-contractor cost and additional cost to purchase data; take 9 months and cost $500,000 to modify price report systems to include U.S. territories, not including programming cost.

Another commenter estimated that it would take 4 months and cost $250,000 to analyze how 25,000 existing customers should be categorized under the new AMP inclusions and exclusions; take 3 months and cost $500,000 for drafting new assumptions, policies, documents, and training employees and $4.2 million for reprogramming cost.

Response: As discussed previously in the Determination of AMP section of this rule (section II.C.), we have decided not to require that drug manufacturers adopt the buildup approach when calculating AMP in which drug manufacturers were to report AMP based solely upon their actual sales to retail community pharmacies or wholesalers for drugs distributed to retail community pharmacies. Instead, we believe it is reasonable that drug manufacturers continue to presume, in the absence of guidance and adequate documentation to the contrary, that prices paid to drug manufacturers by wholesalers are for drugs distributed to retail community pharmacies, provided those assumptions are consistent with the requirements of section 1927 of the Act and federal regulations. Therefore, a drug manufacturer's time and effort as noted in the comments pertaining to the buildup model will not be considered as an impact of this final rule. We believe this will greatly alleviate the need for the drug manufacturer to make system changes necessary to process, validate, and reconcile data concerning the actual distribution; hence reducing the costs and burden on drug manufacturers to pay rebates associated with the changes in the Affordable Care Act and adopted as part of this final rule.

However, we have revised our estimates pertaining to the implementation of the revised definitions of AMP and best price under the existing presumed inclusion approach. Specifically, we have revised our estimates to reflect that reconfiguring the manufacturers' pricing systems to implement the AMP and best price definitions will require 1,200 hours per drug manufacturer, for a one-time total of 732,000 hours with a one-time total cost of $67,175,884 for 610 participating drug manufacturers. In addition to the one-time burden of

reconfiguring pricing systems, we estimate a one-time start-up cost of $384,704 per drug manufacturer, with 610 participating drug manufacturers, totaling $234,669,440. Once the pricing systems have been reconfigured, there should be no additional burden in time or effort other than that which already exists.

We will work with drug manufacturers regarding the collection of data they need from the territories to pay their rebates. We have accounted for the administrative and financial burden associated with the changes to the definitions of AMP and best price in the burden estimates in this section, and we considered the changes necessary to collect data on sales to territories to be included in these estimates. As previously noted in the Definition section of this final rule (section II.B.20.), the inclusion of the territories in the definitions of state and United States is effective 1 year after the effective date of the final rule. Therefore, the application of the MDR program to the territories is also effective 1 year after the effective date of this final rule; which we believe will enable the drug manufacturers to make the necessary changes in their systems.

5. ICRs Regarding Requirements for States (§ 447.511, § 447.512, and § 447.518)

The state requirements include the collection of rebates as well as changes to the reimbursement methodology based on AAC (as discussed in detail in sections II.J. and II.M. of this final rule) and the finalization of the FULs (as discussed in detail in section II.K. of this final rule).

Consistent with section 1927(b)(2)(A) of the Act, we proposed a new § 447.511 to clarify the reporting requirements for states (77 FR 5345 and 5366) addressing the data that the state must provide to participating drug manufacturers within 60 days of the end of each quarter; the requirement that states must submit this same data to CMS on a quarterly basis; and the requirement that states that have participating Medicaid MCOs, which include CODs in their contracts, must report data pertaining to drugs dispensed through those Medicaid MCOs separately from the data pertaining to drugs dispensed on a FFS basis.

As discussed in detail in section II.I. of this rule, we are finalizing § 447.511 (Requirements for States) as proposed (77 FR 5366). As such, states must report the total rebates (both fee-for-service and Medicaid MCO CODs) they receive from drug manufacturers onto the MBES CMS–64 form and submit this data to CMS on a quarterly basis. The information collection requirements and burden associated with CMS–64 for states and territories are approved by OMB under control number 0938–1265 (CMS–10529). Since this final rule does not impose any new or revised burden or reporting or recordkeeping requirements concerning CMS–64, a revised PRA package is not applicable.

We had also proposed (77 FR 5326) to revise the definition of the term ''states'' to include the territories (the Commonwealth of Puerto Rico, the Virgin Islands, Guam, the Northern Mariana Islands and American Samoa), in addition to the 50 states and the District of Columbia. We also proposed to add a definition of ''United States'' to include the territories (the Commonwealth of Puerto Rico, the Virgin Islands, Guam, the Northern Mariana Islands and American Samoa), in addition to the 50 states and the District of Columbia.

As discussed in detail in section II.B.20. of this rule, we are finalizing the definitions of state and United States to specify that territories will be added to these definitions effective 1 year after the effective date of this rule. As a result, the territories will able to receive drug manufacturer rebates through the MDR program in the same manner that the 50 states and the District of Columbia are currently receiving rebates, beginning 1 year after the effective date of this rule.

To begin collecting rebates from drug manufacturers, the territories must first come into compliance with the MDR program because the systems that the territories currently have in place are not set up for the MDR program. As a result, the territories will likely use contractors to ensure that their systems are in place to begin collecting rebates from drug manufacturers. In the proposed rule, we indicated that we were unsure of the time, effort, and cost for this compliance process and sought comments specific to this issue. A summary of comments we received pertaining to this issue are provided in this section along with our response.

Under § 447.502, we also proposed to replace the term, ''estimated acquisition cost'' (EAC) with ''actual acquisition cost'' (AAC) and to define AAC as ''the agency's determination of the pharmacy providers' actual prices paid to acquire drug products marketed or sold by specific drug manufacturers'' (77 FR 5320 and 5359). We also proposed to replace the term ''dispensing fee'' with ''professional dispensing fee'' as the drug ingredient cost is only one component of the two-part formula used to reimburse pharmacies for prescribed drugs dispensed to Medicaid beneficiaries (77 FR 5361). We also proposed to require states to reconsider the dispensing fee methodology consistent with the revised requirements (discussed in more detail at 77 FR 5326). As discussed in detail in sections II.B. and II.J. of this rule, we are finalizing the definitions of AAC and professional dispensing fee as proposed.

As discussed in detail in section II.K. of this final rule, upon consideration of the comments received, as well as a result of our ongoing analysis of the draft Affordable Care Act FULs in comparison with the monthly NADAC pricing files, we are making a revision to the methodology we will use to calculate the FUL. Specifically, the FUL will be calculated at an amount equal to 175 percent of the weighted average of the most recently reported monthly AMPs for pharmaceutically and therapeutically equivalent multiple source drugs, except where that amount is less than the average retail community pharmacies' acquisition cost for such drug products as determined by the most current national survey of such costs. In situations where the FUL is less than the average retail community pharmacies' acquisition cost, we will establish the FUL using a higher multiplier so that the FUL amount would equal the average retail community pharmacies' acquisition cost as determined by the most current national survey of such costs.

As a result of these changes, and as discussed in sections II.J. and II.M. of this final rule, states are required to consider both the ingredient cost reimbursement and the professional dispensing fee reimbursement when proposing changes to either or both of these components of the reimbursement for Medicaid covered drugs to ensure that total reimbursement to the pharmacy provider is in accordance with the requirements under section 1902(a)(30)(A) of the Act. In addition, states must submit to CMS the proposed change in reimbursement and the supporting data through a SPA through the formal review process.

We recognize that there will be some additional burden to the states to implement the new AAC and professional dispensing fee requirements as well as the new reimbursements for the FULs and other federal programs, such as 340B, IHS, and I/T/U. This burden may include the time and cost for administrative processes and requirements such as legislative and regulatory action, operational changes, and the submission of a SPA for formal review; therefore,

we are revising the state estimate for these burdens to include an additional 300 hours per state. We believe that it will take a Business Operations Specialist 300 hours at $70.20/hr for a one-time total of 16,800 hours (56 states × 300 hours) at a cost of $1,179,360. Once the state has submitted and CMS has approved the SPA, there should be no additional burden in time or effort for the states other than that which already exists. The requirements and burden estimates will be submitted to OMB for approval under control number 0938–1148 (CMS–10398).

We received the following PRA-related comments regarding requirements for states, including comments pertaining to the costs associated with the territories coming into compliance with the requirements of the MDR program. A summary of the comments along with our response follow.

Comment: One commenter stated that CMS did not consider the costs to the territories of implementing a rebate system for territories and stated that it estimated these costs at a minimum of $500,000 annually. Another commenter noted that a specific territory would need to take several actions to ensure compliance with the requirements of the final rule including upgrade its current computer systems and estimated the cost at $500,000 to $900,000 to hire a contractor to perform the upgrades.

Response: We appreciate this comment. As noted in the proposed rule, we did not have any estimates of the costs that the territories would incur by participating in the MDR program. Since we only received one comment with an estimate of cost for the territories to implement a rebate system, we have based our estimate in this final rule on that comment, as well as the information we have obtained regarding the salaries for certain occupations that would be involved in this process (see Table 1: Hourly Wage Estimates). We believe it is reasonable to expect that the territories will have to hire a contractor that specializes in the MDR program to develop the system to collect rebates from drug manufacturers. Furthermore, based on the estimates that we have included above (see section III.B.4. of this final rule) for drug manufacturers to reconfigure their pricing systems to correctly calculate AMP and best price, we believe that the estimate provided by the commenter is consistent with what it would cost for the territories to implement the rebate system by utilizing a contract with expertise in the MDR program. Therefore, we are estimating that each territory that chooses to participate in the program will incur a minimum of a one-time cost of $500,000 to participate in the rebate program. We are also estimating that the on-going operational costs will be $500,000 annually for the territories that participate in the program. Because the rebate requirements pertaining to the territories will not become effective until 1 year after the effective date of this final rule, we will submit these costs in a future PRA package and have not included these costs in Table 2.

Comment: Several commenters stated that CMS did not take into account the costs associated with annual AAC surveys and periodic dispensing fee surveys. The commenters report that these costs could be in the range of $50,000–$100,000 per survey.

Response: Although we are requiring in § 447.518 that states must provide adequate data such as a state or national survey of retail pharmacy providers or other reliable data other than a survey to support any proposed changes to either or both of the components of the reimbursement methodology, we are not requiring states, on their own, to perform acquisition cost surveys. We have provided states with two reimbursement benchmarks that they can use in determining AAC; AMPs, which are reported and certified by drug manufacturers, and NADAC, which is based on a national survey. Therefore, we have not included time and cost burdens for individual state ingredient cost surveys and dispensing fee surveys in this final rule. During the SPA process, the state must demonstrate how such disclosure of the AMP-based prices are consistent with the confidentiality requirements set forth by the statute and other applicable federal regulations and statutory requirements, including the requirement in section 1902(a)(30)(A) of the Act that payments be consistent with efficiency, economy and quality of care and sufficient to assure access.

We recognize that there will be some additional burden to the states to implement the new AAC and professional dispensing fee requirements, as well as the new reimbursement requirements for the FULs and other federal programs, such as 340B, IHS, and I/T/U. This burden may include the time and cost for administrative processes and requirements such as legislative and regulatory action, operational changes, and the submission of a SPA for formal review; therefore, we are revising the state estimate for these burdens to include an additional 300 hours per state.

C. Summary of Annual Burden Estimates

TABLE 2—ANNUAL RECORDKEEPING AND REPORTING REQUIREMENTS

Regulation section(s) in Title 42 of the CFR	Description	OMB Control No.	Frequency	Respondents	Total responses	Burden per response (hours)	Total annual burden (hours)	Total labor cost of reporting ($)	Total capital/ maintenance costs ($)	Total cost ($)
447.507(b)(4) ...	5i Determination.	0938–0578	Monthly	610	7,320	30	219,600	20,851,020	0	20,851,020
447.509(a)(4) ...	Line Extension Determination.	0938–0578	Once*	610	610	26	15,860	1,407,551	0	1,407,551
447.509(a)(4) ...	Line Extension Reporting.	0938–0578	Quarterly ..	610	2,440	20	48,800	4,675,528	0	4,675,528
447.510	AMP/BP Reconfiguring Pricing System.	0938–0578	Once*	610	610	1,200	732,000	67,175,884	0	67,175,884

TABLE 2—ANNUAL RECORDKEEPING AND REPORTING REQUIREMENTS—Continued

Regulation section(s) in Title 42 of the CFR	Description	OMB Control No.	Frequency	Respondents	Total responses	Burden per response (hours)	Total annual burden (hours)	Total labor cost of reporting ($)	Total capital/ maintenance costs ($)	Total cost ($)
447.510	AMP/BP Training/ Start-up Costs.	0938–0578	Once*	610	610	4,000	2,440,000	0	**234,669,440	234,669,440
447.512, 447.514, and 447.518.	States' burden to implement new reimbursement requirements.	0938–1148	Once*	56	56	300	16,800	1,179,360	0	1,179,360
Total	.....	.....	.....	666	11,646	.....	3,473,060	95,289,343	234,669,440	329,958,783

*We do not anticipate any additional burden after OMB's initial 3-year approval period. Consequently, we expect to remove our one-time burden estimates before the initial 3-year approval period expires.
**Start-up costs.

D. Submission of PRA-Related Comments

We have submitted a copy of this rule to OMB for its review of the rule's information collection and recordkeeping requirements. These requirements are not effective until they have been approved by the OMB.

To obtain copies of the supporting statement and any related forms for the proposed paperwork collections referenced above, access CMS's Web site at *http://www.cms.hhs.gov/Paperwork@cms.hhs.gov*, or call the Reports Clearance Office at 410–786–1326.

We invite public comments on this rule's information collection requirements. If you would like to comment, please submit your comments to the Office of Information and Regulatory Affairs, Office of Management and Budget, Attention: CMS Desk Officer, (CMS–2345–F) Fax: (202) 395–6974; or Email: *OIRA_submission@omb.eop.gov.*

Comments must be received by March 2, 2016.

IV. Regulatory Impact Analysis

A. Introduction

We examined the impacts of this rule as required by Executive Order 12866 on Regulatory Planning and Review (September 30, 1993), Executive Order 13563 on Improving Regulation and Regulatory Review (January 18, 2011), the Regulatory Flexibility Act (RFA) (September 19, 1980, Pub. L. 96–354), section 1102(b) of the Act, section 202 of the Unfunded Mandates Reform Act of 1995 (March 22, 1995, Pub. L. 104–4), Executive Order 13132 on Federalism (August 4, 1999), and the Congressional Review Act (5 U.S.C. 804(2)).

Executive Orders 12866 and 13563 direct 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). Executive Order 13563 emphasizes the importance of quantifying both costs and benefits, of reducing costs, of harmonizing rules, and of promoting flexibility. This rule has been designated an ''economically'' significant rule, under section 3(f)(1) of Executive Order 12866. Accordingly, the rule has been reviewed by the Office of Management and Budget.

B. Statement of Need

This final rule implements changes to section 1927 of the Act as set forth in sections 2501, 2503, and 3301(d)(2) of the Affordable Care Act, section 1927 of the Act as set forth in sections 1101(c) and 1206 of the HCERA, and section 1927 of the Act as set forth in section 202 of the Education Jobs and Medicaid Funding Act. This rule will also implement changes to section 1927 of the Act as set forth in section 221 of Division F, Title II, of the Appropriations Act. It also codifies other requirements in section 1927 of the Act pertaining to the MDR program and revised certain regulatory provisions presently codified at 42 CFR part 447, subpart I, and makes other changes concerning Medicaid prescription drug payments.

C. Overall Impacts

In the proposed rule, we estimated this final rule would save approximately $17.7 billion for federal fiscal years (FFYs) 2010 through 2014, reflecting $13.7 billion in federal savings and $4.0 billion in state savings (77 FR 5353). These impact estimates represented the increased percentages of rebates on generic and brand name drugs, the treatment of new formulations, the change in the maximum rebate amounts, the extension of rebate collection for Medicaid MCOs, and providing for adequate pharmacy reimbursement. Lastly, we estimated costs to Medicaid MCOs, drug manufacturers, and states in the amount of $81.4 million for FFYs 2010 through 2014 which included administrative and infrastructure expenses necessary to implement the required systems changes.

As discussed in detail in the introduction to section I of this final rule, the amendments made by subsections 2501(a), (b), (d) and (e) of the Affordable Care Act were effective January 1, 2010, and the amendments made by section 2501(c) of the Affordable Care Act were effective March 23, 2010. Furthermore, section 2503(d) of the Affordable Care Act specified that the amendments made by section 2503 of the Affordable Care Act were effective October 1, 2010, without regard to whether final regulations to carry out such amendments have been issued by October 1, 2010. However, as stated in a November 2014 Informational Bulletin, we have delayed the release the Affordable Care Act FULs and announced that we expect to release them at or about the same time that we publish the final rule. This informational bulletin can be found on the Medicaid.gov Web site at *http://www.medicaid.gov/Federal-Policy-Guidance/Downloads/CIB-11-20-2014.pdf.*

The other amendments made by section 2503 of the Affordable Care Act, including the definitions of multiple source drug, AMP, retail community pharmacy, and wholesaler; as well as the requirement that drug manufacturers report, not later than 30 days after the last day of each month of a rebate period under the agreement, on the drug manufacturer's total number of units that are used to calculate the monthly AMP for each COD; and the requirement that the Secretary post, on a Web site accessible to the public, the weighted average of the most recently reported monthly AMPs for each multiple source drug were effective and implemented as of October 1, 2010.

As a result, the estimates for those sections already implemented are currently reflected in the Medicaid baseline projections.

D. Detailed Economic Analysis

As discussed in the Overall Impact section above, subsections 2501(a), (b), (c), (d), and (e) of the Affordable Care Act have been implemented, and are currently reflected in the Medicaid baseline projections. While publication of this final rule would not have an impact on subsections (a), (b), (c), or (e) of section 2501 of the Affordable Care Act, we expect the following impacts to section 2501(d) of the Affordable Care Act.

We note that the final rule contains two modifications that would affect the administration of section 2501(d) of the Affordable Care Act, which requires a change in the rebate formula for line extension drugs. First, as discussed in sections II.B. and II.G. of this final rule, at this time we are not finalizing the regulatory definition of a line extension drug. Instead, manufacturers will rely on the statutory definition of line extension at section 1927(c)(2)(C) of the Act, and where appropriate, are permitted to use reasonable assumptions in their determination of whether their drug qualifies as a line extension drug. In addition, as discussed in section II.G. of this final rule, we are finalizing the requirements of § 447.509(a)(4)(i), which specifies the rebate calculation requirements for line extension drugs. Second, the final rule requires drug manufacturers of line extension drugs to calculate the alternative rebate only if they also manufactured the initial brand name listed drug, or have a corporate relationship with the drug manufacturer of the initial brand name listed drug. We are finalizing this requirement at revised § 447.509(a)(4)(ii). We will rely upon the manufacturers to determine which drugs meet the definition of a line extension, and when the alternative rebates apply.

