

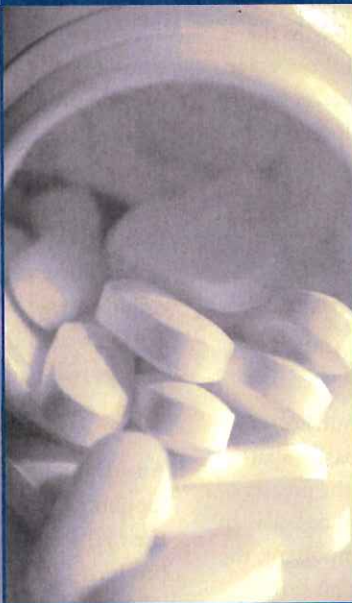
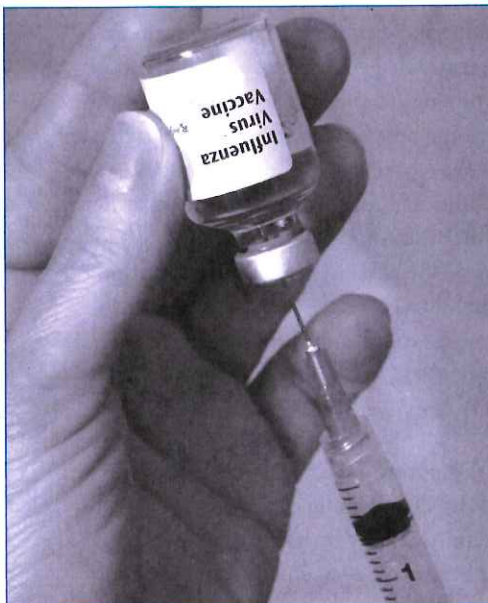
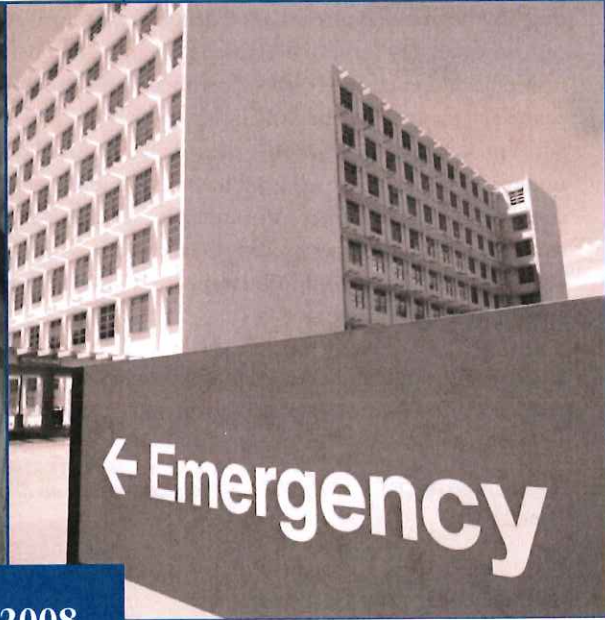
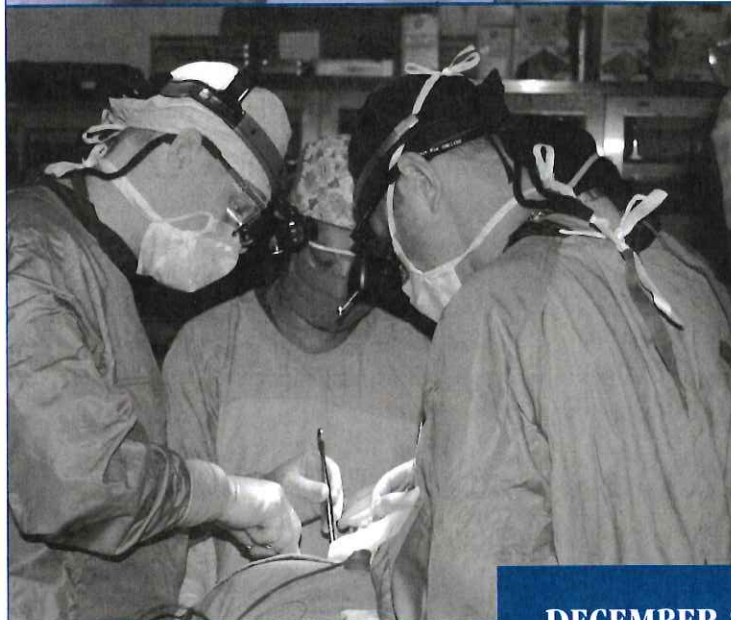
September 14, 2015

Materials submitted to OMB:

- December 2008 Congressional Budget Office (CBO) budget option 76 on Medicaid rebate
- Patient Protection and Affordable Care Act (PPACA) legislative language
- CMS Proposed Rule on the Average Manufacturer Price (AMP)
- Comment letter from 21 Pain Care Organizations
- Comment letter from Purdue Pharma
- Four Congressional letters and one response letter from HHS
- Energy and Commerce's Committee Report (111-299) on H.R. 3200, America's Affordable Health Choices Act of 2009 on Section 1742, Prescription Drug Rebates (page 634-635)
- March 2015 Line extension Question For the Record from House Labor/HHS Appropriations Subcommittee hearing (attached)
- September 10, 2015 Letter to HHS Secretary Burwell from 29 patient organizations, provider groups and manufacturers

CBO

Budget Options Volume I Health Care

A photograph of a "HEALTH INSURANCE CLAIM FORM". The form is filled out with various details, including patient information, insurance plan details, and a section for the provider to complete. The form is titled "HEALTH INSURANCE CLAIM FORM" at the top.

DECEMBER 2008

Option 76**Apply the Medicaid Additional Rebate to New Formulations of Existing Drugs**

(MILLIONS OF DOLLARS)	2010	2011	2012	2013	2014	Total	
						2010-2014	2010-2019
Change in Mandatory Spending	-130	-260	-280	-290	-310	-1,270	-2,970

In the fee-for-service portion of the Medicaid program, drug manufacturers must enter into a rebate agreement with the Centers for Medicare and Medicaid Services (CMS) to have their products covered. For each prescription drug that is covered by Medicaid, participating manufacturers must report two market prices to CMS: the average manufacturer price (AMP), which is the average price that a drugmaker receives for sales to retail pharmacies and mail-order establishments, and the lowest transaction price, or “best price,” that the manufacturer receives from sales to certain private buyers of the drug. Those prices, which serve as reference points for determining manufacturers’ rebate obligations, must be reported for each formulation and dosage of each prescription drug purchased on behalf of Medicaid beneficiaries.

For brand-name prescription drugs, the manufacturer’s rebate obligation has two components: the basic rebate and an additional rebate. The basic rebate is the greater of either 15.1 percent of the AMP or the difference between the AMP and the best price. The second component, the additional rebate, may also apply depending on how quickly the manufacturer raises a drug’s price to private purchasers. Every form of every drug purchased on behalf of Medicaid beneficiaries has its own base-period AMP that is determined by the drug’s original market date. No additional rebate is owed if the drug’s current AMP does not exceed its inflation-adjusted base period level, as measured using the consumer price index for all urban consumers; if the AMP does exceed the allowed inflation-adjusted level, then an additional rebate is owed that is equal to the excess amount.

Currently, modifications to existing drugs—new dosages or formulations—are generally considered new products

for purposes of reporting AMPs to CMS. As a result, drugmakers can often avoid incurring an additional rebate obligation by making a slight alteration to an existing product.

This option would treat a certain type of new formulation—specifically, extended-release versions—of existing drugs more like the original product for purposes of calculating the additional rebate. Under the option, when a new, extended-release version of an existing drug was introduced, the additional rebate obligation for that new drug would be either the AMP percentage that is owed under current law or the AMP percentage owed for the original drug, whichever is greater. Implementing the option would increase rebate amounts and reduce federal outlays by an estimated \$1.3 billion over the 2010–2014 period and by \$3 billion over the 2010–2019 period.

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An advantage of this option is that it would remove a loophole that enables drug manufacturers to circumvent their rebate obligations simply by altering an existing product. Under current law, even a minor change to an existing drug can lead to a “new” product designation that does not trigger the inflation-related rebate even if the initial price for that new product is substantially higher than the price for the original formulation.

A potential drawback to this option is that it could discourage some manufacturers from developing new formulations even when the new products might offer advantages over older versions of the same product. Also, the additional rebate, like the basic rebate, limits drugmakers’ pricing flexibility in private markets because changes in prices for private buyers can affect their rebate obligation.

RELATED CBO PUBLICATION: *The Rebate Medicaid Receives on Brand-Name Prescription Drugs*, Letter to the Honorable Charles E. Grassley, June 21, 2005

«CBO»

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these services are unevenly available within and across States, and reach a small percentage of eligible individuals.

(b) SENSE OF THE SENATE.—It is the sense of the Senate that—

(1) during the 111th session of Congress, Congress should address long-term services and supports in a comprehensive way that guarantees elderly and disabled individuals the care they need; and

(2) long term services and supports should be made available in the community in addition to in institutions.

Subtitle F—Medicaid Prescription Drug Coverage

SEC. 2501. PRESCRIPTION DRUG REBATES.

(a) INCREASE IN MINIMUM REBATE PERCENTAGE FOR SINGLE SOURCE DRUGS AND INNOVATOR MULTIPLE SOURCE DRUGS.—

(1) IN GENERAL.—Section 1927(c)(1)(B) of the Social Security Act (42 U.S.C. 1396r–8(c)(1)(B)) is amended—

(A) in clause (i)—

(i) in subclause (IV), by striking “and” at the end;

(ii) in subclause (V)—

(I) by inserting “and before January 1, 2010” after “December 31, 1995.”; and

(II) by striking the period at the end and inserting “; and”;

(iii) by adding at the end the following new subclause:

“(VI) except as provided in clause (iii), after December 31, 2009, 23.1 percent.”; and

(B) by adding at the end the following new clause: “(iii) MINIMUM REBATE PERCENTAGE FOR CERTAIN DRUGS.—

“(I) IN GENERAL.—In the case of a single source drug or an innovator multiple source drug described in subclause (II), the minimum rebate percentage for rebate periods specified in clause (i)(VI) is 17.1 percent.

“(II) DRUG DESCRIBED.—For purposes of subclause (I), a single source drug or an innovator multiple source drug described in this subclause is any of the following drugs:

“(aa) A clotting factor for which a separate furnishing payment is made under section 1842(o)(5) and which is included on a list of such factors specified and updated regularly by the Secretary.

“(bb) A drug approved by the Food and Drug Administration exclusively for pediatric indications.”.

(2) RECAPTURE OF TOTAL SAVINGS DUE TO INCREASE.—Section 1927(b)(1) of such Act (42 U.S.C. 1396r–8(b)(1)) is amended by adding at the end the following new subparagraph:

“(C) SPECIAL RULE FOR INCREASED MINIMUM REBATE PERCENTAGE.—

“(i) IN GENERAL.—In addition to the amounts applied as a reduction under subparagraph (B), for

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rebate periods beginning on or after January 1, 2010, during a fiscal year, the Secretary shall reduce payments to a State under section 1903(a) in the manner specified in clause (ii), in an amount equal to the product of—

“(I) 100 percent minus the Federal medical assistance percentage applicable to the rebate period for the State; and

“(II) the amounts received by the State under such subparagraph that are attributable (as estimated by the Secretary based on utilization and other data) to the increase in the minimum rebate percentage effected by the amendments made by subsections (a)(1), (b), and (d) of section 2501 of the Patient Protection and Affordable Care Act, taking into account the additional drugs included under the amendments made by subsection (c) of section 2501 of such Act.

The Secretary shall adjust such payment reduction for a calendar quarter to the extent the Secretary determines, based upon subsequent utilization and other data, that the reduction for such quarter was greater or less than the amount of payment reduction that should have been made.

“(ii) MANNER OF PAYMENT REDUCTION.—The amount of the payment reduction under clause (i) for a State for a quarter shall be deemed an overpayment to the State under this title to be disallowed against the State’s regular quarterly draw for all Medicaid spending under section 1903(d)(2). Such a disallowance is not subject to a reconsideration under section 1116(d).”.

(b) INCREASE IN REBATE FOR OTHER DRUGS.—Section 1927(c)(3)(B) of such Act (42 U.S.C. 1396r–8(c)(3)(B)) is amended—

(1) in clause (i), by striking “and” at the end;

(2) in clause (ii)—

(A) by inserting “and before January 1, 2010,” after “December 31, 1993,”; and

(B) by striking the period and inserting “; and”; and

(3) by adding at the end the following new clause:

“(iii) after December 31, 2009, is 13 percent.”.

(c) EXTENSION OF PRESCRIPTION DRUG DISCOUNTS TO ENROLLEES OF MEDICAID MANAGED CARE ORGANIZATIONS.—

(1) IN GENERAL.—Section 1903(m)(2)(A) of such Act (42 U.S.C. 1396b(m)(2)(A)) is amended—

(A) in clause (xi), by striking “and” at the end;

(B) in clause (xii), by striking the period at the end and inserting “; and”; and

(C) by adding at the end the following:

“(xiii) such contract provides that (I) covered outpatient drugs dispensed to individuals eligible for medical assistance who are enrolled with the entity shall be subject to the same rebate required by the agreement entered into under section 1927 as the State is subject to and that the State shall collect such rebates from manufacturers, (II) capitation rates paid to the entity shall be based on actual cost experience

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related to rebates and subject to the Federal regulations requiring actuarially sound rates, and (III) the entity shall report to the State, on such timely and periodic basis as specified by the Secretary in order to include in the information submitted by the State to a manufacturer and the Secretary under section 1927(b)(2)(A), information on the total number of units of each dosage form and strength and package size by National Drug Code of each covered outpatient drug dispensed to individuals eligible for medical assistance who are enrolled with the entity and for which the entity is responsible for coverage of such drug under this subsection (other than covered outpatient drugs that under subsection (j)(1) of section 1927 are not subject to the requirements of that section) and such other data as the Secretary determines necessary to carry out this subsection.”

(2) CONFORMING AMENDMENTS.—Section 1927 (42 U.S.C. 1396r-8) is amended—

(A) in subsection (b)—

(i) in paragraph (1)(A), in the first sentence, by inserting “, including such drugs dispensed to individuals enrolled with a medicaid managed care organization if the organization is responsible for coverage of such drugs” before the period; and

(ii) in paragraph (2)(A), by inserting “including such information reported by each medicaid managed care organization,” after “for which payment was made under the plan during the period,”; and

(B) in subsection (j), by striking paragraph (1) and inserting the following:

“(1) Covered outpatient drugs are not subject to the requirements of this section if such drugs are—

“(A) dispensed by health maintenance organizations, including Medicaid managed care organizations that contract under section 1903(m); and

“(B) subject to discounts under section 340B of the Public Health Service Act.”

(d) ADDITIONAL REBATE FOR NEW FORMULATIONS OF EXISTING DRUGS.—

(1) IN GENERAL.—Section 1927(c)(2) of the Social Security Act (42 U.S.C. 1396r-8(c)(2)) is amended by adding at the end the following new subparagraph:

“(C) TREATMENT OF NEW FORMULATIONS.—*[Replaced by section 1206(a) of HCERA]* 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 with respect to such drug under this section shall be the amount computed under this section for such new drug or, if greater, the product of—

“(i) the average manufacturer price of the line extension of a single source drug or an innovator multiple source drug that is an oral solid dosage form;

“(ii) the highest additional rebate (calculated as a percentage of average manufacturer price) under this section for any strength of the original single source drug or innovator multiple source drug; and

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“(iii) 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).

In this subparagraph, the term ‘line extension’ means, with respect to a drug, a new formulation of the drug, such as an extended release formulation.”

(2) EFFECTIVE DATE.—The amendment made by paragraph

(1) shall apply to drugs that are paid for by a State after December 31, 2009.

(e) MAXIMUM REBATE AMOUNT.—Section 1927(c)(2) of such Act (42 U.S.C. 1396r-8(c)(2)), as amended by subsection (d), is amended by adding at the end the following new subparagraph:

“(D) MAXIMUM REBATE AMOUNT.—In no case shall the sum of the amounts applied under paragraph (1)(A)(ii) and this paragraph with respect to each dosage form and strength of a single source drug or an innovator multiple source drug for a rebate period beginning after December 31, 2009, exceed 100 percent of the average manufacturer price of the drug.”

(f) CONFORMING AMENDMENTS.—

(1) IN GENERAL.—Section 340B of the Public Health Service Act (42 U.S.C. 256b) is amended—

(A) in subsection (a)(2)(B)(i), by striking “1927(c)(4)” and inserting “1927(c)(3)”; and

(B) by striking subsection (c); and

(C) redesignating subsection (d) as subsection (c).

(2) EFFECTIVE DATE.—The amendments made by this subsection take effect on January 1, 2010.

SEC. 2502. ELIMINATION OF EXCLUSION OF COVERAGE OF CERTAIN DRUGS.

(a) IN GENERAL.—Section 1927(d) of the Social Security Act (42 U.S.C. 1397r-8(d)) is amended—

(1) in paragraph (2)—

(A) by striking subparagraphs (E), (I), and (J), respectively; and

(B) by redesignating subparagraphs (F), (G), (H), and (K) as subparagraphs (E), (F), (G), and (H), respectively; and

(2) by adding at the end the following new paragraph:

“(7) NON-EXCLUDABLE DRUGS.—The following drugs or classes of drugs, or their medical uses, shall not be excluded from coverage:

“(A) Agents when used to promote smoking cessation, including agents approved by the Food and Drug Administration under the over-the-counter monograph process for purposes of promoting, and when used to promote, tobacco cessation.

“(B) Barbiturates.

“(C) Benzodiazepines.”

(b) EFFECTIVE DATE.—The amendments made by this section shall apply to services furnished on or after January 1, 2014.

SEC. 2503. PROVIDING ADEQUATE PHARMACY REIMBURSEMENT.

(a) PHARMACY REIMBURSEMENT LIMITS.—

(1) IN GENERAL.—Section 1927(e) of the Social Security Act (42 U.S.C. 1396r-8(e)) is amended—

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Part 447

[CMS-2345-P]

RIN 0938-AQ41

Medicaid Program; Covered Outpatient Drugs

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

ACTION: Proposed rule.

SUMMARY: This proposed rule would revise requirements pertaining to Medicaid reimbursement for covered outpatient drugs to implement provisions of the Patient Protection and Affordable Care Act of 2010, as amended by the Health Care and Education Reconciliation Act of 2010 (collectively known as the Affordable Care Act). This proposed rule would also revise other requirements related to covered outpatient drugs, including key aspects of Medicaid coverage, payment, and the drug rebate program. Therefore, we are proposing to amend 42 CFR part 447, subpart I to implement specific provisions of the Affordable Care Act.

DATES: To be assured consideration, comments must be received at one of the addresses provided below, no later than 5 p.m. on April 2, 2012.

ADDRESSES: In commenting, please refer to file code CMS-2345-P. 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 <http://www.regulations.gov>. Follow the instructions under the "More Search Options" tab.

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-P, P.O. Box 8016, Baltimore, MD 21244-8016.

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-P, Mail Stop C4-26-05, 7500 Security Boulevard, Baltimore, MD 21244-1850.

4. *By hand or courier.* If you prefer, you may deliver (by hand or courier) your written comments 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 must 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. The comments delivered must also be stamped in to verify timeliness of submission.)

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 if received after the comment period closes may not be considered.

Submission of comments on paperwork requirements. You may submit comments on this document's paperwork requirements by following the instructions at the end of the "Collection of Information Requirements" section in this document.

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

FOR FURTHER INFORMATION CONTACT:

Angel Davis, (410) 786-4693, and Meagan Khau, (410) 786-1357, for issues related to rebates for line extensions.

Lisa Ferrandi, (410) 786-5445, for issues related to the Collection of Information Requirements.

Joseph Fine, (410) 786-2128, for issues related to the determination of Best Price, definition of covered outpatient

drug and rebates for drugs dispensed by Medicaid managed care organizations.

Christine Hinds, (410) 786-4578, Kimberly Howell, (410) 786-6762, Terry Simananda, (410) 786-8144, or Wendy Tuttle, (410) 786-8690, for issues related to the determination of Average Manufacturer Price (AMP). Meagan Khau, (410) 786-1357, for issues related to the offset of rebates. Madlyn Kruh, (410) 786-3239, for issues related to authorized generics, nominal price, investigational drugs, and the coverage of tobacco cessation drugs under the Medicaid State Plan. Bernadette Leeds, (410) 786-9463, for issues related to drug rebates. Gail Sexton, (410) 786-4583, for issues related to Federal upper limits. Marge Watchorn, (410) 786-4361, 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.

I. Background

A. Introduction

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

of the Act. Section 1927 of the Act provides specific requirements for rebate agreements, drug pricing submission and confidentiality requirements, the formulas for calculating rebate payments, and requirements for States for covered outpatient drugs.

This proposed rule would implement 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 known as the Affordable Care Act). It would also implement changes to section 1927 of the Act as set forth in section 202 of Pub. L. 111–226, enacted on August 10, 2010 (referred to as the Education Jobs and Medicaid Funding Act). This proposed rule would implement other miscellaneous provisions pertaining to covered outpatient drugs. It would implement 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). It would also codify other requirements in section 1927 of the Act pertaining to the Medicaid drug rebate (MDR) program and revise certain regulatory provisions presently codified at 42 CFR part 447, subpart I and make other changes concerning rebate requirements. As discussed below, these proposed 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) of the Act by specifying new conditions for managed care organization (MCO) contracts, including that covered outpatient drugs 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) 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 § 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) 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) 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 covered outpatient drugs are not subject to the rebate requirements if such drugs are both subject to discounts under section 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, as revised by section 1206(a) of HCERA, added a new subparagraph (C) to section 1927(c)(2) 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 Public Health Service Act, which are not addressed in this proposed rule.

Section 2503(a) of the Affordable Care Act amended 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. 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 under Medicare Part B. It amended section 1927(k) of the Act by revising the definition of AMP to mean 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.

It also amended the definition of multiple source drug to specify, in part, that a covered outpatient drug qualifies as a multiple source drug if at least one other therapeutically equivalent drug product is sold or marketed in the United States, as opposed to in a State, during the rebate period. It 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 covered outpatient drug. 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.

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" under Medicaid at section 1927(c)(1)(C) 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 discount program under section 340B of the Public Health Service Act (PHSA) to include certain children's hospitals, freestanding cancer hospitals, critical access hospitals, rural referral centers and sole community hospitals.

Section 204 of the Medicare and 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) of the Act by providing that discounts provided by manufacturers under the Medicare coverage gap discount program under section 1860D-14A of the Act are excluded from a manufacturer's determination of AMP, effective March 30, 2010.

C. Final Rule With Comment Period Published July 17, 2007

On July 17, 2007, CMS published a final rule with comment period in the **Federal Register** (72 FR 39142). The purpose of the final rule with comment

period was to finalize the provisions of the proposed rule CMS published in the **Federal Register** on December 22, 2006 (71 FR 77174) and to allow for further public comment on the AMP and Federal upper limit (FUL) outlier sections of the final rule. We received a variety of comments from drug manufacturers, membership organizations, wholesalers, law firms, PBMs, consulting firms and pharmacists in support of, and raising concerns with, the AMP and FUL provisions. However, we note that these regulatory provisions were withdrawn through the final rule published in the November 15, 2010 **Federal Register** (75 FR 69591).

Accordingly, we will not be considering the comments received on the July 17, 2007, rule in this rulemaking document. Further, because the Affordable Care Act made substantial changes to the AMP and FUL provisions in section 1927 of the Act, we no longer expect to publish that final rule and we do not expect to address those comments in subsequent rulemaking.

D. Other Changes Concerning the Medicaid Drug Rebate Program

We are also proposing changes to address other program issues related to covered outpatient drugs, including key aspects of Medicaid payment and the MDR program, such as reimbursement to pharmacies for the ingredient cost of a drug, determination of AMP for authorized generic drugs, and the inclusion of territories in the MDR program. These changes are described in greater detail below under section II. Provisions of the Proposed Regulations.

II. Provisions of the Proposed Regulations

This proposed rule would revise regulations concerning the MDR program, set forth at section 1927 of the Act. It implements, consistent with our general rulemaking authority, sections 2501, 2503, and 3301(d)(2) of the Affordable Care Act and sections 1101(c) and 1206 of HCERA, which revise requirements concerning the rebate program and payments for prescription drugs under the Medicaid program. The specific provisions we propose are described in detail below.

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. We propose to add § 447.500(a)(4) which would specify sections

1903(m)(2)(A)(xiii) and 1927(b) of the Act as the basis for rebates for covered outpatient drugs dispensed to individuals eligible for medical assistance who are enrolled in Medicaid MCOs. We propose to add § 447.500(a)(5) which would add section 1902(a)(30)(A) as an additional basis for calculating payments for covered outpatient drugs.

B. Definitions (§ 447.502)

1. Actual Acquisition Cost

States generally reimburse pharmacies for covered outpatient drugs that are prescribed and dispensed to Medicaid beneficiaries based on a two-part formula, which addresses the ingredient cost of a drug and a reasonable dispensing fee. Each State has the flexibility to determine the amount it will reimburse for each component of the formula based on the agency's best estimate of the price generally and currently paid by providers for a drug marketed or sold by a particular drug labeler and the cost associated with ensuring that possession of the appropriate covered outpatient drug is transferred to a Medicaid beneficiary. These reimbursement formulas are subject to review and approval by CMS through the State plan amendment (SPA) process.

In general, States currently reimburse for the covered outpatient drug based, in part, on the estimated acquisition cost (EAC). The EAC, as currently defined in Federal regulations at § 447.502 is the agency's best estimate of the price generally and currently paid by providers for a drug marketed or sold by a particular manufacturer or labeler in the package size of drug most frequently purchased by providers. We are proposing to both rename and revise this definition in this proposed rule.

Section 1902(a)(30)(A) of the Act requires, in part, that States have methods and procedures to assure that payment for Medicaid care and services is consistent with efficiency, economy, and quality of care. In accordance with these provisions and in light of the OIG reports concerning published prices (OIG Audit reports—A-06-00-00023, A-06-01-00053, A-06-02-00041),¹ we believe it is necessary for States to have a more accurate reference price to base reimbursement for prescription drugs. Therefore, we propose to replace the term, "estimated acquisition cost" with "actual acquisition cost" (AAC). We believe that changing this definition for

¹ <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>.

the drug ingredient component of the reimbursement formula to AAC will be more reflective of actual prices paid, as opposed to estimates based on unreliable published compendia pricing. While we recognize that States may not be able to determine the actual price of each individual drug, payment based on an average of the actual acquisition costs from a number of representative pharmacies would still fit within this definition, as data used in the calculation of the average acquisition cost would be reflective of actual purchase prices for pharmacy providers. Within this framework, States can develop payment methodologies consistent with this regulatory definition for their Medicaid pharmacy reimbursement. Therefore, in § 447.502, we propose to define actual acquisition cost as the agency's determination of the actual prices paid by pharmacy providers to acquire drug products marketed or sold by specific manufacturers. This issue and its possible effects on ingredient cost reimbursement is discussed further in both § 447.512 Drugs: Aggregate upper limits of payment and § 447.518 State plan requirements, findings, and assurances.

