

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Part 447

[CMS-2238-F2]

RIN 0938-AP67

**Medicaid Program; Withdrawal of Determination of Average
Manufacturer Price, Multiple Source Drug Definition, and
Upper Limits for Multiple Source Drugs**

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

ACTION: Final rule.

SUMMARY: This final rule withdraws two provisions from the "Medicaid Program; Prescription Drugs" final rule (referred to hereafter as "AMP final rule") published in the July 17, 2007 **Federal Register**. The provisions we are withdrawing are as follows: the determination of average manufacturer price, and the Federal upper limits for multiple source drugs. We are also withdrawing the definition of "multiple source drug" as it was revised in the "Medicaid Program; Multiple Source Drug Definition" final rule published in the October 7, 2008 **Federal Register**.

EFFECTIVE DATE: These regulations are effective on [Insert date 30 days after the date of publication in the **Federal Register**].

FOR FURTHER INFORMATION CONTACT:

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SUPPLEMENTARY INFORMATION:**I. Background**

On September 3, 2010, we published a proposed rule (75 FR 54073) in the **Federal Register** to withdraw two provisions from the "Medicaid Program; Prescription Drugs" final rule published in the July 17, 2007 **Federal Register** (72 FR 39142) (referred to hereafter as "AMP final rule"). The provisions we proposed to withdraw are as follows:

- Section 447.504 "Determination of AMP."
- Section 447.514 "Upper limits for multiple source drugs."

We also proposed to withdraw the definition of "multiple source drug" as it was revised in the "Medicaid Program; Multiple Source Drug Definition" final rule published in the October 7, 2008 **Federal Register** (73 FR 58491).

The AMP final rule, published in the July 17, 2007 **Federal Register** (72 FR 39142), implemented sections 6001(a) through (d), 6002, and 6003 of the Deficit Reduction Act of 2005 (Pub. L. 109-171, enacted on February 8, 2006) (DRA) as well as codified parts of section 1927 of the Social Security Act (the Act) that pertain to requirements for drug

manufacturers' calculation and reporting of AMP and best price, and revised existing regulations that set FULs for certain covered outpatient drugs. The AMP final rule also implemented section 1903(i)(10) of the Act, as revised by the DRA with regard to the denial of FFP in expenditures for certain physician administered drugs. Finally, the AMP final rule addressed other provisions of the Medicaid Drug Rebate Program.

On November 7, 2007, a complaint was filed with the United States District Court for the District of Columbia by the National Association of Chain Drug Stores (NACDS) and the National Community Pharmacists Association (NCPA) (collectively, the Plaintiffs), which alleged that the AMP final rule unlawfully changed the methodology by which pharmacies are reimbursed for dispensing prescription drugs to Medicaid patients. On December 19, 2007, the Court issued a preliminary injunction which prohibits CMS from "[u]ndertaking any and all action to implement the AMP Rule to the extent such action affects Medicaid reimbursement rates for retail pharmacies under the Medicaid program," and, subject to certain exceptions, prohibits CMS from "[p]osting any AMP data on a public website or otherwise disclosing any AMP data to any individual or entities." The

preliminary injunction, however, does not enjoin implementation of the AMP final rule as it relates to the calculation of rebates for the Medicaid rebate program, or the disclosure of AMP data to States as necessary for the administration of that program.

In response to this litigation, CMS published an interim final rule with comment period on March 14, 2008, followed by a final rule on October 7, 2008 to revise the definition of multiple source drug to better conform to the statutory definition of "multiple source drug" found in section 1927(k)(7) of the Act, and to inform the public of the procedures and practices the Agency would follow to ensure compliance with those statutory provisions. The Plaintiffs, however, amended their filing with the Court contending that the revised multiple source drug definition and implementation procedures remained inconsistent with the statute.

On July 15, 2008, the Medicare Improvements for Patients and Providers Act of 2008 (Pub. L. 110-275) (MIPPA) was enacted. Section 203 of MIPPA prohibited HHS from imposing FULs prior to October 1, 2009 for multiple source drugs under §447.514(b) as published in the July 17, 2007 AMP final rule. In accordance with MIPPA, CMS resumed

publishing FULs for multiple source drugs using the methodology in §447.332 as in effect on December 31, 2006. The methodology in §447.332 applied through September 30, 2009.