We are not able to quantify the impact that the decision to not finalize the regulatory definition of line extension drug will have on the rebates that were originally estimated to be collected due to this rule. We also believe that the impact of the provision about related drug manufacturers would have a small impact, and the total effect on Medicaid payments is smaller than can be credibly estimated.

Section 2503(a), which revised section 1927(e) of the Act to require that the Secretary calculate a FUL for certain multiple source drugs, has been delayed in implementation since the original passage of the Affordable Care Act. In the proposed rule, we proposed to calculate the FUL at 175 percent of the weighted average (determined on the basis of utilization) of the most recently reported monthly AMPs for pharmaceutically and therapeutically equivalent multiple source drug products that are available for purchase by retail community pharmacies on a nationwide basis. The calculation of the FUL using this methodology was projected to reduce net costs through average reduction in prices paid to pharmacies. However, in this final rule we are establishing an exception option to calculating the FUL, whereby we are making a revision to calculate the FUL at an amount equal to 175 percent of the weighted average of the most recently reported monthly AMPs for pharmaceutically and therapeutically equivalent multiple source drugs, except where that amount is less than the average retail community pharmacies' acquisition cost for such drug products as determined by the most current national survey of such costs. In situations where the FUL is less than the average retail community pharmacies' acquisition cost, we will establish the FUL using a higher multiplier so that the FUL amount would equal the most current average retail community pharmacies' acquisition cost as determined by the most current national survey of such costs.

Our analysis was based on the drug utilization and price data for December 2013, which was the most recent period prior to the Medicaid eligibility expansion. The projected impact of implementing the FULs is consistent with the projections of Medicaid expenditures in the President's FY 2016 Budget. Based on previous modeling of the impact of FULs to Medicaid and a measurement of the weighted average price difference for such drugs, we estimate that the impact of applying the NADAC as a lower bound to FUL calculations would reduce the savings impact of the FULs. This reduction was about 1.6 percent, which is very similar to the results that GAO found (1.4 percent) in a recent study on Medicaid prescription drugs (''Medicaid Prescription Drugs: CMS Should Implement Revised Federal Upper Limits and Monitory Their Relationship to Retail Pharmacy Acquisition Costs,'' GAO, December 2013).

We believe that the revised process to calculate the FUL, as stated in this section, will provide a more reliable and credible benchmark for states as they apply the FUL aggregate upper limit. Table 3 provides the estimated savings of the FULs policy being finalized in this final rule.

TABLE 3—ESTIMATED SAVINGS OF APPLYING FEDERAL UPPER LIMIT TO REIMBURSEMENT OF DRUGS UNDER THE MEDICAID REBATE PROGRAM

[Section 2503(a)(1) of the Affordable Care Act]

Cost to Medicaid of section 2503 of the Affordable Care Act	FY 2016	FY 2017	FY 2018	FY 2019	FY 2020	Total FY 2016–2020
Federal	−180	−355	−355	−360	−360	−1,610
State	−125	−250	−250	−250	−250	−1,125
Total	−305	−605	−605	−610	−610	−2,735

Estimates are in $ millions; negative values reflect a savings.

Added effect of interaction with section 2501(c) of the Affordable Care Act for managed care premiums does not change estimate due to rounding.

The savings to the state government are due to the reduction in transfers from the state government to retail pharmacies as well as the increased transfers from drug manufacturers to the state government. The savings to the federal government do not include the savings to the state government.

These estimates rely on assumptions about prescription drug utilization and prices, including the assumption that there would be no change in the behavior of the manufacturers for their decisions to develop new treatments or modify prices to account for the Medicaid drug rebate. Changes in the utilization and prices of prescription drugs in the future (including new prescription drugs coming to the market) may lead these savings to be greater than or less than projected here. Furthermore, these projections rely on assumptions and projections of future Medicaid expenditure and enrollment growth, which may vary from the projections in the President's Budget.

As discussed earlier in the final rule (sections II.B, J. and M) we are replacing the term ''dispensing fee'' with ''professional dispensing fee'' and are revising § 447.518(d) to provide that, when states are proposing changes to either the ingredient cost reimbursement or professional dispensing fee reimbursement, they are required to consider both the ingredient cost reimbursement and the professional dispensing fee reimbursement when proposing changes to either or both of these components of the reimbursement for Medicaid covered drugs to ensure adequate pharmacy reimbursement. However, as discussed in section II.M. of this final rule, there is no requirement that states perform a state-specific cost of dispensing survey.

Since states have several options when reviewing and adjusting their professional dispensing fee (including using a neighboring state's survey results, conducting their own survey, or using survey data from a prior survey [within a reasonable timeframe]), we have no way to definitively estimate the number of states that will actually choose to perform individual state surveys. There are many factors and variables that need to be taken into consideration when trying to determine a cost estimate for a state to perform a cost of dispensing survey. For example, not only will the size of the state (geographic as well as population) impact the cost, but other variables such as the elements included in the scope of work and the number of pharmacies involved in the survey will impact the cost. Based on the limited information we received from comments and a contractor who performs such studies, we estimate that a cost of dispensing survey and study could range from $30,000 to $150,000 depending on the scope of work, number of pharmacies involved in the survey and the size of the state. Taking into consideration that ten states have already implemented a reimbursement methodology using AAC and a professional dispensing fee and another two states are currently in the process of having their state plans reviewed by CMS to make this transition, the field drops from 56 (states and territories) to 44 (states and territories) that will have to evaluate their cost of dispensing and may choose to do so by conducting a state-specific cost of dispensing survey. Based on the limited information available, the potential range of the cost in conducting the dispensing survey could be from $0 (if no states choose to conduct a cost of dispensing survey) to $6,600,000 (if all 44 states conduct a cost of dispensing survey that costs $150,000). However, since we cannot accurately estimate how many states will choose to conduct a state-specific cost of dispensing survey, we have not included this estimate in the ICRs found in section III. of this final rule, nor are the estimates accounted for in tables 2 or 4 of this final rule.

As discussed earlier in this rule (section II.B), we are revising the definitions of ''states'' and ''United States'' to include the U.S. territories (the Commonwealth of Puerto Rico, the Virgin Islands, Guam, the Northern Mariana Islands and American Samoa). We have delayed the inclusion of the territories in the program for one year to give territories and manufacturers time to make necessary system changes and develop the mechanisms and processes necessary to comply with the requirements of the Medicaid drug rebate program. We also will consider allowing a territory to use existing waiver authority to elect not to participate in the MDR program consistent with the statutory waiver standards.

As such there are many complicating factors that make it difficult to provide an accurate estimate of the voluntary start-up and ongoing operational costs for the territories that will participate in the MDR program. First, we do not know which of the territories will participate in the MDR program and which will seek a waiver from participation. Second, each territory is unique in how it is funded and operates. Third, we are unaware of the existing infrastructure of each territory. Furthermore, we only received one comment that contained an estimate of $500,000 to $900,000 for the start-up costs for Puerto Rico and another comment which estimated a minimum annual expense of $500,000 in operating costs for the territories.

Additionally, the number of beneficiaries served, the structure of each territory's Medicaid program, as well as the factors discussed above, are just some of the reasons why it is difficult to accurately provide a reliable quantitative analysis of the economic impact on the territories if they were to participate in the MDR program. Therefore, we believe it is appropriate to instead provide the following qualitative assessment of the benefits that the territories might see if they participate in the MDR program. One benefit that a territory which participates in the MDR program will realize is a savings in providing coverage of prescription drugs to Medicaid beneficiaries through the receipt of rebate payments. It is our understanding that at least some of the territories already have agreements with some manufacturers to provide rebates on certain brand name prescription drugs. These agreements are operated outside of the MDR program and do not encompass the full range of drugs covered by the MDR program. Therefore, a territory that participates in the MDR program will have access to rebates on a much larger number of drugs than they currently do, including physician-administered drugs and drugs dispensed through MCOs. While we are unable to quantify the savings benefit the territories would realize from this, we would expect the savings to be beneficial simply for the fact that a greater number of drugs would be eligible for rebates. Territories, as with the other states, would also be able to negotiate supplemental rebate agreements with drug manufacturers to obtain even greater savings. The availability of rebates on more drugs will result in savings for the territories, which will likely free up some currently constrained resources to provide a greater number of beneficiaries with access to needed drugs. While territories will retain their ability to develop their own preferred drug list, they will also have access to rebates on any covered outpatient drug provided to a Medicaid beneficiary.

We understand that each territory will have to consider the size and makeup of

its beneficiary population, its Medicaid system and current operational costs, as well as its funding sources before determining if it will seek a waiver from participation in the MDR program or if the anticipated benefits will justify the voluntary start-up cost and the ongoing operational expenses of participating in the MDR program. Therefore, as discussed earlier in this final rule, we have delayed the inclusion of the territories in the program for 1 year to give territories time to consider their options and either make necessary system changes and develop the mechanisms and processes necessary to comply with the requirements of the Medicaid drug rebate program or seek a waiver from participation in the MDR program.

Since we do not know how many of the territories will participate in the MDR program, nor can we accurately estimate the startup costs or ongoing operational expenses for the territories that participate in the MDR program, we have not included these estimates in the ICRs found in section III. of this final rule, nor are the estimates accounted for in tables 2 or 4 of this final rule.

Table 4 provides a cost estimate to drug manufacturers and states for FFYs 2016 through 2020 based on the burden estimates discussed in the Collection of Information section (section III.) of this final rule.

TABLE 4—COST TO DRUG MANUFACTURERS AND STATES

[FFYs 2016 through 2020]

Provision(s)	Regulation section(s)	In $Millions					Total
		2016	2017	2018	2019	2020	
Requirements for states to implement new reimbursement provisions	§ 447.512 § 447.514 § 447.518	1.18	0	0	0	0	1.18
Requirements for drug manufacturers	§ 447.507(b)(4) § 447.509(a)(4) § 447.510	328.78	25.5	25.5	25.5	25.5	430.78
Total Costs		329.96	25.5	25.5	25.5	25.5	431.96

1. Anticipated Effects on Drug Manufacturers

As previously indicated in Collection of Information section (section III.) of this final rule, there are approximately 610 drug manufacturers that participate in the MDR program. The final rule requires all drug manufacturers to provide an increased rebate percentage for generic and brand name drugs.

Section III. of this final rule provides the detailed breakdown of the burden associated with drug manufacturer's participation in the Medicaid Drug Rebate program. This burden includes the time and cost for drug manufacturers to gather, calculate, and report pricing (AMP and/or best price) and unit information associated with their drug sales on a monthly and quarterly basis. As previously discussed in section III. of this final rule, the one-time total burden hours for the 610 drug manufacturers participating in the MDR program to reconfigure pricing systems is estimated to be a total cost of $67,175,884. In addition, we now also estimate a one-time start-up cost to include the cost of training drug manufacturer staff on the new, reconfigured pricing systems to be a total cost of $234,669,440. These estimates are accounted for in Table 2, as well as Table 4.

For each of their products, drug manufacturers also are required to submit the FDA application number issued by FDA when the product is approved. If the product does not currently have an FDA application number, the drug manufacturer must provide either evidence that the product is a COD, or the COD status. As specified in section III., the requirements and burden to report the FDA application number and, if applicable, the COD status code have been approved by OMB under control number 0938–0578 (CMS–367), and therefore, are not accounted for in the estimates provided in Tables 2 and 4.

In addition, we believe that it will take time for drug manufacturers to identify the drugs that fall into 5i drug categories. As previously discussed in section III. of the final rule, the burden for the one-time reporting requirement for all drug manufacturers to identify 5i drugs to CMS through the DDR system have been approved by OMB under control number 0938–0578 (CMS–367), and therefore, are not accounted for in Tables 2 or 4.

In addition to this one time reporting requirement to identify 5i drugs, in accordance with § 447.507(b)(1) of this final rule, the drug manufacturer is required to determine whether the percentage of sales for the 5i drugs has met the threshold to be considered not generally dispensed through a retail community pharmacy on a monthly basis. This is estimated to be an annual cost of $20,851,020. The requirements and burden estimates will be submitted to OMB for approval under control number 0938–0578 (CMS–367) and are accounted for in Tables 2 and 4.

Lastly, as previously discussed in section III. of the final rule, the new one-time burden for all 610 drug manufacturers to complete the new reporting requirements to report the Line Extension Drug Indicator is estimated to be a total cost of $1,407,550.60. In addition, for the drugs that have been determined to be a line extension product, the new annual burden for all 610 drug manufacturers to complete the quarterly reporting of the initial brand name listed drug and the line extension drug is estimated to be a total cost of $4,675,528. The requirements and burden estimates will be submitted to OMB for approval under control number 0938–0578 (CMS–367) and are accounted for in Tables 2 and 4. Additional information on these reporting requirements for drug manufacturers can be found in sections II.C., II.G., and II.H., as well as section III. of this final rule.

We received the following comments on the anticipated effects on drug manufacturers:

Comment: Many commenters stated that the Financial Impact Analysis section of the proposed rule grossly underestimates the significant costs, enormous operational challenges, and the resource burdens that drug manufacturers will incur for them to be compliant with the proposed rule, and that it did not account for the fact that drug manufacturers will need to completely overhaul their current pricing systems to accommodate the buildup methodology, costs which will be borne solely by the drug manufacturers. A few commenters noted that the proposed rule is acting as a mandate for drug manufacturers to abandon their current systems to acquire new ones, which are not accounted for in the impact analysis. Several commenters requested that CMS reconsider how it calculates and reports the cost to drug manufacturers for collecting this information to more accurately reflect the true level of effort expended by drug manufacturers. One commenter stated that CMS appears not to appreciate the complexity involved in completing the tasks included in this broadly described regulation and did not account for several important complexities and ambiguities.

Several commenters provided adjustments and specific cost estimates that drug manufacturers would be likely to incur should the buildup methodology be implemented. One commenter stated that CMS considered only the cost and time of drug manufacturers' computer analysts, at one flat rate ($60/hour), however they anticipate the need for a dedicated team of ten full-time contract IT professionals at a significantly higher rate. One commenter believed that CMS has grossly underestimated the amount of time that it would take for drug manufacturers to understand and implement these new requirements and they estimate that the costs associated with implementing the proposed changes to be approximately $2.8 million to $6.5 million, respectively. One commenter stated that they would require at least one year to implement the proposed rule at a cost of at least $6.85 million, including $2.65 million for upfront costs and an additional $4.2 million for reprogramming costs. Another commenter compared their costs to implementing the DRA final rule, in which their cost for outside consulting services and IT support was approximately $8 million. The commenter noted that they had approximately 15 full-time employees dedicated to implementing the DRA Final Rule over a more than 2-year period. Given the far greater scope of CMS's current proposals, the commenter believed implementing them would impose even greater costs and burdens on drug manufacturers.

One commenter stated that small or mid-sized drug manufacturers have estimated that it would take between 3 and 12 months to become fully compliant with the proposed rule, and large drug manufacturers have estimated that it would take between 12 and 24 months to become fully compliant. They also state that the time and resources already spent reviewing and understanding the proposed rule exceeds CMS's implementation cost estimates. One commenter stated that switching to a buildup methodology would drastically increase compliance burdens and would require millions of dollars of extra compliance costs.

Another commenter supplied several estimates that the different sectors within their company (government price reporting team, finance department, product teams, legal experts, and outside consultants) would incur. They stated it will take their stakeholders 3 months analyzing and interpreting the final rule to finalize the new AMP and best price calculation methodologies and cost over $400,000; they estimated they would need 12 months to replace the default rule with a buildup methodology in their systems, including analysis, reprogramming, and testing and validation time and estimate the costs associated with the changes to be $3.6 million; they estimated their stakeholders will need to research data limitations and potential remediation strategies for their wholesaler data in connection with the proposed abandonment of the default rule, and develop a solution for implementing the new rule, which they estimated will take 12 months and cost $1 million, not including the costs of contract IT professionals and additional costs to purchase data that may be available (should CMS seek to require drug manufacturers to purchase data on wholesaler re-sales); and they estimated that many of their stakeholders will work to draft new reasonable assumptions, policies, and procedural documents, and train employees on the same, which could take an additional 3 months and cost approximately $500,000.

Another commenter stated that it estimated the costs to reconfigure pricing systems and perform AMP and best price calculations correctly under the proposed rule to be approximately $0.3 million to $1.7 million per small or mid-sized drug manufacturer and $0.5 million to $6.8 million per large drug manufacture. One commenter stated that they estimated their cost to update their systems to accommodate a presumed inclusion would be at least $1 million plus internal resources estimated at 2,000 hours.

Another commenter noted that its company would incur one-time costs up to 450 times the costs identified by CMS, with a total between approximately $0.3 million and $1.7 million for small or mid-sized companies and from $1.5 million to $6.8 million for large companies. The commenter stated that these ''one-time efforts'' will impose substantial costs because the complete data necessary to perform the calculations do not currently exist and, if they are possible to acquire, they will either have to be obtained from a third party or will have to be created by manipulating and adding to several existing internal data sets. Another commenter stated they would incur ongoing costs associated with processing and validating third party data that may be needed due to the reversal of the default rule (if the data are even available).

Response: As discussed previously in this rule, we are not requiring that drug manufacturers report AMP based solely upon their actual sales to retail community pharmacies or wholesalers for drugs distributed to retail community pharmacies. Instead, we believe it is reasonable that drug manufacturers continue to presume, in the absence of documentation to the contrary, that prices paid to drug manufacturers by wholesalers are for drugs distributed to retail community pharmacies. Therefore, we believe the commenters' burden and cost estimates associated with the requirements set forth in this final rule are overstated given that most of the expense to these estimates was predicated on the anticipated change to a buildup methodology for calculating AMP. As discussed in detail in section III. of this final rule as well as later in this section, we have revised our burden estimates to include the one-time costs to manufacturers to reconfigure pricing systems and train staff. However, since the use of the buildup methodology will not be required and manufacturers retain the ability to make reasonable assumptions in the calculation of AMP and best price as long as such assumptions are consistent with the requirements and intent of section 1927 of the Act and federal regulations, the estimates provided in the final rule are lower than those specified in these comments.

Comment: One commenter stated that even if CMS decides to allow drug manufacturers to continue using the current gross-to-net methodology for AMP, costs would still be over $250,000 plus internal resources of 1,200 hours on government pricing systems work. Another commenter estimated that it will take 4 months and approximately $250,000 for their stakeholders to analyze how their approximately 25,000 existing customers should be categorized under the new AMP inclusions and exclusions.