2. Authorized Generic Drug

The definition of "authorized generic drug", presently set forth in § 447.506(a), applies to rebate calculations, as set forth in subpart I "Payment for Drugs." Therefore, we propose to remove the definition of "Authorized generic drug" from § 447.506 and move this definition to § 447.502. We would continue to define the term "Authorized generics drugs" as any drug sold, licensed or marketed under an 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 listed brand drug.

For purposes of the MDR Program, an authorized generic is any drug product marketed under the innovator or brand manufacturer's New Drug Application (NDA) approved under section 505(c) of the FFDCA, but labeled with a different NDC than the innovator or brand product. Authorized generics are categorized as innovator multiple source drugs for the purpose of computing the drug rebate.

3. Bona Fide Service Fee

In the July 17, 2007 AMP final rule, we defined bona fide service fees as fees

paid by a manufacturer to an entity that represent fair market value for a bona fide, itemized service actually performed on behalf of the manufacturer that the manufacturer would otherwise perform (or contract for) in the absence of the service arrangement and that are not passed on in whole or in part to a client or customer of an entity, whether or not the entity takes title to the drug. The Affordable Care Act specifies that the AMP shall exclude bona fide service fees paid by manufacturers to wholesalers or retail community pharmacies including, but 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). In § 447.502, we propose to revise our current definition of bona fide service fees to include these fees paid by manufacturers to wholesalers or retail community pharmacies.

4. Bundled Sales

In the AMP final rule published on July 17, 2007, bundled sale was defined as an arrangement, regardless of physical packaging, under which the rebate, discount, or other price concession is conditioned upon the purchase of the same drug, drugs of different types (that is, at the nine-digit National Drug Code (NDC) level) or another product or some other performance requirement (for example, the achievement of market share, inclusion or tier placement on a formulary), or where the resulting discounts or other price concessions are greater than those which would have been available had the bundled drugs been purchased separately or outside the bundled arrangement. For bundled sales, the discounts are allocated proportionally to the total dollar value of the units of all drugs sold under the bundled arrangement. 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 in the bundle. In response to manufacturer questions regarding whether a discount and resulting price for each product in a single customer contract that is independent and not contingent on the discount or pricing of any other product in the contract should be applied across all products; we stated previously that where a discount or price concession is established independently and not conditioned upon any other purchase or performance requirement (for example

the achievement of market share, inclusion or tier placement on a formulary), or where the discount is not greater than if purchased outside of multi-product arrangement, there is no bundle within the meaning described in § 447.502. Though this is not addressed in the Affordable Care Act, we continue to agree with our response to this issue and thus have decided to include it in this discussion in order to further clarify the bundled sale definition. Therefore, we propose to add the following clarifying statement to the definition of bundled sale: The discounts in a bundled sale, including but not limited to those discounts resulting from a contingent arrangement, are allocated proportionally to the total dollar value of the units of all drugs sold under the bundled arrangement.

5. Clotting Factor

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. Consistent with these provisions, we propose to define clotting factors as those drugs or products for which a separate furnishing payment is authorized under section 1842(o)(5) of the Act and which are included on a list of such factors specified and updated quarterly by CMS.

6. Covered Outpatient Drug

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 covered outpatient drugs for which payment has been made under the state plan. Manufacturers are responsible for submitting required drug product data, including each drug's NDC. This NDC information is placed on the MDR file and used for assuring compliance with the statutory requirements.

There have been products identified in the drug product data file that do not meet the definition of a covered outpatient drug. Therefore, we believe it is necessary to provide clarification regarding the definition of a covered outpatient drug in section 1927(k)(2) of the Act and the limiting definition at section 1927(k)(3) of the Act. Accordingly, we propose to add a definition of covered outpatient drug to § 447.502.

We propose that a drug is considered a covered outpatient drug when the drug may be dispensed only upon prescription (except as discussed below with respect to certain non-prescription drugs), and it meets the following criteria as described in section 1927(k)(2) of the Act:

- The drug has been approved for safety and effectiveness as a prescription drug by the FDA under section 505 or 507 of the FFDCA where the manufacturer has obtained a NDA or under section 505(j) of the FFDCA where the manufacturer has obtained an Abbreviated New Drug Application (ANDA);

- The drug was commercially used or sold in the United States before the date of the enactment of the Drug Amendments of 1962, or is identical, similar or related (within the meaning of section 310.6(b)(1) of title 21 of the CFR) to such a drug; and 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 Federal Food, Drug, and Cosmetic Act) or an action brought by the Secretary under section 301, 302(a), or 304(a) of such Act to enforce section 502(f) or 505(a) of such Act;

- The drug is one which 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 to such a drug and 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 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;

- The drug is a biologic product, other than a vaccine which—

- (1) May only be dispensed upon prescription,

- (2) Is licensed under section 351 of the Public Health Service Act, and

- (3) Is produced at an establishment licensed under such section to produce such product; or

- The drug is insulin certified under section 506 of the FFDCA.

Consistent with section 1927(k)(3) of the Act, we propose that, except as discussed below, a drug, biological product, or insulin would not be considered a covered outpatient drug 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:

- Inpatient Hospital Services;
 - Hospice Services;
 - Dental Services, except that drugs for which the State plan authorizes direct reimbursement to the dispensing dentist are covered outpatient drugs;
 - Physician services;
 - Outpatient hospital services;
 - Nursing facility and services provided by an intermediate care facility for the mentally retarded;
 - Other laboratory and x-ray services;
- or
- Renal dialysis.

We further propose that the above exemptions to the definition of covered outpatient drug for combined services would not apply if the drug is carved out and billed separately from the service (for example, an infusion drug and x-ray are billed separately, not as a composite radiology service; therefore, the infusion drug is a covered outpatient drug).

Additionally, section 1927(k)(3) of the Act provides that the definition of covered outpatient drug does not include any such drug or product for which a NDC number is not required by the FDA or a drug or biological used for a medical indication which is not a medically accepted indication. We note that for the purposes of the MDR we use an NDC format at either the NDC-9, which includes the labeler code and product code, to identify the product information, or the NDC-11, which includes the labeler code, product code, and the package code, to identify the product's package information. We are aware that FDA has a slightly different NDC format than what is used in the MDR program. (Please see the discussion under the definition of NDC.) For the purpose of the MDR program, we will continue to use the current NDC format of NDC-9, which includes the labeler code and the product code, to identify the product information and NDC-11, which includes the labeler code, product code, and package code, to identify the product's package information. However, if there is change to the current NDC format as a result of FDA action, then we will issue guidance, as necessary, to notify the public as well as to explain its impact on the MDR program.

We are not involved with and do not have oversight for the designation of the NDC. The FDA requires NDCs for drugs that must be listed with the FDA in accordance with Federal Food, Drug, and Cosmetics Act (FFDCA), as amended by the Food and Drug Administration Amendments Act of 2007 (FDAAA) (Pub. L. 110-85). (21 CFR 207.25(b)(8)). The FDAAA amended section 510(p) of the FFDCA

(21 U.S.C 360) to explicitly require that registration and listing information (including the submission of updated information) required under section 510 of the FFDCA, which includes information from both domestic and foreign establishments, be submitted by electronic means, unless the Secretary of Health and Human Services grants a request for waiver of this requirement because use of electronic means is not reasonable for the person requesting the waiver.

Section 1927(k)(3) of the Act provides that a covered outpatient drug does not include any such drug or product for which an NDC number is not required by the FDA. However, in accordance with section 1927(k)(2), and the requirements of section 510 of the FFDCA, we propose that a drug, whether prescription or over-the-counter (OTC), would only be treated as a covered outpatient drug if the drug is both required to have an NDC and is listed electronically with the FDA. We believe this additional standard is needed to ensure compliance with the prescribed drug provisions, FDA approval provisions, and the NDC listing provisions. Furthermore, this proposal is necessary in order for us to assure compliance with the drug rebate submission requirements, for CMS to verify State utilization data and manufacturer product data, and to assure the correct calculation of the offset amounts mandated by the Affordable Care Act. Additionally, this proposal aligns with a proposal submitted as part of the fiscal year (FY) 2012 President's Budget to require drugs to be properly listed electronically with the FDA as a requirement to be covered under Medicaid.

Therefore, if a manufacturer is required to list all of its NDCs electronically with the FDA, this would ensure that all the products in the MDR program meet the definition of section 1927(k)(3) of the Act. In addition, it would permit us to verify State and manufacturer submissions by referencing the FDA's electronic drug listing information.

Manufacturers are required to update their registration and listing information electronically in accordance with FDA's current registration and listing requirements.

Additionally, in order for us to fully implement these provisions, we are requiring that manufacturers submit any relevant approved FDA application numbers. When a product is listed with the FDA, the manufacturer is required to provide to the FDA the NDC and the application number, if any, for the product (21 CFR 207.25(b)). An

application number will help CMS find information on the approval status to market a drug. See <http://www.fda.gov/Drugs/InformationOnDrugs/ucm079436.htm>. The application number assists CMS in obtaining information from FDA as to whether a drug has been approved under a NDA under section 505 of FFDCA or an ANDA under section 505(j) of FFDCA. This information is critical to the definition of a covered outpatient drug under section 1927(k)(2) of the Act. Under the MDR program reporting requirements, drug manufacturers are required to report to CMS a drug category for each NDC. The drug category represents whether an NDC is classified as a brand name drug (single source drug (S) or innovator multiple source drug (I)) or a generic drug (noninnovator multiple source drug (N)). We use these drug category indications to determine the appropriate rebate percentage to calculate the unit rebate amounts, as well as the offset amounts under the Affordable Care Act.

We are also aware that some products that do not have an approved application number may be covered outpatient drugs. For example, we believe that certain products, such as prenatal prescription vitamins, potassium chloride, codeine sulfate, and hydrocortisone acetate may fall into this category. If a product does not have an FDA application number, in order to be considered a covered outpatient drug, the manufacturer must provide evidence demonstrating that its products meet the statutory definition of a covered outpatient drug under section 1927(k)(2) to 1927(k)(4). We will refer to this evidence of demonstration as covered outpatient drug status, or COD status. We are seeking public comments on this requirement, and in particular, comments identifying drugs or classes of drugs that do not have approved applications but should be deemed covered outpatient drugs.

This submission of data would provide critical information needed to calculate and verify the accuracy of such drug information.

Therefore, we propose that manufacturers report to CMS the number of an approved FDA application for a product or otherwise show that the product meets the statutory definition of a covered outpatient drug under sections 1927(k)(2) and (3) of the Act, in order for CMS to calculate the offset amounts and validate product data to ensure the correct rebate calculation for each NDC in the MDR Program. By having a correct approved FDA application number or the COD status, CMS can more accurately determine the

unit rebate amounts and product classification, critical to the rebate percentage calculation.

7. Customary Prompt Pay Discounts

In § 447.502, we propose to add a definition of customary prompt pay discount to ensure consistent application of such discounts among manufacturers when calculating AMP. Therefore, we propose 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 timeframe that is consistent with its customary business practices for payment.

8. 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 new drug application (NDA) approved by the 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 product license approval (PLA), establishment license approval (ELA), or antibiotic drug approval (ADA). In this rule, we propose to add multiple source drugs originally marketed under a 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 definition of single source drug. To ensure that the correct drug category is reported for an innovator multiple source drug, as was discussed in Manufacturer Release #82, we wish to remind manufacturers, as is consistent with current policy, that an innovator multiple source (I) drug should be reported to CMS for a brand name drug that has therapeutic equivalents available. To determine if therapeutic equivalents are available for a brand name drug or not, you can access the FDA's Drugs@FDA at http://www.accessdata.fda.gov/scripts/cder/drugsatfda/index.cfm?fuseaction=Search.Addlsearch_drug_name and search by the Application Number. If therapeutic equivalents are available, then you will see the link to "Therapeutic Equivalents" in the "Drugs Details" page. If there are therapeutic equivalents available for the NDA or BLA, then the brand name drug should be reported as an innovator multiple source drug (I) to CMS.

Additionally, over the course of the MDR program, questions have arisen regarding whether an "original NDA" is

the same as an NDA and whether the drug category may be different if a drug is approved under an NDA. We are proposing 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 the FDA for safety and effectiveness. In light of this definition, we are also proposing 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 this proposed rule.

9. Line Extension Drug (New Formulation)

The Affordable Care Act established a separate calculation for the unit rebate amount 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 propose 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 the FDA, listed in Drugs@FDA <http://www.accessdata.fda.gov/scripts/cder/drugsatfda/application> file, 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. We propose 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.

These modifications to the initial brand name listed drug are often approved under section 505(b)(2) of the FFDCA. A section 505(b)(2) application is a new drug application submitted under section 505(b)(1) and approved under section 505(c) of the FFDCA. A section 505(b)(2) application is one for which one or more of the investigations relied upon by the applicant to show whether a drug is safe and effective were not conducted by or for the applicant and for which the applicant has not obtained a right of reference or use from the person by or for whom the investigations were conducted. Section 505(b)(2), as described in FDA

regulations at 21 CFR 314.54, may be used in certain circumstances to seek approval of a drug product that represents a modification to a listed drug product. Examples of drugs that have been approved under the 505(b)(2) application include drugs with a new formulation, dosing regimen, change in active ingredient (such as a different salt or ester, combination product), and/or new drug indication. These types of drugs are assigned a Chemical Type by the FDA for the new drug application. A section 505(b)(2) application may be granted 3 years of exclusivity, may be eligible for orphan drug exclusivity or pediatric exclusivity. We have included these changes within our definition of line extension drugs. (See G.2. Treatment of New Formulations for further explanation of CMS' proposal.)

10. Manufacturer

For purposes of the MDR Program, we propose to clarify our current definition of manufacturer by revising it to state that a "manufacturer means any entity that holds the NDC for a covered outpatient drug or biological product". This change in terminology is not intended change the scope of the definition.

11. Multiple Source Drug

On November 15, 2010, we published the "Medicaid Program; Withdrawal of Determination of Average Manufacturer Price, Multiple Source Drug Definition, and Upper Limits for Multiple Source Drugs" final rule in the *Federal Register* (75 FR 69591). That final rule withdrew the regulatory definition of multiple source drug. As previously noted, section 2503(a)(3) of the Affordable Care Act amended the definition of multiple source drug set forth in section 1927(k)(7) of the Act.

Therefore, in accordance with section 1927(k)(7) of the Act, as revised, we propose to define multiple source drug in § 447.502 as a covered outpatient drug for which there is at least one other drug product which—

(1) Is rated as therapeutically equivalent. For the list of drug products rated as therapeutically equivalent, we will use the FDA's most recent publication of "Approved Drug Products with Therapeutic Equivalence Evaluations" which is currently available at <http://www.fda.gov/cder/orange/default.htm> or which can be viewed at the FDA's Freedom of

Information Public Reading Room at 5600 Fishers Lane, Rm. 12A-30, Rockville, MD 20857;

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

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

12. National Drug Code

The Drug Listing Act of 1972 requires each registered drug establishment to provide the FDA with a current list of all drugs manufactured, prepared, propagated, compounded, or processed by it for commercial distribution. (See section 510 of the FDCA (21 U.S.C. 360)). Drug products are identified and listed with FDA using a unique identifier called the National Drug Code (NDC). Under FDA regulations in 21 CFR part 207, the NDC is identified as a 10-digit, 3-segment number. The first segment, the labeler code, is assigned by the FDA. A labeler is a firm that manufactures the drug, including a repacker or relabeler, or a firm that distributes the drug under its own trade name or label. The second segment, the product code, identifies a specific strength, dosage form, and formulation for a particular firm. The third segment, the package code, identifies the trade package size and type. Both the product and package codes are assigned by the firm. The NDC will be in one of the following configurations: 4-4-2, 5-3-2, or 5-4-1.

In this proposed rule, we clarify that even though FDA currently uses a unique 10-digit NDC, for the purposes of the MDR program and this subpart we will continue to use an NDC format with the NDC-9, which includes the labeler code and the product code, to identify the product information and the NDC-11, which includes the labeler code, product code, and package code, to identify the product's package information. Manufacturers may include a leading zero in the product code or the package code segments of the NDC in order to arrive at the 5-4 NDC-9 or 5-4-2 NDC-11 when reporting their product to the MDR program.

13. Noninnovator Multiple Source Drug

As currently defined in § 447.502, a noninnovator multiple source drug means: (1) A multiple source drug that is not an innovator multiple source drug or a single source drug, (2) a multiple source drug that is marketed under an abbreviated NDA (ANDA) or an

abbreviated antibiotic drug application, and (3) a drug that entered the market before 1962 that was not originally marketed under an NDA.

In addition to a noninnovator multiple source drug as described, currently, there are other drugs on the market that have not gone through the FDA approval process, including but not limited to certain prescription prenatal vitamins.

Therefore, we propose to amend the definition of a noninnovator multiple source drug to also include these other drugs that have not gone through FDA approval process but otherwise meet the definition of "covered outpatient drug". However, if any of the drug products listed in this amended definition of a noninnovator multiple source drug subsequently receives a new NDA or ANDA approval from the FDA, the manufacturer must change the reporting of the product's drug category to correlate with the new product application type and furnish the appropriate information.

We also propose 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.

14. Oral Solid Dosage Form

CMS proposes to interpret oral solid dosage form in accordance to the 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. We also clarify that although FDA regulations at 21 CFR 206.3 uses the term "solid oral dosage form," section 1927(c)(2)(C) specifically used the term "oral solid dosage form" in reference to the treatment of new formulations. Therefore, CMS will treat the term "oral solid dosage form" to mean the same as FDA's "solid oral dosage form."

CMS proposes to further interpret an oral route of administration as any drug that is intended to be taken by mouth. In accordance with these provisions, CMS is providing manufacturers with guidance in order to assist them in determining which drugs should be considered as oral solid dosage forms (please see Table 1). This list will be updated based on any changes to the FDA's definition of solid dosage forms.

TABLE 1—LIST OF ORAL SOLID DOSAGE FORMS

Bar, Chewable	Capsule
Capsule (Immediate/Complete Release) (Hard Or Soft Gelatin, Chewable Or Perle)	Capsule, Coated
Capsule, Coated (Hard Or Soft Gelatin)	Capsule, Coated Pellets
Capsule, Coated, Extended Release	Capsule, Delayed Action (Hard Or Gelatin, Coated, Enteric Coated)
Capsule, Delayed Release Pellets	Capsule, Enteric Coated Pellets
Capsule, Extended Release	Capsule, Film Coated (Hard Gelatin)
Capsule, Film Coated, Extended Release	Capsule, Gelatin Coated
Capsule, Hard Gelatin	Capsule, Liquid Filled
Capsule, Repeat Action	Capsule, Soft Gelatin
Capsule, Soft Gelatin Liquid-Filled	Capsule, Sustained Action (Hard Or Soft Gelatin, Coated, Film Coated)
Dispersible Tablet	Granule, Enteric Coated
Granule, Delayed Release	Lollipop
Gum (Chewing, Medicated)	Pellet, Coated, Extended Release
Lozenge	Tablet (Immediate/Complete Release) (Coated, Film Coated, Sugar Coated, Multilayer, Uncoated, Buccal, Chewable)
Tablet	Tablet, Coated
Tablet, Chewable	Tablet, Controlled Release
Tablet, Coated Particles	Tablet, Delayed Release
Tablet, Delayed Action (Coated, Enteric Coated)	Tablet, Dispersible
Tablet, Delayed Release Particles	Tablet, Extended Release
Tablet, Enteric Coated Particles	Tablet, Film Coated, Extended Release
Tablet, Film Coated	Tablet, Multilayer, Extended Release
Tablet, Multilayer (Coated, Film Coated)	Tablet, Orally Disintegrating
Tablet, Orally Disintegrating, Delayed Release	Tablet, Soluble
Tablet, Repeat Action (Coated)	Tablet, Sustained Action (Coated, Film Coated, Multilayer, Uncoated)
Tablet, Sugar Coated	Tablet, Uncoated, Lozenge
Tablet, Sustained Release, Film Coated	Tablet, Uncoated, Troche
Tablet, Uncoated, Lozenge, Lypophilized	Pastille
Tablet, Sustained Action, Membrane Controlled	Wafer
Troche/Lozenge	

CMS would not consider the following as oral solid dosage forms because these dosage forms are intended to be made into a liquid or suspension prior to oral consumption.

TABLE 2—LIST OF OTHER DOSAGE FORMS

Capsule, for Micro-emulsion	Granule, Effervescent, for Solution
Granule Effervescent	Tablet, Effervescent
Granule, Effervescent, for Solution	Tablet, for Solution
Granule Effervescent, for Suspension	Tablet Effervescent for Solution
Granule, for Oral Suspension	Tablet, for Suspension

15. Over-the-Counter (OTC) Drug

With the exception of certain tobacco cessation drugs for pregnant women, or an EPSDT service, section 1927(d)(2) of the Act currently allows States to exclude from coverage or otherwise restrict coverage of OTC drugs. We propose to add a definition of OTC drugs in order to clarify which products would be treated as OTC drugs in the Medicaid program. This definition is consistent with our current policy and would not change how these drugs are treated for purposes of coverage under the Medicaid program. We propose 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, although for Medicaid coverage a prescription continues to be required. OTC drugs may be marketed under an approved premarket application (NDA or ANDA) or in many cases, may be marketed under an OTC monograph. In some instances, FDA permits these drugs to be marketed under a monograph that is not yet final (such as where there is an OTC tentative final monograph), as stated in 21 CFR part 330 and FDA guidance. Unlike NDAs which are based on premarket approval of specific, finished drug products, monographs specify the active ingredients, indications, dosages, and claims that can be made by the OTC drug products.

16. Pediatric Indications

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 the FDA exclusively for pediatric indications. To implement this requirement, we propose to clarify which drugs will be subject to this minimum rebate percentage. In regulations at 21 CFR 201.57 and 21 CFR 201.80, the FDA defines pediatric

use for most drug labeling to mean use for pediatric populations and pediatric patients, that is, “the pediatric age group, from birth to 16 years, including age groups often called neo-nates, infants, children, and adolescents.” Accordingly, given the statutory amendments, we propose to define “a drug approved by the Food and Drug Administration exclusively for pediatric indications” to mean a drug product approved by the FDA exclusively with indications for pediatric use, with the pediatric age group defined from birth to 16 years. Drugs that are not approved and labeled exclusively for pediatric use, that merely reference use in children in any part of the labeling, or that receive a supplemental indication for pediatric use, will not qualify for the minimum rebate of 17.1 percent of AMP as specified in section 1927(c)(1)(B)(iii) of the Act. In accordance with the statute, we propose to apply this definition only to drug products whose FDA-approved labeling includes only indications for children from birth to 16 years of age. Drugs without this explicit age labeling will not satisfy the requirement that the drug be approved exclusively for pediatric use and will not qualify for the minimum rebate of 17.1 percent of AMP. We are proposing to apply such a definition only when this specific pediatric age cohort

appears in the "Indication and Usage" section of the FDA-approved labeling.

17. Professional Dispensing Fee

The definition of dispensing fee will remain unchanged as it already enumerates those costs to dispense a drug that the pharmacy incurs. However, we propose to replace the term "dispensing fee" with "professional dispensing fee" as drug ingredient cost is only one component of the two-part formula that States generally use to reimburse pharmacies for prescribed drugs dispensed to Medicaid beneficiaries; and, we feel that this change from "dispensing fee" to "professional dispensing fee" reinforces our position that once the reimbursement for the drug is properly determined, the dispensing fee should reflect the pharmacist's professional services and costs associated with ensuring that possession of the appropriate covered outpatient drug is transferred to a Medicaid beneficiary. Therefore, as States change their payment for ingredient cost, we also propose to require States to reconsider the dispensing fee methodology consistent with the revised requirements.

18. Single Source Drug

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

As previously stated in the discussion of the proposed changes to the definition of innovator multiple source drug, for purposes of the MDR program, we have defined an original NDA as an NDA filed by the manufacturer with the FDA for purposes of approval for safety and effectiveness. Further, we wish to remind a manufacturer that as long as it has an approved NDA number issued by the FDA, a drug is considered to be a single source drug and is required to be reported with as an "S" drug category to CMS under the MDR program unless there are FDA approved therapeutic equivalents. To determine if therapeutic equivalents are available, you can access the FDA's Drugs@FDA and search by the Application Number. If therapeutic equivalents are available for the NDA, then you will see the link to "Therapeutic Equivalents" in the "Drugs Details" page. If there are no therapeutic equivalents available for the

NDA, then the brand name drug should be reported as an "S" to CMS.

19. States

Currently, for purposes of this subpart, the term "States" is defined as the 50 States and the District of Columbia. However, excluding the territories from this definition of States prevents them from receiving manufacturer rebates through the MDR program. We recognize that the territories have, over the years, expressed an interest in participating in the MDR program and that such rebates would in part offset the costs of providing Medicaid drugs. We have decided, in accordance with section 1101(a)(1) of the Act, to propose revising the definition of 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). Therefore, for drug rebates, we believe it is in the best interests of the Medicaid program to include the territories in the definition of States so that they may achieve the savings that drug rebates provide and we propose that the definition of States should be revised accordingly. We also acknowledge that there may be concerns with the territories participating in the MDR program; therefore, we request comments regarding the inclusion of the territories in the definition of States.

20. United States

Similar to our review of the term "States", we also examined our use of the term "United States". As with the term "States," we defined United States only to mean the 50 States and the District of Columbia. However, section 1101(a)(2) of the Act provides that when used in a geographic sense, the term "United States" means, except where otherwise provided, the States. In accordance with this definition, we think it is reasonable to conclude that in this context, the term is used in the geographical sense in that it contemplates the sales of drugs in any of the States. (Please see section II.K. Upper limits for multiple source drugs (§ 447.514) of the preamble for further discussion on the sale of drugs on a nationwide basis.) Therefore, for the purposes of this subpart, we propose, in accordance with section 1101(a) of the Act, to define the "United States" to mean the 50 States plus the District of Columbia and the territories as described above.

21. Wholesaler

The Affordable Care Act added a definition of the term "wholesaler" at section 1927(k)(11) of the Act. We propose to adopt that definition and 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.

We are not proposing 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. In considering how to clarify this term, we reviewed the definition of "wholesale distributor," that appears in section 510(g) of the FDCA, and regulations at 21 CFR 807.3(s), which provide that the term "wholesale distributor" means "any person (other than the manufacturer or the initial importer) who distributes a device from the original place of manufacture to the person who makes the final delivery or sale of the device to the ultimate consumer or user." While this definition is helpful, it does not provide additional clarity to the definition in the Act. Therefore, we are proposing to define wholesaler as set forth in the Act, but are specifically seeking comment on further data sources or definitions we could apply here that would help to further clarify the term wholesaler.

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 became effective on January 1, 1991. OBRA '90 established the MDR program and defined the AMP with respect to a covered outpatient drug 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.

The Deficit Reduction Act of 2005 (DRA) made significant changes to the Medicaid prescription drug provisions of the Act. 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, with respect to a covered outpatient drug 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.

Section 6001(c)(3) of the DRA required the Office of Inspector General (OIG) to review the requirements for and manner in which AMP was to be determined and recommend changes to the Secretary by June 1, 2006. Section 6001(c)(3) of the DRA also required the Secretary to clarify the requirements for and the manner in which AMPs are determined by promulgating a regulation no later than July 1, 2007, taking into consideration the OIG's recommendation.