As a result of the lawsuit, and subsequent preliminary injunction, CMS has been enjoined from implementing the AMP-based FULs that the DRA had required. However, manufacturers were not affected by the injunction and continue to calculate and report AMP for the purpose of Medicaid rebates, in accordance with the determination of AMP as specified in the AMP final rule.

Section 2503(a) of the Patient Protection and Affordable Care Act (Affordable Care Act) (Pub. L. 111-148, enacted on March 23, 2010), amends section 1927(e) of the Act by revising the Federal upper reimbursement limit 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. It also amends section 1927(k) of the Act by revising the definitions of AMP and multiple source drug. In addition, it adds to section 1927(k) of the Act

definitions of the terms "retail community pharmacy" and "wholesaler," and eliminates the term "retail pharmacy class of trade." The amendments made by section 2503(a) of the Affordable Care Act, as amended by section 1101(c) of the Health Care and Education Reconciliation Act (Pub. L. 111-152, enacted on March 30, 2010) and section 202 of the FAA Air Transportation Modernization and Safety Improvement Act (Pub. L. 111-226, enacted on August 10, 2010), were effective October 1, 2010.

II. Provisions of the Proposed Regulations

In the proposed rule published on September 3, 2010, we proposed the following revisions to the AMP final rule published on July 17, 2007:

- Section 447.504, "Determination of AMP," should be withdrawn in its entirety;
- Section 447.514, "Upper limits for multiple source drugs," should be withdrawn in its entirety; and
- The definition of "multiple source drug" in §447.502, "Definitions" (as it was amended by the Multiple Source Drug rule published on October 7, 2008), should be withdrawn.

We proposed that the terms "average manufacturer price" and "multiple source drug" be defined in accordance with

section 1927 of the Act, including changes made by section 2503 of the Affordable Care Act, as amended by the Health Care and Education Reconciliation Act, and the FAA Air Transportation Modernization and Safety Improvement Act. In particular, drug manufacturers would be advised to base their AMP calculations on the definitions set forth in section 1927 of the Act, instead of on the AMP and AMP-related definitions provided in existing regulations and guidance.

Additionally, we proposed to revise three sections within the AMP final rule that make reference to the sections being proposed for withdrawal. Section 447.510 "Requirements for manufacturers", makes reference to §447.504 "Determination of AMP", and §447.512 "Drugs: Aggregate upper limits for payment", and §447.518 "State plan requirements", make reference to §447.514 "Upper limits for multiple source drugs. We proposed conforming regulatory amendments to those sections.

III. Analysis of and Responses to Public Comments

We received 16 comments in response to the September 3, 2010 proposed rule. We received comments from drug manufacturers, membership organizations, law firms, pharmacy benefit managers, a consulting firm, and a not-for-profit

organization. A summary of the issues and our responses follow:

General Comments

Comment: Many commenters expressed general support for the provisions of the proposed rule. One commenter commended the agency's withdrawal proposal and commitment to develop regulations that will implement provisions of section 2503 of the Affordable Care Act. Another commenter stated that they believe it is appropriate that CMS withdraw these sections of the regulation as Congress recently amended several sections of section 1927 in the Affordable Care Act. One commenter applauded the Agency for moving forward with withdrawing the provisions of the AMP final rule as well as the Multiple Source Drug rule.

Response: We appreciate the comments in support of the withdrawal of the determination of AMP and the upper limits for multiple source drugs provisions as well as the withdrawal of the definition of multiple source drug. CMS is committed to developing further regulations that will provide the necessary guidance to all parties impacted by the revisions made to the Medicaid Drug Rebate Program by the Affordable Care Act.