Response: We appreciate these commenters' estimates which provide the impact of updating systems to meet the revised definition of AMP and best price under this final rule. As discussed in detail in section III. of this final rule, we have revised our estimates to reflect that the AMP and best price definitions will require 1,200 hours per drug manufacturer, for a one-time total of 732,000 burden hours with a one-time total estimated burden cost of $67,175,884 for 610 participating drug manufacturers. In addition to the one-time burden of reconfiguring pricing systems, we believe that there will also be one-time start-up costs for the 610 drug manufacturers, totaling $234,669,440. Once the pricing systems have been reconfigured, there should be no additional burden in time or effort other than that which already exists.

Comment: One commenter stated that ongoing costs identified by CMS were estimated by the interviewed drug manufacturers to be approximately $155,000 per year per drug manufacturer and stated that the commenter's member drug manufacturers estimated that the ongoing cost of implementing the proposed rule are more than six times the CMS estimate. The commenter stated that their member companies indicated that CMS appears to have neglected other ongoing costs necessary to comply with the new regulations, such as the costs of validating the third party data and the cost of providing additional oversight necessary given the increased penalties and tighter reporting timelines.

The commenter also stated that the ongoing costs of processing (including determining whether new customers are retail community pharmacies), validating, and checking/reconciling third party data are estimated to be approximately $150,000 for small or mid-sized drug manufacturers and $250,000 to $350,000 for large drug manufacturers. Finally, the commenter stated that CMS did not anticipate nor include in its estimates, that drug manufacturers will incur any one-time or ongoing capital costs to comply with the new regulations.

Response: Because we are not requiring that drug manufacturers adopt the buildup approach, which may have necessitated the purchase of third party data, drug manufacturers' ongoing time and effort, as well as associated costs of third party data purchasing, processing, reconciling and validation as noted in these comments will not be considered an impact of this final rule. However, as discussed in detail in section III. of this final rule, as well as in the previous response, we have revised our burden estimates to include the one-time costs to manufacturers to reconfigure pricing systems and train staff. However, we are not aware of any ongoing capital costs to comply with the new regulations, nor did we receive any comments to specify such costs, so we are not including any burden estimates associated with such costs.

Comment: Several commenters stated that if they are required to purchase third party data, this would require significant, costly, and time consuming system changes for them to accommodate this data. Commenters stated that the Financial Impact Analysis in the proposed rule completely ignores the ongoing costs of purchasing third party data on an ongoing basis, as well as the system changes that would be required to accommodate this data. The commenters indicated that if CMS were to require the purchase of such data to identify 100 percent of sales going to retail community pharmacies, the cost of acquiring these data could be extraordinary, and there is meaningful uncertainty about whether the necessary data can be acquired at any cost.

Response: As discussed in more detail in the comments and responses in the Determination of AMP section (section II.C.) of this final rule, we are not requiring drug manufacturers to calculate AMP using a buildup methodology. Drug manufacturers will continue to be able to presume, in the absence of adequate documentation to the contrary, that prices paid to drug manufacturers by wholesalers are for drugs distributed to retail community pharmacies. Therefore, we believe this will satisfy the concerns raised by commenters pertaining to the costs they would incur to purchase third party data in using a buildup methodology.

Comment: A commenter stated that they may face costs associated with litigation or enforcement actions because of prices that are alleged to be misreported despite their best faith efforts to obtain the necessary data and calculate prices according to the new regulations. Another commenter specified there would be ongoing costs of providing additional oversight given the tighter reporting timelines, as well as costs and uncertainty associated with potential future liabilities arising out of alleged misreporting under the new calculations.

Response: While the drug manufacturers are responsible for reporting accurate pricing information to CMS within the timeframes specified in the statute and this final rule, we believe our decision to allow drug manufacturers to calculate AMP using a presumed inclusion approach instead of a buildup approach will minimize the operational burden and difficulties drug manufacturers could encounter to ensure that AMP is calculated consistent with the requirements of this final rule. However, as discussed in section III. of the final rule, we have revised our estimates pertaining to the implementation of the revised definitions of AMP and best price under the existing presumed inclusion approach. We believe that concerns related to costs associated with litigation or enforcement risks related to misreported AMP as a result of third party data are outside the scope of this rule.

Comment: Several drug manufacturers commented on the burden they would incur if CMS were to implement regulations to collect rebates for 5i drugs that are not generally dispensed through retail community pharmacies, in which a few drug manufacturers commented that the operational costs will be particularly high if CMS expects drug manufacturers to use separate baselines for AMP in months or quarters during which drugs change their 5i status. One commenter stated that contrary to the underlying assumptions of CMS's burden estimate of $38,850 per year, the data used to complete the 5i analysis are not currently available in their government pricing systems and therefore obtaining the necessary data to determine 5i systematically would require significant reprogramming of the government pricing system. One commenter stated that determining whether the percentage of sales for 5i drugs has met the threshold will require them to hire or allocate approximately one additional full-time employee (FTE) and that the additional FTE, based on a standard 2,000 hours per year would be approximately $150,000 per year, which is substantially higher than CMS's estimate of 80 hours per year and $19,200 per drug manufacturer.

Another commenter agreed that the one-time costs that CMS has identified for reporting FDA application number

or the CODs status for their drugs and identifying potential 5i drugs, are far less resource and system intensive than other tasks, and stated that CMS's estimates of the hours necessary to complete these tasks appear to reasonably approximate the expected effort involved. However, maintaining separate base date AMPs and calculating a product's AMP by both the regular method and by the 5i method would be a significant burden on drug manufacturers, particularly for generic drug manufacturers which operate with very low margins. Another commenter stated that it will be extremely challenging for drug manufacturers to calculate a quarterly AMP when the three underlying monthly AMPs are calculated using different methodologies and will require drug manufacturers to make substantial systems upgrades and hire additional processing staff which will far outweigh the benefit of monthly determinations.

Response: As discussed in the Base Date AMP comments and responses found in section II.H. of this final rule, section 1927(c)(2)(A) through (B) does not contemplate drug manufacturers reporting more than one base date AMP for a drug.

Therefore, we will not require drug manufacturers to calculate two base date AMPs. Further discussion of the base date AMP and its application to 5i drugs is included under the Base Date AMP section of the final rule. In addition to the statutory requirement for a single base date AMP, we believe that two base date AMPs will not be necessary.

Also, our decision to allow drug manufacturers to continue using a presumed inclusion approach when determining AMP, along with the addition of the smoothing process for determining when a drug is not generally dispensed through a retail community pharmacy will likely result in drug manufacturers not experiencing the erratic changes in calculated AMPs that they anticipated. Therefore, the system and staff changes associated with the monthly determinations and reporting will not be as onerous on drug manufacturers as the commenters predict.

Comment: One commenter stated that most of their member companies suggested that CMS's estimate of the time required to identify brand name and line extension drugs appears reasonable.

Response: Thank you for your comment.

Comment: One commenter objected to the use of a fixed percentage of sales to determine whether the drug is not generally dispensed through a retail community pharmacy as it creates a serious administrative burden on drug manufacturers.

Response: We have accounted for the administrative burden on drug manufacturers within the regulatory impact analysis section of this final rule.

Comment: One commenter stated that the proposed rule proposes a number of significant changes to the calculations of AMP and best price which involve an operational burden for drug manufacturers to implement and maintain, including the requirement that drug manufacturers who do not submit and certify monthly or quarterly price reports on time, be reported to OIG and be subjected to civil penalties of $10,000 per day. The commenter requested that CMS exercise discretion in determining whether CMPs are warranted, based on specific facts and circumstances, as opposed to automatically levying a significant and burdensome penalty.

A few commenters further stated that imposing the penalty on a per drug basis, as well as a per day basis, would disproportionately penalize generic drug manufacturers because they tend to offer more extensive product lines than do branded houses and in some instances would be arguing for penalties that are so large as to be unreasonable and unconscionable. The commenter continued by requesting that CMS revise the proposed rule to more closely track the statute, and thereby, avoid the potential for extremely large fines that would unduly burden the generic industry with one commenter specifying that for a company with many products, the cost of uploading the monthly AMP file one day late would be well over $10 million.

Response: As discussed in the Requirements for Manufacturers section of this final rule (section II.H.), we are not finalizing these proposed changes at this time, and thus there is no additional burden to drug manufacturers as a result of these proposed provisions.

Comment: A commenter estimated that nearly a quarter of their NDC–9s would potentially qualify as line extensions under CMS's proposed definition and calculating alternative URAs for this vast number of NDCs would create a huge burden on CMS, because CMS is responsible for calculating URAs under the MDR program.

Response: As discussed in sections II.B. and II.G. of this final rule, at this time we are not finalizing the regulatory definition of a line extension drug. Instead, manufacturers will rely on the statutory definition of line extension at section 1927(c)(2)(C) of the Act, and where appropriate, are permitted to use reasonable assumptions in their determination of whether their drug qualifies as a line extension drug. However, we are finalizing the requirements of § 447.509(a)(4)(i), which specifies the rebate calculation requirements for line extension drugs, and we are also finalizing revised § 447.509(a)(4)(ii) to require the alternative rebate be calculated if there is a corporate relationship between the manufacturer of the line extension drug and the manufacturer of the initial brand name listed drug. While we appreciate the concern for the impact on CMS, we note that since all drug manufacturers are responsible for calculating the URAs and CMS only calculates a URA value for the convenience of the states, there is minimal to no added burden on CMS.

Comment: A few commenters stated that the proposed rule subjects products to higher rebate obligations without consideration of substantial time and financial resource investments. It was further noted by commenters that the provisions would make rebate calculations more burdensome.

Response: As discussed previously (see section II.G.1. of this final rule), section 1927(c) of the Act, as revised by section 2501 of the Affordable Care Act, increased the rebate percentages for single source and multiple source drugs. This rule is designed to address those requirements.

Comment: One commenter stated that drug development is an expensive and time consuming process and even after FDA approval, research costs continue to climb with additional post-approval requirements. The commenter further stated that where drug manufacturers make changes that require a significant investment of research and development, tying those products to the base date AMP of a product already on the market will hamper a drug manufacturer's ability to recoup its investment.

Response: We do not believe that the line extension provision is meant to create a disincentive to drug manufacturers in developing and marketing innovative products, but that the provision is meant to discourage drug manufacturers from circumventing existing rebate liability under the MDR program. The provision requires drug manufacturers to identify if they have line extension drugs and to calculate an alternative rebate amount, if applicable, which compares the pricing of the line extension drug to the pricing of the original drug. We appreciate the insights the commenters provided on pharmacy

innovation and the challenges and benefits the pharmaceutical industry brings and have no reason to believe that such innovation will not continue.

Comment: Commenters stated that the changes that involve operational burden for drug manufacturers to implement and maintain include identifying which of their products are line extension drugs, identifying all potential initial brand name listed drugs, determining which of those initial brand name listed drugs should be used for the calculation of the alternative URA, and requiring that, if owned by separate entities, drug manufacturers exchange product and pricing data to calculate the alternative URA for the line extension drug.

Response: As discussed in sections II.B. and II.G. of this final rule, at this time we are not finalizing the regulatory definition of line extension. Instead, manufacturers will rely on the statutory definition of line extension at section 1927(c)(2)(C) of the Act, and where appropriate, are permitted to use reasonable assumptions in their determination of whether their drug qualifies as a line extension drug, and we are also finalizing revised § 447.509(a)(4)(ii) to require the alternative rebate be calculated if there is a corporate relationship between the manufacturer of the line extension drug and the manufacturer of the initial brand name listed drug. Since we have decided to limit the line extension provisions to provide that a drug by one drug manufacturer will not be treated as a line extension by a different drug manufacturer, unless there is a corporate relationship between the drug manufacturers, we believe the operational burden for the drug manufacturers of line extension drugs will be lessened. Furthermore, we have accounted for the burden estimate for drug manufacturers to identify and report the brand name listed drug and the line extension drug to CMS in section III. of this final rule.

Comment: We received several comments noting that scientific progress and innovation should not be economically penalized by CMS and that CMS must not inappropriately punish drug manufacturers of innovative products and deprive them of appropriate returns on their investments. We received several comments that the proposed handling of the line extension provisions threatens innovation. One commenter stated that the Congress passed the Orphan Drug Act to provide financial incentives for drug manufacturers to develop treatment for rare conditions. Without these incentives, it might not be economically feasible for drug manufacturers to develop treatments for these conditions because of the small target patient population. The commenter believes that because the alternative rebate calculation factors in additional rebates on the original drug, it does not account for the investments required to gain approval for a new indication of an already approved drug or the financial risk inherent in seeking approval for new indication that benefit small patient populations.

Response: The line extension provision is not meant to create a disincentive to drug manufacturers in developing and marketing innovative products or products used to treat orphan diseases, but rather the provision is meant to discourage drug manufacturers from circumventing existing rebate liability under the MDR program. The provision requires drug manufacturers to identify if they have line extension drugs and to calculate an alternative rebate calculation, if applicable. As described earlier in section II.G.2. of this final rule, section 1927(c)(2)(C) of the Act provides that the rebate obligation for a line extension drug shall be the amount computed under section 1927 of the Act for the line extension product or, if greater, the product of the AMP of the line extension drug, the highest additional rebate (calculated as a percentage of AMP), and the total number of units paid for under the state plan in the rebate period. We appreciate the insights the commenters provided on pharmacy innovation and the challenges and benefits the pharmaceutical industry brings and believe such innovation will continue.

Comment: One commenter noted that the data sharing requirements among drug manufacturers were not defined in the proposed rule and the cost burden associated with gathering such data was not provided. The commenter stated that drug manufacturers might have to stop selling a line extension product if they could not comply with getting data from the drug manufacturer of the initial reference drug, and further noted that a drug manufacturer may be unable to divest a line extension product because a potential buyer would know that it could not obtain the information necessary to comply with the line extension provisions.

Response: We agree with the commenters regarding the sharing of pricing data between competing and unrelated drug manufacturers. We also understand the challenges of obtaining pricing information from non-related drug manufacturers. Therefore, as discussed in more detail in section II.G.2., we have decided to limit the line extension provisions to provide that a drug by one drug manufacturer will not be treated as a line extension if the initial brand name listed drug is manufactured by a different drug manufacturer, unless there is a corporate relationship between the drug manufacturers. Drug manufacturers of line extension drugs that have a corporate relationship with the drug manufacturer of the initial brand name listed drug will have, or are expected to obtain, the necessary pricing data to perform the alternative rebate calculation each quarter.

Comment: We received many comments pertaining to the significant financial, administrative, and regulatory burdens, as well as overall increased costs that drug manufacturers would incur should pre-1962 drugs be categorized as innovator drugs. Some commented that the Financial Impact Analysis section did not include the fact that some generic drug manufacturers currently do not calculate best price for any product but would be required to develop a best price methodology based on this revised definition, which would amount to a significant increase in administrative burden and costs, ultimately resulting in higher health care costs for consumers and for government health care programs.

Response: We are aware that our definition of single source and innovator multiple source drugs can cause some products to be subject to a higher rebate percentage due to the change in the drug category from noninnovator to innovator. It is not our intention through this final rule to lead to a discontinuation of production or to cause any companies to go out of business, and least of all to lead to higher healthcare costs. Because we believe that manufacturers should have been reporting drugs marketed under an original NDA as either single source or innovator multiple source drugs prior to this rulemaking, we do not believe that the final rule is the reason that manufacturers will need to develop best price methodologies. Therefore, we did not include this in the proposed rule under the regulatory impact section because we do not believe the final rule will cause this impact upon manufacturers.

Comment: Another commenter stated that as proposed by CMS, drug manufacturers would be exempt from paying rebates on Medicaid MCO drugs if the drugs are dispensed by Medicaid MCOs and discounted under the 340B program. The commenter continued that this will have a huge impact on the little revenue that Medicaid MCOs currently pay a local county. In addition to the

fiscal impact, passing through the 340B cost to the Medicaid MCO would be administratively burdensome on pharmacy operations. The commenter also opposed the action of states requiring hospitals to carve-out their Medicaid managed care drugs. The impact on this local government commenter if they were required to carve out drug costs could negatively impact their budget by $3 million annually. The commenter supported the creation of a pharmacy-friendly mechanism that states can use to prevent the collection of rebates on 340B MCO drugs.

Response: The issue of passing on the 340B cost to Medicaid MCOs and whether states have the authority to mandate that 340B covered entities carve out their Medicaid MCO drugs from their 340B purchases is beyond the scope of this final rule. States are responsible for establishing a mechanism to prevent the collection of rebates on 340B MCO drugs.

Comment: We received several comments stating the significant overall burden, as well as the specific burden (financial, administrative, compliance, operational, time, and human) drug manufacturers would incur if the MDR program is expanded to include the territories.

Several commenters stated that the proposed Regulatory Impact Analysis severely underestimated the amount of resources that would be required to implement an expansion of the MDR program to the territories. Many commenters stated that this expansion would pose significant financial burden for drug manufacturers as it will require alterations to existing systems and collection of data not currently captured. A few commenters stated that they would incur expenses through the engagement of external auditors in evaluating the accounting practices of wholesalers in Puerto Rico and the territories.

Several commenters stated that drug manufacturers would see an increase in their administrative burden, with one commenter stating that processing invoices for five additional jurisdictions would result in an approximate 10 percent increase of their current administrative burden in preparing the quarterly MDR program remittance advices. Several commenters also stated that the administrative burden of such an expansion would be significant since some companies would have to reconfigure their government pricing and/or financial management systems to permit them to capture territory sales in their AMP and best price calculations and all would face higher rebate invoice processing costs. One commenter estimated that it will take approximately nine months and cost roughly $500,000, not including programming costs, for their stakeholders (government price reporting team, finance department, product teams, legal experts, and outside consultants) to understand how to capture the necessary data and modify our price reporting systems to include sales and units to U.S. territories.

A few commenters stated that CMS should not require drug manufacturers to include the territories in their AMP and best price calculations because of the enormous burden and compliance concerns that such an expansion would pose. One commenter added that increased operational costs for generic drug manufacturers will inevitably impact health care consumers and public and private payers. One commenter in particular remarked that the inclusion of sales in best price would create a financial hurdle that could result in fewer products reaching patients, as drug manufacturers would be forced to terminate deeply discounted sales that would, under the proposed rule, become eligible for inclusion in best price calculations. A commenter stated that CMS should permit drug manufacturers to exclude from best price the differential in prices between mainland prices and price-controlled prices in the territories as these price differentials can have a significant and detrimental effect on a drug manufacturer's best price.