In May 2006, the OIG issued a report, "Determining Average Manufacturer Prices for Prescription Drugs under the Deficit Reduction Act of 2005". In this report the OIG recommended that CMS:

- Clarify the requirements in regards to the definition of retail pharmacy class of trade and treatment of pharmacy benefit manager (PBM) rebates and Medicaid sales; and
- Consider addressing issues raised by industry groups, such as:
 - + Administrative and service fees,
 - + Lagged price concessions for returned goods,
 - + The frequency of AMP reporting,
 - + AMP restatements, and
 - + Base date AMP.

The OIG also recommended that the Secretary direct CMS to:

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

At that time, we recognized that there had been concerns expressed by the OIG and GAO in several prior reports regarding AMP because of inconsistencies in the way manufacturers determine AMP, changes

in the marketplace, and the introduction of newer business practices such as payment of services fees. We also realized that, in light of the DRA amendments, AMP would serve two distinct purposes: determining rebates, and serving as the basis for establishing the FUL for multiple source drugs. As a result of a preliminary injunction that had been entered in a lawsuit challenging the definition of AMP, CMS had never used the AMP final rule as a basis for calculating FULs.

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. As noted above, section 2503 of the Affordable Care Act revised the definition of AMP. The Affordable Care Act was further amended by section 202 of the Education Jobs and Medicaid Funding Act (Pub. L. 111-226), which was enacted on August 10, 2010.

For the determination of AMP, the Affordable Care Act revises the definition in section 1927(k) of the Act to eliminate the term "retail pharmacy class of trade" and adds a definition of the term "retail community pharmacy", as well as wholesaler. It identifies specific entities drug manufacturers are to include and exclude from the determination of AMP and (as amended by Pub. L. 111-226) clarifies exceptions to the excluded entities for inhalation, infusion, instilled, implanted, or injectable drugs that are not generally dispensed through a retail community pharmacy.

In this proposed rule, we propose a new § 447.504 "Determination of AMP," which would be based on section 1927(k)(1) of the Act as amended by the Affordable Care Act. Below we provide a detailed discussion of the proposed definition of retail community pharmacy, other terms used in the determination of AMP, the entities proposed for inclusion 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, defined in proposed § 447.507), that are not generally dispensed through a retail community pharmacy in the determination of AMP.

These provisions of the Affordable Care Act became effective on October 1, 2010 without regard to whether final regulations to carry out the provisions have been promulgated. Section 2503(a)(2) of the Affordable Care Act revised the definition of AMP to mean, for a covered outpatient drug of a manufacturer for a rebate period, the average price paid to the manufacturer for the drug in the United States by wholesalers for drugs distributed to retail community pharmacies, and by retail community pharmacies that purchase drugs directly from the manufacturer.

In accordance with section 1927(k)(1)(B)(i) of the Act, as amended by section 2503(a)(2)(B) of the Affordable Care Act, drug manufacturers are to exclude the following from the determination of the AMP:

- Customary prompt pay discounts extended to wholesalers;
- Bona fide service fees paid by manufacturers to wholesalers or retail community pharmacies, including (but not limited to) distribution service fees, inventory management fees, product stocking allowances, and fees associated with administrative services agreements and patient care programs (such as medication compliance programs and patient education programs);
- Reimbursement by manufacturers for recalled, damaged, expired, or otherwise unsalable returned goods, including (but not limited to) reimbursement for the cost of goods and any reimbursement of costs associated with return goods handling and processing, reverse logistics, and drug destruction;
- Payments received from, and rebates or discounts provided to, PBMs, managed care organizations, health maintenance organizations, insurers, hospitals, clinics, mail order pharmacies, long term care providers, manufacturers, or any other entity that does not conduct business as a wholesaler or retail community pharmacy, unless the drug is an inhalation, infusion, instilled, implanted, or injectable drug that is not generally dispensed through a retail community pharmacy.

• Discounts provided by manufacturers under the Medicare Coverage Gap Discount Program (section 1860D-14A of the Act).

Section 1927(k)(1)(B)(ii) of the Act specifies that, notwithstanding section 1927(k)(1)(B)(i) of the Act, manufacturers are to include in the determination of AMP for a covered outpatient drug any other discounts, rebates, payments, or other financial transactions that are received by, paid

by, or passed through to retail community pharmacies.

How AMP is defined and what sales are included in the determination of AMP affects manufacturers, pharmacy groups, the Federal and State governments and Medicaid beneficiaries, and often there are competing interests at play. The provisions of the Affordable Care Act regarding AMP serve two distinct purposes: Determining rebates and determining the basis for the FUL for multiple source drugs.

There is a direct relationship between which entities are to be included and excluded from AMP calculations and the basis for determining the FUL for multiple source drugs. The Affordable Care Act defines AMP to include prices paid to manufacturers by wholesalers for drugs distributed to retail community pharmacies and by retail community pharmacies that purchase drugs directly from the manufacturer. These sales are typically at higher prices than those of the specifically excluded entities such as the pharmacy benefit managers, managed care organizations, health maintenance organizations, insurers, hospitals, clinics, mail order pharmacies, long term care providers, and manufacturers. AMP calculations based on those sales to retail community pharmacies, as opposed to other pharmacies (such as mail order pharmacies), would likely result in a higher AMP value, given that AMP would be limited to higher priced sales. This higher AMP value would benefit the retail pharmacy industry because it is likely that the FUL, based on those AMPs, would be higher and in turn the maximum pharmacy reimbursement, based on those FULs, would be higher. On the other hand, a higher AMP would, in all likelihood, result in higher rebate payments from manufacturers. A broader definition of AMP, which would include sales to entities that purchase drugs at lower prices, would likely lower the AMP value, which in turn would lower drug manufacturer rebate liabilities.

AMP values also have an impact on States and potentially beneficiaries. Increasing AMP values and associated rebate payments would have a direct impact on State expenditures. However, increasing the FULs would also have a direct impact on State payments. On the other hand, if pharmacy reimbursement rates are too low, then it is conceivable that some pharmacies may elect not to participate in the Medicaid program, which could impact beneficiary access to pharmacy services. Similarly, States and the Federal government have an interest in assuring an appropriate level

of rebates and beneficiaries' access to care.

3. Definitions

Following is a detailed discussion of the specific terms associated with AMP calculations that we propose to define at § 447.504(a).

a. Average Unit Price

We propose 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. The quarterly sales figure used in this definition represent sales of the drug unit in the lowest identifiable amount (for example, tablet or capsule for solid dosage forms, milliliter for liquid forms, gram for ointments or creams) as reported by the manufacturer.

b. Charitable and Not-for-Profit Pharmacies

For the purposes of this subpart, we propose to define charitable and not-for-profit pharmacies as organizations described in section 501(c)(3) of the Internal Revenue Code of 1986.

c. Insurers

The DRA amended section 1902(a)(25) of the Act by modifying the definition of "third parties" and "health insurers" to clarify the inclusion of self-insured plans, managed care organizations, PBMs, or other parties that are by statute, contract, or agreement, legally responsible for payment of a claim for a health care item or service. Although, the DRA clarified "third parties", the Affordable Care Act referenced the term "insurer" in section 1927(k)(1)(B)(IV) of the Act and provided that payments received from many of these third party organizations (for example, pharmacy benefit managers, managed care organizations, health maintenance organizations, insurers) be excluded from the AMP calculation.

For the purposes of this subpart, we propose to define insurers as entities that are responsible for the payment of drugs but do not directly purchase drugs from manufacturers and are not in the supply chain to receive delivery of these drugs. Instead, insurers are responsible for payment to pharmacies for drugs dispensed to their members, and do not take actual possession of these drugs.

d. Net Sales

We propose 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 section 1927 of the Act, or regulations under this subpart) which reduce the amount received by the manufacturer.

e. Retail Community Pharmacy

The Affordable Care Act eliminated the term "retail pharmacy class of trade" from the definition of AMP, and added section 1927(k)(10) of the Act to include a definition of the term "retail community pharmacy." This change significantly narrows the entities previously included in the definition of retail pharmacy class of trade. In accordance with the Act, we propose 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. We further propose 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.

Section 1927(k)(1) of the Act as amended by the Affordable Care Act specifies that manufacturers are responsible for reporting the AMP based upon their sales to retail community pharmacies or wholesalers for drugs dispensed to retail community pharmacies.

In addition, the statutory provision for the determination of AMP suggests there are entities (for example, specialty pharmacies, home infusion pharmacies, and home health care providers), which are conducting business as wholesalers or retail community pharmacies which could be included in the determination of AMP. Section 1927(k)(1)(B)(i)(IV) of the Act excludes from the determination of AMP "payments received from and rebates or discounts provided to * * * any other entity that does not conduct business as a wholesaler or a retail community pharmacy * * *". We believe that to give the provision some meaning, the statute contemplates the inclusion of payments and discounts from those entities that actually conduct business as a wholesaler or retail community pharmacy. This

interpretation gives meaning to this broad exclusion, and provides for a calculation of AMP consistent with our reading of the statute. If an entity that does not conduct business as a wholesaler or retail community pharmacy is to be excluded from the determination of AMP, we considered whether or not it would be reasonable to conclude that payments received from and rebates or discounts provided to an entity that conducts business as a wholesaler or retail community pharmacy should be included in the determination of AMP. Based upon our understanding of the program, certain covered outpatient drugs may only be dispensed through such entities that are conducting business as wholesalers or retail community pharmacies, such as certain oral covered outpatient drugs approved by the FDA requiring a Risk Evaluation and Mitigation Strategy (REMS), to ensure that the benefits of a drug or biological product outweigh its risks. A list of REMS drugs is publicly accessible on the FDA Web site at <http://www.fda.gov/Drugs/DrugSafety/PostmarketDrugSafetyInformationforPatientsandProviders/ucm111350.htm>.

Some REMS drugs are required to be dispensed by specially certified pharmacies, resulting in certain manufacturers utilizing a restricted network of certified specialty and home infusion pharmacies, which are not specifically included in the definition of retail community pharmacy at section 1927(k)(10) of the Act. In addition, certain oral covered outpatient drugs are dispensed solely through these specialty and home infusion pharmacies. Therefore, if these entities were to be excluded from AMP calculations, an AMP would not be available for these oral covered outpatient drugs. As a result, manufacturers would not be able to calculate rebates for these products and the statutory provisions requiring rebates for such drugs would, in essence, be rendered meaningless. We do not believe that the law should be read to create such a result. Section 1927(b)(1) of the Act requires that manufacturers must provide rebates for all of their covered outpatient drugs for which payment was made under the State plan. These provisions were not amended by the Affordable Care Act. Therefore, we believe in light of the provisions of section 1927(k)(1)(B)(i) of the Act, there is a basis for allowing sales, rebates, and discounts provided to entities conducting business as wholesalers or retail community pharmacies to be included in the determination of AMP for those drugs for which an AMP could not otherwise

be calculated. Such an interpretation continues to give meaning to the rebate responsibilities of manufacturers in section 1927(b) of the Act. Therefore, we propose to include in the determination of AMP payments received from and rebates or discounts provided to an entity that conducts business as a wholesaler or retail community pharmacy, such as specialty and home infusion pharmacies, and home healthcare providers, since these entities dispense medications to segments of the general public at retail prices. We specifically invite comments on this part of the proposed rule.

Manufacturers contend that there is an administrative burden and difficulty in obtaining records assuring that their sales to wholesalers are distributed to retail community pharmacies. We took their concerns into consideration and considered whether or not to propose that the sales which cannot be definitely identified as sales to retail community pharmacies or wholesalers for drugs dispensed to retail community pharmacies would be eligible for inclusion in the sales that manufacturers use for AMP calculations. We received comments during the comment period for the Proposed Rule "Withdrawal of Determination of Average Manufacturer Price, Multiple Source Drug Definition, and Upper Limits for Multiple Source Drugs" published in the **Federal Register** on September 3, 2010 (75 FR 54073) that raised issues regarding the implementation of the new definition of AMP. As these comments were outside the scope of that proposed rule, these comments were not specifically addressed as part of final rule published on November 15, 2010 (75 FR 69591). However, these comments do provide insight into issues of concern for the various stakeholders, especially in regards to the implementation of the new proposed definition of AMP.

One of the issues raised was whether manufacturers should be allowed to presume that sales of drugs are distributed to retail community pharmacies when those sales of drugs are to wholesalers that do not further differentiate their sales among end purchasers.

Based on information provided from these comments it is our understanding that wholesalers generally resell either to manufacturer-contracted customers (which would generate a chargeback or similar record), or to other purchasers with no contract discount arrangement with the manufacturer. In the case of sales to wholesalers where no chargeback record is generated, manufacturers contend that they have

minimal to no verifiable information regarding the final transactions on this category of wholesaler re-sales. Manufacturers have expressed concern that they would not have adequate data regarding the wholesaler's actual purchaser to accurately determine if the drug was ultimately sold to retail community pharmacies. Therefore, we considered proposing a so-called "presumed inclusion" policy, where the manufacturer could (absent documentation to the contrary) presume that sales to wholesalers are for drugs distributed to retail community pharmacies, without data concerning that actual distribution. Based upon the comments we received from manufacturers we believe such a policy would be consistent with the market based on the typical chargeback arrangements that manufacturers have in place for institutional and other non-retail community pharmacy purchasers. The presumed inclusion policy would not require manufacturers to obtain data regarding the actual distribution to retail community pharmacies. Through the presumed inclusion policy, in the absence of chargeback or other verifiable data, manufacturers would be able to presume that the sales of drugs to wholesalers are for drugs that are distributed to retail community pharmacies.

However, we recognize that there could be concerns with respect to whether manufacturers should be permitted to presume, in the absence of adequate documentation to the contrary, that prices paid by wholesalers are for drugs that are actually distributed to retail community pharmacies. Allowing this practice of presumptive inclusion could affect the calculation of the FULs for multiple source drugs because it arguably would permit the inclusion of lower AMPs in that calculation based on sales that may not have been actually distributed to retail community pharmacies. It could be argued that if manufacturers are allowed to presume that all drug sales are distributed to retail community pharmacies, AMP would be lower because it could include sales to entities (for example, mail order pharmacies and hospitals) that are able to buy the drugs at lower prices than retail community pharmacies. On the other hand, it could also be argued that, despite these concerns, there would be no adverse consequences to the FULs if manufacturers could presume sales distribution to retail community pharmacies because the sales that would be captured using the presumptive inclusion policy are those sales that do not generate chargebacks. In comments

we received during the comment period for the Proposed Rule, "Withdrawal of Determination of Average Manufacturer Price, Multiple Source Drug Definition, and Upper Limits for Multiple Source Drugs" published in the **Federal Register** on September 3, 2010 (75 FR 54073), manufacturers claim that allowing the presumed inclusion policy would not create any adverse consequences concerning pharmacy payments. They believe that these sales would, in all likelihood, have a higher net price than institutional or chargeback-generating sales. Additionally, they contend that the volume of AMP-eligible sales used in calculating the FUL could be increased because the additional sales to wholesalers without chargeback data would be added to the volume calculation for determining the weighted average of monthly AMPs. Therefore, they argue that calculating AMPs utilizing the presumptive inclusion policy could result in higher AMPs than AMPs based on actual data and those higher AMPs would be weighted more heavily in the FULs calculation.

We also considered instances where manufacturers are only including in their calculation of AMP those sales where there is adequate verifiable documentation showing that the drug was actually distributed to a retail community pharmacy, whether directly or through a wholesaler. However, we recognize that in this approach there may be instances where the wholesaler actually re-sells the drug to the retail community pharmacies but the manufacturer does not have documentation regarding that actual sale to the retail community pharmacy. Therefore, in contravention of the statute, those sales would not be included in the AMP calculation since the manufacturer does not have adequate documentation.

While we recognize such concerns, we have decided to propose that manufacturers report the AMP based upon their actual sales to retail community pharmacies or wholesalers for drugs distributed to retail community pharmacies. Although we are not proposing a presumed inclusion policy, we did consider both approaches and recognize that there are obstacles with each. We acknowledge that a reasonable alternate approach would be one of presumed inclusion because the statute provides a more structured definition of what is to be included and excluded from AMP. However, we have concerns that a presumed inclusion policy would lead to the inclusion of sales by a manufacturer to entities not

contemplated in the statutory definition. Accordingly, for purposes of this proposed rule, we are proposing that manufacturers must calculate AMP based on sales: (1) To wholesalers for drugs distributed to retail community pharmacies, or (2) to retail community pharmacies. We seek comments regarding this section and request information concerning distribution data, specifically data concerning wholesaler sales to the retail community pharmacies so that we can further consider this policy decision.

4. Sales Included in the Determination of AMP

Following is a discussion of specific sales, discounts, rebates, payments, nominal price sales, and other financial transactions that we propose to include in the determination of AMP at § 447.504(b).

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

The definition of AMP in section 1927(k)(1) of the Act, as amended by the Affordable Care Act, specifies that AMP is to be calculated, in part, based on the prices paid by wholesalers for drugs dispensed through retail community pharmacies. Therefore, we propose that sales to wholesalers for drugs distributed to retail community pharmacies are to be included in the determination of AMP.

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

We propose 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. This provision should be read in concert with the definition of wholesaler found in section 1927(k)(11) of the Act.

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

Section 1927(k)(1)(B)(iii) of the Act, as revised by the Affordable Care Act specifies that manufacturers are to include in the determination of AMP, discounts, rebates, payments or other financial transactions that are received by, paid by, or passed through to, retail community pharmacies, as defined earlier in this section. Therefore, we propose to include in the determination of AMP, notwithstanding those price reductions specifically excluded by statute or this regulation, discounts, rebates, payments, or other financial transactions that are received by, paid by, or passed through to, retail community pharmacies. Again, we are unsure to what extent the manufacturer

knows that such transactions occur. However, in accordance with our reading of the statute, the manufacturer must include such discounts where it has evidence or documentation demonstrating that such discounts have been passed through to the pharmacy.

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

As discussed earlier, we believe in light of the provisions of section 1927(k)(1)(B)(i) of the Act, there is a basis for allowing sales, rebates, and discounts provided to entities conducting business as wholesalers or retail community pharmacies to be included in the determination of AMP for those drugs for which an AMP could not otherwise be calculated. It is our understanding that certain covered outpatient drugs are dispensed primarily, if not solely, through such entities as specialty pharmacies, home infusion pharmacies, or home healthcare providers. We propose that these pharmacies be considered entities that are conducting business as wholesalers or retail community pharmacies. While not specifically identified in the statutory definition of retail community pharmacy, these pharmacies do conduct business as a retail community pharmacy inasmuch as they dispense medications to the general public at retail prices and are licensed by the State as a pharmacy. While they may be serving a specific part of the general public based on a certain medical condition, the drugs dispensed by these pharmacies are sold in the retail marketplace and are available to any member of the general public who has one of these medical conditions. Therefore, we propose that manufacturers are to include in the determination of AMP the sales of covered outpatient drugs that are dispensed through entities conducting business as wholesalers or retail community pharmacies, which include but are not limited to specialty pharmacies, home infusion pharmacies, and home healthcare providers.

5. Sales Excluded From the Determination of AMP

Following is a discussion of specific sales, discounts, rebates, payments and other payments that we propose to exclude from the determination of AMP at § 447.504(c).

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

Manufacturers that participate in the MDR program can also participate in other Federal programs which set the prices and/or discounts for drugs, and these prices are not generally available to retail community pharmacies. We propose that in light of section 1927(k) of the Act, prices to Federal programs should be excluded from AMP. These Federal programs include the Indian Health Service (IHS), the DVA, a State home receiving funds under section 1741 of title 38, United States Code, the Department of Defense (DoD), the Public Health Service (PHS), 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 Federal Supply Schedule (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.

On March 17, 2009, the Department of Defense (DoD) issued a regulation entitled, Civilian Health and Medical Program of the Uniformed Services (CHAMPUS)/TRICARE: Inclusion of TRICARE Retail Pharmacy Program in Federal Procurement of Pharmaceuticals (74 FR 11279). That regulation implements section 703 of the National Defense Authorization Act for fiscal year 2008 (NDAA, Pub. L. 110–181) which states that for any prescription filled on or after the date of enactment of the NDAA, the TRICARE Retail Pharmacy Program will be treated as an element of the DoD for purposes of procurement of drugs by Federal agencies under section 8126 of title 38, United States Code (U.S.C.). In accordance with that provision as well as the revised definition of AMP in section 1927(k)(1) of the Act, we propose that TRICARE Retail Pharmacy Program prices should be treated as prices to DoD and therefore excluded from the calculation of AMP.

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

The proposed definition of “United States” in § 447.502 would define “United States” to mean the 50 States, the District of Columbia and the territories. We, therefore, propose 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 these entities would not be

considered eligible sales within the definition of AMP. Therefore, we propose that sales to entities not within the 50 States, the District of Columbia or the territories be excluded from the manufacturers’ determination of AMP.

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

Section 1927(k) of the Act, as revised by the Affordable Care Act, specifies that sales to hospitals are excluded from the determination of AMP. Further, the term “retail community pharmacy” excludes hospital pharmacies. Therefore, we propose to clarify that sales to hospitals, including direct and indirect sales where the drug is used in either the inpatient setting or the outpatient pharmacy for outpatient hospital use are excluded from the determination of AMP.

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

Section 1927(k) of the Act, as revised by the Affordable Care Act, specifies that sales to HMOs and MCOs are excluded from the determination of AMP. The Affordable Care Act does not specifically address HMO/MCO operated pharmacies. However, given the broad reference in the statute to HMOs and MCOs, we propose to clarify that sales and associated rebates and discounts to HMO/MCO operated pharmacies are excluded from the determination of AMP.

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

Section 1927(k) of the Act, as revised by the Affordable Care Act, specifies that sales and associated rebates and discounts to long-term care providers are excluded from the determination of AMP. Further, the term retail community pharmacy excludes nursing home pharmacies and long-term care facility pharmacies. Therefore, we propose to clarify that 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, 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.

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

Section 1927(k) of the Act, as revised by the Affordable Care Act, specifies that the term retail community pharmacy excludes pharmacies that dispense prescription medications to patients primarily through the mail. We consider these to be mail order pharmacies and as such we propose to clarify that sales to mail order pharmacies are excluded from the determination of AMP.

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

Section 1927(k) of the Act, as revised by the Affordable Care Act, specifies that sales to clinics are excluded from the determination of AMP. In 42 CFR 440.90, clinic services is defined as preventative, diagnostic, therapeutic, rehabilitative, or palliative services that are furnished by a facility that is not part of a hospital but is organized and operated to provide medical care to outpatients. The term includes the following services furnished to outpatients: (a) Services furnished at the clinic by or under the direction of a physician or dentist, and (b) Services furnished outside the clinic by clinic personnel under the direction of a physician to an eligible individual who does not reside in a permanent dwelling or does not have a fixed home or mailing address.

Although the Affordable Care Act did not specifically address the treatment of outpatient facilities in the determination of AMP, we believe that in accordance with the definition of AMP in section 1927(k)(1) of the Act, as well as the definition of clinic in 42 CFR 440.90, sales to outpatient facilities such as surgical centers, ambulatory care centers, dialysis centers, End-Stage Renal Disease clinics, outpatient hospital clinics and mental health centers should be excluded from the AMP. Therefore, we propose to exclude sales and associated rebates and discounts to clinics and outpatient facilities from the determination of AMP.

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

Section 1927(k) of the Act, as revised by the Affordable Care Act, specifies that the definition of retail community pharmacy does not include government pharmacies. We propose to define government pharmacies as pharmacies operated or owned by Federal, state, county, and municipal governments. We also propose that sales to government

pharmacies are excluded from the determination of AMP.

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

Section 1927(k) of the Act, as revised by the Affordable Care Act specifies that the definition of retail community pharmacy does not include charitable or not-for-profit pharmacies. We propose to define charitable or not-for-profit pharmacies as section 501(c) organizations. Section 501(c) organizations are those described in the Internal Revenue Code and are tax-exempt, nonprofit corporations or associations. We propose that sales to these not-for-profit and charitable pharmacies be excluded from the determination of AMP.

j. Insurers § 447.504(c)(13))

The Affordable Care Act defined AMP by specifying that payments received from, and rebates or discounts provided to insurers are to be excluded from the determination of AMP. Therefore, we propose to exclude from the determination of AMP 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.

However, we note that drugs sold to wholesalers for distribution to retail community pharmacies or drugs sold directly to retail community pharmacies that are subsequently reimbursed by insurers when sold by the pharmacy to beneficiaries are part of the chain of sales from manufacturers to wholesalers or retail community pharmacies. In accordance with our reading of the statute, the sales to wholesalers for drugs distributed to retail community pharmacies and retail community pharmacies would be included in AMP calculations, regardless of how the drug is ultimately reimbursed when provided to the beneficiary.

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

As described earlier, we propose to revise the definition of bona fide service fees in § 447.502 to include fees provided as specific examples of bona fide service fees in the Affordable Care Act. The Affordable Care Act specifies that bona fide service fees paid by manufacturers to wholesalers or retail community pharmacies include, but are 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).

The current regulations define bona fide service fees, in part, to mean fees paid by a manufacturer to an entity that represent fair market value for a bona fide, itemized service. We continue to be concerned that these fees could be used as a vehicle to provide discounts, as opposed to fees at “fair market value” for bona fide services. Thus, to avoid potential fraud concerns, we are retaining our definition, but we have chosen not to define “fair market value” at this time. Due to the rapidly changing market in which new types of arrangements arise, we believe that manufacturers should appropriately determine fair market value and make reasonable assumptions consistent with adequate documentation that will support their payment for these services at fair market rates sufficient that an outside party can determine the basis for the fair market value determination. This is consistent with the 2007 AMP Final Rule (72 FR 39184) and the ASP reporting rule (71 FR 69667).

In accordance with the statute, we propose that bona fide service fees should be excluded from the calculation of AMP. We further propose that, in light of the statutory definition, administrative fees and other fees which are not specifically excluded by the Affordable Care Act, but which meet the definition of bona fide service fees, should also be excluded from the determination of AMP. We are not proposing to further define the type of fees used as examples in the definition of bona fide service fees because we believe that these terms can be read in concert with the current definition of bona fide service fee. As noted previously, they provide specific examples of what could qualify as a bona fide service fee. We note however that retroactive price adjustments, sometimes also known as price appreciation credits, do not meet the definition of a bona fide service fee as they do not reflect any service or offset of a bona fide service performed on behalf of the manufacturer.

The statute does not specifically exclude GPO fees from the AMP calculation. To the extent that bona fide service fees, including, but 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) and other fees to GPOs meet the definition of

“bona fide service fee,” we propose that such fees should be excluded from the determination of AMP and are not considered price concessions. However, as consistent with the definition of bona fide service fee at § 447.502 where these fees are passed on in whole or in part to a wholesaler or retail community pharmacy, the fees would not qualify as bona fide service fees. To the extent this occurs, such fees cannot be considered bona fide service fees and, in accordance with section 1927(k)(1)(B)(ii) of the Act, should be included in AMP.