Definition of Bona fide service fees

Comment: We received several comments regarding the definition of bona fide service fees. A few commenters indicated the need for CMS to ensure that when it promulgates new regulations to implement the changes made by the Affordable Care Act, it seeks stakeholder input and provides further clarity on the treatment of bona fide service fees for the purposes of AMP reporting. Two commenters expressed concern that in the proposed rule, CMS did not propose to withdraw the definition of bona fide service fee. These commenters recommended that CMS also withdraw the definition of bona fide service fee to be consistent with the definition of bona fide service fee enacted by the Affordable Care Act. Other commenters recommended that despite the change the Affordable Care Act makes to the definition of bona fide service fee, the existing definition should remain intact and unchanged. One commenter noted that the language in the Affordable Care Act presupposes a background definition of bona fide service fees that would be applied to the named fees and any others paid by a manufacturer. Another commenter recommended that CMS provide clarification on how manufacturers should evaluate the language in the Affordable Care Act to be consistent with the historical definition.

Response: We appreciate the comments pertaining to bona fide service fees. At this time, we believe it would be inappropriate to withdraw the definition of bona fide service fee from the AMP final rule because the definition of bona fide service fee that is in §447.502 "Definitions" was intended to apply to both AMP and best price calculations. While the Determination of AMP (§447.504) is being withdrawn, at this time, no change is being made to the Determination of Best Price (§447.505). Therefore, we see no need to withdraw the definition of bona fide service fees. We do note, however, that the definition of bona fide service fee at §447.502 should not be used in the calculation of AMP. Issues related to the Affordable Care Act's treatment of bona fide service fees will be addressed in future rulemaking.

Definition of multiple source drug

Comment: We received a few comments on the definition of "multiple source drug". One commenter indicated that an accurate definition of "multiple source drug" is critical to the implementation of the provisions of the Affordable Care Act. Two commenters stated that CMS should allow for public review and comment on a definition for what constitutes a "multiple source drug" that is available for purchase by

retail community pharmacies on a nationwide basis.

Response: CMS continues to believe that the definition of "multiple source drug" in §447.502 should be withdrawn in light of changes to the relevant statutory language in the Affordable Care Act. In the absence of Federal guidance or regulation, manufacturers should rely on section 1927(k)(7) of the Act, as amended by the Affordable Care Act, for the definition of "multiple source drug."

Withdrawal of Determination of AMP (§447.504)

Comment: We received one comment indicating support for the position that AMP continue to be calculated using the current regulation (42 CFR §447.504(g)(1)). This commenter indicated that if CMS were to change the definition of AMP and therefore require manufacturers to purchase data from wholesalers in order to calculate AMP, it would be a substantial burden and expense and could result in less accurate data.

Response: CMS interpreted this comment to mean the commenter disagreed with the withdrawal of §447.504 in its entirety since the commenter specifically mentioned §447.504(g)(1) in support of continuing to calculate AMP using the current regulation. We appreciate this comment, but in light of the changes in relevant statutory language,

CMS continues to believe that withdrawing §447.504 in its entirety is the appropriate action at this time.

Monthly AMP Calculations

Comment: One commenter suggested that CMS modify the quarterly AMP calculation requirement under §447.504(i)(2) by eliminating the requirement that manufacturers report monthly AMP for single source drugs.

Response: In light of the changes in relevant statutory language made by the Affordable Care Act, we continue to believe it is necessary to withdraw all of §447.504 at this time. In addition, we are not making further changes to the monthly AMP reporting requirements in this final rule.

Quarterly AMP Calculations

Comment: One commenter requested that CMS confirm the methodology for calculating quarterly AMPs stating that the proposed rule would delete the current provision (42 CFR §447.504(i)(2)) that provides that the "[q]uarterly AMP is calculated as a weighted average of the monthly AMPs in the quarter." This commenter requested clarification on whether manufacturers should continue to calculate quarterly AMPs as a function of the monthly AMPs or whether a separate calculated quarterly AMP would be permitted or required.

Response: CMS recognizes that with the deletion of §447.504 Determination of AMP, manufacturers will have questions regarding the calculation of AMP, including monthly and quarterly AMP calculations. Manufacturers should rely on the statutory language found at section 1927(k)(1) of the Act, as amended by the Affordable Care Act, and regulations (except those regulations or portions thereof have been withdrawn).