Response: As discussed in the Definition section of the final rule (section II.B.), in accordance with section 1101(a)(1) of the Act, we have the authority to adopt the revised definitions of states and United States in this final rule. We recognize the challenges and complexities that this change in definition creates for both the territories and the drug manufacturers and we will work with drug manufacturers regarding the collection of the data they need from the territories to pay rebates to the territories. As previously noted in the Definition section of this final rule (section II.B.), the definitions of state and United States will be revised to include the territories beginning 1 year after the effective date of the final rule. As a result, the effective date for drug manufacturers' requirement to include sales to territories in their calculation of AMP and best price, as well as their obligation to pay rebates on CODs dispensed to Medicaid patients in the territories is also delayed until 1 year after the effective date of the final rule. We believe this delay will provide more time for the drug manufacturers to make the necessary changes in their systems.

2. Anticipated Effects on Retail Community Pharmacies

Retail community pharmacies will be affected by this regulation, because it will result in FULs that are closer to the acquisition cost of the drug. In a 2009 OIG report titled ''A Comparison of Medicaid Federal Upper Limit Amounts to Acquisition Costs, Medicare Payment Amounts, and Retail Prices,'' the OIG found that for the fourth quarter of FY 2007 the pre-DRA FUL reimbursement was more than double the average pharmacy acquisition cost for 46 of the 50 highest expenditure FUL drugs. In the proposed rule, we stated that the Affordable Care Act FULs will generally reduce those limits in comparison to the highly inflated pre-DRA FULs and, thereby, reduce Medicaid payment for drugs subject to the limits. However, we noted that many states have implemented MACs, which were likely lower than the pre-DRA FUL amounts and provided an example of this as exemplified in comparing the pre-DRA FUL, the Affordable Care Act FUL and Indiana's SMAC, as explained the preamble of § 447.514 of the proposed rule (77 FR 5355).

However, other than the comparison chart provided in the discussion regarding proposed § 447.514 (77 FR 5348), we did not analyze how each state's MAC program will impact the total savings under the new Affordable Care Act FUL methodology. Therefore, we invited public comments on this impact. The estimated federal savings associated with the proposed rule implementing section 2503 of the Affordable Care Act, as specified in the proposed rule, reflected this change in reimbursement for retail community pharmacies. Additionally, in the proposed rule (77 FR 5355), we specified that although there are savings to the Medicaid program largely realized because of lower payment to pharmacies, pharmacies may receive a higher reimbursement under the Affordable Care Act FUL than they will when compared to what states currently reimburse pharmacies.

As discussed in detail in section II.K., upon consideration of the comments received, as well as a result of our ongoing analysis of the draft Affordable Care Act FULs in comparison with the monthly NADAC pricing files, we are making a revision to calculate the FUL at an amount equal to 175 percent of the weighted average of the most recently reported monthly AMPs for pharmaceutically and therapeutically equivalent multiple source drugs,

except where that amount is less than the average retail community pharmacies' acquisition cost for such drug products as determined by the most current national survey of such costs. In situations where the FUL is less than the average retail community pharmacies' acquisition cost, we will establish the FUL using a higher multiplier so that the FUL amount will equal the average retail community pharmacies' acquisition cost as determined by the most current national survey of such costs. This revised process is codified in § 447.514(b)(1) and (2) of this final rule.

Additionally, in the proposed rule, at § 447.502, we proposed to replace the term, ''estimated acquisition cost'' (EAC) with ''actual acquisition cost'' (AAC) and to define AAC as ''the agency's determination of the pharmacy providers' actual prices paid to acquire drug products marketed or sold by specific drug manufacturers'' (77 FR 5320 and 5359). We believe that this revision would give states the flexibility to establish a more accurate methodology for establishing prices, while assuring access, consistent with section 1902(a)(30)(A). Furthermore, in the proposed rule at § 447.502 we proposed to replace the term ''dispensing fee'' with ''professional dispensing fee'' as the drug ingredient cost is only one component of the two-part formula used to reimburse pharmacies for prescribed drugs dispensed to Medicaid beneficiaries (77 FR 5361). We also proposed to require states to reconsider the dispensing fee methodology consistent with the revised requirements (discussed in more detail at 77 FR 5326). As discussed in detail in sections II.B. and II.J. of this final rule, we are finalizing the definitions of AAC and professional dispensing fee as they were proposed. We received the following comments on the anticipated effects of these policies on retail community pharmacies:

a. AAC and Professional Dispensing Fee

Comment: One commenter stated that they cannot stay in business if a cost based system is utilized without the inclusion of a profit margin. The commenter requested that CMS not approve any SPA that does not factor this into consideration. Another commenter stated that if a cost-based method is utilized for drug product reimbursement, the states must be mandated to provide a realistic dispensing fee. The fee must be determined by each state through an open and transparent process that covers the unique cost of doing business and if a survey is not done annually to assure professional dispensing fees are adequate, then an annual adjustment fee must be made to cover increased operating costs. One commenter noted that there needs to be a process for adjustments to allow for recouping price increases or other instances where products cannot be purchased at the cost basis. If a cost-based product reimbursement is utilized, it must be tied to an adequate and regularly updated dispensing fee.

Response: As noted in the discussion regarding professional dispensing fees in sections II.A., J., and M. of this final rule, we are finalizing the requirement that states review their professional dispensing fees when they propose to change their reimbursement methodology. We review each SPA to assure that the professional dispensing fees are established in accordance with applicable federal provisions regarding beneficiary access to care. We are not requiring that a state conduct a cost of dispensing fee survey on an annual basis, but states must review their current professional dispensing fee whenever they propose to change their reimbursement methodology.

This final rule is not designed to mandate state payment rates. We set aggregate upper limit requirements, and as we stated in the proposed rule, states have the flexibility to establish an AAC reimbursement in their state plan based on several different pricing benchmarks, for example, the NADAC files, a state survey of retail pharmacy providers, or AMP-based pricing (77 FR 5350). States have the responsibility to ensure that Medicaid pharmacy providers are adequately reimbursed and to establish payment rates in their state plan consistent with such requirements. To the extent that entities have concerns with prices established under a state's AAC methodology, those concerns should be raised to the state, especially given that states are responsible for setting payment rates and complying with a public notice process when setting those rates.

Comment: A few commenters stated that unique products that require unique handling such as specially compounded, special storage, short dating, special product handling, should require an above and beyond the ''standard'' professional dispensing fee. Another commenter further stated that adequate reimbursement for additional services such as compliance packaging and review of medication regimens need to be addressed since the cost effectiveness of these services have been well documented.

Another commenter stated that an annual adjustment to the fee must be made to cover increased operating costs and that dispensing fees should account for the practice type of a specialty pharmacy (for example, a pharmacy that provides factor replacement products) because these pharmacies will have significantly higher operating costs per prescription than that of a traditional retail pharmacy.

Response: In accordance with the definition of professional dispensing fee that we are finalizing at § 447.502 (see section II.B.18.), states should calculate their professional dispensing fees to include those costs which are associated with ensuring that possession of the appropriate COD is transferred to a Medicaid beneficiary. The states retain the flexibility to establish, and if necessary, revise, their professional dispensing fee to ensure that the Medicaid pharmacy providers are adequately reimbursed in accordance with the requirements of section 1902(a)(30)(A) of the Act.

Comment: A few commenters stated that to serve patients with the best care, providers need to be able to cover the cost of the product, the cost of provision of the product, and make a modest profit. Several commenters indicted that there are many components that are involved in purchasing, storing, and dispensing the medication beyond just the overhead, rent, utilities, salaries, computer updates, vials and bottles, labels, and other overhead costs associated with running a pharmacy business. One commenter indicated that the costs to dispense a medication run approximately $10.50 per prescription and suggested that CMS ensure this is factored into the equation.

One commenter noted that the current reimbursement fee for insurance companies is between $1.00 and $3.00. The commenter stated that this is not enough for pharmacies to survive on and requested that CMS consider this as it finalizes its policies.

Another commenter stated that margins are already below a level that community pharmacies can remain viable and going to a net cost model will only further shrink those margins and limit access to pharmacists that have the time to provide real patient care. Another commenter stated that there is increased demand for professional interventions, documentation, responsibilities, technologies, inventories, safety measures, and those increases can no longer be absorbed by the provider. Several commenters indicated that increasing the dispensing fees must follow the other increases and stated that without an increase in fees, the patient will be put in a position of risk. Another commenter requested that

CMS consider the rising cost of doing business and the valuable services being provided by small pharmacies which serve the communities. One commenter stated that the cost of dispensing formula should be used in all states, including states with waivers.

Several commenters commended CMS's recognition that reimbursement for drug ingredient costs and professional dispensing fees must be adjusted in tandem. The commenter was concerned, however, that the discussion of professional fees and costs of dispensing studies do not contemplate the need for reasonable margins that for-profit companies need to sustain their businesses and invest in quality, safety and efficiency improvements. The commenter requested that CMS strengthen its oversight of SPAs to ensure that once states adopt AAC, they cannot unilaterally reduce dispensing fees without a follow-up cost-to-dispense study.

Another commenter stated that because so few providers are willing to participate in the Medicaid program due to low reimbursement, new Medicaid beneficiaries will rely on safety net providers as their only access point for primary and preventative care. The commenter stated that this will present a fiscal challenge for those health centers which already do not receive sufficient reimbursement from Medicaid to cover the costs of delivering healthcare. One commenter stated that if cuts to pharmacy reimbursement happen, then over half the pharmacies in the country will close because they are already seeing reimbursement rates below cost and believe that further cuts will also cause the rural pharmacists to close.

One commenter stated that it shares CMS's view that the dispensing fee should reflect the actual costs of pharmacists services tied to dispensing the product. The commenter urged CMS to require the states to factor in the operational costs associated with providing pharmacy services as part of the professional dispensing fee calculation and suggested that at the very least, the following five factors should be included: Prescription department payroll; prescription department costs; facilities costs; other store/location costs; and corporate costs allocated to prescription department.

Another commenter stated that currently in one particular state, pharmacies have been losing money on generically filled prescriptions simply because the federal upper limit pricing has not been updated to reflect market price increases. This is in spite of the state currently having a higher dispensing fee than most states, due to a recent increase from a cost to dispense survey.

Response: As discussed in section II.J. of this final rule, payment to Medicaid pharmacy providers must be consistent with efficiency, economy, and quality of care while assuring sufficient beneficiary access, consistent with section 1902(a)(30)(A) of the Act, and we believe the total reimbursement should take into account the pharmacy's cost to acquire the drug and the pharmacist's professional services and costs to dispense the drug product to a Medicaid beneficiary. We do not anticipate that the aggregate upper limit, as finalized at § 447.512(b), will limit pharmacy participation or compromise a Medicaid beneficiary's access to pharmacy coverage or services.

In accordance with longstanding Federal regulations, the FULs are designed as an aggregate upper limit to give states flexibility to establish payment rates and adjust those rates for individual drugs consistent with those aggregate limits.

Comment: One commenter stated that the majority of the cost of filling a prescription lies not with the pharmacies which have excelled at reducing costs to keep up with decreasing reimbursements, but rather with PBMs who take an ever increasing share of the profits under the guise of saving employers on their prescription expenses. The commenter requested that CMS mandate that all PBMs open their books and show how much money they receive from drug manufacturers to keep their drugs on a formulary.

Response: While we appreciate the comment, this final rule addresses requirements for states to reimburse pharmacies for CODs at AAC and professional dispensing fees. It does not address reimbursement methods or profit sharing that may occur through PBMs.

Comment: One commenter noted that the potential financial and other possible effects of the revised definition of AAC and professional dispensing fee are unclear and recommended that CMS issue an interim final rule that addresses the financial effect of the revised definitions which would provide clarification and allow the opportunity for comment.

Response: We do not believe that it is necessary to issue an interim final rule to address the financial impact of replacing the term EAC with AAC, which revises the reimbursement standard for prescription drugs. We believe that a change to AAC is more consistent with the statutory provisions at section 1902(a)(30)(A) of the Act as AAC requires states to calculate reimbursement amounts based on the prices actually paid by pharmacy providers.

We have cited examples in the proposed rule (77 FR 5350) that the states can use to develop or support an AAC. States retain the flexibility to establish an AAC reimbursement based on several different pricing benchmarks, but they have the responsibility to ensure that Medicaid pharmacy providers are adequately reimbursed in accordance with the requirements of section 1902(a)(30)(A) of the Act.

Further, as discussed in detail in section II.M., we are revising § 447.518(d) to specify that when states are proposing changes to either the ingredient cost reimbursement or professional dispensing fee reimbursement, they are required to review their proposed changes in accordance with the revised requirements of this final rule, and states must consider both the ingredient cost reimbursement and the professional dispensing fee reimbursement when proposing such changes. Furthermore, states must utilize adequate data, including, but not limited to, data from a state or national survey of retail pharmacy providers or other reliable data, to support any proposed changes to either or both of the components of the pharmacy reimbursement methodology.

Comment: A few commenters stated that dispensing blood clotting factors require enhanced services and activities that vary greatly from those performed by a typical retail pharmacy. One of these commenters requested that CMS consider using the rulemaking process to issue a unique Medicaid reimbursement for blood clotting factor that takes into account the effort required to provide blood clotting factor to Medicaid recipients. Another commenter stated that as a specialty pharmacy that dispenses infusion medications, it is necessary for them to have full-time and ''as needed'' nursing staff to assist patients with home infusions, to provide continuing education, and perform annual in-home assessments.

Response: At this time, we are not establishing an enhanced pharmacy reimbursement requirement for home infusion or blood clotting factor products. However, states have the option of reimbursing providers for nursing services and supplies provided to Medicaid patients when billed separately from CODs, to the extent that such reimbursement is consistent with the Medicaid state plan.

Comment: One commenter stated that the independent pharmacy Medicaid population is typically more costly than that of the chain pharmacy. The commenter stated that for the independent pharmacy, it is impossible to offer enhanced services to the most needy if they were to be reimbursed as outlined in the proposed rule. The commenter further noted that it is important to understand that much more goes into the cost of a pharmacist's care for a Medicaid patient than just the cost of the drug product. The commenter anticipated that there would be an increase in hospitalizations with a reduction of these services, which in turn will be much more costly at the state and federal level.

Response: As discussed in detail in section II.J. of this final rule, we have no reason to believe that pharmacies will be forced to leave the Medicaid program or that patient care will suffer as a result of the revised requirements in § 447.512(b). Based on information provided to us from the states that are already paying based on an AAC methodology, this change in methodology has not caused pharmacies to leave the Medicaid program or other adverse effects on patient care. However, we will continue to monitor the issue.

b. Reimbursement Based on FULs

Comment: One commenter stated that their review of Indiana's State MAC list suggests that CMS's economic analysis has several short comings. The commenter analyzed 290 commonly-used products on the Indiana MAC list, finding that 140 products, or 48 percent of these products, had FUL values set below their respective MAC value, with an average per unit loss in this group of products of 16 cents. Furthermore, the commenter's analysis of FUL reimbursement suggested that 94 or 32 percent of all products analyzed had FUL values set below their respective AAC, with an average loss of 13 cents per product.

The commenter continued that these findings reinforce their concerns that CMS's proposed rule does not properly take into consideration the impact that reduced reimbursement will have on the small independent community pharmacy, many of which continue to purchase generic drugs at a premium of up to 50 percent relative to national chains. The commenter stated that most of these small pharmacies are located in rural communities where many Medicaid patients reside, and over 1,000 of these pharmacies are the sole pharmacy in their community. Furthermore, the commenter stated that 92 percent of these pharmacies' revenues are derived from prescription drugs, with 16 percent of this revenue coming from Medicaid. The commenter stated that further cuts to Medicaid revenues will force many of these small rural pharmacies to close their doors, negatively impacting the very patients that CMS purports to represent.

The commenter continued that to illustrate the competitive disadvantage that small community pharmacies face, they conducted an analysis of the negative impact from these reimbursement changes. The commenter analyzed the six draft FUL lists that have been issued to date by CMS. In almost every monthly draft list, more than one third of all products with FULs are lower than independent community pharmacy acquisition costs. The commenter cannot assume that states will reimburse pharmacies above their MACs, so the commenter assumed that products where the FUL is higher than pharmacies' costs, that states would drop the FULs to the state MAC.

The commenter applied these new FULs to a market basket of Medicaid drugs that are typically dispensed by a common independent community pharmacy for each month. They looked at the impact on low, medium, and high volume pharmacies. The commenter stated that the results illustrated that in most cases, pharmacies lost anywhere from a third to 40 percent of their Medicaid revenues, and such revenue losses are not sustainable. The commenter further notes that the closure of these small community pharmacies will result in increased costs for Medicaid because these pharmacies have a well-established records of dispensing lower priced generic drugs and providing face-to-face counseling which increases medication adherence, leading to fewer hospital visits. The commenter stated that CMS appears insensitive to the needs of small businesses in this proposed regulation.

Response: As discussed earlier in this section and in detail in section II.K., upon consideration of the comments received, as well as a result of our ongoing analysis of the draft FULs in comparison with the monthly NADAC pricing files, we are making a revision to calculate the AMP-based FUL at an amount equal to 175 percent of the weighted average of the most recently reported monthly AMPs for pharmaceutically and therapeutically equivalent multiple source drugs, except where that amount is less than the average retail community pharmacies' acquisition cost for such drug products as determined by the most current national survey of such costs. In situations where the FUL is less than the average retail community pharmacies' acquisition cost, we will establish the FUL using a higher multiplier so that the FUL amount would equal the average retail community pharmacies' acquisition cost as determined by the most current national survey of such costs. This change in the final methodology, which would establish a process for using a higher multiplier, is codified in § 447.514(b)(1) and (2) of this final rule.

We note that, as discussed previously and in the proposed rule (77 FR 5347), this final rule is not designed to mandate state payment rates. Therefore, states have the discretion to adjust reimbursement on a drug-by-drug basis using pricing benchmarks, such as the NADAC pricing file, or other reliable data, to adjust reimbursement, as long as such payments are consistent with the state plan.

Comment: Several commenters noted that a comparison by an investment bank of the posted draft September 2011 FULs for the top twenty drugs to current state MACs for the 10 states representing the greatest number of Medicaid prescriptions found that 72 percent of the draft FULs were lower than the corresponding state MACs, and stated that calculating FULs at such a low level would contradict the Congress' goal to ensure adequate pharmacy reimbursement.