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

Section 1927(k) of the Act, as revised by the Affordable Care Act, specifies that customary prompt pay discounts that are extended to wholesalers are to be excluded from the determination of AMP. Therefore, we are proposing that customary prompt pay discounts extended to wholesalers be excluded from the determination of AMP.

m. Returned Goods (§ 447.504(c)(16))

Section 1927(k) of the Act, as revised by the Affordable Care Act, specifies that reimbursement by manufacturers for recalled, damaged, expired, or otherwise unsalable returned goods, including (but not limited to) reimbursement for the cost of goods, and any reimbursement of costs associated with return goods handling and processing, reverse logistics, and drug destruction are excluded from the determination of AMP. We propose to incorporate this definition into this rule, but note that it is applicable only to the extent that payment for these returned goods covers the cost of returns and does not otherwise serve as payment to the pharmacy as a price concession. In addition, we propose to exclude the value of returned goods themselves from the determination of AMP when returned in good faith.

We are not proposing to define the terms recalled, damaged, and expired as we believe they are self-explanatory within the standard industry practice. We likewise are not defining unsalable, but would also base it on standard industry practice to determine under what conditions and/or circumstances drugs would be considered unsalable. We are requesting comments regarding whether we should define these terms or further define how these industry standards should be set. We also request examples of what would qualify as unsalable.

n. Medicare Coverage Gap Discount
(\$ 447.504(c)(17))

Section 3301 of the Affordable Care Act established the Medicare Coverage Gap Discount Program under sections 1860D-43 and 1860D-14A of the Act. Section 1101(c) of the Affordable Care Act further specified that discounts provided by manufacturers under the Medicare coverage gap discount program will be excluded from AMP. Therefore, we propose that discounts under the Medicare coverage gap discount program should be excluded from AMP.

o. PBM Price Concessions
(\$ 447.504(c)(18))

Section 1927(k)(1)(B) of the Act, as revised by the Affordable Care Act, revised the definition of AMP by excluding payments received from, and rebates or discounts provided to, pharmacy benefit managers (PBMs) and mail order pharmacies. Therefore, we propose to exclude from the calculation of AMP, payments received from and rebates or discounts provided to PBMs, including their mail order pharmacy's purchases to the extent that no part of the rebates, discounts or payments are received by, paid by, or passed through to retail community pharmacies.

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

We propose 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. We are doing so in light of the definition of section 1927(k)(1) of the Act, because these rebates affect the manufacturer and the State, and there is no direct effect on the sale price of these drugs to retail community pharmacies.

Entities not specifically addressed in the statute.

q. Sales to Hospices (\$ 447.504(c)(20))

The Affordable Care Act did not specifically address the treatment of sales to hospices in the determination of AMP. We propose, in light of the revisions in sections 1927(k)(1)(A) and 1927(k)(10) of the Act, to exclude hospice sales from the definition of AMP. Hospice pharmacies are outside the scope of the definition of retail community pharmacy. Further, these pharmacies serve a defined population and do not dispense medications to the general public at retail prices.

r. Sales to Prisons (\$ 447.504(c)(21))

We propose that the sales to prisons are outside the scope of the definition of retail community pharmacy; drugs

sold to these entities serve a defined population in that facility and are not available to the general public.

s. Direct Sales to Physicians
(\$ 447.504(c)(22) and \$ 447.504(d)(1))

Except for the sale of inhalation, infusion, instilled, implanted and injectable drugs (also referred to as the 5i drugs, and which are discussed in detail later in this section) we do not believe, in light of the definition of retail community pharmacy in section 1927(k)(10) of the Act, that physicians meet the definition of a retail community pharmacy. However, in light of the specific revisions to section 1927(k)(1)(B)(i)(IV) by section 202 of the Education Jobs and Medicaid Funding Act (Pub. L. 111-226), we believe that certain sales to physicians should be included in AMP. Since we have defined the 5i drugs as those which are primarily physician-administered, we believe in light of the statutory amendments, the case can be made that the sale (and associated discounts) of these 5i drugs to physicians should be included in the determination of AMP. Therefore, we propose in § 447.504(d)(1) that for 5i drugs, sales (and associated rebates or discounts) to physicians are included in the determination of AMP. However, in the case of non-5i drugs, we propose at § 447.504(c)(26) that direct sales to physicians be excluded from the determination of AMP.

t. Direct Sales to Patients
(\$ 447.504(c)(23))

We propose that direct sales to patients be excluded from AMP as these sales are outside the scope of the definition of retail community pharmacy in section 1927(k)(10) of the Act.

u. Free Goods (\$ 447.504(c)(24))

We propose that where a drug or any other item is given away, but not contingent on any purchase requirement, there is no sale and, therefore, that transaction would be excluded from the determination of AMP.

v. Manufacturer Coupons
(\$ 447.504(c)(25))

We propose in light of the revised definition of AMP that manufacturer coupons to a consumer redeemed by the manufacturer, agent, 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 retail community pharmacy does not receive any discount, rebate or

price concessions in connection with the manufacturer coupons.

w. Voucher Programs (\$ 447.504(c)(26))

We propose that manufacturer vouchers would be excluded from the determination of AMP because the benefits of such vouchers are passed onto the patient and the retail community pharmacy does not receive any discount, rebate or price concessions in connection with the manufacturer voucher programs. However, to the extent that the retail community pharmacy receives a discount, rebate, or other price concession, in accordance with section 1927(k)(1)(B)(ii) of the Act, it shall be included in AMP.

x. Manufacturer-Sponsored Drug Discount Card Programs
(\$ 447.504(c)(27))

We propose in light of the revised definition of AMP that prices negotiated under a manufacturer-sponsored drug discount program would be excluded from the determination of AMP, provided the discount is passed on to the patient and the retail community pharmacy does not receive any discount, rebate or price concessions in connection with the manufacturer-sponsored drug discount card program.

y. Manufacturer-Sponsored Patient Refund/Rebate Programs
(\$ 447.504(c)(28))

The Affordable Care Act did not explicitly address the treatment of prices negotiated under a manufacturer-sponsored patient refund or rebate program. To the extent the manufacturer provides a full or partial refund or rebate to the patient for out-of-pocket costs and the retail community pharmacy does not realize any discounts or rebates or receive any price concession in connection with the manufacturer-sponsored patient refund/rebate programs, we propose in light of the revised definition of AMP that prices negotiated under a manufacturer-sponsored patient refund or rebate program would be excluded from the determination of AMP.

z. Copayment and Patient Assistance Programs (\$ 447.504(c)(29))

The Affordable Care Act did not address the treatment of patient assistance programs, including copayment assistance programs. We believe in light of the revised definition of AMP that patient assistance programs, including copayment assistance programs that provide free goods that are not contingent on future purchases to patients would be

excluded from the determination of AMP. Therefore, we propose that such patient assistance programs and copayment assistance programs are excluded from the determination of AMP. However, to the extent that the retail community pharmacy receives a discount, rebate, or other price concession in connection with the copayment and patient assistance programs, in accordance with section 1927(k)(1)(B)(ii) of the Act, it shall be included in AMP.

6. Inhalation, Infusion, Instilled, Implanted, and Injectable Drugs (§ 447.504(d) and § 447.507)

In accordance with section 1927(k)(1)(B)(i)(IV) of the Act, manufacturers are to exclude from the determination of AMP for a covered outpatient drug for a rebate period, any payments received from, and other discounts or rebates, that are provided to any other entity that does not conduct business as a wholesaler or retail community pharmacy. Certain specialty covered outpatient drugs are not generally dispensed through retail community pharmacies and in those instances manufacturers would be unable to generate an AMP which would prevent rebate calculations for those drugs. Section 202 of the Education, Jobs and Medicaid Funding Act (Pub. L. 111–226), enacted August 10, 2010, amended the Affordable Care Act definition of AMP at section 1927(k)(1) of the Act to include sales for the 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 the 5i drugs that are not generally sold at retail community pharmacies. (See 156 Cong. Rec. S6766 (Aug. 5, 2010)).

This provision went into effect on October 1, 2010 and revises a manufacturer's AMP calculation for the 5i drugs to include entities other than retail community pharmacies that dispense such drugs.

While the enactment of this legislation addressed the need to ensure that rebates would be collected for these 5i drugs that are “not generally dispensed through retail community pharmacies,” it also raised additional issues that were not directly addressed in the statute. Based upon section 1927(k)(1)(B)(i)(IV) of the Act, we have identified the following issues that would require further clarification: (1) Identification of 5i drugs, (2) clarification of the term “not generally dispensed,” (3) determination of sales, discounts and rebates included in the 5i

calculation, and (4) identification of other entities included in the definition.

We also received requests from manufacturers and pharmacies requesting guidance on this provision; specifically regarding how to interpret “not generally dispensed through a retail community pharmacy” and how to identify these 5i drugs.

We considered issuing a list identifying the specific 5i drugs that are to be included in this category. Second, we considered how to define the term “not generally dispensed.” Finally, we considered clarifying which sales, discounts, and other financial transactions would be included in the determination of AMP for these drugs.

Based on our understanding of the market as well as other Federal programs, we believe most 5i drugs are administered parenterally or through an item of durable medical equipment (DME) and often require physician supervision during administration. We considered defining each type of administration route; however, we believe that it is not necessary to define the terms because the terms are essentially self explanatory. We are seeking comments on this decision.

We considered using the Medicare Part B standards to identify 5i drugs, given that Medicare Part B covers a limited number of outpatient prescription drugs that are not usually self-administered, such as those given in a hospital outpatient department or doctor's office. In addition, Medicare Part B covers outpatient prescription drugs provided through an item of durable medical equipment, such as an infusion pump or nebulizer, and injectable drugs administered by a licensed medical practitioner, if considered reasonable and necessary.

Medicare Part B does not have a comprehensive, all inclusive list of covered inhalation, infusion, injectable, instilled, or implanted drugs. However, it already has a publicly available reference which lists drugs that are “not usually self-administered” and could be considered for coverage under Medicare Part B. In addition, the Medicare Part B ASP NDC–HCPCS Crosswalk file identifies drugs that could be considered for coverage under Medicare Part B; it is publically accessible on the CMS Web site at http://www.cms.gov/McrPartBDrugAvgSalesPrice/01a19_2010aspfiles.asp and is updated on a quarterly basis. The Medicare Part B ASP NDC–HCPCS Crosswalk file also includes drugs which do not meet the 5i criteria, specifically those oral drugs covered by Part B following a transplant as well as Part B oral anti-emetics and oral cancer drugs. We considered using

the Medicare Part B ASP NDC–HCPCS Crosswalk file to identify 5i drugs. However, we believe it would not be optimal because it is not an all inclusive list of inhalation, infusion, instilled, implanted and injectable drugs and therefore would likely miscategorize some 5i drugs.

We also considered whether CMS or the manufacturers should determine which drugs qualify as a 5i drug. In doing so, we considered whether or not it would be difficult for manufacturers to determine which drugs should be classified as an inhalation, infusion, instilled, implanted, or injectable drugs for the determination of AMP using the route of administration approved by the FDA or based upon the drug's NDC.

We also considered if we should identify the 5i drugs based upon their NDC number. If we were to identify the 5i drugs, we determined it would not provide reliable data and still require us to make available, as well as continuously update, a set of guidelines that would likely require an outside data source. In addition to the nuances of identifying existing drugs, it would be a continuous challenge to maintain a reliable list due to an evolving marketplace with the introduction of new drugs and removal of existing drugs.

Although we determined it would not be practical for CMS to provide a list identifying the 5i drugs, we considered providing a list of routes of administration as identified by the FDA that we believe would be applicable for 5i drugs. We believe this list would serve as a guide that manufacturers would use to determine if a drug could be considered as a 5i drug. We are proposing to add § 447.507 Identification of 5i drugs to indicate how 5i drugs are to be identified. In § 447.507(a) we propose to use the FDA's Routes of Administration as a guide to identify 5i drugs. Below is a list of FDA routes of administration that we are proposing manufacturers use to identify 5i drugs. It includes, but is not limited to, the routes of administration listed in Table 3. This list comes from the FDA Structured Product Labeling, Route of Administration data standards located at <http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/ucm162034.htm>.

TABLE 3—ROUTES OF ADMINISTRATION FOR 5I IDENTIFICATION

Auricular (Otic)	Intracavernous
Conjunctival	Intracavitary
Endocervical	Intracerebral
Endosinusial	Intracisternal

TABLE 3—ROUTES OF ADMINISTRATION FOR 5i IDENTIFICATION—Continued

Endotracheal	Intracorneal
Epidural	Intracoronary, Dental
Extra-Amniotic	Intracoronary
Hemodialysis	Intracorporus
	Cavernosum
Infiltration	Intradermal
Interstitial	Intradiscal
Intra-Abdominal	Intraductal
Intra-Amniotic	Intraduodenal
Intra-Arterial	Intradural
Intra-Articular	Intraepicardial
Intrabiliary	Intraepidermal
Intrabronchial	Intraesophageal
Intrabursal	Intragastric
Intracardiac	Intragingival
Intracartilaginous	Intrahepatic
Intracaudal	Intraileal
Intralesional	Iontophoresis
Intralingual	Irrigation
Intraluminal	Laryngeal
Intralymphatic	Nasal
Intramammary	Nasogastric
Intramedullary	Ophthalmic
Intrameningeal	Parenteral
Intramuscular	Percutaneous
Intranodal	Periarticular
Intraocular	Peridural
Intraomentum	Perineural
Intraovarian	Periodontal
Intrapericardial	Rectal
Intraperitoneal	Respiratory (Inhalation)
Intrapleural	Retrobulbar
Intraprostatic	Soft Tissue
Intrapulmonary	Subarachnoid
Intraruminal	Subconjunctival
Intrasinal	Subcutaneous
Intrasplinal	Subgingival
Intrasynovial	Submucosal
Intratendinous	Subretinal
Intratesticular	Transendocardial
Intrathecal	Transmucosal
Intrathoracic	Transplacental
Intratubular	Transtracheal
Intratumor	Transtympanic
Intratympanic	Ureteral
Intrauterine	Urethral
Intravascular	Vaginal
Intravenous	
Intraventricular	
Intravesical	
Intravitreal	

We propose that manufacturers identify 5i drugs based upon the FDA route of administration list that we have provided. We are interested in comments on this proposal, including comments regarding other FDA routes of administration that could be used to identify 5i drugs that are not reflected on the provided list.

We believe that by utilizing the FDA route of administration, manufacturers will be readily able to identify products which are inhaled, infused, instilled, implanted, and injected as the information is readily available. However, manufacturers would need to determine if those products identified as 5i drugs are “not generally dispensed

through a retail community pharmacy”. Therefore, we also considered how to establish a standard by which manufacturers would determine when a drug is “not generally dispensed through a retail community pharmacy.”

We considered adopting the Medicare Part B guidelines used to determine if a drug is to be classified as self-administered as a way to determine when a drug is “not generally dispensed” through a retail community pharmacy. In accordance with section 1861(s)(2)(A) and 1861(s)(2)(B) of the Act, the Medicare Benefit Policy Manual, Chapter 15—Covered Medical and Other Services, § 50.2(C) provides guidance regarding the term “usually.” Specifically, it provides that the term is used to mean more than 50 percent of the time in determining when a drug is to be classified as self-administered. In light of this guidance, we believe that if a drug can be self administered, it is reasonable to assume that it is usually dispensed through a retail community pharmacy; however, for physician-administered drugs, we believe it is reasonable to conclude that the drug may be provided by physicians or other licensed practitioner in a variety of entities (such as clinics and physician’s offices), and given the nature of the drugs, are usually not dispensed by a retail community pharmacy.

If we were to adopt a similar 50 percent methodology for determining when a drug is not generally dispensed through a retail community pharmacy, it would mean that a drug would be classified as “not generally dispensed” through a retail community pharmacy if more than 50 percent of the sales were to an entity other than a wholesaler for distribution to retail community pharmacies or retail community pharmacies that purchase drugs directly from the manufacturer. We believe that if we were to adopt a 50 percent methodology, some 5i drugs which are self-administered and generally dispensed through retail community pharmacies would be included in the alternate 5i AMP calculation due to the breadth of the percentage allowed in this calculation methodology.

We also considered whether we could use the methodology commonly used by manufacturers to calculate the Department of Veterans Affairs (DVA) non-Federal Average Manufacturer Price (non-FAMP). This methodology is described in the draft “Amended Master Agreement”,² between the Secretary of

² While the Amended Master Agreement (9/7/00 draft) between the Secretary of Veterans Affairs and the Manufacturer Identified in Section VIII of this Agreement has not been finalized and is therefore

Veterans Affairs and the Manufacturer in section VII of this Agreement. Manufacturers, manufacturer associations, pharmacies and pharmacy associations have repeatedly referred to this draft “Amended Master Agreement” when requesting guidance from CMS on the issue of defining “not generally dispensed”. According to the definition of Wholesaler found in the draft “Amended Master Agreement,” manufacturers are to consider a buyer to be a wholesaler when drugs with unit sales of 90 percent or greater are to retailers, other merchants, industrial, institutional or commercial users. Manufacturers are responsible for using this 90 percent principle as a guideline to determine when their sales are to wholesalers in their determination of non-FAMP. We considered whether it would be reasonable to apply the same principle to 5i drug determinations as to when a drug is “not generally dispensed” through a retail community pharmacy. We considered adopting a similar 90 percent principle because the definition of AMP, as specified in section 1927(k)(1)(B) of the Act, as revised by the Affordable Care Act, reflects sales to wholesalers for drugs distributed to retail community pharmacies (and retail community pharmacies that purchase drugs directly from the manufacturer). Therefore, for 5i drugs, our understanding of the 90 percent principle would be that if 90 percent or more of the manufacturer’s sales for the respective drug were to an entity other than a wholesaler for distribution to retail community pharmacies or retail community pharmacies that purchase drugs directly from the manufacturer, then the drug would be classified as “not generally dispensed” through a retail community pharmacy.

We believe providing a quantitative method to determine when a drug is “not generally dispensed” through a retail community pharmacy would be preferable to a more qualitative drug specific approach as it provides a more definitive meaning to the term “not generally dispensed” through a retail community pharmacy. Therefore, in this proposed rule, we propose at § 447.507(b)(1) to use the 90 percent principle to determine when a drug is not generally dispensed through a retail community pharmacy. However, we continue to have some concerns regarding whether the 90 percent threshold is reasonable because it might result in a portion of drugs eligible for

not an official DVA document, it is our understanding that it is still utilized by those in the industry when determining non-FAMP.

the 5i alternate AMP calculation to be omitted from AMP because the percentage of sales required to classify a drug as "not generally dispensed through a retail community pharmacy" may be too high. Manufacturers that enter into and have in effect a Medicaid drug rebate agreement, as set forth in section 1927(a) of the Act, are responsible for reporting AMP on a monthly and quarterly basis. Therefore, we propose at § 447.507(b)(2) that the determination of a 5i drug's status as "not generally dispensed" through a retail community pharmacy will need to be evaluated on a monthly and quarterly basis. We invite comments on this approach, including comments indicating if we should consider other quantitative options (for example, 75 percent, or 50 percent) to identify if a 5i drug is "not generally dispensed" through a retail community pharmacy and reasons as to why those options would be appropriate. We also invite comments on whether manufacturers should evaluate the status of a 5i drug's status as "not generally dispensed" through a retail community pharmacy on a monthly or quarterly basis.

We further propose at § 447.504(d) that, in light of section 1927(k)(1)(B)(i)(IV) of the Act, AMP for these drugs will include all sales, rebates, discounts, or other financial transactions already proposed for inclusion in the determination of AMP as well as the sales, rebates, discounts, or other transactions concerning these drugs, that are provided to the following non-retail community pharmacy entities:

- Direct sales to physicians.
- Sales to pharmacy benefit managers, including their mail order pharmacy's purchases.
- Sales to HMOs, including MCOs.
- Sales, discounts, or rebates paid directly to insurers.
- Sales to hospitals.
- Sales to clinics and outpatient facilities.
- Sales to mail order pharmacies.
- 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.
- Sales to hospices.
- Sales to other manufacturers who conduct business as wholesalers or retail community pharmacies.

7. Further Clarification on the Calculation of AMP—§ 447.504(e)

a. Chargebacks and Other Discounts (§ 447.504(e)(1))

We propose that chargebacks must be included in the calculation of AMP, except for those chargebacks provided to any of the entities that are excluded from the determination of AMP. Inasmuch as we believe chargebacks are based on identified sales to a specific entity, a manufacturer cannot make assumptions regarding these chargebacks and must identify them to included or excluded AMP sales. Additionally, we propose that AMP is to include cash discounts except customary prompt pay discounts extended to wholesalers, free goods that are contingent on any purchase requirement, volume discounts, incentives, administrative fees, service fees (other than bona fide service fees), distribution fees, and any other rebates, discounts or other financial transaction, other than rebates under section 1927 of the Act, which reduce the price received by the manufacturer for drugs distributed to retail community pharmacies.

b. Quarterly AMP (§ 447.504(e)(2))

Based on prior experience and on the MDR program submissions we believe that the quarterly AMP should be calculated as a weighted average of the monthly AMPs in the quarter. We believe that, based on our prior experience and the similarities of both calculations, this approach will minimize discrepancies between the monthly and the quarterly AMPs. Therefore, we propose that quarterly AMP is to be calculated as a weighted average of monthly AMPs in the quarter.

c. Manufacturer Adjustments (§ 447.504(e)(3))

To account for discounts, rebates or other price concessions that may not be available during the rebate reporting period, we propose 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.

D. Determination of Best Price (§ 447.505)

1. Definitions of Best Price and Providers

We are proposing re-codifying the terms "best price" and "Providers"

under newly proposed § 447.505(a). Additionally, we are proposing to revise the definition of the term "best price" at newly proposed § 447.505(a) so that it is consistent with the definition of best price found in section 1927(c)(1)(C) of the Act.

2. Prices Included in Best Price

We believe that revising the definition of best price to be consistent with the definition provided in the statute provides sufficient detail as to which prices are to be included in the determination of best price. Therefore, we further propose the "Prices included in best price," currently located in regulations at § 447.505(c)(1)–(11), be redesignated to § 447.505(b) and that it would be revised to remove the list of prices included in best price. Instead, the paragraph would read as follows: "Except for those prices identified in paragraph (c) of this section, best price for covered outpatient drugs includes all prices and associated rebates, discounts, or other transactions that adjust prices either directly or indirectly."

3. AMP Methodology Applied to Best Price

In order to provide consistency between the AMP and best price sections, where applicable, we are proposing to apply the same methodology to best price that we are applying to AMP. This will be accomplished by making the following revisions to the prices exempt from best price section. We propose the "Prices excluded from best price," currently located in regulations at § 447.505(d)(1)–(13), be redesignated to § 447.505(c)(1)–(18). The current list of prices excluded from best price would be expanded to include three new price exclusions not currently identified in regulations. They are (1) manufacturer vouchers, (2) manufacturer-sponsored patient refund/rebate programs and (3) sales outside of the United States. These terms have been discussed earlier in the Determination of AMP section and the addition of them to the prices excluded from best price serves to align best price and AMP. We also propose to revise the phrasing of several of the existing prices listed in the "prices excluded from best price" section so they are consistent with the phrasing of the same items listed in the "sales excluded from the determination of AMP" section of the regulation. These changes do not alter the meaning or intention of the section, and applies the same treatment of sales, prices and discounts, where applicable, to best price that we are applying to AMP.

4. 340B Expanded List of Covered Entities Exempt From Best Price

In accordance with section 7101 of the Affordable Care Act, we are proposing 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. The Affordable Care Act expanded the list of entities eligible to enroll in the 340B drug pricing program to include certain children's hospitals, freestanding cancer hospitals, critical access hospitals, rural referral centers, and sole community hospitals. Additionally, the Affordable Care Act amended the PHSA by excluding certain orphan drugs from being considered covered outpatient drugs for these newly covered entities. Section 204 of the Medicare and Medicaid Extenders Act of 2010 (Pub. L. 111-309) excludes certain children's hospitals from this exclusion, effective as if included in the enactment of section 2302 of the HCERA of 2010. In accordance with sections 1927(a)(5)(B) and 1927(c) of the Act, we propose that manufacturers can exclude only drugs purchased under the 340B Drug Pricing program from their best price calculation where the covered entities meet the conditions set by PHSA. We believe there may be circumstances in which covered entities purchase drugs outside of the 340B program, such as instances when drugs are purchased for inpatient use, drugs that have both inpatient and outpatient uses, and when a covered entity purchases drugs outside the 340B program to dispense to its Medicaid patients. In order to better understand the purchasing practices of covered entities and the scope of our proposed policy on best price, we invite comments regarding other circumstances in which covered entities purchase drugs outside of the 340B program. We believe that this position is consistent with our reading of these provisions and as a result strengthens the integrity of the MDR program because covered entities are prohibited from diverting drugs purchased under 340B authority to anyone who is not a patient of the covered entity. These requirements are proposed in a new regulation at § 447.505(c)(2)(i) and (ii).

5. Medicare Coverage Gap Discount Program (The Discount Program)

The Affordable Care Act established the Discount Program under sections 1860D-43 and 1860D-14A of the Act. The Discount Program makes manufacturer discounts available to applicable Medicare beneficiaries

receiving applicable covered Part D drugs while in the coverage gap.

In general, 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 Affordable Care Act, manufacturer discounts attributed to the Discount Program will be excluded from the determination of best price as defined in § 447.505(c)(6).

E. Authorized Generics Drugs (§ 447.506)

We propose to remove the definition of "Authorized generic drugs" from § 447.506(a), as discussed in section II.B.1 of this regulation. In § 447.506(a), we propose to define the term "Primary manufacturer" to mean a manufacturer that holds the NDA of the authorized generic drug. We also propose 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. In § 447.506(b), we propose to revise the existing paragraph to specify that sales of an authorized generic drug must be included in the AMP calculation of the manufacturer holding the NDA, referred to in this discussion as the primary manufacturer, when such drugs are being sold directly to a wholesaler. In accordance with section 1927(k)(1)(C) of the Act, we propose in § 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 product sold or licensed to a secondary manufacturer, including transfer prices and fees paid by the secondary manufacturer to the primary manufacturer, when the secondary manufacturer is acting as a wholesaler, as set forth in section 1927(k)(11) of the Act. Additionally, the primary manufacturer holding the NDA must also include those sales in its AMP calculation that it makes directly to wholesalers including other manufacturers acting as wholesalers.

In § 447.506(c), we propose to revise the existing paragraph 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 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, when such drugs are being sold by the primary manufacturer holding the NDA.

Further, we propose to add a new § 447.506(d) to specify that the

secondary manufacturer of an authorized generic drug must also provide a rebate based on its sales of authorized generic drugs, and must calculate AMP and best price consistent with the requirements specified at § 447.504 and § 447.505 respectively.

F. Exclusion From Best Price of Certain Sales at a Nominal Price (§ 447.508)

Currently, the existing regulations at § 447.508(a) defines nominal sales which should be excluded from a manufacturer's best price calculation only when made to 340B covered entities as defined in section 340B(a)(4) of the PHSA, ICFs/MR, State-owned or operated nursing facilities and safety net providers or facilities/entities which the Secretary determines to be eligible.