Customary Prompt Pay Discounts

Comment: We received a few comments regarding the definition of "customary prompt pay discounts." One commenter noted that the removal of §447.504 would remove the definition of "customary prompt pay discounts" and would therefore create ambiguity as to whether a discount is customary. The commenter suggested that the definition of "customary prompt pay discounts" should remain in the regulation. Another commenter requested that CMS confirm that when it issues future regulations, it does not intend to change the definition of "customary prompt pay discounts," which the proposed rule would withdraw.

Response: Given the amendments made by the Affordable Care Act, we continue to believe that withdrawing §447.504 in its entirety is the appropriate action at this time. We

do expect to address this issue in future rulemaking. Until such time as those rules are issued and finalized, manufacturers should operate consistent with the Medicaid drug rebate statute, and regulations (except those regulations or portions thereof that have been withdrawn).

Reasonable Assumptions

Comment: We received one comment asking if the proposed regulation was designed to change the reasonable assumption option provided to manufacturers in the AMP final rule. The commenter went on to request that CMS confirm that manufacturers' reasonable assumptions may include assumptions based on the current AMP regulations to the extent that those regulations do not appear inconsistent with the statutory changes.

Response: We wish to remind manufacturers that they may not rely on regulatory provisions and language that have been withdrawn. Until a subsequent rule is issued and finalized, manufacturers should rely on section 1927 of the Act, as amended by the Affordable Care Act, and regulations (except those regulations or portions thereof that have been withdrawn).

Base date AMP Recalculation

Comment: A few commenters noted that CMS revised the language in the regulatory text of §447.510(c), pertaining to a manufacturer's recalculation of the base date AMP. One commenter suggested that CMS should take this opportunity to amend §447.510(c)(1) by removing the notation "[OFR: insert publication date of the final rule]" and specify when these recalculations will be permitted in light of the evolving definition of AMP. Another commenter thought that the revision implied that manufacturers could submit revised base date AMPs on a product-by-product basis. A third commenter suggested that manufacturers be allowed a one-time restatement of AMP in order to have a more accurate comparison between base AMP and the current AMP.

Response: As indicated in the proposed rule, CMS proposed conforming regulatory amendments to §§447.510, 447.512, and 447.518 as these sections made specific references to the provisions being proposed for withdrawal. It would have been inappropriate to keep these references to §§447.504 and 447.514 since they would no longer exist in the regulatory text. By changing the references to section 1927 of the Act, CMS did not address whether manufacturers could restate base date AMPs. The reference to section 1927 of the Act merely replaces the references to

the withdrawn regulatory text. As to the comment that CMS take this opportunity to replace the notation with the date when the recalculations would be permitted, while we appreciate the comment, taking such action would be outside the scope of the proposed rule.

Lagged Price Concessions

Comment: We received one comment expressing confusion over whether the proposed rule, if finalized, would delete the regulatory language on the AMP rolling average methodology for lagged price concessions that currently appears as 42 CFR §447.510(d)(2). Specifically, this commenter questioned whether the proposed rule would delete all of current 42 CFR §447.510(d)(2) and replace it with a single sentence, or whether it is just the first sentence being replaced and the rolling average provision would remain intact. The commenter recommended that CMS retain the current rolling average provision in the regulations as this approach has worked well to date and is consistent with the Affordable Care Act smoothing process. The commenter further stated that during the first year under the new AMP definition, manufacturers would like confirmation from CMS that they may choose whether to blend pre-ACA lagged price concessions with post-ACA lagged price concessions.

Response: We appreciate the commenter's concern about the methodology previously described in §447.510(d)(2) regarding the calculation of monthly AMP. We have decided to revise the first sentence of this paragraph as stated in the proposed rule and delete the remaining sentences. We will address this issue in future rulemaking.

Regulatory Impact Statement

Comment: We received one comment regarding CMS' determination that this is not an economically significant rule. The commenter expressed concern that CMS indicated that the proposed rule will not have a significant impact on a substantial number of small entities. The commenter went on to share their view that withdrawing parts of the existing regulation will undoubtedly help maintain the economic viability of some community retail pharmacies, but remained concerned regarding CMS' implementation of the Affordable Care Act.