Response: As noted in this section, we are revising our implementation of the FULs to ensure that the pharmacy reimbursement is consistent with the pharmacies' cost to acquire the drug. While we have not analyzed how each state's MAC program will impact the total expenditures under the new Affordable Care Act FUL methodology, the actual impact recognized by individual states and pharmacy providers will depend on the specific circumstances and programs that pertain to each state.

c. Miscellaneous Comments

Comment: One commenter stated that the requirements regarding certification of brand name drugs at § 447.512 would appear to be in conflict with many state laws and regulations in which brand substitution requirements are already defined, including acceptable language and the use of check boxes. The commenter stated that CMS should more appropriately refer to those laws in the aggregate and allow state regulations to prevail in determining appropriate substitution. To do otherwise imposes a burden on providers.

Response: The requirement at § 447.512 is not new. A medical provider retains the right to prescribe a specific brand drug for a Medicaid beneficiary; however, in accordance with § 447.512(c), if a multiple source drug has a FUL calculated, the upper payment limit (FUL) applies, unless the prescriber certifies in his or her own handwriting (or by an electronic alternative means approved by the Secretary), that a specific brand drug is medically necessary. Section 447.512 does allow states to decide what certification form and procedure are used, but also specifies that a check off box on a form is not an acceptable means to communicate that a brand drug is medically necessary and should be dispensed. States must ensure compliance with federal requirements to qualify for federal matching payment. Further, the NCPDP coordinated with CMS to determine functionality that would satisfy the intent of § 447.512(c) for electronic prescribing. NCPDP Implementation Recommendations Version 1.3 contains the guidelines established for electronic prescribing related to the brand medically necessary requirement in federal regulation. Like the federal regulation, the NCPDP standard does not recognize a check off box to satisfy this requirement.

Comment: One commenter agreed with CMS that something needs to be done to reduce the cost of healthcare expenditures for our society, but stated that increasing the rebates that drug manufacturers are required pay to Medicaid will only lead to drug manufacturers raising their prices to cover these higher rebates. The commenter continued that pharmacies cannot raise their prices, because CMS is mandating what they get paid for products but is not mandating what a drug manufacturer can charge.

Response: We note that the overall cost of healthcare in the country is beyond the scope of this final rule. Further, we are not, in this final rule, prohibiting pharmacies from raising their prices. In addition, we note that the increased rebates that drug manufacturers will now pay are required in statute at section 1927(c) of the Act. It is not known if drug manufacturers will increase prices as a result of the statutory requirement.

Comment: One commenter stated that the most important thing for healthcare professionals is the care of the patient and that the proposed rule compromises optimal care to patients. The commenter stated that in the end, money may be saved, but quality may suffer as a consequence.

Response: We appreciate the comment and agree that quality patient care is of the utmost importance in the Medicaid program and we believe the provisions of the final rule are consistent with that principle.

3. Anticipated Effects on State Medicaid Programs

States share in the savings from this final rule. As noted in the Table 3, we estimate a 5-year state savings of approximately $1.125 billion due to the implementation of the FULs as revised in this final rule. We also note states have already been impacted by the provisions of this regulation by the inclusion the requirement that, consistent with section 1927(b) of the Act, as amended by section 2501(c) of the Affordable Care Act, participating drug manufacturers must pay rebates for covered outpatient drugs dispensed to individuals enrolled in Medicaid MCOs if the MCO is responsible for coverage of such drugs. Per the effective date mandated by the Affordable Care Act, this provision was effective as of March 23, 2010. Furthermore, as noted earlier in this section, state administrative costs associated with this regulation are estimated at $800,000 to implement the reimbursement methodologies being finalized in this final rule.

As stated earlier in section III., this final rule does not impose any new or revised reporting or record keeping requirements concerning CMS–64. Also, as a result of the increased rebate amounts under the national rebate agreement, drug manufacturers may reduce rebates they pay to states through supplemental rebate agreements. While this potential loss of supplemental rebates is not a direct consequence of this proposed rule, we recognize that this may occur due to the statutory change to the rebate amounts in 1927(c) of the Act.

We received the following comments on the anticipated effects on State Medicaid programs:

a. Line Extension Drugs and Supplemental Rebates

Comment: A few commenters stated that while the UROA for line extension products may effectively reduce the cost of these products, the benefit of the cost reduction will go entirely to CMS and not to the states. Commenters further noted that attributing the amount of rebate offset due to new indications is currently not possible and would result in a large, as yet unquantified, burden to states and providers to identify and report.

The commenters requested that CMS reconsider the definition of line extension products to preserve state supplemental rebate arrangements and patient access to combination products. Another commenter stated that as proposed, this rule reduces states' supplemental rebates, which would be further exacerbated by the retroactive implementation of the regulation, and would impact prior federal rebate amounts previously determined and owed by the state. Commenters noted that this loss of supplemental rebates is not detailed in the proposed rule's Regulatory Impact Analysis and that the statement of need's estimated savings of $1.6 billion to the program for line extensions does not account for supplemental rebates that will be lost by states as a result of line extension penalties. Commenters requested that CMS revise its analysis to note that the line extension penalty reduces the share of rebates to states, thereby increasing their cost share for drugs above and beyond the normal arrangement.

Response: We recognize that drug manufacturers may decide to change the amount of supplemental rebates they pay states due to the increase in the rebate amounts under the Affordable Care Act, this action is not a direct result of this final rule. As described in Table 6 of the proposed rule (77 FR 5354), the recapture/offset amount is included as part of the line extension provision in this table and, thus, it is included in $1.6 billion of savings. As there is no Federal legislative change to the treatment of supplemental rebates, we have no basis to account for any costs or savings for supplemental rebates in this final rule. However, based on the supplemental rebate data reported to CMS on the Medicaid and Children's Health Insurance Program Budget and Expenditure System (MBES), *http://medicaid.gov/Medicaid-CHIP-Program-Information/By-Topics/Data-and-Systems/MBES/CMS-64-Quarterly-Expense-Report.html,* we do not see any significant impact so far for states on their supplemental rebates and believe that as the marketplace adjusts to these rebate amounts, we expect supplemental rebates will continue at their previous levels. The effective date of the line extension and offset provisions, as set forth in section 2503 of the Affordable Care Act, was January 1, 2010; however, the provisions in this final rule will be implemented on a prospective basis.

Comment: One commenter stated that it has been proposed that the line extension requirement be retroactive to March 2010. The commenter requested that consideration should be given to implementing this requirement after some period upon publication of the

final rule to allow states time to plan a strategy for accommodating line extension drugs and to restructure state budgets to account for reduced rebates due to line extension offset for FFS claims and for claims billed by Medicaid MCOs where states may not control MCO preferred drug lists.

Response: The effective date of the line extension and offset provisions, as set forth in section 2503 of the Affordable Care Act, was January 1, 2010. The requirement that drug manufacturers pay rebates for drugs dispensed to Medicaid beneficiaries through Medicaid MCOs, in accordance with section 2501(c) of the Affordable Care Act, was effective March 23, 2010. However, the provisions in this final rule will be implemented on a prospective basis.

b. Costs Associated With Medicaid MCO Rebates

Comment: One commenter stated that they have concerns with the proposed language to establish a new requirement that states invoice drug manufacturers on a quarterly basis for managed care utilization. The commenter stated that since a reduced portion of the rebates collected will be kept by the states, the states will be acting as collecting agents for rebates and an intermediary for disputes. Based on this commenter's analyses of these provisions, the commenter stated that CMS underestimated the cost for state Medicaid programs to comply with these provisions.

Another commenter requested that CMS consider establishing a reasonable percentage of rebates that states could retain to reflect the costs incurred in complying with these Medicaid MCO requirements, especially for products for which states are not receiving any rebates. Commenters requested that CMS revise its analysis that the rule would not impose additional costs to states since the collection of Medicaid MCO rebates imposes system changes, programming, and staffing burden to bill for and collect rebates, as well as burden of mediating disputes. The commenter also noted that there is a cost associated with retraining staff or contracting with a vendor to complete these activities.

One of the commenters further estimated that the cost associated with collection of Medicaid MCO rebates appears to be underestimated by approximately $100,000 annually and that this amount may vary by state.

Response: We appreciate the comment. However, as noted in section III. of this final rule, the information collection requirements and burden associated with the collection of Medicaid MCO rebates is part of the CMS–64 form and is already approved by OMB under control number 0938–1265 (CMS–10529). In addition, states are required to collect rebates from manufacturers on all covered outpatient drugs. Since this final rule does not impose any new or revised burden or reporting or record keeping requirements concerning CMS–64, a revised PRA package is not applicable at this time.

Comment: One commenter stated they will not accrue savings in line with the CMS projections because the bulk of savings are attributable to revenue from rebates on drugs provided through Medicaid MCOs and the commenter realized these savings through its carve-out in 2008. The commenter stated that for those states that cannot realize such savings and already have aggressive state MAC plans, the costs of the proposed regulation far outweigh the potential savings and that states would in fact be a victim of its own progressive innovations.

Response: States have the option of continuing to carve out their drug coverage from Medicaid MCOs and reimbursing pharmacies for CODs through FFS. Further, we recognize that the actual savings recognized by individual states will depend on the specific circumstances and programs that pertain to each state.

c. Costs Associated With AAC and Professional Dispensing Fee

Comment: Several commenters indicated that states project that the new requirements of reimbursement based on AAC will significantly increase state Medicaid program costs in at least two ways: (1) Administrative costs, including additional staff on an ongoing basis to perform the new work to process the rebates; and (2) infrastructure costs to ensure Medicaid systems can comply with the proposed requirements. One of these commenters noted the cost of a contractor to perform an AAC survey is estimated to be around $100,000 annually and the costs of dispensing fee surveys vary, but are estimated to be between $30,000 and $65,000. The commenter also noted that the frequency of the surveys would affect costs.

Another commenter requested that CMS provide states with flexibility under the revised reimbursement regulations to allow state-specific approaches to implementation because without this flexibility, the commenter expected its reimbursement expenditures to increase.

The commenter continued that it will take up to 2 years to solicit a Request for Proposal (RFP) for a pharmacy invoice audit, conduct the audit, make system changes, and update the state plan and administrative rules. The commenter stated that it would be less burdensome for them to work directly with the drug manufacturers to obtain the actual costs the drug manufacturer charges for each drug.

Response: As discussed in section II.M., we are not requiring states to perform state-specific AAC surveys and there are other options that states can consider to develop reimbursement rates based upon AAC, such as the NADAC files or AMP. Furthermore, there is also no requirement that states perform a professional dispensing fee state-specific survey; however, states are required to reconsider their professional dispensing fee in light of the revised requirement to reimburse at AAC. However, as discussed earlier in the Overall Impact section, based on the limited information available, we have provided an estimated range of $0 (if no states choose to conduct a cost of dispensing survey) to $6,600,000 (if all 44 states conduct a cost of dispensing survey that costs $150,000).

Comment: One commenter stated that to determine the AAC for each 340B entity on a regular basis would be extremely burdensome and manual for states.

Response: As discussed in section II.M. of this final rule, we are requiring that states need to reimburse at AAC for all CODs, including drugs purchased at 340B prices for Medicaid patients. States have the option of reimbursing 340B drugs at the ceiling price which would meet the AAC requirements in this final rule. States are able to calculate the ceiling price for 340B purchased drugs since they have access to both the AMPs and the URAs. We will work with states as they implement the requirement to specify their 340B reimbursement method in their Medicaid state plan.

Comment: One commenter stated that states project that a requirement to use AAC via either the NADAC or a state-specific survey plus a study-supported dispensing fee could increase pharmacy program costs to the state and federal government, depending on a state's existing State MAC program, current generic utilization rate, and other pricing and utilization strategies. As such, the commenter stated that a methodology other than AAC may be more cost-effective and efficient in some situations.

Response: As specified in more detail in sections II.J., and II.M. of this final rule, payment for Medicaid covered drugs is dependent on the

methodologies set forth in the state plan. The definition of AAC in this final rule does not mandate that states use a specific formula or methodology to establish their AAC reimbursement. Further, we do not encourage or mandate that states have only one approved methodology for reimbursement. We agree that states can continue their state MAC programs; further, we are not requiring that states change their existing reimbursement methodologies at this time; however, after the effective date of the final rule, in line with our policy, states should evaluate their proposed changes in the context of the revised requirements prior to proposing changes to pharmacy reimbursement.

d. Costs Associated With Affordable Care Act FULs

Comment: One commenter stated that as drafted, they do not expect a negative financial impact to result from implementation of the new FULs. However, the commenter noted that to update the state's systems to be in compliance with the new FULs would be an additional cost and take the state Medicaid agency 3 to 6 months to implement.

Response: The provisions of the final rule are effective on April 1, 2016 unless otherwise noted in the **DATES** section of this final rule. To implement these revised requirements, we published draft AMP-based FULs, beginning in September 2011, including a Draft Methodology and Data Elements Guide on the Medicaid.gov Web site. We believe that the notification previously issued by CMS that the FULs would not be finalized until this final rule is published provided states sufficient time to plan for the implementation of the Affordable Care Act FULs. In section III., we have accounted for the states' burden to implement the new reimbursement requirements, which include the implementation of the Affordable Care Act FULs.

e. Miscellaneous Comments

Comment: One commenter stated that Tables 6 and 7 of the Regulatory Impact Analysis in the proposed rule (77 FR 5354) are not specific enough to determine the itemized actual costs and savings for the states. Indeed, it appears likely that the $84 million cost of the changes outlined in these tables will be borne primarily by the states, while savings from the rebate offset will accrue mostly to the federal government.

Response: Tables 6 of the proposed rule (77 FR 5354) shows the state and federal savings reflected in implementing requirements from the Affordable Care Act which include provisions for the increased rebate percentages for brand name and generic drugs; the recapture of total savings; the extension of collection of rebates for Medicaid MCOs; rebates for new formulations; and the revised FULs methodology. The rebate offset provisions established by the Affordable Care Act are statutorily mandated; therefore, we have no authority to modify those statutory requirements in this regulation. The regulations are designed to implement the provision in section 1927(c) of the Act regarding the determination of the rebate amount. Whereas, Table 7 of the proposed rule (77 FR 5354) shows the 5-year estimated costs to Medicaid MCOs, drug manufacturers, and states to implement the requirements of the proposed rule and is based on the estimated information collection requirements described in the Collection of Information section of the proposed rule (77 FR 5351 through 5353). As noted in the Collection of Information section of this final rule (section III.), we have updated the estimated costs to states to account for the states' burden to implement new reimbursement requirements being finalized in this rule.

Comment: One commenter stated, in reference to the definition of COD, that determining if the use of a particular medication is outside of a medically accepted indication is difficult and would result in undue administrative burden to states and providers. The commenter requested that CMS clarify the rule to state that the requirement of use for medically accepted indication is met by the presence of an NDC and that the drug is listed electronically with FDA, or one of the other definitions listed in the chapter, as being acceptable.

Response: The language that a drug is not a COD if it is used for an indication that is not a medically accepted indication is not a change from what was previously provided in the statutory definition of COD at section 1927(k)(2) of the Act. The language regarding medically accepted indication in section 1927(k)(2) of the Act was not revised under the Affordable Care Act and we do not intend in this final rule to modify this requirement. As noted in the earlier discussion regarding the definition of COD (section II.B.7.), where there is concern, states will continue to have the flexibility to require prior authorization to limit the use of a COD to only medically accepted indications.

4. Anticipated Effects on U.S. Territories

As discussed in the Definition section of this final rule (section II.B.20.), the definitions of the terms ''states'' and ''United States'' will be revised to include the territories: The Commonwealth of Puerto Rico, the Virgin Islands, Guam, the Northern Mariana Islands, and American Samoa, in addition to the 50 states and the District of Columbia. The territories will be able to receive manufacturer rebates through the MDR program in the same manner that the 50 states and the District of Columbia are currently receiving rebates.

For territories to be able to begin collecting rebates from the manufacturers, the territories will be required to come into compliance with the MDR program because the computer systems that the territories currently have are not setup for the MDR program. As a result, these territories will likely have to utilize contractors to ensure that their computer systems are in place to begin to collect rebates from manufacturers. As specified in the proposed rule (77 FR 5356), we do not have cost estimates for this compliance process to be completed and solicited comment specific to this issue. We received the following comments on the anticipated effects on U.S. territories:

Comment: One commenter supported CMS's proposal to expand the MDR program into the territories and suggested that the increase in federal contributions to Medicaid in a particular territory will provide a great opportunity to mitigate the continuous cost increases for providing Medicaid beneficiaries with drugs and will achieve savings through drug rebates and improved pricing.

Response: While we believe the territories will incur administrative costs to set up their computer systems, we agree with the commenter and believe there will be a net savings to the territories as a result of rebate collections through the MDR program.

Comment: Several commenters stated that complying with all aspects of the MDR program will drive up the overall administrative costs for the territories including upgrades to the information technology systems. One of these commenters indicated that they are unable to estimate those costs at this time but they are concerned that this increase in administrative costs could adversely impact the section 1008 cap unless CMS allows the territory to claim the computer systems and related contract costs necessary to set up the manufacturer and CMS reporting systems for the MDR as MMIS costs

which are outside of the section 1108 cap and which receive enhanced 90 percent and 75 percent matching rates.

Another one of these commenters noted that a specific territory would need to take several actions to ensure compliance with the requirements of the final rule including upgrade its current computer systems and estimated the cost at $500,000 to $900,000 to hire a contractor to perform the upgrades. Another commenter stated that CMS did not consider the costs to the territories of implementing a rebate system for territories and stated that it estimated these costs at a minimum of $500,000 annually.

Response: We agree that the territories will incur administrative costs to set up and maintain their systems; may have varying capacity to comply with these requirements; and will require additional time to comply to implement the MDR program. However, as discussed in the introduction to the Detailed Economic Analysis section of the final rule (section IV.D.) there are many complicating factors that make it difficult to provide an accurate estimate of the voluntary start-up and ongoing operational costs for the territories that will participate in the MDR program. First, we do not know which of the territories will participate in the MDR program and which will seek a waiver from participation. Second, each territory is unique in how it is funded and operates. Third, we are unaware of the existing infrastructure of each territory. Furthermore, we only received one comment that contained an estimate of $500,000 to $900,000 for the start-up costs for Puerto Rico and another comment which estimated a minimum annual expense of $500,000 in operating costs for the territories. Since we do not know how many of the territories will participate in the MDR program, nor can we accurately estimate the startup costs or ongoing operational expenses for the territories that will participate in the MDR program, we have not included these estimate in the ICRs found in section III. of this final rule, nor are the estimates accounted for in tables 2 or 4 of this final rule.