Previously, the Secretary did not exercise the authority to add other safety net providers for which sales at nominal prices are excluded from best price. Section 221 of the Omnibus Appropriations Act, 2009, Public Law 111-8, enacted on March 11, 2009, revised section 1927(c)(1)(D) of the Act by expanding the definition of nominal priced sales to include sales of covered outpatient drugs to two new categories of entities. The expansion allows public or nonprofit entities (as defined by the Internal Revenue Service (IRS)), or State-owned or operated facilities providing the same services to the same populations as 340B(a)(4) entities of the PHSA but not funded as such and in compliance with the prohibition on abortion services as set forth in section 1008 of the PHS Act or academic health care centers providing family planning services to be eligible for the nominal priced sales.

We propose to revise § 447.508(a) to include the additional entities to which manufacturers may have nominal price sales excluded from best price. To qualify for the exception, entities must meet the criteria set forth below for either of the two new categories:

- Category 1 criteria:

- + The entity is an exempt organization as defined by section 501(c)(3) of the Internal Revenue Code of 1986; and exempt from tax under section 501(a) of such Act, or is State-owned or operated; and,

- + Provides the same type of services to the same type of populations as a covered entity described in 340B(a)(4) of the PHS Act but does not receive funding under such section.

- Category 2 criteria: The entity is a public or nonprofit 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 a

service or services as described under section 1001(a) of the PHS Act, 42 U.S.C. 300.

The legislation further provides that nothing in section 1927(c)(1)(D) of the Act should be construed to alter any existing statutory or regulatory prohibition on services for Category 1 entities, including the prohibition set forth in section 1008 of the PHSA.

Because these additions appear to address those nominal price sales that are not related to a manufacturer's attempt to influence market share or for other marketing reasons, we are again choosing not to identify any further entities for which manufacturer nominally priced sales would be exempt from best price.

G. Medicaid Drug Rebates (§ 447.509)

1. Determination of Rebate Amount (§ 447.509(a))

Manufacturers that participate in the MDR program are required to pay rebates for covered outpatient drugs that are dispensed to Medicaid patients. The rebates are calculated based on formulas described in section 1927(c) of the Act. As described in the "Background" section above, the Affordable Care Act made several revisions to the statutory rebate formulas. In light of these revisions, we propose to incorporate the rebate formulas into Federal regulations.

We propose in § 447.509(a)(1) that the basic rebate, for each dosage form and strength of a single source drug or an innovator multiple source drug, will be equal to the total number of units of each dosage form and strength paid for under the State plan in the rebate period multiplied by the greater of the difference between the AMP and best price of the drug or the AMP multiplied by:

- 17.1 percent for a clotting factor for which a separate furnishing payment is made under section 1842(o)(5);
- 17.1 percent for a drug approved by the FDA exclusively for pediatric indications; or
- 23.1 percent for all other single source drugs and innovator multiple source drugs.

We note that all clotting factors would not qualify for the minimum rebate percentage of 17.1 percent of AMP. Only those clotting factors for which a separate furnishing payment is made under section 1842(o)(5) of the Act would qualify as defined under the definition of clotting factors. Similarly, all drugs with pediatric indications would not qualify for the minimum rebate percentage of 17.1 percent of AMP. Only those drugs approved by the FDA exclusively for pediatric

indications, in accordance with our proposed definition in § 447.502, would qualify.

We propose in § 447.509(a)(2) that the additional rebate for single source and innovator multiple source drugs will be equal to the number of units for such dosage form and strength paid for under the State plan in the rebate period multiplied by the amount, if any, by which the AMP for the dosage form and strength of the drug for the period exceeds the base date AMP for such dosage form and strength, increased by the percentage by which the CPI-U for the month before the month in which the rebate period begins exceeds such index.

We propose in § 447.509(a)(3) that the total rebate amount for single source drugs and innovator multiple source drugs will be equal to the basic rebate amount plus the additional rebate amount, if any. We also propose at § 447.509(a)(5) that in no case will the total rebate amount exceed 100 percent of the AMP of the drug.

2. Treatment of New Formulations (§ 447.509(a)(4))

The Affordable Care Act established a separate formula for calculating the unit rebate amount 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 a line extension drug, the rebate amount will be the amount calculated under section 1927 of the Act or, if greater, the product of the AMP for the line extension drug, the highest additional rebate (calculated as a percentage of AMP) under section 1927 for any strength of the original single source or innovator multiple source drug, and the total number of units of each dosage form and strength of the line extension drug paid for under the State plan in the rebate period (as reported by the State). We propose to incorporate this calculation in § 447.509(a)(4).

The statute defines a line extension for purposes of the rebate calculation as a new formulation of a drug such as an extended release formulation. However, the statute did not provide further specificity as to how line extensions should be defined. Therefore, as previously described in the definition of a line extension, we will define line extension at § 447.502. CMS plans to define a line extension drug as a single source or innovator multiple source drug that is 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 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. Single source or innovator multiple source drugs that receive exclusivity are not proposed to be excluded from the definition of a line extension drug. For the purpose of calculating the unit rebate amount under the Affordable Care Act, we propose that both the initial brand name drug and the line extension drug have to be an oral solid dosage form drug. We also propose to exclude a new strength of the initial brand name drug from the definition of a line extension drug. We have adopted this policy in order to capture all new formulations (including extended release formulations) and potential line extensions of single source or innovator multiple source drugs. Further, we believe this policy is consistent with our understanding of the line extension provisions in the Affordable Care Act. We invite comments from the public on this proposed policy.

We do not plan to exclude reformulations of existing products that incorporate abuse deterrent technologies from the definition of line extension drugs. The goal of these new formulations are to mitigate the risk of abuse—as opposed to the outright elimination of abuse—by preventing alternate routes of administration, or employing physical barriers that resist common methods of tampering, thus abuse deterrent formulations (ADFs) have the potential to decrease abuse of prescription drugs and improve patient and public safety. Some examples of abuse deterrent strategies that are under development include combination oral formulation products with an opioid agonist and opioid antagonist, formulations with other aversive characteristics, prodrugs, physically impenetrable formulations, and drug-device combinations with patient recognition capability. However, the statute does not exclude reformulated drugs incorporating abuse deterrent technologies from the definition of a line extension drug and thus we do not plan to exclude drugs with this labeling from the definition. The types of drugs that we are considering as line extension drugs include these reformulated products.

FDA draft guidance on the assessment of abuse potential of drugs can be found at <http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM198650.pdf>.

We are soliciting feedback from the industry, the public, and other

stakeholders regarding whether existing or future reformulated products incorporating an abuse deterrent technology should be subject to the additional rebate formula under the Affordable Care Act.

We have determined that we do not have the ability to identify the line extension of the initial brand name listed drug based on manufacturer rebate submissions. We consulted with the FDA to determine if the FDA currently keeps a list of line extension drugs as we have defined the term, and the FDA does not. Thus, we reviewed the drug information and data files publicly available at the FDA and propose to use the FDA's list of Chemical Types to identify the line extension drug as well as the initial brand name listed drug of the line extension drug.

The FDA classification is given to nonbiologic products during the review process and is finalized when the NDA is approved. This classification consists of Chemical Type classification, which classifies these drugs according to the type of change made to the initial brand name product. Chemical Type represents the newness of a drug formulation or a new indication for an existing drug formulation, as noted in <http://www.fda.gov/Drugs/informationondrugs/ucm079436.htm>. The FDA classifies all NDAs based on Chemical Type. One measure of innovation is the newness of the listed drug or the drug's active ingredient. The Chemical Type may identify the drug as new, or as related to the active ingredient of another drug that has already been approved.

Based on the analysis of the FDA's drug information and data files, we propose to use Chemical Types 2, 3, 4, and 6 on the FDA's list of Chemical Types below as an indicator for line extension drugs as shown in Table 4.

TABLE 4—NEW DRUG APPLICATION
CHEMICAL TYPES

Number	Meaning
1	New molecular entity (NME).
2	New ester, new salt, or other noncovalent derivative.
3	New formulation.
4	New combination.
5	New manufacturer.
6	New indication.
7	Drug already marketed, but without an approved NDA.
8	OTC (over-the-counter) switch.

Chemical Type 2 (new ester, new salt, or other noncovalent derivative) represents the incorporation of different salts or esters, or other noncovalent

derivatives (such as a complex, chelate, or clathrate) of the molecule, responsible for the physiological or pharmacological action of the drug substance of an approved pharmaceutical ingredient into a marketed dosage form which represents a change to the listed drug (21 CFR 314.108(a)). We propose to identify this Chemical Type as a line extension because it describes a new version of the initial brand name listed drug.

Chemical Type 3 (new formulation of a previously approved drug) (not a new salt or new molecular entity) represents a change in the inactive ingredients (excipients) in a drug but no change in the amount of active ingredient. A new formulation may be a dosage form that contains the same active ingredient as was previously approved in a different dosage form as the initial brand name listed. Chemical Type 4 (new combination) represents a drug comprised of two or more components that are physically, chemically, or otherwise combined or mixed to produce a single drug product. We propose to identify this Chemical Type as a line extension because the new combination of the initial brand name listed drug of two or more active ingredients represents a new formulation of the initial brand name listed drugs that are combined to form one drug product.

Chemical Type 6 (new indication for an already marketed drug) represents a change in the description of use of an already marketed initial brand name listed drug in the prevention, treatment, or diagnosis of a recognized disease or condition. According to the National Institute for Health Care Management, research performed on drugs that are already on the market may reveal that they provide safe and effective treatments for diseases or conditions other than the indication(s) for which the product was originally approved. We propose to identify this Chemical Type as a line extension because there is an approval for a new indication that represents a change to the initial brand name listed drug.

Chemical Type 1 (new molecular entity) represents an active ingredient that has never before been marketed in the United States in any form. CMS proposes to use this Chemical Type to identify the initial brand name listed drug of a line extension.

Chemical Type 5 (new manufacturer) is assigned to an already marketed drug when it has: (1) A new manufacturer, or (2) a product that duplicates another manufacturer's already marketed drug product. We do not propose to consider this Chemical Type as a line extension

because the change is a non drug-related change; rather, it is simply a transfer of the application from one manufacturer to another.

Chemical Type 7 (drug already marketed, but without an approved new drug application (NDA)) represents drugs that have not been approved by the FDA. We do not propose to consider this Chemical Type as a line extension because these drugs have not been approved by the FDA.

Chemical Type 8 (OTC (over-the-counter) switch) represents the process of transferring FDA-approved prescription medications to nonprescription, OTC status. We do not propose to consider this Chemical Type as a line extension because there is no new formulation of the initial brand name listed drug.

We plan to identify line extension drugs by using drug information that is publicly available on the FDA Web sites. As stated, CMS currently does not have the ability to identify whether a drug is a line extension and which drug is the initial brand name listed drug of the line extension drug based on manufacturers' MDRP submissions. Therefore, we plan to rely on drug information obtained from the FDA. In order for us to identify the line extension drugs using the FDA's drug information to calculate the additional rebate, there are essentially five criteria that we believe must be met. First, the line extension drug should be a single source drug or innovator multiple source drug. Manufacturers are already required to report to CMS if their nine-digit NDC drug is a single source drug, innovator multiple source drug, or non-innovator multiple source drug; therefore, we have the information to make this determination.

Second, the line extension drug has to be an oral solid dosage form of a single source drug or innovator multiple source drug in accordance with the definition of an oral solid dosage form previously provided.

Third, the line extension is identified based on Drugs@FDA's application file. Since we currently do not have the ability to identify whether the drug is the actual line extension of the initial brand name listed drug based on manufacturers' submissions, we propose to rely on the FDA's list of Chemical Types to identify which drug is a line extension drug, as described above. Because we do not approve new drugs or changes to a drug, using the Chemical Types would permit us to identify line extension drugs based on FDA data, since the FDA currently has an identifier for the Chemical Types in their Drugs@FDA's application file.

Fourth, the initial brand name listed drug of the line extension drug needs to be identified to calculate the Affordable Care Act unit rebate amount for the line extension drug. Again, as described above, we plan to use Chemical Type 1 to assist us in tracking back to the initial brand name listed drug of the line extension drug. Chemical Type 1 is assigned to an active ingredient that has not been marketed in the United States in any form; therefore, we have decided that this can be used as the initial brand name listed drug identifier. An active ingredient that has never been marketed in the United States would be approved by the FDA under a new NDA with no therapeutic equivalents, which would meet our definition of a single source drug. If there are therapeutic equivalents for the single source drug, then the drug category would change to an innovator multiple source drug in accordance with the rebate definition of an innovator multiple source drug. However, the innovator multiple source drug would retain the same NDA that was assigned to the single source drug that was first approved by the FDA. Additionally, the initial brand name listed drug has to be an oral solid dosage form per our definition of an oral solid dosage form.

Lastly, CMS currently collects drug product and pricing information by NDC, not by active ingredient. However, the FDA information is mainly available by active ingredient. Therefore, we need to identify the line extension drugs by NDC. In order for CMS to translate the active ingredient into NDC, a manual matching process has to be done to match the Drugs@FDA's application file against the FDA's Orange Book's product file: (1) To extract the Chemical Type and the application number, (2) to identify the oral solid dosage form, and (3) to obtain the FDA approval date for each drug. This file will then be matched with the FDA's NDC Directory's application and listing files to identify the NDC of each active ingredient to compile a master list of all initial brand name listed drugs and their line extension drugs by NDC. This master list will then be matched by NDC against the CMS' drug product file to identify which of CMS' NDCs are the initial brand name listed drugs and which are the line extension drugs.

Since NDCs enter and exit the MDRP frequently, we propose to update the master list based on the FDA's drug information on a quarterly basis and then match the master file against CMS' drug product file to identify new initial brand name listed drugs and new line extension drugs for the initial three quarters. Following these initial three updates, manufacturers will be

responsible for identifying and reporting to CMS which of their NDCs is the initial brand name listed drug and which is the line extension drug. This is necessary to effectuate the line extension provisions of the Affordable Care Act. Additionally, as mentioned in the definition of a line extension drug, we propose that a new strength of the initial brand name listed drug would not qualify as a line extension drug. Furthermore, if we were to consider a new strength to be a line extension, it would be difficult to identify the first strength of the initial brand name listed drug because multiple strengths are often launched simultaneously and CMS would not be able to track back to the first strength of the initial brand name listed drug. We invite comments from the public on all aspects of this proposed policy.

We also do not plan to exclude a single source or innovator multiple source drug that receives 3-year exclusivity, pediatric exclusivity, or 7-year orphan drug exclusivity from the definition of a line extension drug. Drug manufacturers may separately obtain a 3-year exclusivity or a pediatric exclusivity. Drug manufacturers can reformulate a drug before it goes off patent by developing a new formulation such as a time-release version or by combining it with another existing drug, marketing it for another illness, or claiming a patent on an inactive ingredient. The 3-year exclusivity protection as indicated in sections 505(c)(3)(D)(iii), (c)(3)(D)(iv), (j)(5)(D)(iii), and (c)(5)(D)(iv) of the FFDCA, and at 21 CFR 314.108 is granted for a drug product that contains an active moiety that has been previously approved, when the application contains reports of new clinical investigations (other than bioavailability studies) conducted or sponsored by the sponsor that were essential to approval of the application. This exclusivity requires conducting new clinical studies that are judged to be essential for approval of the change. Changes to a drug that qualify for this exclusivity are changes that we are considering for the definition of a line extension drug.

According to section 505A of FFDCA (Food and Drug Administration Modernization Act (FDAMA) and Best Pharmaceuticals for Children Act (BPCA), drug manufacturers can also apply for a pediatric exclusivity, which permits certain applicants to obtain an additional 6-month period of exclusivity on the use of a drug moiety in pediatric patients. We do not plan to exclude drugs that have this exclusivity from the definition of line extension drugs.

According to sections 526–527 of FFDCA and regulations at 21 CFR 316, drug manufacturers can apply for a 7-year orphan drug exclusivity. Orphan drug exclusivity promotes research and marketing for the development of drugs to treat rare diseases, defined as a disease affecting 200,000 or fewer patients in the United States, by granting a 7-year protection against competition for the designated orphan indication. We do not plan to exclude drugs that have this exclusivity from the definition of line extension drugs.

For the purpose of calculating the unit rebate amount (URA) for the line extension drug, the highest additional rebate as added by the Affordable Care Act for a line extension shall be referred to as the Alternative URA. We propose to interpret section 1927(c)(2) to provide that the URA determination is based on the greater of the Standard URA calculated under section 1927 of the Act without regard to the alternative rebate calculation provided in the Affordable Care Act, or the Alternative URA for the line extension drug under the Affordable Care Act. As previously stated, to effectuate the line extension provisions of the Affordable Care Act, we propose that both the initial brand name listed drug and the line extension drug are reported to CMS under the MDR program for the purpose of calculating the URA for a line extension drug.

Additionally, to calculate the Alternative URA, the line extension drug should be tracked back to the initial brand name listed drug. We recognize that there are multiple issues when it comes to tracking the line extension back to the initial brand name drug, such as when the line extension drug and the initial brand name listed drug are marketed by two different manufacturers or when the initial brand name listed drug has been terminated from the Medicaid drug rebate program. However, in accordance with the statute, manufacturers are responsible for calculating the Alternative URA for their line extension drugs.

We propose that when the initial brand name listed drug has been terminated that manufacturers should not be responsible for calculating the Alternative URA. The initial brand name listed drug must be active in the Medicaid drug rebate program to calculate the Alternative URA. We propose that we would calculate the URA for line extension drugs and will provide this amount to States on the quarterly rebate tape as in the current rebate process. However, in accordance with the current process, manufacturers are responsible for calculating and

making rebate payments to each State Medicaid Agency. Therefore, manufacturers are responsible for ensuring that all necessary product and pricing data, whether such information is for the initial brand name listed drug or the line extension drug, are exchanged between the manufacturer of the initial brand name listed drug and the manufacturer of the line extension drug to accurately calculate the URA for the line extension drug and provide rebates in accordance with the statute.

As provided in § 447.509(a)(5), section 2501(e) of the Affordable Care Act added section 1927(c)(2) of the Act to cap the URA at 100 percent of AMP for all brand name drugs. Therefore, this cap will also apply to the URA calculation for the line extension drugs as well.

Below are the proposed steps outlining how we plan to calculate the URA for a line extension drug. For clarification purposes, the highest additional rebate as added by the Affordable Care Act for a line extension shall be referred to as the "Alternative URA" and the URA calculation based on section 1927 of the Act (without regard to the alternative rebate calculation provided in the Affordable Care Act) shall be referred to as "Standard URA."

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 original 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.
- b. If the URA is less than 100 percent of AMP, then use the calculated URA.

Below is an example of calculating the URA 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. $AMP \times 23.1\% = 300.00 \times 23.1\% = 69.30$
- or
- b. $AMP - \text{Best Price} = 300.00 - 250.00 = 50.00$

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 section 1927 of the Act Formula: If the $[(\text{Baseline AMP}/\text{Baseline CPI-U}) \times \text{CPI-U}]$ is

less than the quarterly AMP, subtract $[(\text{Baseline AMP}/\text{Baseline CPI-U}) \times \text{CPI-U}]$ from the quarterly AMP to determine the additional URA. If the $[(\text{Baseline AMP}/\text{Baseline CPI-U}) \times \text{CPI-U}]$ is equal to or greater than the quarterly AMP, the additional URA is equal to zero.

$[(\text{Baseline AMP}/\text{Baseline CPI-U}) \times \text{CPI-U}] = 100/170 \times 200 = 0.5882 \times 200 = 117.65$
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 = 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 = $125/275 = 0.5636$

Strength C additional rebate amount ratio = $110/270 = 0.4074$

Highest additional rebate (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 (calculated as a percentage of AMP) for any strength of the original drug
Alternative URA = $300 \times 0.7143 = 214.29$

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) = $300.00 = 100\% \times 300.00 = 300.00$

URA = 251.65

URA is less than 100 percent of AMP; therefore, URA is equal to 251.65

3. Rebates for Drugs Dispensed Through Medicaid Managed Care Organizations (MCOs) (§ 447.509(b))

From the inception of the MDR program, section 1927(j)(1) of the Act exempted participating manufacturers from paying drug rebates for drugs dispensed to individuals enrolled in MCOs. The Affordable Care Act eliminated this exemption. 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 drug rebate program to pay rebates for drugs dispensed to individuals enrolled with a Medicaid MCO if the MCO is

responsible for coverage of such drugs. The requirement to collect rebates beginning March 23, 2010 is irrespective of any existing contracts States may have with MCOs. To comply with this section of the law and to assure that States fully collect these increased rebates, States must obtain utilization data from each Medicaid MCO in order for States to request quarterly rebates from manufacturers as well as report it in their quarterly utilization reports to CMS. This data reporting will also have other quality-related benefits for States and the Medicaid program in terms of providing timely information on drug utilization.

Section 2501(c) of the Affordable Care Act also amended section 1903(m)(2)(A) of the Act, effective March 23, 2010, by adding new conditions for Federal financial participation for MCO contracts including that:

- Any covered outpatient drug provided by the MCO is eligible for the rebates authorized under section 1927 of the Act;

- MCO capitation rates will be based on actual cost experience related to rebates and subject to Federal regulations at § 438.6 regarding actuarial soundness of capitation payments; and

- The MCO must report to the State information on the total number of units of each dosage form, strength and package size by NDC of each covered outpatient drug dispensed to Medicaid MCO enrollees and such other data that the Secretary determines necessary for the State to access the rebates authorized by this provision.

Section 2501(c) also made a conforming amendment to section 1927(j)(1) of the Act, effective March 23, 2010, to specify that certain covered outpatient drugs in this section are not subject to the rebate requirements if such drugs are both dispensed by health maintenance organizations (HMOs), including Medicaid MCOs that contract under section 1903(m), and are subject to discounts under section 340B of the Public Health Service Act.

In accordance with these revisions to sections 1927 and 1903 of the Act, we propose a new § 447.509(b). In § 447.509(b)(1), we propose to require participating manufacturers to pay rebates for covered outpatient drugs dispensed to individuals enrolled in Medicaid MCOs if the MCO is responsible for payment for such drugs. In § 447.509(b)(2), we propose that manufacturers are exempt from the requirement in paragraph (b)(1) if such drugs are dispensed by health maintenance organizations, including MCOs that contract under section 1903(m) of the Act, and subject to

discounts under section 340B of the PHS Act. In § 447.509(b)(3), we propose that a Medicaid MCO that is responsible for covered outpatient drugs dispensed to Medicaid beneficiaries must submit a report to the State within thirty days of the end of each quarter. We also propose the specific data that MCOs must include in such reports. It is expected that the States will ensure that the MCOs comply with providing timely utilization data to meet the State reporting requirements.

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 described above 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 propose to calculate the offset as described below.

For single source or innovator multiple source drugs that are subject to a minimum rebate percentage of 23.1 percent of AMP:

- If the difference between AMP and best price is less than or equal to 15.1 percent of AMP, then we propose to offset the full 8 percent of AMP (the difference between 23.1 percent of AMP and 15.1 percent of AMP).
- If the difference between AMP and best price is greater than 15.1 percent of AMP but less than 23.1 percent of AMP, then we propose to offset the difference between 23.1 percent of AMP and AMP minus best price.
- If the difference between AMP and best price is greater than or equal to 23.1 percent of AMP, then we propose to not take any offset amount.

For single source or innovator multiple source drugs that are blood clotting factors and drugs approved by the FDA exclusively for pediatric indications that are subject to a rebate percentage of 17.1 percent of AMP:

- If the difference between AMP and best price is less than or equal to 15.1 percent of AMP, then we propose to offset the full 2 percent of AMP (the difference between 17.1 percent of AMP and 15.1 percent of AMP).
- If the difference between AMP and best price is greater than 15.1 percent of AMP but less than 17.1 percent of AMP, then we propose to offset the difference between 17.1 percent of AMP and AMP minus best price.
- If the difference between AMP and best price is greater than or equal to 17.1

percent of AMP, then we propose to not take any offset amount.

In the September 28, 2010 State Medicaid Director (SMD) letter, #10-019, 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 apply the same offset calculation as described above to the basic rebate. Further, we planned to offset only the difference in the additional rebate of the reformulated 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 reformulated drug, if greater, in accordance with the Affordable Care Act. If there is no difference in the additional rebate amount in accordance with the Affordable Care Act, then we do not plan to take any offset amount. (A copy of the SMD letter can be found at <http://www.cms.gov/smdl/downloads/SMD10019.pdf>.)

However, after further review of the offset provisions in section 2501 of the Affordable Care Act, we have decided to reconsider our instructions regarding the calculation of the offset provisions for line extension drugs to reflect 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 Act and the calculation of the URA for the line extension drug, if greater, in accordance with the Affordable Care Act. If there is no difference between the URA for the line extension drug based on the Affordable Care Act and URA calculation based on the applicable rebate percentage in section 1927 prior to the Affordable Care Act, then we do not plan to take any offset amount. If there is a difference then we will offset the amount of that difference.

For noninnovator multiple source drugs, we plan to offset an amount equal to 2 percent of the AMP (the difference between 13 percent of AMP and 11 percent of AMP) since these drugs are unaffected by best price.

For covered outpatient drugs that are dispensed to Medicaid MCO enrollees, we propose to offset the non-Federal share limited to the difference between the rebate percentages in effect outside of the MCO context on December 31, 2009 and the rebate percentages in effect on January 1, 2010, as described previously. Specifically, we planned for States to retain the non-Federal share of rebates below the 15.1 percent rebate percentage for single source or innovator multiple source drugs and 11 percent for noninnovator multiple source drugs as in effect on December 31, 2009. In addition, we planned for

States to retain the non-Federal share of the amount above the revised minimum rebates for brand name drugs.

Additionally, we do not plan to offset the non-Federal share of any supplemental rebate States may receive above the increased Federal rebate percentages.

To ensure efficiency and uniformity, CMS plans to calculate a unit rebate offset amount (UROA) that will, on a quarterly basis, identify the amount of offset per unit of drug at the 9-digit NDC for States. The UROA will be provided to States in a manner similar to how States currently receive the URA every quarter. States will then match the UROA with the number of units of the drug for which they receive payment from a manufacturer to determine the Quarterly Rebate Offset amount (QROA) for that drug. All QROAs for all drugs of all manufacturers will then be added together to determine the Total QROA. This then will be the amount that States offset on the Quarterly Expenditure reports. Adjustments to the UROA will be treated as prior period adjustments (PPAs) and will be reported to the States the same way that URA PPAs are currently transmitted.

Please note that the offset provision would also apply to the Territories that participate in the MDR program.

H. Requirements for Manufacturers (§ 447.510)

In the Medicaid Program; Withdrawal of Determination of Average Manufacturer Price, Multiple Source Drug Definition, and Upper Limits for Multiple Source Drugs final rule published in the November 15, 2010 **Federal Register** (75 FR 69591), we made conforming amendments to delete references to § 447.504 "Determination of AMP" from § 447.510 "Requirements for Manufacturers". In this proposed rule, we are proposing conforming regulatory amendments to add regulatory text to § 447.510. Specifically, those references that will be added are at § 447.510(a)(1), § 447.510(c)(2)(i), and § 447.510(d)(2).

We are also proposing a conforming amendment to § 447.510(g) to clarify that the electronic format in which the product and pricing data is submitted to CMS must be submitted in a format designated by CMS.