Response: This final rule withdraws regulatory provisions that have been superseded by the Affordable Care Act. In light of the new provisions established by the Affordable Care Act, we do not expect that this final rule will have any significant economic effects on small business entities. Therefore, CMS continues to believe this is not an economically significant rule.

Issues Not Addressed in the Proposed Rule

We received several comments on issues that were not addressed in the proposed rule. Many of the comments were in regards to the implementation of the Affordable Care Act.

A summary of these comments is provided below. However, CMS does wish to clarify that while we appreciate the comments provided and recognize that the changes made by the Affordable Care Act are far reaching, the comments that follow are outside the scope of this proposed rule. CMS plans on issuing a proposed regulation addressing the Affordable Care Act provisions.

Effective date of Affordable Care Act changes to AMP and FULs

Comment: One commenter indicated that manufacturers will have to implement changes to AMP calculations beginning in October 2011 rather than October 2010.

Response: We wish to remind all interested parties, as noted in the "Background" section of this final rule, that the new statutory definition of AMP went into effect as of October 1, 2010. Manufacturers should rely on the statute, as revised by the Affordable Care Act, in calculating AMP.

Implementation of new AMP definition

Comment: We received a number of comments regarding the changes the Affordable Care Act makes to the definition and determination of AMP. Several commenters expressed concern about the implementation of the new Affordable Care Act definition when CMS has yet to complete the rulemaking process. These commenters requested that CMS delay the implementation of the new requirements until such time as further guidance is provided. One commenter encouraged CMS to provide sub-regulatory guidance prior to the issuance of regulations, while another commenter indicated that CMS should not issue sub-regulatory guidance as it could result in ongoing revisions to AMP calculations. This commenter stated that manufacturers should be provided the ability to make the necessary reasonable assumptions for AMP calculations until official regulations are published. Some commenters provided specific recommendations as to how CMS should define AMP, while other commenters encouraged CMS to seek stakeholder input as to how to interpret the statute regarding which entities are to be included and excluded from the calculation of AMP, as well as the planned implementation schedule. One commenter specifically requested that CMS ensure that PBM rebates be excluded from AMP. Another commenter requested that a smoothing process

be implemented for discounts to minimize the potential fluctuations in AMP from month to month. One commenter stated that AMP calculations should be consistent with both Average Sales Price (ASP) and Non-Federal Average Manufacturer Price (Non-FAMP) for the VA.

Response: While we appreciate these comments and suggestions, they raise issues that we believe are outside the scope of the proposed rule and will not be addressed in this final rule. CMS does expect to issue proposed regulations addressing the Affordable Care Act provisions. Federal Upper Limit (FULs)

Comment: We received comments regarding the implementation of the Federal Upper Limit (FUL) requirements. Several commenters encouraged CMS to delay the implementation of the new FULs requirement for multiple source drugs until a more precise definition of AMP is available. One commenter specifically recommended at least a 60-day transition between the issuance of a final regulation to implement the Affordable Care Act and the effective date of such regulation. A few commenters wanted to ensure that CMS would provide clear guidance that a FUL will be calculated when three or more therapeutically and pharmaceutically equivalent multiple source drug products

are available for purchase by retail community pharmacies on a nationwide basis. Several commenters recommended that CMS develop a methodology to determine when it would be appropriate to exceed 175 percent of AMP when calculating a FUL. One commenter suggested that CMS develop a formal mechanism to appeal FULs in certain cases. A few commenters suggested that CMS establish a process to permit more frequent changes in a FUL or the suspension of a FUL, if it were warranted.

Response: This proposed rule does not address the implementation of the Affordable Care Act; and while we appreciate these comments, they raise issues that are outside the scope of the proposed rule and will not be addressed in this final rule. CMS does intend to issue a proposed regulation addressing the Affordable Care Act provisions.

Inhalation, Infusion, Instilled, Implanted and Injectable Drugs

Comment: CMS received a number of comments regarding the statutory amendment passed by Congress in August 2010 as part of Pub. L. 111-226 that addressed inhalation, infusion, instilled, implanted and injectable drugs that are not generally dispensed through retail community pharmacies. A

few commenters stated that the Congressional intent of this amendment was to provide CMS with the authority to continue collecting rebates for these drugs that are not generally dispensed through a retail community pharmacy and was not intended to impact reimbursement to retail community pharmacies. Several commenters provided CMS with suggestions on how to define the phrase "not generally dispensed." Others commented that manufacturers need interpretive guidance in determining which of these drugs are not generally dispensed by a retail community pharmacy.