As discussed in the Definition section of this final rule (section II.B.20.), while federal matching dollars are not specifically addressed in the proposed rule, we will work with the territories that participate in the MDR program, and address any questions they have regarding the need to claim administrative costs associated with the MDR program. Furthermore, as stated in the Definition section of this final rule (section II.B.20.), the definitions of ''states'' and ''United States'' will be revised by including the territories 1 year after the effective date of the final rule.

Comment: We received several comments opposing CMS's proposal to expand the MDR program into the territories until there could be a public discussion to ensure that the benefits would outweigh the costs. A few commenters stated that the costs in developing and maintaining the required computer systems may outweigh the benefit of the program to the territories. Another commenter was concerned that the proposal could have a series of unintended consequences which might offset any incremental revenue as historically the extension of rebates and inclusion of more drugs in the Medicaid best price has led to higher prices for other consumers. The commenter stated that businesses in a particular territory are not prepared to pay higher prices for prescription drugs while facing a difficult economic environment.

Response: We appreciate the concerns raised by these commenters and, as discussed in detail in the Definition section of the final rule (section II.B.20.), have decided to allow the territories to seek a waiver from participation in the MDR program using their existing waiver authority. Therefore, we believe the territories will each have an adequate opportunity to evaluate the benefits of participating in the MDR program. Furthermore, as discussed in the determination of AMP section (section II.C.) of this final rule, we recognize that manufacturers may have to evaluate their current business practices in regards to sales to territories. We will continue to monitor this situation are will work with states, manufacturers and other stakeholders regarding the implementation of this policy.

Comment: Several commenters stated that the expansion of the MDR program to the territories may disrupt contracts and pricing structures currently in place and have the unintended consequence of adversely affecting commercial pricing in the territories.

Response: We recognize that some territories may engage in voluntary drug rebate collections. Since territories will cover more drugs that will be eligible for rebates under the MDR program, we believe that the rebates under the MDR program will result in higher revenues overall. Also, we note that we are allowing the territories the choice to opt out of the MDR program and will provide guidance regarding the exact mechanism for opting out.

Comment: One commenter stated that the proposed rule would provide specific benefits and areas of improvement and expansion for rebate collections for a particular territory through the ability to collect rebates on drugs dispensed to Medicaid MCOs as well as rebates on physician administered drugs since this is an area where the territory's current Medicaid program is not able to benefit.

Response: We appreciate the comment and note that when territories participate in the MDR program, they will be subject to all of the requirements of section 1927 of the Act that apply to the states, including that NDC information identifying physician-administered drugs be included on claims.

E. Alternatives Considered

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

As mentioned in the Determination of AMP section of the proposed rule (77 FR 5334), a goal of the Affordable Care Act is to capture the AMP for those drugs that will be difficult for manufacturers to calculate an AMP based on only retail community pharmacy sales. Therefore, to eliminate any problems that may result from a manufacturer not able to determine an AMP for a particular drug, the Congress amended the Affordable Care Act to include an exception for inhalation, infusion, instilled, implanted, or injectable drugs that are not generally dispensed through retail community pharmacies. In this final rule, we considered whether we need to define and determine which drugs constitute 5i drugs. Also, we looked at Medicare Part B drugs and considered using their list to define these drugs. However, as discussed in the proposed rule (77 FR 5334), the ASP NDC–HCPCS crosswalk file includes drug which do not meet the 5i criteria, specifically, oral drugs covered by Part B following a transplant as well as oral anti-emetics and oral cancer drugs (*http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Part-B-Drugs/McrPartBDrugAvgSalesPrice/2015ASPFiles.html*). In addition to using the Medicare Part B list, we also considered whether CMS or manufacturers will be responsible for defining which drugs will fall into this category. Additionally, we considered using the FDA's dosage forms and route of administrations to assist drug manufacturers in determining which drugs meet this requirement.

We proposed to use a multistep process to identify if the drug is not generally dispensed through a retail community pharmacy. To recap, drug manufacturers would identify which

drugs that will fall within the parameters of the 5i drugs. Then, they would need to determine if the drug is not generally dispensed through a retail community pharmacy. As discussed in detail in the Determination of AMP section of this final rule (section II.C.7.), in light of comments received, we decided not to finalize our proposal regarding the use of the FDA Structured Product Labeling Routes of Administration file when identifying 5i drugs. Instead, manufacturers are responsible for making a determination, based on the statute and these regulations, as to whether their drugs qualify as 5i drugs.

With regard to the offset of the increased rebate percentages, as discussed in the proposed rule (77 FR 5342), we considered offsetting the non-federal share of the entire difference between the minimum rebate percentages in effect on December 31, 2009 and the new minimum rebate percentages in effect under Affordable Care Act, regardless of whether states received a rebate amount based on the difference between AMP and best price. However, after careful consideration of the provision in 2501 of the Affordable Care Act, we will finalize that the offset amount will be calculated to reflect rebates based on the difference between AMP and best price.

As discussed in the proposed rule (77 FR 5342), we also considered a different interpretation in calculating the offset for line extension drugs in the September 28, 2010 State Medicaid Director (SMD) letter, #10–019. In the SMD letter, we stated that for a drug that is a line extension of a brand name drug that is an oral solid dosage form, we planned to offset only the difference in the additional rebate of the line extension drug based on the calculation methodology of the additional rebate for the drug preceding the requirements of the Affordable Care Act and the calculation of rebates for the line extension drug, if greater, in accordance with the Affordable Care Act. However, after further review of section 1927(c)(2)(C) of the Act, we proposed in the proposed rule to offset the difference between the URA for the drug calculated based on the applicable rebate percentage in section 1927 of the Act prior to the Affordable Care Cat and the calculation of the URA for the line extension drug, if greater, in accordance with the Affordable Care Act. We are finalizing the calculation of the offset provisions for line extension drug as proposed as we believe that this calculation is more aligned with the statute.

In the proposed rule (77 FR 5345), we also considered determining whether there would be a cost or savings in implementing the Affordable Care Act FUL by comparing simulations of the DRA FUL and new Affordable Care Act FUL, using price, utilization, and reimbursement data from the MDR system combined with generic group codes from First Data Bank. The difference in savings from these simulations (expressed as a percent of total Medicaid drug spending) was applied to projected Medicaid prescription drug spending developed for the mid-session review of the FY 2010 Budget, resulting in a 5-year federal and state cost of $1.7 billion for the Affordable Care Act FULs compared to the DRA FULs. However, this alternative did not take into account a state's ability to choose to reimburse at the state MACs, which may be lower than the FUL for a drug. As a result, this alternative/methodology yields a cost to the states and federal government, when in actuality it should reflect a savings as many states have implemented their own state MAC and reimburse below the FUL. In addition, the DRA FUL was never implemented and therefore this alternative was based on unpublished FULs and not representative of actual reimbursement.

In the proposed rule (77 FR 5356) we solicited comments pertaining to the alternatives considered in drafting the proposed rule. We address comments pertaining to the alternatives considered for identification of 5i drugs that are not generally dispensed through retail community pharmacies in the Determination of AMP (section II.C.7.) of this final rule. Furthermore, we address comments pertaining to the alternatives implementing the Affordable Care Act FUL in the Upper Limits for multiple source drugs (section II.K.) of this final rule. Comments pertaining to calculating the offset for line extension drugs are addressed in the Treatment of new formulations section (section II.G.2.) of this final rule.

F. Accounting Statement and Table

As required by OMB's Circular A–4 (available at *http://www.whitehouse.gov/omb/circulars/a004/a-4.pdf*), in the Table 5 we have prepared an accounting statement showing the classification of the transfers and costs associated with the provisions of this proposed rule.

TABLE 5—ACCOUNTING STATEMENT: CLASSIFICATION OF ESTIMATED TRANSFERS AND COSTS, FROM FFYS 2016 TO 2020

[in $Millions]

Category	Transfers			
Annualized Monetized Transfers	Year Dollar	Discount Rate		Period Covered
	2015 Primary Estimate	7% −$316.9	3% −$319.8	FFYs 2016–2020.
From/To	Reduction in transfers from the Federal Government to State Governments.			
Category	Transfers			
Annualized Monetized Transfers	Year Dollar	Discount Rate		Period Covered
	2015 Primary Estimate	7% −$221.5	3% −$223.5	FFYs 2016–2020.
From/To	Reduction in transfers from the State Governments to Retail Pharmacies and increased transfers from Drug Manufacturers to State Governments.*			
Category	Costs			
	Year Dollar	Units Discount Rate		Period Covered

TABLE 5—ACCOUNTING STATEMENT: CLASSIFICATION OF ESTIMATED TRANSFERS AND COSTS, FROM FFYS 2016 TO 2020—Continued

[in $Millions]

	2015	7%	3%	FFYs 2016–2020.
	Primary Estimate	$94.9	$90.0	
	Costs to Drug Manufacturers and States			

* If manufacturers respond to the rule by increasing prices, these estimates will overstate the transfer effects and some portion of transfers will be borne by non-Medicaid consumers of the affected drugs.

G. Conclusion

In the proposed rule, we estimated savings from this regulation of $17.7 billion over 5 years (2010 through 2014), $13.7 billion to the federal government and $4.0 billion to the states (77 FR 5353). Most of these savings resulted from the increased rebate percentages on brand name drugs and the offsets of the total savings of the increased rebate percentage, treatment of new formulations, and from the collection of rebates from enrollees of Medicaid MCOs, all of which have been in effect since 2010 and are already accounted for in the Medicaid baseline. We estimate the savings from the implementation of the FULs as revised in this final rule of $2.735 billion over 5 years (2016 through 2020), $1.61 billion to the federal government and $1.125 billion to the states. Lastly, we estimate costs to drug manufacturers and states of $431.96 million for FFYs 2016 through 2020.

While the effects of this regulation are substantial, they are primarily a result of changes in the statute.

V. Regulatory Flexibility Act Analysis

The Regulatory Flexibility Act (RFA) requires agencies to analyze options for regulatory relief of small entities, if a rule has 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 businesses are potentially impacted by this final rule. These include small retail community pharmacies, small pharmaceutical manufacturers participating in the Medicaid Drug Rebate Program, and small Medicaid managed care organizations (MCOs). More detailed analysis on the impact of these entities is provided in the Detailed Economic Analysis section (section IV.D.) of this final rule. The great majority of hospitals and most other health care providers and suppliers are small entities, either by being nonprofit organizations or by meeting the Small Business Administration's (SBA) definition of a small business (having revenues of less than $7.5 million to $38.5 million in any 1 year).

For purposes of the RFA, most of the retail pharmacies are considered small businesses according to the SBA's size standards with total revenues of $27.5 million or less in any 1 year (*https://www.sba.gov/sites/default/files/files/Size_Standards_Table.pdf*). The latest data from National Community Pharmacist Association (NCPA) estimates that there are approximately 22,814 independent community pharmacies in 2013. With 73 percent of the independent pharmacies owned by single owner which are likely to meet the threshold of small entities, the possible small pharmacies would be about 16,654. These pharmacies would be affected by this regulation, which will result in lower FULs for most drugs subject to the payment limits. The lower FULs may result in reduced Medicaid payments to pharmacies for generic drugs, depending on how much pharmacies are paid currently under the approved Medicaid state plans. The savings for section 2503 of the Affordable Care Act reflect this statutory change. CMS proposes to replace the term ''estimated acquisition cost'' (EAC) with Actual Acquisition Cost (AAC) and require States to begin paying pharmacy providers based on the AAC of the drug. Additionally States will reimburse providers with a comparable dispensing fee as mentioned in § 447.502 of this final rule. There will be a savings for states and the federal government for reimbursing pharmacists at AAC because of the highly inflated prices that the Medicaid programs are currently reimbursing providers.

According to the SBA size standards, drug manufacturers are considered small businesses if they have fewer than 750 employees (Code 325412, (*https://www.sba.gov/sites/default/files/files/Size_Standards_Table.pdf*). Approximately 610 drug manufacturers currently participate in the Medicaid Drug Rebate Program. We believe most manufacturers are small businesses and anticipate this final rule would have an impact on small drug manufacturers.

The rule would require all drug manufacturers participating in the Medicaid Drug Rebate program to increase the rebate percentages that they are currently paying. Manufacturers are required by the Affordable Care Act to pay the increased percentages. The savings for sections 2501(a)(1), 2501(b) and 2501(d) Affordable Care Act reflect this statutory change.

According to the SBA's size standards, an HMO, of which we have included MCOs, is considered a small business if it has revenues of $32.5 million or less in any 1 year (*https://www.sba.gov/sites/default/files/files/Size_Standards_Table.pdf*). The Census of Bureau (*http://www.census.gov/econ/susb/index.html*) estimates that there are approximately 104 HMO/MCO Medical centers with an average revenue of $22 million annually. Because of limited data available, we are unable to quantify exactly how many MCOs fall within the HMO standard and meet the $32.5 million threshold, and contend that less than half of MCOs meet this standard. The small Medicaid MCOs may be affected by this rule if manufacturers reduce rebate payments to them to any extent that these rebates are paid to the states but these costs would likely be mitigated because it is likely that the MCOs rates would be adjusted.

Therefore, the Secretary has determined that this proposed rule would have a significant economic impact on a substantial number of small entities. We offer an analysis of the alternatives considered in section IV.E. of this final rule. The preceding economic analysis, together with the remainder of this preamble, constitutes the regulatory flexibility analysis.

In addition, section 1102(b) of the Act requires us to prepare a regulatory impact analysis if a rule may have a significant impact on the operations of a substantial number of small rural hospitals. This analysis must conform to the provisions of section 604 of the RFA. For purposes of section 1102(b) of the Act, we define a small rural hospital as a hospital that is located outside of a metropolitan statistical area and has fewer than 100 beds. We do not expect this final rule to have a significant

impact on small rural hospitals although they are required to place NDCs on all claims, including MCO claims, for physician administered drugs since states are required to bill manufacturers for rebates for these drugs. However, the impact on these entities would be minimal because there would be no other requirement except for providing NDC numbers for physician administered drugs. Therefore, the Secretary has determined that this final rule would not have a significant impact on the operations of a substantial number of small rural hospitals. At this time, 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.

VI. Unfunded Mandates Reform Act Analysis

Section 202 of the Unfunded Mandates Reform Act of 1995 (UMRA) requires that agencies assess anticipated costs and benefits before issuing any rule that includes a federal mandate that could result in expenditure in any 1 year by state, local or tribal governments, in the aggregate, or by the private sector, of $100 million in 1995 dollars, updated annually for inflation. In 2015, that threshold level is approximately $144 million. This final rule imposes no mandate on drug manufacturers and other private entities. We believe the rule would not impose additional mandates on states and local governments. This final rule has tribal implications, and in accordance with E.O. 13175 and the HHS Tribal Consultation Policy (December 2010), CMS will consult with Tribal officials prior to the formal promulgation of this regulation.

VII. Federalism Analysis

Executive Order 13132 establishes certain requirements that an agency must meet when it issues a proposed rule (and subsequent final rule) that imposes substantial direct requirement costs on state and local governments, preempts state law, or otherwise has federalism implications. This final rule does not impose substantial direct requirement costs on state or local governments, preempts state law, or otherwise has federalism implications.

VIII. Congressional Review Act

This final regulation is subject to the Congressional Review Act provisions of the Small Business Regulatory Enforcement Fairness Act of 1996 (5 U.S.C. 801 *et seq.*) and has been transmitted to the Congress and the Comptroller General for review.

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

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).

■ 2. Subpart I is revised to read as follows:

Subpart I—Payment for Drugs

Sec.

§ 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 best prices 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.

(4) Implements section 1903(m)(2)(A)(xiii) of the Act, in part, and section 1927(b) of the Act with regard to rebates for covered outpatient drugs dispensed to individuals eligible for medical assistance who are enrolled in Medicaid managed care organizations (MCOs).

(5) Implements section 1902(a)(30)(A) of the Act with regard to the efficiency, economy, and quality of care in the context of payments for covered outpatient drugs.

(b) *Purpose.* This subpart specifies certain requirements in the Social Security Act, including changes from the Affordable Care Act and other requirements pertaining to Medicaid payment for drugs.

§ 447.502 Definitions.

For the purpose of this subpart, the following definitions apply:

Actual acquisition cost (AAC) means the agency's determination of the pharmacy providers' actual prices paid to acquire drug products marketed or sold by specific manufacturers.

Authorized generic drug means any drug sold, licensed, or marketed under a new drug application (NDA) approved by the Food and Drug Administration (FDA) under section 505(c) of the Federal Food, Drug and Cosmetic Act (FFDCA) that is 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 name drug.

Bona fide service fee means 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 the manufacturer would otherwise perform (or contract for) in the absence of the service arrangement, and that is 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. The fee includes, but is not limited to, distribution service fees, inventory management fees, product stocking allowances, and fees associated with administrative service agreements and patient care programs (such as medication compliance programs and patient education programs).

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

Bundled sale means any 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.

(1) The discounts in a bundled sale, including those discounts resulting from a contingent arrangement, are allocated proportionally to the total dollar value of the units of all drugs or products sold under the bundled arrangement.

(2) For bundled sales where multiple drugs are discounted, the aggregate value of all the discounts in the bundled arrangement must be proportionally allocated across all the drugs or products in the bundle.

Clotting factor means a hemophilia clotting factor for which a separate furnishing payment is made under section 1842(o)(5) of the Act and which is included on a list of such factors specified and updated regularly by CMS and posted on the CMS Web site.

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.

Covered outpatient drug means, of those drugs which are treated as a prescribed drug for the purposes of section 1905(a)(12) of the Act, a drug which may be dispensed only upon a prescription (except as provided in paragraphs (2) and (3) of this definition).

(1) A drug can only be considered a covered outpatient drug if it:

(i) Is approved for safety and effectiveness as a prescription drug by the FDA under section 505 or 507 of the FFDCA or under section 505(j) of the FFDCA;

(ii) Was commercially used or sold in the United States before the enactment of the Drug Amendments of 1962 or which is identical, similar, or related (within the meaning described in FDA regulations at 21 CFR 310.6(b)(1)) to such a drug, and which has not been the subject of a final determination by the Secretary that it is a ''new drug'' (within the meaning of section 201(p) of the FFDCA) or an action brought by the Secretary under sections 301, 302(a), or 304(a) of FFDCA to enforce section 502(f) or 505(a) of the FFDCA;

(iii) Is described in section 107(c)(3) of the Drug Amendments of 1962 and for which the Secretary has determined there is a compelling justification for its medical need or is identical, similar, or related (within the meaning described in FDA regulations at 21 CFR 310.6(b)(1)) to such a drug or for which the Secretary has not issued a notice for an opportunity for a hearing under section 505(e) of the FFDCA on a proposed order of the Secretary to withdraw approval of an application for such drug under section 505(e) of the FFDCA because the Secretary has determined that the drug is less than effective for some or all conditions of use prescribed, recommended, or suggested in its labeling;

(iv) Is a biological product other than a vaccine that may only be dispensed upon a prescription and is licensed under section 351 of the Public Health Service Act (PHSA) and is produced at an establishment licensed under section 351 of the PHSA to produce such product; or

(v) Is insulin certified under section 506 of the FFDCA.