1. Failure to Report Quarterly AMP (§ 447.510(a)(5))

In an effort to better ensure timely quarterly AMP reporting at the end of each rebate period, in accordance with the statute at section 1927(b), 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. We propose, in accordance with the statutory requirements at section 1927(b)(3)(C)(i), that manufacturer will be subject to a civil monetary penalty for each product not reported on the thirty-first day. Please see the OIG's Special Advisory Bulletin issued in September 2010 regarding reporting AMP timely, http://oig.hhs.gov/fraud/docs/alertsandbulletins/2010/SpAdvBulletin_AMP_ASP.pdf.

Additionally, we are considering adding regulatory guidance on suspension and termination for manufacturers that do not report quarterly AMP on a timely basis or are otherwise out of compliance with rebate requirements. We have considered a number of formal and informal administrative procedures similar to those set forth in 42 CFR part 498 or 42 CFR 430.18, which would permit an opportunity for reconsideration and administrative appeals. We are considering the appropriate terms and procedures for suspension and termination and, therefore, we invite comments from the public.

2. Reporting Revised Monthly and Quarterly AMP, Best Price, Customary Prompt Pay Discounts, or Nominal Prices (§ 447.510(b))

In this proposed rule, we propose to revise the 12-quarter rule filing limitation currently in place for manufacturers to report revisions to their quarterly AMP, best price, customary prompt pay discounts, or nominal prices. We initially established a time limit of 12 quarters for manufacturers to report revisions to their quarterly pricing data. The 12-quarter period established a time limit within which manufacturers are responsible for reporting revisions to pricing data in part to decrease associated administrative burdens on manufacturers and States. Despite the effective date of January 1, 2004 for the 12-quarter rule, we are still receiving requests from manufacturers to make revisions to the pricing data that fall outside of the 12-quarter period. Therefore, we propose that any request from manufacturers submitted to CMS to revise the monthly and quarterly AMP, best price, customary prompt pay discounts, or nominal prices that are outside of the 12-quarter filing deadline will be considered, only if it falls within one of the following categories:

- The change is a result of the drug category change or a market date change.
- The change is an initial submission for a product.

- 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.

- 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.

- 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.

We propose that § 447.510(b)(1) be revised to clarify that a manufacturer is required to report to CMS any revisions to correct 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. The 12-quarter limit is meant to be a specific time limit for any revision. Any revision request, except for those falling within the exceptions noted above, must be made within this 12-quarter time period. We propose to add to § 447.510(b) that any revision request that falls outside of the 12-quarter time limit will not be considered by CMS, unless it falls under the above five criteria. We also propose to revise timeframe for reporting revised monthly AMP in § 447.510(d)(3) to clarify that the only exceptions to the 36-month limit for reporting monthly AMP would be considered by CMS if it falls under the same five criteria.

We are contemplating whether to allow manufacturers that have revisions to their pricing data beyond the 12-quarter limit that meet the five criteria above to revise their pricing data on a retroactive basis: (1) Without any time limits back to beginning of the program, 1991, or (2) with some time limits outside of the 12-quarter restrictions. In other words, we are considering whether we should impose a timeframe as to how far back we should allow manufacturers to make this revision. We invite public comments on suggestions as to how far back we should allow manufacturers to make revisions to their pricing data if their request meets one of the above five exceptions.

Additionally, to ensure that any revision to pricing data is consistent across the monthly and the quarterly AMP data, if a revision request is submitted for monthly AMP and AMP units, then a revision request is also required for quarterly AMP. In addition, if a revision request is submitted for quarterly AMP, then a revision request is also required for monthly AMP and AMP units.

3. Recalculations Including Good Cause

Separate from pricing data revision request, we are proposing 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 and best price. Our regulations at § 447.510(b) specify that manufacturers have a 12-quarter time limit to report price revisions. Manufacturers are responsible for reporting any revisions to AMP or best price within the 12 quarter limit, which begins with the quarter in which the data was due. As is the case with all pricing data submitted under the MDR program, if a subsequent review of the manufacturers' pricing data by CMS, the OIG, or another authorized government agency determines or reveals that adjustments or revisions are necessary irrespective of the quarter, the manufacturer is responsible under the statute to comply with that determination. Based on questions from manufacturers often as a result of False Claims Act concerns, we have considered allowing manufacturers to submit recalculations of AMP and best price outside of the twelve quarter time limit due to good cause. We plan to establish a good cause option to allow manufacturers to submit their pricing data due to a recalculation of the methodology for calculating AMP and best price outside of the 12-quarter time limit to address underpayments and potential liability regarding those underpayments that may extend outside of that 12-quarter period. We are considering proposing a "good cause" option to extend the time limit for filing a recalculation request, similar to that used in Medicare. We invite comments from the public on this option.

4. Base Date AMP (§ 447.510(c)(1) to § 447.510 (c)(4))

In the 2007 AMP final rule, we allowed manufacturers to report a revised base date AMP to CMS within the first four full calendar quarters following the publication date of the final rule. To differentiate between the timeframe when manufacturers were allowed to report revised base date AMPs in accordance with the DRA-based definition of AMP and the timeframe described below, we propose to revise § 447.510(c)(1) and § 447.510(c)(2) by inserting "DRA" before base date AMP where it occurs. We also propose to remove the notation "[OFR: insert publication date of the final rule]" and replace it with "July 17, 2007" in § 447.510(c)(1).

The Affordable Care Act significantly revised the definition of AMP to mean for a covered outpatient drug (including those sold 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. To reflect the changes to AMP as set forth in the Affordable Care Act, we propose to allow manufacturers to recalculate base AMP in accordance with the definition of AMP in § 447.504 of this subpart. Base AMP is used in the calculation of the additional rebate described in section 1927(c)(2) of the Act. This additional rebate is defined as the difference between the current quarterly AMP reported to CMS and the base date AMP trended forward using the CPI-U. We propose this revision so that the additional rebate would not increase solely due to the changes in the definition of AMP. We propose giving manufacturers the option to report a recalculated base date AMP based on the Affordable Care Act. We propose to allow manufacturers the option to decide whether they will recalculate and report to CMS an Affordable Care Act base date AMP in light of the revised definition of AMP or continue to use their existing base AMP. We propose to give manufacturers this option because we are aware that some manufacturers may not have the actual data needed to recalculate their base date AMP or may find the administrative burden to be more costly than the savings gained. We propose to provide manufacturers with the option to report the recalculated Affordable Care Act base date AMP for a period of four full calendar quarters beginning with the first full quarter after the publication of the final rule.

5. Calculation of Monthly AMP (§ 447.510(d)(2))

Section 1927(e)(5) of the Act specifies that the Secretary is to 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 under Medicare Part B. The Medicare Part B regulations at § 414.804(a)(3) specify that the ASP methodology for smoothing lagged price concessions requires that manufacturers calculate the total lagged price concessions for the previous 12-month period and convert the dollar amount to a percentage of sales over that same 12-month period. This percentage is then applied to the current quarter's sales to estimate the

lagged price concessions for that quarter.

Therefore, we are proposing manufacturers would be required to use a 12-month rolling percentage to estimate the value of lagged price concessions in their calculations of the monthly and quarterly AMPs.

Specifically, we are proposing 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 covered outpatient drug sold by the manufacturer during a month. It is calculated as net sales divided by number of units of the drug sold, excluding goods or any other items specifically excluded in the statute or regulations. The drug unit is the lowest identifiable amount (for example, tablet or capsule for solid dosage forms, milliliter for liquid forms, gram for ointments or creams) as reported by the manufacturer.

Monthly AMP should be calculated consistent with this methodology, based on the best data available to the manufacturer at the time of submission.

In calculating monthly AMP, a manufacturer should estimate the impact of its lagged price concessions using a 12-month rolling percentage to estimate the value of those discounts. Following is an example of how manufacturers would calculate the monthly AMP by using a 12-month rolling percentage to estimate the lagged price concessions:

- Total lagged price concessions over the most recent 12-month period = \$150,000.
- Total sales subject to AMP reporting for the most recent 12-month period = \$600,000.
- $\$150,000 / \$600,000 = 0.25$ (or 25 percent).
- The result (25 percent) is the percentage manufacturers subtract from their total sales for that month to estimate lagged price concessions for that month.
- Current month sales = \$50,000.
- $\$50,000 \times 25$ percent (estimated percentage of lagged price concessions) = \$12,500 estimated lagged price concessions for the current month.
- $\$50,000 - \$12,500 = \$37,500$ (net total sales after subtracting estimated lagged price concessions for the current month).
- Units sold during current month = 10,000 units.
- $\$37,500 / 10,000$ units = \$3.75 AMP.

The only differences between the proposed AMP smoothing process methodology and the ASP smoothing process methodology is that the ASP

smoothing process is applied on a quarterly basis whereas the AMP smoothing process will be applied on a monthly basis and by statutory definition, the ASP calculation includes more sales than in the AMP calculation. We believe this process will result in more stable AMP calculations on a month to month basis, because the estimated lagged price concessions will increase as sales increase, and likewise as sales decrease. In addition, it meets the statutory requirement that the AMP smoothing process be similar to the smoothing process used in determining the ASP.

6. Manufacturer Reported AMP Units (§ 447.510(d)(6))

Section 2503(b) of the Affordable Care Act requires manufacturers to submit to CMS on a monthly basis the total number of units that are used to calculate the monthly AMP for each covered outpatient drug no later than 30 days after the last day of each prior month. We propose that the manufacturer report monthly AMP units as the number of units that are used to calculate the monthly AMP to be reported to CMS. Additionally, in order to be consistent and to implement the rebate and FUL provisions, the monthly units should be of the unit type that is reported as part of the product data and 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 the monthly and quarterly AMP and the AMP units.

7. Failure To Report Monthly AMP and AMP Units (§ 447.510(d)(7))

Currently a manufacturer must submit a monthly AMP to CMS no later than 30 days after the last day of the prior month. Under the Affordable Care Act, a manufacturer will be required to submit the total number of units that are used to calculate the monthly AMP no later than 30 days after the last day of the prior month. To ensure that each manufacturer is reporting timely to CMS, a manufacturer that fails to submit and certify monthly AMP and the AMP Units for a product to CMS by the 30th day after the end of each month will be reported to the OIG. We propose, in accordance with the statutory requirements at section 1927(b)(3)(C)(i), that the manufacturer will be subject to civil monetary penalty for each product not reported on the thirty-first day. Please see the OIG's Special Advisory Bulletin issued in September 2010 regarding reporting AMP timely, http://oig.hhs.gov/fraud/docs/alertsandbulletins/2010/SpAdvBulletin_AMP_ASP.pdf.

Additionally, we are considering adding regulatory guidance on suspension and termination for manufacturers that do not report monthly AMP and AMP Units on a timely basis. As noted previously, we have considered a number of formal and informal administrative procedures similar to those set forth in 42 CFR part 498 or 42 CFR 430.18. Therefore, we invite comments on these procedures from the public.

I. Requirements for States (§ 447.511)

Section 1927(b)(2)(A) of the Act specifies that States are required to report to each manufacturer, not later than 60 days after the end of each rebate period, information on the total number of units of each dosage form and strength and package size of each covered outpatient drug dispensed, and to promptly transmit a copy of such report to the Secretary. Effective March 23, 2010, the Affordable Care Act amended section 1927(b)(2)(A) of the Act to require that the State include in those reports, the information reported by each Medicaid MCO.

We propose a new § 447.511 to clarify the requirements for States. In § 447.511(a), we propose to list the data that the State must provide to participating drug manufacturers. We further propose that States must submit this data within 60 days after the end of each quarter.

In § 447.511(b), we propose that the States report drug utilization data as defined in § 447.511(a) to CMS on a quarterly basis.

In § 447.511(c), we propose that a State that has participating Medicaid MCOs, which includes covered outpatient drugs in its capitated arrangements with the MCOs, report data listed in §§ 447.511(a) for covered outpatient drugs dispensed to individuals eligible for medical assistance who are enrolled with the MCO and for which the MCO is responsible for coverage of such drugs under section 1903 of the Act. We further propose that this data be identified separately from the data pertaining to drugs that the State reimburses on a fee-for-service basis.

With the proposed change in the definition of "State" to include the territories, we recognize that these requirements would ultimately be applicable to the territories. We are also aware that it will take the territories time in order to upgrade their computer systems and come into compliance with the MDR program requirements. Therefore, we are proposing that the requirements discussed in this section would not be effective for the territories

until one year after the first day of the first full quarter after the publication 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 that we published in the November 15, 2010 *Federal Register* (75 FR 69591), we made conforming amendments to remove references to § 447.514 "Upper limits for multiple source drugs" from § 447.512 "Drugs: Aggregate upper limits of payment". We are proposing regulatory amendments to add those references back into the regulatory text of § 447.512.

Currently, § 447.512(b) establishes guidelines for payment levels that the agency has determined to be appropriate. At § 447.512(b)(1), we propose to replace the term "EAC" with the term "AAC" as we have previously proposed to replace "estimated acquisition cost" with "actual acquisition cost". Further, we propose to add the word "professional" to the description of dispensing fee in this section.

We are proposing these changes in terminology in part because we believe that using the AAC in determining the drug ingredient component of the reimbursement formula will be more reflective of actual prices paid, as opposed to unreliable published compendia pricing.

Currently, States usually determine EAC for single source drugs and drugs other than multiple source drugs for which either a specific Federal Upper Limit (FUL) or State maximum allowable cost (SMAC) has been established by paying the lower of:

- A percentage decrease applied to a commercially published reference price such as average wholesale price (AWP) or a percentage increase to wholesale acquisition cost (WAC), or
- The pharmacy's usual and customary charge to the public.

Using a commercially published reference price as the basis for Medicaid pharmacy reimbursement has been problematic for both the States and the Federal government. Several reports issued by the OIG have shown that AWP is often a significantly inflated price, and not necessarily reflective of a pharmacy's actual purchase price for a drug. (OIG Audit reports—A-06-00-

00023, A-06-01-00053, A-06-02-00041).³

Further, AWP raises other concerns when used as a basis for payment, as evidenced by litigation relating to its use. See *New England Carpenters Health Benefits Fund v. First DataBank*, 602 F.Supp.2d 277, 279 (D.Mass. 2009) (in which the Court stated that "despite its name, AWP is not an average of prices charged by wholesalers to providers (such as pharmacies and doctors) and it does not necessarily bear any relationship to any prices actually charged in the marketplace.")

At this time the commercial compendium, First DataBank, Inc. has reported that it is scheduled to cease the publication of AWP as of September 2011. While other drug pricing compendia may publish both AWP and WACs, we have concerns, based on the previously referenced OIG reports, that these prices will not be based on actual costs or reflect actual prices that providers pay for these drugs.

Certain States, in order to calculate more accurate payment rates, have already begun to base some of their drug prices on survey data based on pharmacy invoice prices.⁴ We believe that these surveys of pharmacy providers will assist States in determining valid reference prices from which to develop drug ingredient reimbursement. Section 447.518 of this proposed regulation provides further discussion about how States can develop and justify their AAC.

K. Upper Limits for Multiple Source Drugs (§ 447.514)

Section 2503(a) of the Affordable Care Act revises the definition of "multiple source drug" established in section 1927(k)(7)(A)(i) of the Act to mean, for a rebate period, a covered outpatient drug for which there is at least one other drug product which is rated as therapeutically equivalent (under the FDA's most recent publication of the Orange Book), is pharmaceutically and bioequivalent, as determined by the FDA; and is sold or marketed in the United States during the period. We propose this definition be included in § 447.502 "Definitions." In accordance with these statutory requirements, we also propose that at least two

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>.

⁴ Alabama-10-008, effective date September 22, 2010 (Alabama AAC Survey information available at <http://al.mslic.com/Fags.aspx>) and Oregon-10-13, effective date January 1, 2011 (Oregon AAC Survey information available at <http://or.mslic.com/AACList.aspx> or <http://or.mslic.com/uploadedFiles/Oregon/OR%20Communications%20Plan.pdf>).

therapeutically equivalent ("A" rated) formulations must be listed in the FDA's Orange Book in order for the drug to be defined as a multiple source drug.

Also, section 2503(a) of the Affordable Care Act revised section 1927(e) of the Act to change the requirement for a FUL to be established for each multiple source drug for which the FDA has rated two or more products therapeutically and pharmaceutically equivalent, to three or more products, regardless of other formulations. In accordance with this statutory requirement, we are proposing in § 447.514(a)(1) that a FUL be established for each multiple source drug for which the FDA has rated three or more products therapeutically and pharmaceutically equivalent. We propose that the FUL will be calculated, in accordance with section 1927(e)(4) of the Act, using only therapeutically and pharmaceutically equivalent drugs. Any other formulations of the drug listed in the FDA Orange Book that are not therapeutically and pharmaceutically equivalent to the reference listed drug, for example, "B" rated drugs, will not be used in the calculation of the FUL.

For purposes of applying this rule, we consider drug products to be therapeutically equivalent if they are identified as A-rated in the current edition of FDA's Orange book. Per the FDA's Orange Book, drug products are considered to be therapeutic equivalents only if they are pharmaceutical equivalents and if they can be expected to have the same clinical effect and safety profile when administered to patients under the conditions specified in the labeling. Drug products are considered pharmaceutical equivalents if they contain the same active ingredient(s), are of the same dosage form, route of administration and are identical in strength or concentration. In general, with limitations that may apply to particular patients, the FDA believes that products classified as therapeutically equivalent can be substituted with the full expectation that the substituted product will produce the same clinical effect and safety profile as the prescribed product.⁵

"B" rated drugs are drugs that FDA does not consider therapeutically equivalent to other pharmaceutically equivalent products. Per the FDA Orange Book, drug products designated with a "B" code fall under one of three main policies:

- The drug products contain active ingredients or are manufactured in dosage forms that have been identified by FDA as having documented

bioequivalence problems or a significant potential for such problems and for which no adequate studies demonstrating bioequivalence have been submitted to FDA; or

- The quality standards are inadequate or the FDA has an insufficient basis to determine therapeutic equivalence; or
- The drug products are under regulatory review.⁶

Therefore, we propose that any alternative formulations not therapeutically equivalent to the reference listed product in FDA's Orange Book will not be subject to the FUL. We propose that the FUL will only be applied to those drugs that are therapeutically equivalent to the reference listed drug, that is, "A" rated drugs that are pharmaceutically equivalent to the reference listed drug; however, we are inviting comments on the issue of the FUL being applied to drugs that are not therapeutically equivalent to the reference listed drug.

In accordance with section 2503(a) of the Affordable Care Act, we are proposing that the FUL will be calculated as no less than 175 percent of the weighted average of the most recently reported monthly AMPs for pharmaceutically and therapeutically equivalent multiple source drug products. We plan to determine the weighted average on the basis of manufacturer submitted utilization of the most recently reported monthly AMPs for all therapeutically equivalent innovator (I) and non-innovator (N) multiple source drug products that, by definition elsewhere in this proposed rule, are available for purchase by retail community pharmacies on a nationwide basis.

In computing the FUL, we would use the monthly AMP and the monthly utilization data submitted by the manufacturer. Using the monthly AMP data will provide for the timeliest pricing data and allow revisions to the FUL list on a monthly basis. In addition, the statute requires us to use the recently reported monthly AMPs to calculate the FUL. It will also permit us to update the FULs on a timely basis in accordance with the provisions of section 1927(f)(1)(B) of the Act.

The currently reported AMP is based on the nine-digit NDC and is specific to the product code, combining all package sizes of the drug into the same computation of AMP. Inasmuch as this computation is used to determine the AMP that is currently reported by manufacturers, we propose to use this AMP for the FUL calculation.

Section 2503(a) of the Affordable Care Act redefines AMP, effective October 1, 2010. Due to this change in the determination of AMP, and the requirement that the monthly AMP under this calculation first be reported for October 2010 data, CMS received these revised monthly AMPs and utilization data beginning in November 2010. While the law required manufacturers to change their calculation of AMP effective October 1, 2010, we did not issue FULs based on this data. Further, we decided to not use data submitted before December 15, 2010 to calculate the FULs, as there was some concern within the industry that manufacturers may have based their AMP calculation on prior AMP regulations that were in effect until December 15, 2010.

In the interim, CMS has been reviewing monthly pricing data submitted and continues to work towards increasing labeler compliance of reporting data timely. When establishing a FUL, we propose to disregard the AMP of an NDC which has been terminated. We note that we have published four sets of draft FUL files on our Web site. We invited comments from stakeholders and we have posted several of those comments and our responses to those comments at <http://www.medicare.gov/Medicare-CHIP-Program-Information/By-Topics/Benefits/Prescription-Drugs/Federal-Upper-Limits-.html>.

In calculating the FUL, we propose to eliminate covered outpatient drugs designated as single source (S) drugs from the FUL calculation because the FUL in the statute, is based on the weighted average of AMPs for multiple source drugs, and, single source drugs are, by definition, not multiple source drugs, and should be reported according to the statute. We note here that there should be no instances of an (S) drug in a FUL group, as labelers should be reporting drugs that are therapeutically equivalent drug products as (I) drugs, and statutory provisions require us to use only multiple source drugs when calculating the FUL. We propose to rely on manufacturer submitted data in determining if a drug product is used in the calculation of the FUL, that is, if it is an (I) or an (N) drug. CMS has issued guidance previously, and more recently, requested drug labelers to review the drug category for which their NDC is reported, and if they determine that an incorrect drug category has been reported to CMS for a product, they are required to request a drug category change for the product. We have also recently reminded labelers that changing a drug category from (S) to (I)

⁵ <http://www.fda.gov/downloads/Drugs/DevelopmentApprovalProcess/UCM071436.pdf>.

⁶ *Id.*, vii.

has no prior approval requirement from CMS, and that these changes can and should be made timely by the labeler via the Drug Data Reporting for Medicaid system. See Manufacturer Releases No. 80 and No. 82 (issued on January 5, 2010 and November 1, 2010, respectively). Accordingly, we propose to include pharmaceutically and therapeutically equivalent innovator multiple source and non-innovator multiple source drugs when calculating the weighted average of monthly AMPs.

In light of our experience with the implementation of section 1927 of the Act, we believe that when a drug product has at least one other FDA-approved, pharmaceutically and therapeutically equivalent drug product, the drug is generally sold or marketed on a nationwide basis. Further, we believe that when a drug product has at least two FDA-approved, pharmaceutically and therapeutically equivalent drug products, that all retail community pharmacies would be able to purchase at least one of the drug products through a pharmaceutical market channel of distribution, including, but not limited to, a national, regional, or specialty drug wholesaler, chain warehouse, group purchasing organization, or directly from the drug manufacturer. We do not believe it is necessary that each retail community pharmacy have the ability to purchase every supplier's pharmaceutically and therapeutically equivalent drug in order for the Secretary to calculate the FUL for pharmaceutically and therapeutically equivalent multiple source drug products, provided the retail

community pharmacy is able to purchase at least one of the drug products. We invite comments on the issue of national availability in the context of the FUL requirements and request comments regarding specific instances where such drug products are not available for purchase by retail community pharmacies on a nationwide basis. Further, as noted previously, we will not be using the AMP of a terminated NDC to set the FUL beginning with the first day of the month after the termination date reported by the manufacturer to CMS, and a weighted average, using the monthly AMP unit data, will be used to calculate the FUL.

We further propose to establish the upper limit reimbursement at 175 percent of the weighted average of monthly AMPs in the aggregate.

We analyzed the FUL and determined that the weighted AMP multiplied by 175 percent including (I) and (N) drugs would be an adequate reimbursement methodology, per the below chart that shows the analysis of the fiscal year 2009 estimated aggregate expenditures, comparing reimbursement using the DRA AMP-based FUL methodology to the pre-DRA FUL methodology, weighted AMP FUL, weighted AMP multiplied by 175 percent, and Indiana's State Maximum Allowable Cost (IN's SMAC). Utilization data provided to CMS by States were used to calculate the total number of units reimbursed for each drug group and was multiplied by the DRA AMP-based FUL, the pre-DRA FUL, the weighted AMP FUL, the weighted AMP multiplied by

175 percent FUL, and IN's SMAC to get the aggregate limit for each drug group based on each formula used to calculate the FUL. We chose IN's SMAC as one of the formulas in our comparative analysis because IN's SMAC, in accordance with its State plan, is developed by using pharmacy invoices, and is equal to the average AAC per drug adjusted by a multiplier of at least 1.0. IN's Office of Medicaid Policy and Planning reviews the SMAC rates on an ongoing basis, and adjusts the rates as necessary to reflect prevailing market conditions and ensure reasonable access by providers to drugs at or below the applicable SMAC rate. Currently, IN adjusts their average AAC using a multiplier of 1.2. There are approximately 550 drug groups reflected in this estimated analysis. Because utilization data are reported on a quarterly basis while the DRA AMP-based FUL is generated on a monthly basis, the estimated aggregate limit is calculated for each month using the quarterly utilization data averaged out by the 3 months. This calculation was done for all four quarters of fiscal year 2009, which was then aggregated to get the fiscal year 2009 estimated aggregate expenditure for each FUL formula. Each bar represents the aggregate expenditure while the percentage amount represents the comparison to the DRA AMP-based FUL.

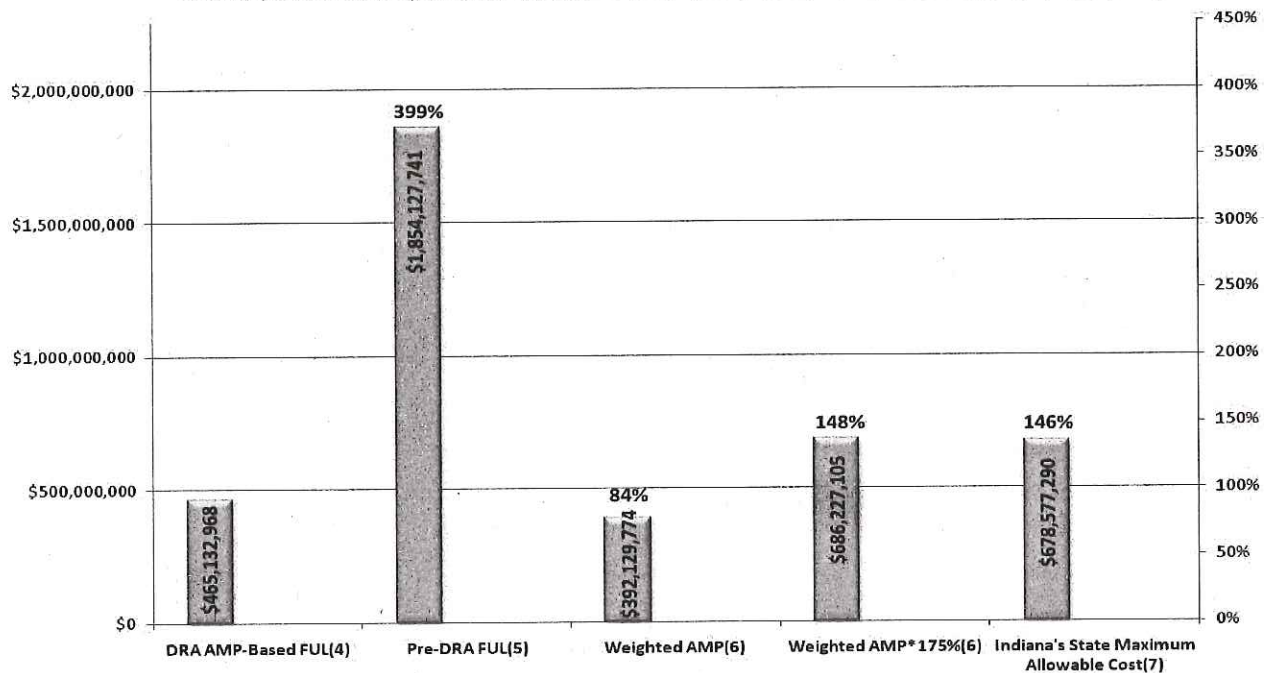
The estimated aggregate is calculated with the availability of at least three therapeutically equivalent drug products.