One commenter suggested that CMS publish a list of drugs that meet the statutory definition of inhalation, infusion, instilled, implanted and injectable drugs. A few commenters indicated that CMS should exercise its discretionary authority to increase the FUL of these drugs, while others commented that a FUL should not be calculated for these drugs under any circumstances.

Response: While CMS appreciates these comments, the topic of inhalation, infusion, instilled, implanted and injectable drugs is beyond the scope of the proposed rule and will not be addressed in this final rule. CMS plans to issue a proposed regulation addressing these provisions of the Affordable Care Act.

340B Drug Prices

Comment: CMS received several comments regarding the impact of the AMP calculation on the discounted drug prices that 340B covered entities receive. One commenter urged that CMS coordinate with the Health Resources and Services Administration (HRSA) with respect to the application of the new AMP definition to 340B price calculations and to ensure that the new definition of AMP is used to calculate 340B ceiling prices as HRSA uses AMP data to calculate the 340B drug prices. CMS received a few comments in regard to the relationship between 340B drug prices and the amendment to the statute regarding inhalation, infusion, instilled, implanted and injectable drugs. One commenter stated that calculating AMP for these types of drugs based solely on retail community pharmacies' prices would have had a devastating impact on 340B discount prices of Factor Replacement Product (FRP) because only about 1 percent to 2 percent of FRP is distributed through retail community pharmacies. Another commenter stated that calculating AMP by taking into account discounts and rebates provided to non-retail pharmacies is important for 340B entities because the use of retail pricing alone would distort 340B price calculations.

Response: While we appreciate these comments, the topic of 340B drug pricing is outside the scope of the proposed rule and therefore will not be addressed in this final rule.

Adequate Documentation

Comment: CMS received several comments regarding the use of the phrase "adequate documentation" in §447.504(g)(1), which states that sales to wholesalers are to be included in the calculation of AMP unless the manufacturer has adequate documentation showing the drugs are subsequently resold to an excluded entity as specified in paragraph (h). A few commenters recommended that CMS reverse this provision and instead provide guidance to manufacturers that sales and discounts should be excluded from AMP calculations unless the manufacturers have adequate documentation to show that the sales and discounts fit the statute's definition of AMP. Other commenters expressed support for retaining the current language. One commenter claimed that this language has worked well to date in promoting stability of AMP calculations and is not inconsistent with new statutory provisions. This commenter further stated that this language poses no risk of creating adverse consequences for pharmacies that serve Medicaid

beneficiaries and would be unlikely to decrease FULs inappropriately. Another commenter stated that the Affordable Care Act seems to remain silent on this issue and recommends that the current language remain in effect in future regulations. One commenter supports the current language as a better approach than requiring manufacturers to generate or purchase data necessary to calculate an AMP that includes wholesaler sales, only if resale to a retail community pharmacy is documented.

Response: While we appreciate these comments, they are outside the scope of the proposed rule and therefore will not be addressed in this final rule, except to emphasize that §447.504, including paragraph (g)(1), is being withdrawn by this final rule.

Authorized Generics

Comment: We received a few comments requesting CMS provide clarification regarding manufacturers with authorized generics. Two commenters requested that CMS confirm that transactions related to the transfer of authorized generics to secondary manufacturers that resell to community pharmacies are to be treated as wholesalers and therefore should be included in AMP. Another commenter stated that with the broader definition of wholesaler it is

unclear whether authorized generics manufacturers would be considered in AMP.

Response: These comments are outside the scope of the proposed rule and will not be addressed in this final rule.

However, CMS does wish to clarify that while the definition of "wholesaler" as defined in §447.504 of the AMP final rule will no longer exist, the Affordable Care Act does provide a new definition of wholesaler. Therefore, in the absence of regulatory guidance, manufacturers should refer to the statute, as revised by the Affordable Care Act. CMS does intend to issue a proposed regulation addressing the changes made by the Affordable Care Act.