(2) A covered outpatient drug does not include any drug, biological product, or insulin provided as part of or incident to and in the same setting as any of the following services (and for which payment may be made as part of that service instead of as a direct reimbursement for the drug):

(i) Inpatient Services;

(ii) Hospice Services;

(iii) Dental Services, except that drugs for which the State plan authorizes direct reimbursement to the dispensing dentist are covered outpatient drugs;

(iv) Physician services;

(v) Outpatient hospital services;

(vi) Nursing facility and services provided by an intermediate care facility for individuals with intellectual disabilities;

(vii) Other laboratory and x-ray services; or

(viii) Renal dialysis.

(3) A covered outpatient drug does not include:

(i) Any drug product, prescription or over-the-counter (OTC), for which an NDC number is not required by the FDA;

(ii) Any drug product for which a manufacturer has not submitted to CMS evidence to demonstrate that the drug product satisfies the criteria in paragraph (1) of this definition;

(iii) Any drug product or biological used for a medical indication which is not a medically accepted indication; or

(iv) Over-the-counter products that are not drugs.

Customary prompt pay discount means 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 timeframe and consistent with customary business practices for payment.

Innovator multiple source drug means a multiple source drug that was originally marketed under an original new drug application (NDA) approved by FDA, including an authorized generic drug. It also 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 biologics license application (BLA), product license application (PLA), establishment license application (ELA) or antibiotic drug application (ADA). For purposes of this definition and the Medicaid drug rebates (MDR) program, an original NDA means an NDA, other than an Abbreviated New Drug Application (ANDA), approved by the FDA for marketing, unless CMS determines that a narrow exception applies.

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 holds the NDC for a covered outpatient drug or biological product and meets the following criteria:

(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) For authorized generic products, the term ''manufacturer'' will also include the original holder of the NDA.

(4) For drugs subject to private labeling arrangements, the term ''manufacturer'' will also include the entity under whose own label or trade name the product will be distributed.

Multiple source drug means, for a rebate period, a covered outpatient drug for which there is at least one other drug product which meets the following criteria:

(1) Is rated as therapeutically equivalent as reported in the FDA's

''Approved Drug Products with Therapeutic Equivalence Evaluations'' which is available at *http://www.accessdata.fda.gov/scripts/cder/ob/.*

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

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

National drug code (NDC) means the numerical code maintained by the FDA that includes the labeler code, product code, and package code. For purposes of this subpart, the NDC is considered to be an 11-digit code, unless otherwise specified in this subpart as being without regard 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 or her designee and a manufacturer to implement section 1927 of the Act.

Nominal price means a price that is less than 10 percent of the average manufacturer price (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 ANDA or an abbreviated antibiotic drug application;

(3) A covered outpatient drug that entered the market before 1962 that was not originally marketed under an NDA;

(4) Any drug that has not gone through an FDA approval process, but otherwise meets the definition of covered outpatient drug; or

(5) If any of the drug products listed in this definition of a noninnovator multiple source drug subsequently receives an NDA or ANDA approval from FDA, the product's drug category changes to correlate with the new product application type.

Oral solid dosage form means capsules, tablets, or similar drugs products intended for oral use as defined in accordance with FDA regulation at 21 CFR 206.3 that defines solid oral dosage form.

Over-the-counter (OTC) drug means a drug that is appropriate for use without the supervision of a health care professional such as a physician, and which can be purchased by a consumer without a prescription.

Pediatric indication means a specifically stated indication for use by the pediatric age group meaning from birth through 16 years of age, or a subset of this group as specified in the ''Indication and Usage'' section of the FDA approved labeling, or in an explanation elsewhere in the labeling that makes it clear that the drug is for use only in a pediatric age group, or a subset of this group.

Professional dispensing fee means the professional 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 beneficiary. 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.

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 FDA and has an approved NDA number issued by 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 biologics license application (BLA), product license application (PLA), establishment license application (ELA), or antibiotic drug application (ADA). For purposes of this definition and the MDR program, an original NDA means an NDA, other than an ANDA, approved by the FDA for marketing, unless CMS determines that a narrow exception applies.

States means the 50 States and the District of Columbia and beginning April 1, 2017, also includes the Commonwealth of Puerto Rico, the Virgin Islands, Guam, the Northern Mariana Islands and American Samoa.

United States means the 50 States and the District of Columbia and beginning April 1, 2017 also includes the Commonwealth of Puerto Rico, the Virgin Islands, Guam, the Northern Mariana Islands, and American Samoa.

Wholesaler means a drug wholesaler that is engaged in wholesale distribution of prescription drugs to retail community pharmacies, including but not limited to manufacturers, repackers, distributors, own-label distributors, private-label distributors, jobbers, brokers, warehouses (including manufacturer's and distributor's warehouses, chain drug warehouses, and wholesale drug warehouses), independent wholesale drug traders, and retail community pharmacies that conduct wholesale distributions.

§ 447.504 Determination of average manufacturer price.

(a) *Definitions.* For the purpose of this section, the following definitions apply:

Average manufacturer price (AMP) means, for 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), the average price paid to the manufacturer for the drug in the United States by wholesalers for drugs distributed to retail community pharmacies and retail community pharmacies that purchase drugs directly from the manufacturer.

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

Charitable and not-for profit pharmacies means organizations exempt from taxation as defined by section 501(c)(3) of the Internal Revenue Code of 1986.

Insurers means entities that are responsible for payment to pharmacies for drugs dispensed to their members, and do not take actual possession of these drugs or pass on manufacturer discounts or rebates to pharmacies.

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.

Retail community pharmacy means an independent pharmacy, a chain pharmacy, a supermarket pharmacy, or a mass merchandiser pharmacy that is licensed as a pharmacy by the State and that dispenses medications to the general public at retail prices. Such term does not include a pharmacy that dispenses prescription medications to patients primarily through the mail, nursing home pharmacies, long-term

care facility pharmacies, hospital pharmacies, clinics, charitable or not-for-profit pharmacies, government pharmacies, or pharmacy benefit managers.

(b) *Sales, nominal price sales, and associated discounts, rebates, payments, or other financial transactions included in AMP.* Except for those sales, nominal price sales, and associated discounts, rebates, payments or other financial transactions identified in paragraph (c) of this section, AMP for covered outpatient drugs includes the following sales, nominal price sales, and associated discounts, rebates, payments, or other financial transactions:

(1) Sales to wholesalers for drugs distributed to retail community pharmacies.

(2) Sales to other manufacturers who act as wholesalers for drugs distributed to retail community pharmacies.

(3) Sales to retail community pharmacies (including those sales, nominal price sales, and associated discounts, rebates (other than rebates under section 1927 of the Act or as specified in regulations), payments, or other financial transactions that are received by, paid by, or passed through to retail community pharmacies).

(c) *Sales, nominal price sales, and associated discounts, rebates, payments, or other financial transactions excluded from AMP.* AMP excludes the following sales, nominal price sales, and associated discounts, rebates, payments, or other financial transactions:

(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) Sales outside the United States.

(5) Sales to hospitals.

(6) Sales to health maintenance organizations (HMOs) (including managed care organizations (MCOs)), including HMO or MCO operated pharmacies.

(7) Sales to long-term care providers, including nursing facility pharmacies, nursing home pharmacies, long-term care facilities, 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.

(8) Sales to mail order pharmacies.

(9) Sales to clinics and outpatient facilities (for example, surgical centers, ambulatory care centers, dialysis centers, and mental health centers).

(10) Sales to government pharmacies (for example, a Federal, State, county, or municipal-owned pharmacy).

(11) Sales to charitable pharmacies.

(12) Sales to not-for-profit pharmacies.

(13) Sales, associated rebates, discounts, or other price concessions paid directly to insurers.

(14) Bona fide service fees, as defined in § 447.502, paid by manufacturers to wholesalers or retail community pharmacies.

(15) Customary prompt pay discounts extended to wholesalers.

(16) Reimbursement by the manufacturer for recalled, damaged, expired, or otherwise unsalable returned goods, including (but not limited to) reimbursement for the cost of the goods and any reimbursement of costs associated with return goods handling and processing, reverse logistics, and drug destruction, but only to the extent that such payment covers only those costs.

(17) Associated discounts, rebates, or other price concessions provided under the Medicare Coverage Gap Discount Program under section 1860D–14A of the Act.

(18) Payments received from and rebates and discounts provided to pharmacy benefit manufacturers (PBMs).

(19) 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.

(20) Sales to hospices (inpatient and outpatient).

(21) Sales to prisons.

(22) Sales to physicians.

(23) Direct sales to patients.

(24) Free goods, not contingent upon any purchase requirement.

(25) Manufacturer coupons to a consumer redeemed by the manufacturer, 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 AMP-eligible entity does not receive any price concession.

(26) Manufacturer-sponsored programs that provide free goods, including but not limited to vouchers and patient assistance programs, but only to the extent that: The voucher or benefit of such a program is not contingent on any other purchase requirement; the full value of the voucher or benefit of such a program is passed on to the consumer; and the pharmacy, agent, or other AMP eligible entity does not receive any price concession.

(27) Manufacturer-sponsored drug discount card programs, but only to the extent that the full value of the discount is passed on to the consumer and the pharmacy, agent, or other AMP eligible entity does not receive any price concession.

(28) Manufacturer-sponsored patient refund/rebate programs, to the extent that the manufacturer provides a full or partial refund or rebate to the patient for out-of-pocket costs and the pharmacy, agent, or other AMP eligible entity does not receive any price concessions.

(29) Manufacturer copayment assistance programs, to the extent that the program benefits are provided entirely to the patient and the pharmacy, agent, or other AMP eligible entity does not receive any price concession.

(30) Any rebates, discounts, or price concessions provided to a designated State Pharmacy Assistance Program (SPAP).

(d) *Sales, nominal price sales, and associated discounts, rebates, payments, or other financial transactions included in AMP for 5i drugs that are not generally dispensed through retail community pharmacies.* Except for those sales, nominal price sales, and associated discounts, rebates, payments, and other financial transactions identified in paragraph (e) of this section, AMP for inhalation, infusion, instilled, implanted, or injectable drugs (5i) covered outpatient drugs identified in accordance with § 447.507 shall include sales, nominal price sales, and associated discounts, rebates, payments, or other financial transactions to all entities specified in paragraph (b) of this section, as well as the following sales, nominal price sales, and associated discounts, rebates, payments, or other financial transactions:

(1) Sales to physicians.

(2) Sales to pharmacy benefit managers.

(3) Sales to health maintenance organizations (HMOs), including managed care organizations (MCOs).

(4) Sales to insurers (except for rebates under section 1927 of the Act and this subpart).

(5) Sales to hospitals.

(6) Sales to clinics and outpatient facilities (for example, surgical centers,

ambulatory care centers, dialysis centers, mental health centers).

(7) Sales to mail order pharmacies.

(8) Sales to long-term care providers, including nursing facility pharmacies, nursing home pharmacies, long-term care facilities, 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.

(9) Sales to hospices (inpatient and outpatient).

(10) Sales to manufacturers, or any other entity that does not conduct business as a wholesaler or retail community pharmacy.

(e) *Sales, nominal price sales, and associated discounts, rebates, payments, or other transactions excluded from AMP for 5i drugs that are not generally dispensed through retail community pharmacies.* AMP for 5i covered outpatient drugs identified in accordance with § 447.507 excludes the following sales, nominal price sales, and associated discounts, rebates, or other financial transactions:

(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) Sales outside the United States.

(5) Bona fide service fees as defined in § 447.502 paid by manufacturers to wholesalers or retail community pharmacies.

(6) Customary prompt pay discounts extended to wholesalers.

(7) Reimbursement by the manufacturer for recalled, damaged, expired, or otherwise unsalable returned goods, including (but not limited to) reimbursement for the cost of the goods and any reimbursement of costs associated with return goods handling and processing, reverse logistics, and drug destruction, but only to the extent that such payment covers only these costs.

(8) 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 for covered Part D drugs, or by a Qualified Retiree Prescription Drug Plan (as defined in section 1860D–22(a)(2) of the Act) for such drugs on behalf of individuals entitled to benefits under Part A or enrolled under Part B of Medicare, or any discounts provided by manufacturers under the Medicare coverage gap discount program under section 1860D–14A of the Act.

(9) 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.

(10) Any rebates, discounts, or price concessions provided to a designated State Pharmacy Assistance Program (SPAP).

(11) Sales to patients.

(12) Free goods, not contingent upon any purchase requirement.

(13) Manufacturer coupons to a consumer redeemed by the manufacturer, 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 AMP eligible entity does not receive any price concession.

(14) Manufacturer-sponsored programs that provide free goods, including, but not limited to vouchers and patient assistance programs, but only to the extent that the voucher or benefit of such a program is not contingent on any other purchase requirement; the full value of the voucher or benefit of such a program is passed on to the consumer; and the pharmacy, agent, or other AMP eligible entity does not receive any price concession.

(15) Manufacturer-sponsored drug discount card programs, but only to the extent that the full value of the discount is passed on to the consumer and the pharmacy, agent, or other AMP eligible entity does not receive any price concession.

(16) Manufacturer-sponsored patient refund/rebate programs, to the extent that the manufacturer provides a full or partial refund or rebate to the patient for out-of-pocket costs and the pharmacy, agent, or other AMP eligible entity does not receive any price concessions.

(17) Manufacturer copayment assistance programs, to the extent that the program benefits are provided entirely to the patient and the pharmacy, agent, or other AMP eligible entity does not receive any price concession.

(18) Sales to government pharmacies (for example, a Federal, State, county, or municipal-owned pharmacy).

(19) Sales to charitable pharmacies.

(20) Sales to not-for-profit pharmacies.

(f) *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 that can be identified with adequate documentation, incentives, administrative fees, service fees, distribution fees (other than bona fide service fees), and any other rebates, discounts or other financial transactions, other than rebates under section 1927 of the Act, which reduce the price received by the manufacturer for drugs distributed to retail community pharmacies.

(2) Quarterly AMP is calculated as a weighted average of monthly AMPs in that 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, to the extent that such cumulative discounts, rebates, or other arrangements are not excluded from the determination of AMP by statute or regulation.

§ 447.505 Determination of best price.

(a) *Definitions.* For the purpose of this section, the following definitions apply:

Best price means, for a single source drug or innovator multiple source drug of a manufacturer (including the lowest price available to any entity for an authorized generic drug), the lowest price available from the manufacturer during the rebate period to any wholesaler, retailer, provider, health maintenance organization, nonprofit entity, or governmental entity in the United States in any pricing structure (including capitated payments), in the same quarter for which the AMP is computed.

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.

(b) *Prices included in best price.* Except for those prices identified in paragraph (c) of this section, best price for covered outpatient drugs includes all prices, including applicable discounts, rebates, or other transactions that adjust prices either directly or indirectly to the best price-eligible entities listed in paragraph (a) of this section.

(c) *Prices excluded from best price.* Best price excludes the following:

(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, or the PHS.

(2) Any prices charged to 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).

(3) Any prices charged under the FSS of the GSA.

(4) Any prices, rebates, or discounts provided to a designated State Pharmacy Assistance Program (SPAP).

(5) Any depot prices (including TRICARE) and single award contract prices, as defined by the Secretary, of any agency of the Federal government.

(6) 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 for covered Part D drugs, or by a Qualified Retiree Prescription Drug Plan (as defined in section 1860D–22(a)(2) of the Act) for such drugs on behalf of individuals entitled to benefits under Part A or enrolled under Part B of Medicare, or any discounts provided by manufacturers under the Medicare coverage gap discount program under section 1860D–14A of the Act.

(7) Rebates under the national rebate agreement or a CMS-authorized supplemental rebate agreement paid to State Medicaid Agencies under section 1927 of the Act.

(8) Manufacturer-sponsored drug discount card programs, but only to the extent that the full value of the discount is passed on to the consumer and the pharmacy, agent, or other entity does not receive any price concession.

(9) Manufacturer coupons to a consumer 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.

(10) Manufacturer copayment assistance programs, to the extent that the program benefits are provided entirely to the patient and the pharmacy, agent, or other entity does not receive any price concession.

(11) Manufacturer-sponsored patient refund or rebate programs, to the extent that the manufacturer provides a full or partial refund or rebate to the patient for out-of-pocket costs and the pharmacy, agent, or other entity does not receive any price concession.

(12) Manufacturer-sponsored programs that provide free goods, including but not limited to vouchers and patient assistance programs, but only to the extent that the voucher or benefit of such a program is not contingent on any other purchase requirement; the full value of the voucher or benefit of such a program is passed on to the consumer; and the pharmacy, agent, or other entity does not receive any price concession.

(13) Free goods, not contingent upon any purchase requirement.

(14) Reimbursement by the manufacturer for recalled, damaged, expired, or otherwise unsalable returned goods, including, but not limited to, reimbursement for the cost of the goods and any reimbursement of costs associated with return goods handling and processing, reverse logistics, and drug destruction but only to the extent that such payment covers only these costs.

(15) Nominal prices to certain entities as set forth in § 447.508.

(16) Bona fide service fees as defined in § 447.502.

(17) PBM rebates, discounts, or other financial transactions except their mail order pharmacy's purchases or where such rebates, discounts, or other financial transactions are designed to adjust prices at the retail or provider level.

(18) Sales outside the United States.

(19) Direct sales to patients.

(d) *Further clarification of best price.* (1) Best price is net of cash discounts, free goods that are contingent on any purchase requirement, volume discounts, customary prompt pay discounts, chargebacks, 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.

(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) *Definitions.* For the purpose of this section, the following definitions apply:

Primary manufacturer means a manufacturer that holds the NDA of the authorized generic drug.

Secondary manufacturer of an authorized generic drug means a manufacturer that is authorized by the primary manufacturer to sell the drug but does not hold the NDA.

(b) *Inclusion of authorized generic drugs in AMP by a primary manufacturer.* The primary manufacturer must include in its calculation of AMP its sales of authorized generic drugs that have been sold or licensed to a secondary manufacturer, acting as a wholesaler for drugs distributed to retail community pharmacies, or when the primary manufacturer holding the NDA sells directly to a wholesaler.