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Comparing Estimated Federal Upper Limit Aggregate for Fiscal Year 2009 with Three Suppliers (1 & 3)

■ FY 2009 Estimated Aggregate Limit with 3 Suppliers - Including I & N (2)

The percentage shown is calculated by using the DRA AMP-Based FUL as a reference estimated aggregate amount.



Footnotes:

- Each FUL group is established based on the DRA criteria that if all formulations of a multiple source drug are identified as A-rated in the FDA's most current edition of "Approved Drug Products with Therapeutic Equivalence Evaluations" (including supplements or in successor publications), then there must be at least 2 A-rated versions of the drug.
- I is for innovator multiple source drug and N is for noninnovator multiple source drug.
- Calculations excluded drug products that were not therapeutically equivalent, had NDCs with AMP not reported, and NDCs with zero utilization. Additionally, calculation of each formula is based on the availability of three or more suppliers at the NDC-9 level and two different product codes are considered as two different suppliers.
- DRA AMP-based FUL is based on the DRA criteria to calculate FUL, which included the availability of two suppliers and included a 40% outlier.
- Pre-DRA FUL is based on FUL issued by CMS on September 25, 2009.
- States' utilization data are used to calculate weighted AMP (WAMP) and the estimated aggregate limit: FY 1Q09 = 3Q08 Utilization, FY 2Q09 = 4Q08 Utilization, FY 3Q 2Q09 = 1Q09 Utilization, and FY 4Q09 = 2Q09 Utilization. An NDC is excluded if there is no utilization on that NDC.
- Indiana State Maximum Allowable Cost effective as of October 23, 2009 was obtained from Indiana Pharmacy website, <http://www.indianamedicaid.com/ihcp/PharmacyServices/list.asp>. Please note that when making the determination for their State MAC, IN does not use innovator multiple source drugs.

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In a recent report issued by the Government Accountability Office (GAO) "Medicaid Outpatient Prescription Drugs: Estimated Changes to Federal Upper Limits Using the Formula under the Patient Protection and Affordable Care Act" (GAO-11-141R), the GAO found that Affordable Care Act FULs were higher than the

undiscounted average retail pharmacy acquisition costs for 34 of the 40 drugs in the sample and was 35 percent higher than the sum total of the undiscounted pharmacy acquisition costs for these drugs, which would have also lowered the Medicaid expenditures on these drugs by 60 percent.

Furthermore, the GAO stated that the Affordable Care Act FULs could further

exceed the retail pharmacy acquisition costs if the GAO was to take into consideration factors that were not used in the analysis of this report. The GAO stated that the acquisition cost data the GAO used do not include rebates paid by manufacturers to retail pharmacies. If included, any applicable rebates would have reduced the average retail acquisition costs for the drugs in the

sample; thus, the Affordable Care Act FULs would exceed the retail pharmacy acquisition costs by more than 35 percent. Additionally, if the Affordable Care Act FULs were to be calculated using the new AMPs based on the revised definition under the Affordable Care Act, then the Affordable Care Act FULs would have exceeded the retail pharmacy acquisition costs by even greater than 35 percent.

Therefore, based in part on the findings from the GAO report, we believe that calculating the Affordable Care Act FULs at weighted AMP times 175 percent would be a more than adequate reimbursement to the pharmacies.

The Affordable Care Act's revisions to section 1927(e)(5) of the Act allow but do not require the Secretary to calculate the FUL above the 175 percent of the weighted average of AMPs. Based on the data described above, we have decided to calculate the FUL at 175 percent. Using any percentage greater than 175 percent would further inflate the aggregate expenditures depicted on our chart. As provided in the chart above, calculating the FUL as 175 percent of the weighted AMP, including multiple source drugs, that is, I and N drugs, yields a reimbursement that is just slightly higher than Indiana's SMAC which is based on actual pharmacy acquisition data and is consistent with the GAO's findings that these levels are generally in excess of the actual acquisition cost of the drug. Because it is virtually impossible to price each drug at its actual acquisition cost to each pharmacy and reflect the changes in the marketplace at the same time they occur, the upper limit reimbursement continues to be established in the aggregate. States maintain their right to adjust reimbursement on a drug by drug basis to the extent that the State's reimbursement remains under the aggregate upper limit.

Thus, 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 FULs.

L. FULs Smoothing Process

As discussed previously, section 2503(a) of the Affordable Care Act amended the FUL provision at section 1927(e)(5) of the Act to specify that the Secretary shall implement a smoothing process for AMPs which shall be similar to the smoothing process used in determining the ASP of a drug or biological under Medicare Part B. In order to ensure that the smoothing process being utilized by manufacturers

is uniform and consistent with statutory requirements, as was discussed in Manufacturer Release #83, a manufacturer should estimate the impact of its lagged price concessions using a 12-month rolling percentage to estimate the value of those discounts. This guidance is restated in the preamble language of this proposed rule and would be codified in proposed regulatory text at § 447.510(d)(2).

We also considered whether to implement a further smoothing process applicable to the FUL calculation. While the statute requires us to use the most recently reported monthly AMPs to calculate the FUL, it did not address smoothing the FULs themselves.

However, after reviewing the first months of the draft FULs, which we posted on our Web site, we note that there is some variability in the FULs from one month to the next. Therefore, we looked at various approaches for smoothing the FULs, as follows. We considered:

- Using the mean of the most recently reported monthly AMPs over a specific period of time; for example, three months, to minimize the variability of the monthly AMPs before weighting the monthly AMPs and multiplying the result by 175 percent to calculate the FUL;
- Using the median of the most recently reported monthly AMPs over a specific period of time; for example, three months, before weighting the monthly AMPs and multiplying the result by 175 percent to calculate the FUL;
- Weighting the most recently reported monthly AMPs over a specific period of time; for example, three months, to minimize the variability of the monthly AMPs before weighting the monthly AMPs and multiplying the result by 175 percent to calculate the FUL;
- After calculating the FUL as the weighted average of monthly AMPs in a FUL product group, calculate the mean of the FULs for each product group over a specific period of time; for example, three months, to smooth the FUL if there is variability in the calculated FUL from month to month;
- Excluding outlier monthly weighted AMPs that are less than a certain percentage of the next highest monthly AMP for therapeutically and pharmaceutically 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;
- Increasing the calculated FUL by a certain percentage if the FUL is less

than a certain percentage from the last FUL;

- Calculating the FUL using only monthly weighted AMPs within a FUL Product Group that have a certain percentage of the market share based on the monthly AMP units reported to us by drug manufacturers.

- Using the mean of the monthly weighted average of AMPs for an entire FUL Product Group over a specific period of time; for example, three months; and/or,

- Excluding monthly AMPs that are higher or lower than the standard deviation of the mean of all the monthly AMPs in a specific FUL Product Group.

Smoothing the pricing data using one of these methodologies would prevent some month-to-month fluctuations in the FULs. However, implementing any of the smoothing methods would have limitations. For example, it could require that for the entire averaging period, all manufacturers have timely reported monthly AMP and AMP units or that we look at alternatives to that. Further, it would require us to look at how to add newly available generic drugs or other changes in circumstances that affect these FULs. We are concerned that this could skew a resultant FUL so that it would be less representative of the price at which the pharmacy could purchase that drug. For example, it could cause a FUL for a particular FUL group to be lower than if we use only one month of AMP data in the calculation depending on the reported and certified monthly AMP and AMP units over the averaging period. As such, it may not capture price increases in a drug or reflect changes in price caused by a shortage of the drug. Conversely, it could overstate the price of drugs where more manufacturers are coming into the marketplace and the price of the drug was decreasing over time.

After careful consideration, we have decided not to propose a specific methodology to smooth the FULs at this time. Because AMPs are based on prices paid to manufacturers by wholesalers for drugs distributed to retail community pharmacies and by retail community pharmacies that purchase drugs directly from the manufacturer, they are subject to some fluctuations and variances in the generic drug market, which may result in fluctuations in the AMP-based FUL from month to month. Furthermore, these changes may be present even if we decide to implement a smoothing process over and above the smoothing process that manufacturers are presently using for AMP calculations. As previously mentioned, price changes

can occur as a result of product shortages, manufacturing disruptions, seasonal supply and demand, and products with a short shelf life. We are inviting comments on this issue, including the benefit of such a process, the options we considered, options we have not considered, and whether a smoothing process is necessary.

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 published in the November 15, 2010 **Federal Register** (75 FR 69591), we made conforming amendments which deleted references to § 447.514 "Upper limits for multiple source drugs" from § 447.518 "State plan requirements, findings and assurances". We are proposing conforming regulatory amendments to those references and are adding them in the regulatory text of § 447.518.

In addition, to conform with the change from "estimated acquisition cost" to "actual acquisition cost", we propose in § 447.518(c) to require all States to provide data to adequately support proposed changes in reimbursement using AAC. This supporting data could include, but is not limited to, a national survey, to create a database of actual acquisition costs that States may use as a basis for determining State-specific rates. Additionally, a State survey of retail pharmacy providers or other reliable data which reflects the pharmacy provider's price to acquire a drug could be used as a basis to support proposed changes in reimbursement. We believe that surveying pharmacy providers for acquisition costs or using other reliable data, based on actual sales transactions, as a base from which to develop an appropriate ingredient cost reimbursement is reasonable. Alternatively, the use of an AMP, which is based on actual sales data and reported and certified by drug manufacturers, could be considered as a reimbursement metric. The State can also 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 for these costs.

We are inviting 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.

Although we considered various alternatives for how AAC will apply in the case of reimbursement for covered outpatient drugs purchased under other Federal drug programs such as the 340B Drug Pricing Program and the Federal Supply Schedule (FSS) we are not proposing specific methodologies. Through these programs, certain Federal grantees and others can purchase drugs at significant discounts, and these drugs will then be reimbursed through the State Medicaid program for Medicaid beneficiaries. Under current HRSA policy, participating covered entities are permitted to dispense drugs purchased outside of 340B authority for their Medicaid patients, often referred to as the "Medicaid carve out" option. In accordance with section 340B(a)(5) of the PHS Act and section 1927(a)(5)(C) of the Act, a covered entity is not permitted to seek Medicaid payment for a drug that is subject to discounts under the 340B Drug Pricing Program and a Medicaid rebate in order to protect drug manufacturers from paying a Medicaid rebate on drugs that are already subject to a Federal discount. This "duplicate discount" prohibition in the Medicaid statute only applies to drugs purchased through the 340B Drug Pricing Program and does not apply to drugs carved out for Medicaid patients and billed to the Medicaid program.

In a recent OIG report, "State Medicaid Policies and Oversight Activities Related to 340B-Purchased Drugs", OEI-05-00321, the OIG reported that many State Medicaid agencies have written policies that direct covered entities to bill at cost for the ingredient cost of 340B purchased drugs or relied on HRSA's 1993 guidance directing covered entities to bill States at AAC (although that guidance is no longer in effect and was superseded by subsequent HRSA guidance directing covered entities to refer to States' policies). We believe that paying 340B providers at cost for these 340B drugs would meet the AAC requirements but seek further comments on what other methodologies would meet the AAC requirements.

IHS, tribal and urban Indian organization pharmacies may purchase drugs through the FSS or the 340B program and are oftentimes paid the Medicaid reimbursement rates

established in State plans. In turn, States are reimbursed at 100 percent Federal medical assistance percentage for services provided in IHS and tribal pharmacies. While we have considered alternatives for payment methodologies for IHS, tribal and urban Indian pharmacies, we are proposing no specific methodologies and invite public comment on Medicaid payment levels for these facilities. In addition, pursuant to E.O. 13175 and the HHS Tribal Consultation Policy (December 2010), the CMS will consult with Tribal officials prior to the formal promulgation of this regulation.

We propose that States that do not have specific methodologies develop such methodologies for these providers consistent with our proposed shift from EAC to AAC. In addition, we propose to add a new requirement at § 447.518(a) that the State plan must describe the agency's payment methodology for drugs dispensed by a covered entity participating in the 340B Drug Pricing Program or by a contract pharmacy under contract with a participating covered entity.

In addition, States would be required to submit a SPA through the formal review process, as well as comply with all Federal requirements including consultation with tribal governments and IHS, tribal and urban Indian programs pursuant to section 5006 of the American Recovery and Reinvestment Act of 2009 (Pub. L. 111-5), when submitting a request to change their professional dispensing fee. As is true for the drug ingredient reimbursement, we do not intend to mandate a specific formula or methodology which the States must use to determine their dispensing fee, however, as is consistent with current policy, States would still be required to substantiate how their dispensing fee reimbursement to pharmacy providers reasonably reflects the cost of dispensing a drug and will ensure access for these drugs to Medicaid beneficiaries. Where the professional dispensing fee might differ because of unique circumstances for 340B covered entities or IHS and tribal pharmacies, the State should look at these circumstances to determine if a different professional dispensing fee is warranted for these entities. One component of the reimbursement formula should not be revised without appropriately evaluating the other part.

With the proposed change in the definition of "State" to include the territories, we acknowledge that these same requirements could ultimately be applicable to the territories. Since the territories that participate in the

Medicaid Program are already required to submit changes to their State Plans through the State Plan Amendment process, we are proposing that the requirements discussed in this section would be effective for the territories in the same manner in which they would be effective for the 50 States and the District of Columbia.

N. Optional Coverage of Investigational Drugs and Other Drugs Not Subject To Rebate (§ 447.522)

Investigational drugs, also referred to as experimental drugs, do not fall within the definition of covered outpatient drugs set forth in section 1927(k) of the Act; therefore, these drugs are not subject to rebate. However, Medicaid coverage may be provided under section 1905(a)(12) of the Act at the State's option, and FFP is available to the extent it is consistent with section 1903(i) of the Act and § 440.120.

There are a number of 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.

We propose to add § 447.522 to clarify that States providing coverage of investigational drugs may only pay for and receive FFP for these drugs when they are billed for in accordance with the 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 and Investigational New Drug Application" (74 FR 40872) and "Expanded Access to Investigational Drugs for Treatment Use" (74 FR 40900)). These regulations clarify the circumstances under which charging for an investigational drug in a clinical trial is appropriate, set forth criteria for charging for an investigational drug for the different types of expanded access for treatment, and clarify what costs can be recovered.

We are also adding a provision to allow for the coverage of other non-covered outpatient drugs.

III. Collection of Information Requirements

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

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

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

A. ICR's Regarding Medicaid Drug Rebates (§ 447.509)

As discussed earlier in the preamble, section 2501(c) of the Affordable Care Act amended section 1903(m) of the Act by specifying new conditions for MCO contracts, including that covered outpatient drugs 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. Proposed § 447.509(b) adds requirements for States to collect necessary drug utilization data from Medicaid MCOs in order to include MCO data in the quarterly rebate requests.

We estimate that these requirements would affect the 51 State Medicaid Programs, as well as the territories. The burden associated with the inclusion of Medicaid MCOs in the Drug Rebate Program is the time and effort it would take for the State Medicaid Program to gather the drug utilization information from the Medicaid MCOs and the subsequent inclusion of said data in the State's quarterly rebate request to manufacturers. Our current reporting hour burden, specific to the invoice and State utilization data reporting within the MDR Program, for the current State Medicaid Programs is 2,346 hours per quarter or 9,384 hours annually, at a total estimated cost of \$302,165.

As referenced in § 447.509(b) and § 447.511, we believe the collection of drug utilization data from MCOs and the subsequent inclusion of said data in the State's quarterly rebate request to the manufacturers will add a total 678 hours per quarter or 2,712 hours annually to the current reporting burden for the States (which include the 50 States, District of Columbia, and the territories). Therefore, the total new reporting burden, as a result of this proposed rule requesting additional requirements to collect drug utilization data from MCOs,

will be 2,712 hours annually at a total estimated cost of \$98,744.

The aforementioned burden estimates will be submitted for OMB review and approval as a revision to the information collection request currently approved under OMB control number 0938-0582.

Proposed § 447.509(c) would also require States to remit to the Federal government the amount of the savings resulting from the increases in the rebate percentages. The reporting process is similar to the current reporting process for drug expenditures and rebates onto the CMS-64 Form. In addition to reporting onto the CMS-64 Form the quarterly amount for prescribed drug expenditures, Federal rebates, and rebates under State side bar agreements, States will report the total quarterly rebate offset amount that they are remitting to the Federal government for the fee-for-service rebates they currently receive from drug manufacturers and for the MCO rebates they will receive from drug manufacturers. The information collection requirements and burden associated with CMS-64 are already approved by OMB through April 30, 2014, and have been assigned OMB control number 0938-0067. This proposed rule does not impose any new or revised burden or reporting or recordkeeping requirements concerning CMS-64.

B. ICR's Regarding Requirements for Manufacturers (§ 447.510)

Manufacturers 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. The proposed rule would significantly revise the definitions of AMP and best price and, therefore, would require the manufacturers to reconfigure their pricing systems to correctly calculate AMP and best price. In addition, manufacturers must submit the total number of units that are used to calculate the monthly AMP. Therefore, the burden associated with these new requirements is the time and effort it would take for 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 would affect the approximately 600 drug manufacturers in the Medicaid Rebate Program. We believe the changes to the AMP and best price definitions will require 240 hours

per manufacturer, for a one-time total of 144,000 burden hours with a one-time total estimated burden cost of \$8,640,000. Once the pricing systems have been reconfigured, there should be no additional burden in time or effort than that which already exists.

Manufacturers will be 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 manufacturer must submit evidence demonstrating that the product is otherwise a covered outpatient drug. CMS shall refer to this evidence of demonstration as covered outpatient drug status, or COD status.

This information should not be difficult for the manufacturer to determine since the manufacturer should already know the FDA application number of the product when it was approved by FDA, or the reason it qualifies as a covered outpatient drug, if there is no application number.

We estimate that these requirements would affect approximately 600 drug manufacturers that participate in the Medicaid Drug Rebate Program. The burden associated with the reporting of the FDA application number or the COD status is the time and the effort it would take for each drug manufacturer to retrieve this information from their records and submit it to CMS. Therefore, we believe that the new requirements to report the FDA application number and the COD status will require a one-time total of 3,000 hours at a one-time total estimated burden cost of \$180,000.

Manufacturers will also be required to identify drugs that are approved by the FDA exclusively for pediatric indications. These drugs will be referred by CMS as "Exclusively Pediatric" drugs. This information should not be difficult for manufacturers to determine and therefore would not add any significant hourly burden since the exclusively for pediatric indications will be provided by the FDA upon approval of these drugs.

Additionally, manufacturers will need to consider certain requirements when it comes to the calculation of their AMP for inhalation, infusion, instilled, implanted, and injectable drugs (5i), when not generally dispensed through retail community pharmacies. Using the methodology proposed earlier in this rule, a manufacturer would be required to identify and determine the AMP of these drugs. It is our estimate that these requirements would affect approximately 600 drug manufacturers that participate in the Medicaid Drug Rebate Program. The burden associated

with the initial reporting of the 5i drugs is the time and the effort it would take for each drug manufacturer to identify these drugs and then to determine which of the 5i drugs are not generally dispensed through a retail community pharmacy by using the methodology proposed earlier in this rule. However, it is our understanding that each drug manufacturer should have some knowledge as to which drug is a 5i based on the approval information the manufacturer received from the FDA as well as the FDA Route of Administration list that CMS has identified. Once the manufacturer has established its initial list of 5i drugs, it would then be required on both a monthly, as well as quarterly basis, to determine which of those drugs are not generally dispensed through a retail community pharmacy. Therefore, we believe that the new reporting requirements will require a one-time total of 1,500 burden hours for manufacturers to identify the 5i drugs at a one-time total estimated burden cost of \$90,000. In addition, on both a monthly and quarterly basis (12 months, plus 4 quarters, for a total of 16 times per year) the manufacturer will be 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. Specifically, we estimate that it will add 20 hours per response with 16 responses per year for each manufacturer to identify which 5i drugs are not generally dispensed through a retail community pharmacy. This equates to a total estimate of 320 additional hours annually per manufacturer. The total annual burden hours for the 600 drug manufacturers participating in the Medicaid Rebate Program is estimated to be 192,000 hours with a total cost of \$11,520,000.

Furthermore, manufacturers participating in the rebate program that have reformulated drugs are now required to calculate an alternative rebate calculation for certain drugs. In order to calculate the alternative rebate calculation for a line extension drug of a brand name in an oral solid dosage form, the line extension drug and the initial brand name listed drug need to be identified. Although CMS will be identifying both the initial brand name listed drug and the line extension drug for the initial three quarters for manufacturers, they will be responsible for identifying the initial brand name listed drug and the line extension drug after the initial three quarters. Manufacturers are responsible for

calculating the unit rebate amount for the line extension drug.

We estimate that these requirements would affect approximately 600 drug manufacturers that participate in the Medicaid Drug Rebate Program. The burden associated with the reporting of the initial brand name listed drug and the line extension drug is the time and the effort it would take for each drug manufacturer to identify these drugs. However, it is our understanding that each drug manufacturer should have some knowledge on which drug is the line extension based on the approval information that the manufacturer received from the FDA as well as the Chemical Type that CMS has identified as a line extension drug and the initial brand name listed drug. Therefore, we believe that the new reporting requirements to identify the initial brand name listed drug and the line extension drug would add 20 additional hours per quarter, per manufacturer; or 48,000 total hours annually to the drug manufacturers at a total estimated cost of \$2,880,000.

Finally, a manufacturer is required to retain records for 10 years from the date the 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.

The aforementioned burden estimates will be submitted for OMB review and approval as a revision to the information collection request currently approved under OMB control number 0938-0578.

C. ICR's Regarding Requirements for States (§ 447.511)

The definition of the term "States" would 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.

In order 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 systems that the territories currently have are not setup for the MDR program. As a result, these territories will likely have to utilize contractors in order to ensure that their systems are in place to begin to collect rebates from manufacturers.

We are unsure what the time, effort and cost would be for this compliance process to be completed and seek comments specific to this issue.

States will have to report the total MCO rebates they receive from

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 are already approved by OMB through April 30,

2014, and have been assigned OMB control number 0938-0067. This proposed rule does not impose any new or revised burden or reporting or recordkeeping requirements concerning CMS-64.

TABLE 5—ANNUAL RECORDKEEPING AND REPORTING REQUIREMENTS

Regulation Section(s)	OMB Control No.	Respondents	Responses	Burden per response (hours)	Total annual burden (hours)	Hourly labor cost of reporting (\$)	Total labor cost of reporting (\$)	Total capital/maintenance costs (\$)	Total cost (\$)
\$ 447.509(b), \$ 447.511	* 0938-0582	56	224	12.1	2,712	36.41	98,744	0	98,744
\$ 447.510	* 0938-0578	600	600	240	144,000	60	8,640,000	0	8,640,000
\$ 447.510	* 0938-0578	600	600	5	3,000	60	180,000	0	180,000
\$ 447.510	* 0938-0578	600	600	2.5	1,500	60	90,000	0	90,000
\$ 447.510	* 0938-0578	600	9600	20	192,000	60	11,520,000	0	11,520,000
\$ 447.510	* 0938-0578	600	2400	20	48,000	60	2,880,000	0	2,880,000
Total		3,056	14,024		391,212		23,408,744		23,408,744

* The data contained in the table reflects the burden associated with the proposed revisions to the information collection requests approved under the OMB control numbers listed. The table does not display the currently approved burden for the listed OMB control numbers.

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

If you comment on these information collection and recordkeeping requirements, please do either of the following:

1. Submit your comments electronically as specified in the **ADDRESSES** section of this proposed rule; or

2. Submit your comments to the Office of Information and Regulatory Affairs, Office of Management and Budget,

Attention: CMS Desk Officer, [CMS-2345-P] Fax: (202) 395-6974; or Email: OIRA_submission@omb.eop.gov

IV. Response to Comments

Because of the large number of public comments we normally receive on **Federal Register** documents, we are not able to acknowledge or respond to them individually. We will consider all comments we receive by the date and time specified in the **DATES** section of this preamble, and, when we proceed with a subsequent document, we will respond to the comments in the preamble to that document.

V. Economic Analyses

A. Regulatory Impact Analysis

1. Introduction

We have 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.

We solicit comment on the entire Economic Analyses section.

2. Statement of Need

This proposed rule would implement 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). This includes changes to, (1) section 1927 of the Act as set forth in 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), (2) section 1927 of the Act as set forth in 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), and (3) section 1927 of the Act as set forth in section 202 of the Education Jobs and Medicaid Funding Act (Pub. L. 111-226, enacted on August 10, 2010). It also proposes to codify other requirements in section 1927 of the Act pertaining to the Medicaid drug rebate program and revise certain regulatory provisions presently codified at 42 CFR part 447, subpart I and make other changes.

3. Overall Impacts

Overall, we estimate this 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, as shown in the Table 6. These impact estimates represent 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 managed care organizations, and provides for adequate pharmacy reimbursement. Lastly, we estimate costs to MCOs, drug manufacturers, and States in the amount of \$81.4 million for FFYs 2010 through 2014 which includes administrative and infrastructure expenses necessary to implement the required systems changes.

⁷ Except as noted below, savings estimates were developed by the Office of the Actuary (OACT) and the Center for Medicaid, CHIP and Survey & Certification (CMCS) at CMS and are consistent with the President's FY 2012 budget baseline.

(* The estimates for section 2503 were developed by CMS. An alternative methodology discussed below produces a 5-year cost to States and Federal government of \$1.7 billion explained in the alternatives considered section of the Regulatory Impact Analysis.)