Definitions of Retail Community Pharmacy and Wholesaler

Comment: We received comments regarding definitions that were revised or introduced in the Affordable Care Act. One commenter noted that an accurate definition of "retail community pharmacy" is critical to the implementation of the provisions within the Affordable Care Act. Another commenter recommended that CMS provide a table providing a specific breakdown of what is considered to be a retail community pharmacy. A few commenters indicated that CMS should revise the definition of "wholesaler" to be consistent with the new statutory definition of wholesaler.

One commenter stated that an accurate definition of "wholesaler" is critical to the implementation of these new provisions.

Response: We appreciate these comments; however, they are outside the scope of the proposed rule and will not be addressed in this final rule. In the absence of regulatory guidance, interested parties should rely on the statute, as revised by the Affordable Care Act. CMS intends to issue a proposed regulation addressing the changes made by the Affordable Care Act.

Other Comments

Comment: We received comments requesting guidance on Line Extension Drugs, Medicaid Managed Care Organizations (MCOs), and State invoices to manufacturers. One commenter requested guidance on the implementation of the new requirements for calculating rebates for line extension drugs. This commenter noted that Release 81 provided guidance on how to perform the calculation and price comparison but it did not provide a useful interpretation of the term. Another commenter requested guidance regarding the implementation of the new statutory requirement, which requires that rebates to be collected on prescriptions paid by Medicaid MCOs. The commenter stated that companies will

need data from CMS on the number of Medicaid beneficiaries enrolled in MCOs with pharmacy benefits to be able to verify prescription data. Additionally, this commenter had concerns regarding MCOs and 340B drugs and stated that the new statutory requirements for rebates on prescriptions paid by Medicaid MCOs creates the likelihood that double discounts could be imposed on manufacturers unless CMS makes it clear that such utilization may not be reported to Medicaid. One commenter raised concerns with a manufacturer's obligation to pay rebates on claims that are paid primarily by a non-Medicaid payor, where Medicaid is a secondary payor. This commenter was particularly interested in having CMS clarify that States may not invoice a manufacturer for more than 100 percent of the amount paid by the State associated with a drug claim.

Response: While we appreciate the comments, they are outside the scope of the proposed rule and will not be addressed in this final rule. However, CMS does wish to remind all interested parties that in the absence of regulatory guidance, they should refer to the statute as amended by the Affordable Care Act.

Retail Price Survey and Publication of AMP data

Comment: We received one comment regarding the retail

price survey which indicated that it would be important for CMS to only publish weighted average Retail Price Survey (RPS) data for multiple source drugs subject to the FUL and only include reimbursement paid to community retail pharmacies. Another commenter recommended that CMS review several months of the weighted AMP data before making it public.

Response: The issues raised in these comments are outside the scope of the proposed rule and will not be addressed in this final rule.

IV. Provisions of the Final Regulations

This final rule incorporates the provisions of the September 3, 2010 proposed rule.

V. Collection of Information Requirements

This document does not impose any new reporting, recordkeeping, or disclosure requirements. The burden associated with the existing reporting requirements contained in §447.510(a) is currently approved under OCN: 0938-0578.

VI. Regulatory Impact Statement

We have examined the impact of this rule as required by Executive Order 12866 on Regulatory Planning and Review (September 30, 1993) the Regulatory Flexibility Act (RFA)

(September 19, 1980, Pub. L. 96-354), section 1102(b) of the Social Security 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 Order 12866 directs agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). A regulatory impact analysis (RIA) must be prepared for major rules with economically significant effects (\$100 million or more in any 1 year). This regulatory action withdraws those regulatory provisions that have been superseded by the Affordable Care Act. In light of the new provisions established by the Affordable Care Act, we do not expect that this final rule will have any significant economic effects. Therefore, this final rule is not considered an economically significant rule.