(c) *Inclusion of authorized generic drugs in best price by a primary manufacturer.* A primary manufacturer holding the NDA must include the best price of an authorized generic drug in its computation of best price for a single source or an 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 the NDA.

(d) *Inclusion of authorized generic in AMP and best price by a secondary manufacturer.* The secondary manufacturer of an authorized generic drug must provide a rebate based on its sales of authorized generics, and must calculate AMP and best price, consistent with the requirements specified in §§ 447.504 and 447.505.

§ 447.507 Identification of inhalation, infusion, instilled, implanted, or injectable drugs (5i drugs).

(a) *Identification of a 5i drug.* A manufacturer must identify to CMS each covered outpatient drug that qualifies as a 5i drug.

(b) *Not generally dispensed through a retail community pharmacy.* A manufacturer must determine if the 5i drug is not generally dispensed through a retail community pharmacy based on the percentage of sales to entities other than retail community pharmacies.

(1) A 5i drug is not generally dispensed through a retail community pharmacy if 70 percent or more of the sales (based on units at the NDC–9 level) of the 5i drug, were to entities other than retail community pharmacies or wholesalers for drugs distributed to retail community pharmacies.

(2) A manufacturer is responsible for determining and reporting to CMS whether a 5i drug is not generally dispensed through a retail community pharmacy on a monthly basis.

§ 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 as described in section 340B(a)(4) of the PHSA.

(2) An ICF/IID providing services as set forth in § 440.150 of this chapter.

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

(4) A public or non-profit entity, or an entity based at an institution of higher learning whose primary purpose is to provide health care services to students of that institution, that provides family planning services described under section of 1001(a) of PHSA, 42 U.S.C. 300.

(5) An entity that:

(i) Is described in section 501(c)(3) of the Internal Revenue Code of 1986 and exempt from tax under section 501(a) of that Act or is State-owned or operated; and

(ii) Is providing the same services to the same type of population as a covered entity described in section 340B(a)(4) of the PHSA but does not receive funding under a provision of law referred to in such section.

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

(c) *Rule of construction.* Nothing in this section is construed to alter any existing statutory or regulatory prohibition on services for an entity described paragraph (a)(5) of this section, including the prohibition set forth in section 1008 of the PHSA.

§ 447.509 Medicaid drug rebates (MDR).

(a) *Determination of rebate amount*—(1) *Basic rebate for single source drugs and innovator multiple source drugs.* The amount of basic rebate for each dosage form and strength of a single source drug or an innovator multiple source drug is equal to the product of:

(i) The total number of units of each dosage form and strength paid for under the State plan in the rebate period (as reported by the State); and

(ii) The greater of:

(A) The difference between the AMP and the best price for the dosage form and strength of the drug; or

(B) The AMP for the dosage form and strength of the drug multiplied by one of the following percentages:

(*1*) For a clotting factor, 17.1 percent;

(*2*) For a drug approved by FDA exclusively for pediatric indications, 17.1 percent; or

(*3*) For all other single source drugs and innovator multiple source drugs, 23.1 percent.

(2) *Additional rebate for single source and innovator multiple source drugs.* In addition to the basic rebate described in paragraph (a)(1) of this section, for each dosage form and strength of a single source drug or an innovator multiple source drug, the rebate amount will be increased by an amount equal to the product of the following:

(i) The total number of units of such dosage form and strength paid for under the State plan in the rebate period.

(ii) The amount, if any, by which:

(A) The AMP for the dosage form and strength of the drug for the period exceeds:

(B) The base date AMP for such dosage form and strength, increased by the percentage by which the consumer price index for all urban consumers (United States city average) for the month before the month in which the rebate period begins exceeds such index associated with the base date AMP of the drug.

(3) *Total rebate.* The total rebate amount for single source drugs and innovator multiple source drugs is equal to the basic rebate amount plus the additional rebate amount, if any.

(4) *Treatment of new formulations.* (i) In the case of a drug that is a line extension of a single source drug or an innovator multiple source drug that is an oral solid dosage form, the rebate obligation is the amount computed under paragraphs (a)(1) through (3) of this section for such new drug or, if greater, the product of all of the following:

(A) The AMP of the line extension of a single source drug or an innovator multiple source drug that is an oral solid dosage form.

(B) The highest additional rebate (calculated as a percentage of AMP) under this section for any strength of the original single source drug or innovator multiple source drug.

(C) The total number of units of each dosage form and strength of the line extension product paid for under the State plan in the rebate period (as reported by the State).

(ii) The alternative rebate is required to be calculated if the manufacturer of the line extension drug also manufactures the initial brand name listed drug or has a corporate relationship with the manufacturer of the initial brand name listed drug.

(5) *Limit on rebate.* In no case will the total rebate amount exceed 100 percent of the AMP of the drug.

(6) *Rebate for noninnovator multiple source drugs.* The amount of the rebate for each dosage form and strength of a noninnovator multiple source drug will be equal to the product of:

(i) The total number of units of such dosage form and strength for which payment was made under the State plan for the rebate period; and

(ii) The AMP for the dosage form and strength for the rebate period multiplied by 13 percent.

(b) *Rebates for drugs dispensed through Medicaid managed care organizations (MCOs).* (1) Manufacturers participating in the Medicaid drug rebate program will provide a rebate for covered outpatient drugs dispensed to individuals enrolled in Medicaid MCOs if the MCO is contractually required to provide such drugs.

(2) Manufacturers are exempt from the requirement in paragraph (b)(1) of this section if such drugs are the following:

(i) Dispensed by health maintenance organizations including MCOs that contract under section 1903(m) of the Act; and

(ii) Discounted under section 340B of the PHSA.

(c) *Federal offset of rebates.* States must remit to the Federal government the amount of the savings resulting from the following increases in the rebate percentages.

(1) For single source or innovator multiple source drugs other than blood clotting factors and drugs approved by FDA exclusively for pediatric indications:

(i) If AMP minus best price is less than or equal to AMP times 15.1 percent, then the offset amount is the full 8.0 percent of AMP (the difference between 23.1 percent of AMP and 15.1 percent of AMP).

(ii) If AMP minus best price is greater than AMP times 15.1 percent but less than AMP times 23.1 percent, then the offset amount is the difference between AMP times 23.1 percent and AMP minus best price.

(iii) If AMP minus best price is equal to or greater than AMP times 23.1 percent, then there is no offset amount.

(2) For single source or innovator multiple source drugs that are clotting factors and drugs approved by FDA exclusively for pediatric indications that are subject to a rebate percentage of 17.1 percent of AMP:

(i) If AMP minus best price is less than or equal to AMP times 15.1 percent, then the offset amount is the full 2.0 percent of AMP (the difference between 17.1 percent of AMP and 15.1 percent of AMP).

(ii) If AMP minus best price is greater than AMP times 15.1 percent but less than AMP times 17.1 percent, then the offset amount is the difference between AMP times 17.1 percent and AMP minus best price.

(iii) If AMP minus best price is equal to or greater than AMP times 17.1 percent, then there is no offset amount.

(3) For a drug that is a line extension of a single source or innovator multiple source drug that is an oral solid dosage form, the offset amount is the difference between the unit rebate amount (URA) calculation for the drug calculated based on the applicable rebate percentage in section 1927 of the Act prior to the Affordable Care Act and the calculation of the URA for the line extension drug, if greater, in accordance with the Affordable Care Act.

(4) For noninnovator multiple source drugs, the offset amount is equal to 2.0 percent of the AMP (the difference between 13.0 percent of AMP and 11.0 percent of AMP).

§ 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 the following:

(1) AMP, calculated in accordance with § 447.504.

(2) Best price, calculated in accordance with § 447.505.

(3) Customary prompt pay discounts, which are 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.

(4) Prices that fall within the nominal price exclusion, which are reported as an aggregate dollar amount and include all sales of single source and innovator multiple source drugs to the entities listed in § 447.508(a) 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 any revision 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. Any revision request that exceeds 12 quarters will not be considered, except for the following reasons:

(i) The change is a result of the drug category change or a market date change.

(ii) The change is an initial submission for a product.

(iii) The change is due to termination of a manufacturer from the MDR program for failure to submit pricing data and must submit pricing data to reenter the program.

(iv) The change is due to a technical correction; that is, not based on any changes in sales transactions or pricing adjustments from such transactions.

(v) The change is to address specific rebate adjustments to States by manufacturers, as required by CMS or court order, or under an internal investigation, or an OIG or Department of Justice (DOJ) investigation.

(2) A manufacturer must report revised AMP within the 12-quarter time period, except when the revision would be solely as a result of data pertaining to lagged price concessions.

(c) *Base date AMP report*—(1) *Reporting period.* A manufacturer may report a revised Deficit Reduction Act (DRA) base date AMP to CMS within the first 4 full calendar quarters following July 17, 2007.

(2) *Recalculation of the DRA base date AMP.* (i) A manufacturer's recalculation of the DRA base date AMP must only reflect the revisions to AMP as provided for in § 447.504 in effect from October 1, 2007 to December 14, 2010.

(ii) A manufacturer may choose to recalculate the DRA base date AMP on a product-by-product basis.

(iii) A manufacturer must use actual and verifiable pricing records in recalculating the DRA base date AMP.

(3) *Reporting a revised Affordable Care Act base date AMP.* A manufacturer may report a revised Affordable Care Act base date AMP to CMS within the first 4 full calendar quarters following April 1, 2016.

(4) *Recalculation of the Affordable Care Act base date AMP.* (i) A manufacturer's recalculation of the Affordable Care Act base date AMP must only reflect the revisions to AMP as provided for in § 447.504.

(ii) A manufacturer may choose to recalculate the Affordable Care Act base date AMP on a product-by-product basis.

(iii) A manufacturer must use actual and verifiable pricing records in recalculating the Affordable Care Act base date AMP.

(d) *Monthly AMP*—(1) *Definition.* 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 is calculated based on § 447.504, except the period covered is based on monthly, as opposed to quarterly, sales.

(i) The monthly AMP is 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.

(ii) It is calculated as net sales divided by number of units sold, excluding goods or any other items specifically excluded in the statute or regulations. Monthly AMP is calculated based on the best data available to the manufacturer at the time of submission.

(iii) In calculating monthly AMP, a manufacturer must estimate the impact of its lagged AMP-eligible price concessions using a 12-month rolling percentage in accordance with the methodology described in this paragraph (d)(2).

(A) For each NDC–9 with at least 12 months of AMP-eligible sales, after adjusting for sales excluded from AMP, the manufacturer calculates a percentage equal to the sum of the price concessions for the most recent 12-month period (inclusive of the current reporting period) available associated with sales subject to the AMP reporting requirement divided by the total in dollars for the sales subject to the AMP reporting requirement for the same 12-month period.

(B) For each NDC–9 with less than 12 months of AMP-eligible sales, the calculation described in paragraph (d)(2)(iii)(A) of this section is performed for the time period equaling the total number of months of AMP-eligible sales.

(iv) The manufacturer multiplies the applicable percentage described in paragraph (d)(2)(iii)(A) or (B) of this section by the total in dollars for the sales subject to the AMP reporting requirement (after adjusting for sales excluded from AMP) for the month being submitted. The result of this multiplication is then subtracted from the total in dollars for the sales subject to the AMP reporting requirement (after adjusting for sales excluded from AMP) for the month being submitted.

(v) The manufacturer uses the result of the calculation described in paragraph (d)(2)(iv) of this section as the numerator and the number of units sold in the month (after adjusting for sales excluded from AMP) as the denominator to calculate the manufacturer's AMP for the NDC for the month being submitted.

(vi) *Example.* After adjusting for sales excluded from AMP, the total lagged price concessions over the most recent 12-month period available associated with sales for NDC 12345–6789 subject to the AMP reporting requirement equal $200,000, and the total in dollars for the sales subject to the AMP reporting requirement for the same period equals $600,000. The lagged price concessions percentage for this period equals 200,000/600,000 = 0.33333. The total in dollars for the sales subject to the AMP

reporting requirement for the month being reported equals $50,000 for 10,000 units sold. The manufacturer's AMP calculation for this NDC for this month is: $50,000 − (0.33333 × $50,000) = $33,334 (net total sales amount); $33,334/10,000 = $3.33340 (AMP).

(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, except as allowed in paragraph (b)(1) of this section.

(4) *Exception.* A manufacturer must report revisions to monthly AMP within the 36-month time period, 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.

(6) *Monthly AMP units.* A manufacturer must report the total number of units that are used to calculate the monthly AMP in the same unit type as used to compute the AMP to CMS not later than 30 days after the last day of each month.

(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 paragraphs (e)(1) through (3) of this section.

(f) *Recordkeeping requirements.* (1) A manufacturer must retain records (written or electronic) for 10 years from the date the manufacturer reports data to CMS for that rebate period.

(i) 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.

(ii) The 10-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 10-year period if all 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 designated by CMS.

§ 447.511 Requirements for States.

(a) *Invoices submitted to participating drug manufacturers.* Within 60 days of the end of each quarter, the State must bill participating drug manufacturers an invoice which includes, at a minimum, all of the following data:

(1) The State code.

(2) National Drug Code.

(3) Period covered.

(4) Product FDA list name.

(5) Unit rebate amount.

(6) Units reimbursed.

(7) Rebate amount claimed.

(8) Number of prescriptions.

(9) Medicaid amount reimbursed.

(10) Non-Medicaid amount reimbursed.

(11) Total amount reimbursed.

(b) *Data submitted to CMS.* On a quarterly basis, the State must submit drug utilization data to CMS, which will be the same information as submitted to the manufacturers.

(c) *State that has participating Medicaid Managed care organizations (MCO).* A State that has participating Medicaid managed care organizations (MCO) which includes covered outpatient drugs in its contracts with the MCOs, must report data described in paragraph (a) of this section for covered outpatient drugs dispensed to individuals eligible for medical assistance who are enrolled with the MCO and for which the MCO is required under contract for coverage of such drugs under section 1903 of the Act. These data must be identified separately from the data pertaining to drugs that the State reimburses on a fee-for-service basis.

§ 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. If a specific limit has not been established under § 447.514, 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 must not exceed, in the aggregate, payment levels that the agency has determined by applying the lower of the following:

(1) AAC plus a professional dispensing fee 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 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 beneficiary.

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

(3) A check off 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 available for purchase by retail community pharmacies on a nationwide basis that FDA has rated at least three drug products as pharmaceutically and therapeutically equivalent in the ''Approved Drug Products with Therapeutic Equivalence Evaluations'' which is available at *http://www.accessdata.fda.gov/scripts/cder/ob/.* Only pharmaceutically and therapeutically equivalent formulations will be used to determine such limit, and such limit will only be applied to those equivalent drug products.

(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.* (1) The agency's payments for multiple source drugs identified and listed periodically

by CMS in Medicaid Program issuances must not exceed, in the aggregate, prior to the application of any federal or state drug rebate considerations, payment levels determined by applying for each pharmaceutically and therapeutically equivalent multiple source drug product, a professional dispensing fee established by the state agency plus an amount established by CMS that is equal to 175 percent of the weighted average of the most recently reported monthly AMPs for such multiple source drugs, using manufacturer submitted utilization data for each multiple source drug for which a Federal upper limit (FUL) is established.

(2) *Exception.* If the amount established by CMS in paragraph (b)(1) of this section for a pharmaceutically and therapeutically equivalent multiple source drug product is lower than the average retail community pharmacies' acquisition cost for such drug product, as determined by the most current national survey of such costs, CMS will use a percent of the weighted average of the most recently reported monthly AMPs that equals the most current average acquisition costs paid by retail community pharmacies as determined by such survey.

(c) *Ensuring a drug is for sale nationally.* To assure that a multiple source 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 termination date reported by the manufacturer to CMS.

(2) The monthly AMP units data will be used to calculate the weighted average of monthly AMPs for all multiple source drugs to establish the FUL.

(d) The FUL will be applied as an aggregate upper limit.

§ 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.* (1) The State plan must describe comprehensively the agency's payment methodology for prescription drugs, including the agency's payment methodology for drugs dispensed by all of the following:

(i) A covered entity described in section 1927(a)(5)(B) of the Act.

(ii) A contract pharmacy under contract with a covered entity described in section 1927(a)(5)(B) of the Act.

(iii) An Indian Health Service, tribal and urban Indian pharmacy.

(2) The agency's payment methodology in paragraph (a)(1) of this section must be in accordance with the definition of AAC in § 447.502.

(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), are in accordance with the upper limits specified in § 447.514(b).

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

(2) *Assurances.* The agency must make assurances satisfactory to CMS that the requirements set forth in §§ 447.512 and 447.514 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.

(d) *Data requirements.* When proposing changes to either the ingredient cost reimbursement or professional dispensing fee reimbursement, States are required to evaluate their proposed changes in accordance with the requirements of this subpart, and States must consider both the ingredient cost reimbursement and the professional dispensing fee reimbursement when proposing such changes to ensure that total reimbursement to the pharmacy provider is in accordance with requirements of section 1902(a)(30)(A) of the Act. States must provide adequate data such as a State or national survey of retail pharmacy providers or other reliable data other than a survey to support any proposed changes to either or both of the components of the reimbursement methodology. States must submit to CMS the proposed change in reimbursement and the supporting data through a State plan amendment through the formal review process.

§ 447.520 Federal Financial Participation (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 to secure rebates.

(2) 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.

(b) 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 to secure rebates.

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

§ 447.522 Optional coverage of investigational drugs and other drugs not subject to rebate.

(a) Medicaid coverage of investigational drugs may be provided at State option under section 1905(a)(12) of the Act when such drug is the subject of an investigational new drug application (IND) that has been allowed by FDA to proceed.

(b) A State agency electing to provide coverage of an investigational drug must include in its State plan a description of the coverage and payment for such drug.

(c) The State plan must indicate that any reimbursement for investigational drugs by the State are consistent with FDA regulations at 21 CFR part 312 if they are to be eligible to receive FFP for these drugs.

(d) Medicaid coverage of other drugs may be provided at State option under section 1905(a)(12) of the Act provided that they are not eligible to be covered as covered outpatient drugs in the Medicaid Drug Rebate program.

(e) Investigational drugs and other drugs are not subject to the rebate requirements of section 1927 of the Act provided they do not meet the definition of a covered outpatient drug as set forth in section 1927(k) of the Act.

Dated: October 1, 2015.

Andrew M. Slavitt,

Acting Administrator, Centers for Medicare & Medicaid Services.

Dated: November 24, 2015.

Sylvia M. Burwell,

Secretary, Department of Health and Human Services.

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