The RFA requires agencies to analyze options for regulatory relief of small businesses, if a rule has a significant impact on a substantial number of small

entities. For purposes of the RFA, small entities include small businesses, nonprofit organizations, and small governmental jurisdictions. Most hospitals and most other providers and suppliers are small entities, either by nonprofit status or by having revenues of \$7.0 million to \$34.5 million in any 1 year. Individuals and States are not included in the definition of a small entity. We are not preparing an analysis for the RFA because the Secretary has determined that this final rule will not have a significant economic impact on a substantial number of small entities.

In addition, section 1102(b) of the Act requires us to prepare a regulatory impact analysis if a rule may have a significant impact on the operations of a substantial number of small rural hospitals. This analysis must conform to the provisions of section 604 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 for Medicare payment regulations and has fewer than 100 beds. We are not preparing an analysis for section 1102(b) of the Act because the Secretary has determined that this final rule will not have a significant impact on the operations of a substantial number of small rural hospitals.

Section 202 of the Unfunded Mandates Reform Act of 1995 also requires that agencies assess anticipated costs and benefits before issuing any rule whose mandates require spending in any 1 year of \$100 million in 1995 dollars, updated annually for inflation. In 2010, that threshold is approximately \$135 million. This rule will not have consequential effect on State, local, or tribal governments or on the private sector.

Executive Order 13132 establishes certain requirements that an agency must meet when it promulgates a proposed rule (and subsequent final rule) that imposes substantial direct requirement costs on State and local governments, preempts State law, or otherwise has Federalism implications. Since this regulation does not impose any costs on State or local governments, the requirements of Executive Order 13132 are not applicable.

In accordance with the provisions of Executive Order 12866, this regulation was reviewed by the Office of Management and Budget.

List of Subjects in 42 CFR Part 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 - PAYMENT FOR SERVICES

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

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

Subpart I--Payment for Drugs

2. Section 447.502 is amended by removing the definition of "multiple source drug."

§447.504 [Removed and reserved]

3. Section 447.504 is removed and reserved.

4. Section 447.510 is amended by--

A. Republishing paragraph (a) introductory text.

B. Revising paragraphs (a)(1), (c)(2)(i), and (d)(2)

The revisions read as follows:

§447.510 Requirements for manufacturers.

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

(1) AMP, calculated in accordance with section 1927 (k) (1) of the Social Security Act.

* * * * *

(c) * * *

(2) * * *

(i) A manufacturer's recalculation of the base date AMP must only reflect the revisions to AMP as provided for in section 1927(k) (1) of the Social Security Act.

* * * * *

(d) * * *

(2) Calculation of monthly AMP. Monthly AMP should be calculated based on section 1927(k) (1) of the Social Security Act, except the period covered should be based on monthly, as opposed to quarterly AMP sales.

* * * * *

5. Section 447.512 is amended by--

A. Removing and reserving paragraph (a).

B. Revising the introductory text of paragraph (b).

C. Revising paragraph (c).

The revisions read as follows:

§447.512 Drugs: Aggregate upper limits of payment.

(a) [Reserved]

(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 must not exceed, in the aggregate, payments levels that the agency has determined by applying the lower of the--.

* * * * *

(c) Certification of brand name drugs.

(1) The upper limit for payment for multiple source drugs for which a specific limit has been established does not apply if a physician certifies in his or her own handwriting (or by an electronic alternative means approved by the Secretary) that a specific brand is medically necessary for a particular recipient.

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

(3) A 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 [Removed and reserved]

6. Section 447.514 is removed and reserved.

7. Section 447.518 is amended by revising paragraphs (b) (1) (i) and (b) (2) to read as follows:

§447.518 State plan requirements, findings and assurances.

* * * * *

(b) * * *

(1) * * *

(i) In the aggregate, its Medicaid expenditures for multiple source drugs are in accordance with the established upper limits.

* * * * *

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

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Authority: (Catalog of Federal Domestic Assistance Program No. 93.778, Medical Assistance Program).

Dated: October 20, 2010

Donald M. Berwick,
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Centers for Medicare & Medicaid
Services.

Approved: November 3, 2010

Kathleen Sebelius,
Secretary.

BILLING CODE 4120-01-P

CMS-2238-F2

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[FR Doc. 2010-28649 Filed 11/09/2010 at 4:15 pm; Publication
Date: 11/15/2010]