Continued

TABLE 6—STATE AND FEDERAL SAVINGS (–) OR COSTS (+) (FFYs 2010–2014)
[In \$millions]⁷

Affordable Care Act section and provision		2010	2011	2012	2013	2014	Total 2010–2014
Section 2501(a)(1)—Increase minimum rebate percentages for brand name drugs.	Federal	–\$350	–\$730	–\$765	–\$810	–\$865	–\$3,520
	State	0	0	0	0	0	0
Section 2501(a)(2)—Recapture of total savings		Included with affected provisions					
Section 2501(b)—Increase rebate percentages for generic drugs.	Federal	–30	–50	–55	–55	–65	–255
	State	0	0	–0	0	0	0
Section 2501(c)—Extension of collection of rebates for MCOs.	Federal	–580	–720	–720	–770	–820	–3,610
	State	–280	–490	–560	–580	–620	–2,530
Section 2501(d)—Rebates new formulation drugs	Federal	–160	–345	–360	–380	–400	–1,645
	State	0	0	0	0	0	0
Section 2501(e)—Maximum rebate amount	Federal	30	40	40	40	50	200
	State	20	30	30	30	30	140
Section 2503—Providing adequate pharmacy*	Federal	0	–351	–702	–702	–702	–2,457
	State	0	–234	–468	–468	–468	–1,638
Interactions**	Federal	–310	–420	–440	–510	–700	–2,380
	State	0	0	0	0	–5	–5
Total Impact	Federal	–1,400	–2,576	–3,002	–3,187	–3,502	–13,667
	State	–260	–694	–998	–1,018	–1,063	–4,033
Total Federal & State Impacts		–1,660	–3,270	–4,000	–4,205	–4,565	–17,700

TABLE 7—COSTS TO MCOs, DRUG MANUFACTURERS, AND STATES
[FFYs 2010–2014]

Provision(s)	Regulation section(s)	(In \$millions)					Total
		2010	2011	2012	2013	2014	(FFYs 2010–2014)
Drug Rebates for Medicaid MCOs	§ 447.509(b), § 447.511	\$0.1	\$0.1	\$0.1	\$0.1	\$0.1	\$0.49
Requirements for manufacturers	§ 447.510	23.3	14.4	14.4	14.4	14.4	80.91
Total Costs		23.4	14.5	14.5	14.5	14.5	81.4

4. Detailed Economic Analysis

All savings estimates provided were developed by the Office of the Actuary (OACT) and the Center for Medicaid, CHIP and Survey & Certification (CMCS) at CMS. We note that the Congressional Budget Office (CBO), in its estimates of the budgetary effects of these provisions of the Affordable Care Act, reached similar aggregate estimates with a \$600 million difference between CMS and CBO total estimates. The report can be seen at the following link (<http://www.cbo.gov/ftpdocs/113xx/doc11379/AmendReconProp.pdf>). CBO reached an estimated savings of \$13.1 billion in Federal outlay reduction for FFY 2010–2014 compared to CMS' estimates of \$13.7 billion for that same time period.⁸ Savings estimates for sections 2501 and 2503 of the Affordable Care Act reflect increased rebate percentages for generic and brand name drugs, treatment of new formulations, revised FULs, and extended collection of rebates to MCOs. As well as a cost estimate for provision of section 2501(e) of Affordable Care Act for maximum rebate amount. The

following analysis describes the methodology used to reflect each provision's savings estimates.

The estimates for section 2501(a)(1) of the Affordable Care Act were derived from baseline Medicaid prescription drug rebates developed for the mid-session review (MSR) of the FY 2010 budget. Data from the MDR system was used to estimate the share of rebates attributable to single source and innovator multiple source drugs. Using this data, we developed a model to estimate the effect of raising the minimum rebate by fitting a distribution to data on brand drug rebates as a percent of AMP with and without the 15.1 percent minimum. The distribution was then used to calculate the mean rebate percentage taking into account the new minimums specified in section 2501(a) of the Affordable Care Act. These percentages were applied to baseline brand drug rebates to estimate potential savings from the provision. A behavioral offset of 40 percent was applied to the potential savings to account for actions on the part of

manufacturers to minimize the impact of the higher rebate payments (for example, by raising prices).

The estimate for section 2501(a)(2) of the Affordable Care Act represents the State share of savings projected for subsections (a)(1), (b), and (d) of section 2501 and is included in the Federal savings of those subsections.

The impact of section 2501(b) of the Affordable Care Act was estimated using MDR data to estimate the share of baseline Medicaid drug rebates attributable to non-innovator, multiple source drugs. Increasing the rebate from 11 percent to 13 percent of AMP results in additional rebates of 2 percent of AMP, or about 18 percent (2/11) of projected generic drug rebates.

For section 2501(c) of the Affordable Care Act, current projections of Medicaid prescription drug spending and managed care premiums were developed as part of the MSR 2010 Medicaid baseline. The estimated impact represents two different effects of this section. First, current prescription drug spending by Medicaid

(** These are interactions among drug provisions and the interaction of drug provisions with Medicaid expansion.)

⁸ <http://www.cbo.gov/ftpdocs/113xx/doc11379/AmendReconProp.pdf>.

managed care plans would receive additional rebates. Estimates for (1) the portion of managed care plan expenditures going to rebates and (2) the level of additional rebates that could be obtained by the managed care plans were developed to calculate this impact.

Second, it is anticipated that some fee-for-service prescription drug spending that is currently carved out of Medicaid managed care plans would be included in future managed care contracts. To develop this estimate, estimates were made for (1) the increased efficiency of managed care plans in managing prescription drug use, and (2) the increased administrative costs by including additional expenditures under managed care plans. It was also assumed that 10 percent of current fee-for-service drug spending would eventually shift to Medicaid managed care plans.

About 75 percent of the savings to the Federal government from this section are estimated to come from the impact of additional rebates for managed care plan expenditures on prescription drugs, and about 25 percent are estimates to come from the impact of moving fee-for-service prescription drug spending into managed care plans.

The impact for section 2501(d) of the Affordable Care Act utilized MDR data and focused on new formulations that are extended-release forms of the initial brand name listed drug. The analysis concluded that by calculating the additional rebate, based on the initial brand name listed drug, Medicaid rebates would increase by about 5 percent. A behavioral offset of 15 percent was applied to these potential savings.

The estimates for section 2501(e) of the Affordable Act were derived from an analysis of MDR data for single source and innovator multiple source drugs for which the unit rebate amount exceeds the AMP. The amount of rebates in excess of AMP was found to account for approximately one percent of total Medicaid rebates.

The estimate for FULs under section 2503 was developed by calculating the FUL based on weighted AMP times 175 percent, including (I) innovator and (N) non-innovator drugs, for the purpose of savings and providing adequate reimbursement to pharmacy providers.

a. Anticipated Effects on Drug Manufacturers

As previously indicated in the Collection of Information there are approximately 600 drug manufacturers that participate in the Medicaid Drug Rebate program. The rule would require all drug manufacturers to provide an

increased rebate percentage for generic and brand name drugs.

The burden associated with the drug program is for labelers to gather and report existing sales and product information on an additional monthly basis and an expanded quarterly basis. As mentioned previously there are approximately 600 drug manufacturers who will have to provide reporting drug information to CMS. We believe each manufacturer will spend a one-time annual burden of approximately 144,000 total hours in complying with these requirements. The estimated one-time cost to labelers is \$8.6 million. This information is required for the new base AMP and the new best price. This is based on the Bureau of Labor Statistics (BLS) average rate of \$60.00 an hour for a computer systems analyst.

Manufacturers also will be 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 manufacturer must provide a demonstration that product is a covered outpatient drug, or a COD status. We estimate that these requirements would affect approximately 600 drug manufacturers that participate in the Medicaid Drug Rebate Program. The burden associated with the reporting of the FDA application number or the COD status is the time and the effort it would take for each drug manufacturer to retrieve this information from their records and submit it to CMS. Therefore, we believe that the new requirements to report the FDA application number or the COD status will require a total one-time burden of 3,000 hours at an estimated cost of \$180,000. This is based on the BLS average rate of \$60.00 an hour for a computer systems analyst.

In addition, we believe that it will take time for manufacturers to identify the drugs that fall into 5i drugs category. We estimate they will spend a one-time total of 1,500 burden hours to identify these drugs. This translates to a one-time cost for manufacturers to identify the 5i drugs of \$90,000, utilizing the average BLS wage rate of \$60 an hour for this function. Furthermore, we believe that it will require all manufacturers to spend 192,000 total hours annually in identifying which drugs fall into the 5i category. The estimated cost to the labelers for this addition is \$11.5 million. This is also based on the average BLS wage rate of \$60 an hour for this function. More information on manufacturer requirements can be found in § 447.510 of this proposed rule.

Lastly, we believe that the initial identification of the initial brand name listed drug and the line extension would also add an additional 48,000 annual hours to identify which drugs with the extension qualify. The estimated additional cost to labelers for this addition is also \$2.9 million. This figure is also based on the average BLS wage rate of \$60 an hour for this function. Additional information can be found in section § 447.510 of this proposed rule.

b. Anticipated Effects on Retail Community Pharmacies

Retail community pharmacies would be affected by this regulation, as the law 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. The Affordable Care Act FULs would generally reduce those limits in comparison to the pre-DRA highly inflated FULs and, thereby, reduce Medicaid payment for drugs subject to the limits. However, we note that since States had the option to reimburse at their SMAC, instead of the pre-DRA FUL, the actual reimbursement to the pharmacies under the Affordable Care Act FUL may be more compared to that SMAC reimbursement. An example of this is exemplified in comparing the pre-DRA FUL, the Affordable Care Act FUL and Indiana's SMAC, as explained the preamble of § 447.514 of this proposed rule.

However, other than the comparison chart provided in § 447.514 of this proposed rule, we have not analyzed how each State's MAC program would impact the total savings under the new Affordable Care Act FUL methodology. Therefore, we invite public comments on this impact. The Federal savings in section 2503 of the Affordable Care Act reflect this change in reimbursement for retail community pharmacies. 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 would when compared to what States currently reimburse pharmacies.

c. Anticipated Effects on State Medicaid Programs

States share in the savings from this rule. As noted in the Table 6, we

estimate a 5-year State savings of over \$4.0 billion. We also note States would be impacted by the provisions of this regulation that offset the States' share of the increased rebate amounts under the Affordable Care Act. State administrative costs associated with this regulation are minor; as States currently pay based on a FUL, have already determined their drug reimbursement rates, and currently collect claims information on physician administered drugs.

The States will have added reporting data for the MCOs to CMS and we believe that this will require a total of 2,712 hours annually costing the States \$98,744.

Also, as a result of the increased rebate amounts under the national rebate agreement, 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.

The interactions of the drug provisions with the Medicaid expansion in the Affordable Care Act will provide States a savings of \$5 million in FFY 2014. More information can be found in § 447.509(c) and § 447.511 of this proposed rule.

d. Anticipated Effects on U.S. Territories

The definition of the term "States" would 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.

In order 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 systems that the territories currently have are not setup for the MDR program. As a result, these territories will likely have to utilize contractors in order to ensure that their systems are in place to begin to collect rebates from manufacturers. We do not have cost estimates for this compliance process to be completed and solicit comment specific to this issue.

5. Alternatives Considered

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

As mentioned in the Determination of AMP § 447.504, the goal of the Affordable Care Act is to capture the AMP for those drugs that would 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, Congress amended the Affordable Care Act to include inhalation, infusion, instilled, implanted, or injectable drugs that are not generally dispensed through retail community pharmacies. We considered whether we need to define and determine which drugs constitute the five aforementioned. Also, we looked at Medicare Part B drugs and considered using their list to define these drugs. Though, when speaking with our counterparts in Medicare Part B, the ASP NDC-HCPCS covered drugs that are usually not self administered were not all inclusive. In addition to using the Medicare Part B list, we also considered whether CMS or manufacturers would be responsible for defining which drugs would fall into this category. Additionally, we considered using the FDAs dosage forms and route of administrations to assist manufacturers in determining which drugs meet this requirement.

We propose to use a multistep process to identify if the drug is not generally dispensed. To recap, first manufacturers would identify which drugs would fall within the parameters of the five aforementioned drugs. Then, they would need to determine if the drug is "not generally dispensed" through a retail community pharmacy. (See § 447.504 to learn more about the alternatives considered in developing AMP policy.)

With regard to the offset of the increased rebate percentages, we did consider 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 propose to calculate the offset

amount to reflect rebates based on the difference between AMP and best price.

We also considered a different interpretation when calculating the offset for line extension drugs. However, we believe that the new alternative rebate calculation is more aligned than the statute.

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 five-year Federal and State cost of \$1.7 billion for the Affordable Care Act FULs compared to the DRA FULs. However, this alternative does not take into account a State's ability to choose to reimburse at the SMACs, 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 SMAC and reimburse below the FUL. In addition, the DRA FUL was never implemented and therefore this alternative is based on unpublished FULs and not representative of actual reimbursement.

We solicit comment on the Alternatives Considered section.

6. 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 8 we have prepared an accounting statement showing the classification of the transfers and costs associated with the provisions of this proposed rule. Table 9 provides our best estimate of the decreases in Medicaid payments and increase in drug rebates under sections 2501(a), 2501(b), 2501(c), 2501(d), 2501(e), and 2503 of the Affordable Care Act. All transfers to the Federal and State Medicaid program are from retail pharmacies and drug manufacturers. Lastly, we present the costs to MCOs, Drug Manufacturers, and States.

TABLE 8—ACCOUNTING STATEMENT: CLASSIFICATION OF ESTIMATED TRANSFERS AND COSTS, FROM FFYs 2010 TO 2014
[In \$millions]

Category	TRANSFERS			
Annualized Monetized Transfers	Year Dollar	Discount Rate		Period Covered
	2011	7%	3%	FFYs 2010–2014
	Primary Estimate	–\$2,667.5	–\$2,704.8	
From/To	Reduction in transfers from the Federal Government to State Governments.			
Category	TRANSFERS			
Annualized Monetized Transfers	Year Dollar	Discount Rate		Period Covered
	2011	7%	3%	FFYs 2010–2014
	Primary Estimate	–\$780.0	–\$795.1	
From/To	Reduction in transfers from the State Governments to Retail Pharmacies and increased transfers from Drug Manufacturers to State Governments.			
Category	COSTS			
Annualized Monetized Transfers	Year Dollar	Units Discount Rate		Period Covered
	2011	7%	3%	FFYs 2010–2014
	Primary Estimate	\$16.5	\$16.4	
	Costs to MCOs, Drug Manufacturers, and States.			

7. Conclusion

We estimate savings from this regulation of \$17.7 billion over 5 years, \$13.7 billion to the Federal government and \$4.0 billion to the States. Most of these savings result 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 MCOs. Lastly, we estimate costs to MCOs, drug manufacturers, and States of \$81.4 million for FFYs 2010 through 2014.

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

B. Regulatory Flexibility Act Analysis

The 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 proposed 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 (V.A.4) above. 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 \$7.0 million to \$34.5 million in any one year).

TABLE 9—IMPACT ON SMALL ENTITIES

Small entity type	Number of entities	Impact (FFYs 2010–2014)
Pharmaceutical Manufacturers in Medicaid Drug Rebate Program	600	Decrease in revenue of \$5.4 billion as a result of higher rebates over 5 years.
Small Retail Community Pharmacies	17,069	Minimal impact.
Small Rural Hospitals	700	Minimal impact.
Small (HMOs/MCOs) Health Maintenance Organizations/Managed care organizations	*118	Decrease in revenue of \$6.1 billion over 5 years.

(* Figure may reflect overestimation relative to overall MCOs.)

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 \$25.5 million or less in any 1 year (<http://ecfr.gpoaccess.gov/cgi/t/text/text-idx?c=ecfr&sid=2465b064ba6965cc1fbd2eae60854b11&rgn=div8&view=text&node=13:1.0.1.1.16.1.266.9&idno=13>). The latest 2007 SBA estimates that there are approximately 17,069 small pharmacies. These pharmacies would be affected by this regulation as the law will result in lower FULs for most drugs subject to the payment limits, thus reducing Medicaid payments to pharmacies for generic drugs. The revision to the FULs would generally reduce those limits and, thereby reduce Medicaid payments for drugs that are subject to the payment limits. The savings for section 2503 of the Affordable Care Act reflect this statutory change. Beginning September 2011, the publication of AWP by First Databank would in all likelihood cease; therefore, CMS proposes to replace the term "estimated acquisition cost" 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 proposed 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 (<http://ecfr.gpoaccess.gov/cgi/t/text/text-idx?c=ecfr&sid=2465b064ba6965cc1fbd2eae60854b11&rgn=div8&view=text&node=13:1.0.1.1.16.1.266.9&idno=13>). Approximately 600 drug manufacturers currently participate in the Medicaid Drug Rebate Program. We believe most manufacturers are small businesses. We anticipate this rule would have an impact on small drug manufacturers. We believe there will be an impact on these entities and solicit comments on this analysis.

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) 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 \$10 million or less in any one year (<http://ecfr.gpoaccess.gov/cgi/t/text/text-idx?c=ecfr&sid=2465b064ba6965cc1fbd2eae60854b11&rgn=div8&view=text&node=13:1.0.1.1.16.1.266.9&idno=13>). The SBA estimates that there are approximately 118 small HMO/MCO Medical centers that meet this threshold. Because of limited data available, we are unable to quantify how many MCOs fall within the HMO standard and meet the \$10 million threshold. We do contend that only a small portion of the small MCOs meet this standard. We request any information that may help us better estimate the portion of MCOs that meet the SBA 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 V.A.5 of this proposed rule. The analysis above, together with the remainder of this preamble, constitutes the initial regulatory flexibility analysis. We solicit comment on the RFA 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 603 of the RFA. For purposes of section 1102(b) of the Act, we define a small rural hospital as a hospital that is located outside of a metropolitan statistical area and has fewer than 100 beds. There are approximately 700 small rural hospitals that meet this definition. We do not expect this rule to have a significant impact on small rural hospitals although States are now required to furnish rebates from MCOs including NDCs for physician administered drugs. The national cost of this provision would be estimated at \$580 million for FY 2010. 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 proposed 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. We request any information that may help us better assess those effects before we make final decisions.

C. Unfunded Mandates Reform Act Analysis

Section 202 of the Unfunded Mandates Reform Act of 1995 (UMRA) 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 2011, that threshold is approximately \$136 million. We expect this proposed rule would impose additional costs to manufacturers, whereas it would likely increase savings for States and the Federal government. A detailed discussion on costs is offered below. We believe the rule would not impose additional costs to States and local governments. This proposed rule will have 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.

There would be additional costs for drug manufacturers. This occurs as a result of the increased rebate percentages for generic and brand name drugs, and the treatment of new formulation drugs which for manufacturers, total over \$11.2 billion dollars over the next 5 years.

VI. Federalism Analysis

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

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 proposes to amend 42 CFR chapter IV as set forth below:

PART 447—PAYMENTS FOR SERVICES

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

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

2. Subpart I is revised to read as follows:

Subpart I—Payment for Drugs

Secs.

- 447.500 Basis and purpose.
- 447.502 Definitions.
- 447.504 Determination of Average Manufacturer Price.
- 447.505 Determination of best price.
- 447.506 Authorized generic drugs.
- 447.507 Identification of 5i drugs.
- 447.508 Exclusion from best price of certain sales at a nominal price.
- 447.509 Medicaid drug rebates.
- 447.510 Requirements for manufacturers.
- 447.511 Requirements for States.
- 447.512 Drugs: Aggregate upper limits of payment.
- 447.514 Upper limits for multiple source drugs.
- 447.516 Upper limits for drugs furnished as part of services.
- 447.518 State plan requirements, findings, and assurances.
- 447.520 FFP: Conditions relating to physician-administered drugs.
- 447.522 Optional coverage of investigational drugs and other drugs not subject to rebate.

Subpart I—Payment for Drugs

§ 447.500 Basis and purpose.

(a) *Basis.* This subpart—

(1) Interprets those provisions of section 1927 of the Act that set forth requirements for drug manufacturers' calculating and reporting average manufacturer prices (AMPs) and 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:

5i drug means an inhalation, infusion, instilled, implanted, or injectable drug that is not generally dispensed through a retail community pharmacy.

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 wholesalers or retail community pharmacies; 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 but not limited to those discounts resulting from a contingent arrangement, are allocated proportionally to the total dollar value of the units of all drugs 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 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 the 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 where the manufacturer has obtained a NDA and also under section 505(j) of the FFDCA where the manufacturer has obtained an ANDA;

(ii) Was commercially 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. This provision specifies 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 biologic 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, biologic 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 is 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 the mentally retarded;

(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 OTC, for which an NDC number is not required by the FDA;

(ii) Any drug product that is not listed electronically with the FDA;

(iii) 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;

(iv) Any drug product or biological used for a medical indication which is not a medically accepted indication; or

(v) 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 marketed under

a new drug application (NDA) approved by the FDA, including an authorized generic drug. It includes a drug product marketed by any cross-licensed producers, labelers, or distributors operating under the NDA and a covered outpatient drug approved under a biologic license application (BLA), product license approval (PLA), establishment license approval (ELA) or antibiotic drug approval (ADA). 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.

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.

Line extension means 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.

Manufacturer means any entity that holds the NDC for a covered outpatient drug or biological product and—

(1) Is engaged in the production, preparation, propagation, compounding, conversion, or processing of covered outpatient drug products, either directly or indirectly by extraction from substances of natural origin, or independently by means of chemical synthesis, or by a combination of extraction and chemical synthesis; or

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

(3) 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—

(1) Is rated as therapeutically equivalent as reported in the 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 the FDA’s Freedom of Information Public Reading Room at 5600 Fishers Lane, rm. 12A-30, Rockville, MD 20857 or successor publications and Web sites;

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

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

National drug code (NDC) means the 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 AMP in the same quarter for which the AMP is computed.

Noninnovator multiple source drug means—

(1) A multiple source drug that is not an innovator multiple source drug or a single source drug;

(2) A multiple source drug that is marketed under an abbreviated NDA or an abbreviated antibiotic drug application;

(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 meet the definition of covered outpatient drug; or

(5) Any noninnovator drug that is not therapeutically equivalent.

(6) If any of the drug products listed in this definition of a noninnovator multiple source drug subsequently receives a new NDA or ANDA approval from the FDA, the manufacturer must change the reporting of the product’s drug category to correlate with the new product application type and furnish the appropriate information.

Oral solid dosage form means capsules, tablets, or similar drugs products intended for oral use as defined in accordance with the FDA regulation at 21 CFR 206.3 that defines solid oral dosage form.

Over-the-counter 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 "Indications and Usage" section of the FDA approved labeling.

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 NDA approved by the FDA and has an approved NDA number issued by the FDA, including a drug product marketed by any cross-licensed producers or distributors operating under the NDA. It also includes a covered outpatient drug approved under a biological license application (BLA), product license approval (PLA), establishment license approval (ELA), or antibiotic drug approval (ADA). 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 FDCA for purposes of approval by the FDA for safety and effectiveness.

States means the 50 States, the District of Columbia and the territories (the Commonwealth of Puerto Rico, the Virgin Islands, Guam, the Northern Mariana Islands and America Samoa).

United States means the 50 States, the District of Columbia, and the territories (the Commonwealth of Puerto Rico, the Virgin Islands, Guam, the Northern Mariana Islands and America 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, with respect to a covered outpatient drug of a manufacturer (including those sold under an NDA approved under section 505(c) of the Federal Food, Drug, and Cosmetic Act (FFDCA)), 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, and 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, discounts, rebates, payments, or other transactions included in AMP.** Except for those sales, nominal price sales, rebates, discounts and 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 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, discounts, rebates (other than rebates under section 1927 of the Act or as otherwise specified in regulations), payments, or other financial transactions that are received by, paid by, or passed through to retail community pharmacies.

(4) Sales, discounts, rebates (other than rebates under section 1927 of the Act or as otherwise specified in regulations), 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 healthcare providers.

(c) **Sales, nominal price sales, rebates, discounts, or other transactions excluded from AMP.** AMP excludes the following sales, nominal sales, rebates, discounts, or other 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) Direct and indirect 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 paid by manufacturers to wholesalers, retail community pharmacies, or any other entity that conducts business as a wholesaler or a retail community pharmacy, including but 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 Group Purchasing Organizations.

(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) Sales to PBMs, including their mail order pharmacy's purchases.

(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) Direct 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 entity does not receive any price concession.

(26) Manufacturer vouchers.

(27) Prices negotiated under Manufacturer-sponsored drug discount card programs.

(28) Goods provided free of charge under Manufacturer-sponsored patient refund/rebate programs.

(29) Goods provided free of charge under Manufacturer copayment assistance programs and patient assistance programs.

(d) *Sales and associated discounts, rebates, payments, or other transactions included in AMP for inhalation, infusion, instilled, implanted, or injectable drugs (5i drugs) not generally dispensed through a retail community pharmacy.* AMP for 5i covered outpatient drugs identified in accordance with § 447.507 of this subpart shall include sales and associated discounts, rebates, payments or other financial transactions to all entities as specified in paragraph (b) of this section, as well as the following sales and associated discounts, rebates, payments or other transactions:

(1) Sales to physicians.

(2) Sales to pharmacy benefit managers where the PBM is not acting as an insurer, including its mail order pharmacy purchases.

(3) Sales to health maintenance organizations (HMOs), including managed care organizations (MCOs).

(4) Sales, discounts, or rebates paid directly 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.

(10) Sales to other manufacturers who conduct business as a wholesaler or retail community pharmacy.

(e) *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, 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 any such drug of a manufacturer that is sold under an NDA approved under section 505(c) of the FDCA), 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 and associated rebates, discounts, or other transactions that adjust prices either directly or indirectly.

(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) Prices to 340B covered entities.

(i) Prices charged under the 340B drug pricing program to a covered entity described in section 1927(a)(5)(B) of the Act; and

(ii) Any 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 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 with respect to covered Part D drugs, or by a Qualified Retiree Prescription Drug Plan (as defined in section 1860D-22(a)(2) of the Act) 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) Prices negotiated under manufacturer-sponsored drug discount card programs.

(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) Goods provided free of charge under Manufacturer copayment assistance programs and patient assistance programs.

(11) Goods provided free of charge under Manufacturer-sponsored patient refund or rebate programs.

(12) Manufacturer vouchers.

(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 it only covers these costs.

(15) Nominal prices to certain entities as set forth in § 447.508 of this subpart.

(16) Bona fide service fees paid by manufacturers to wholesalers, retail community pharmacies, or any other entity that conducts business as a wholesaler or a retail community pharmacy, including but 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 Group Purchasing Organizations.

(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.

(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, returns, incentives, promotional fees, administrative fees, 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, 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 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 of this subpart.

§ 447.507 Identification of 5i drugs.

A manufacturer must identify each covered outpatient drug that is a 5i drug that is not generally dispensed through a retail community pharmacy.

(a) *Identification of a 5i drug.* A manufacturer must use the list of FDA's Routes of Administration posted on the CMS Web site to identify 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 90 percent or more of the sales of the 5i drug, during the reporting period, were to entities other than retail community pharmacies or wholesalers for drugs distributed to retail community pharmacies.

(2) A manufacturer is responsible for determining whether a 5i drug is not generally dispensed through a retail community pharmacy on a monthly and quarterly 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/MR 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 § 440.150 of this chapter.

(4) 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 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 is not in receipt of grant funds under that Act.

(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 subpart is construed to alter any existing statutory or regulatory prohibition on services for an entity described paragraph (a) of this section, including the prohibition set forth in section 1008 of the PHSA.

§ 447.509 Medicaid drug rebates.

(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 the 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—

(i) The total number of units of such dosage form and strength paid for under the State plan in the rebate period; and

(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 (a)(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 term “line extension” means, with respect to a drug, a new formulation of the drug, such as an extended release product.

(iii) *Identification of line extension drugs.*

(A) The FDA’s list of Chemical Types, listed in FDA Drugs in FDA’s database, is used to identify the line extension drug and the initial brand name listed drug.

(B) Chemical Type 2, new ester, new salt, or other noncovalent derivative; Chemical Type 3, new formulation; Chemical Type 4, new combination; and Chemical Type 6, new indication are determined to be line extension drugs.

(C) Chemical Type 1, new molecular entity, represents 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 pay rebates 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:

(i) Dispensed by health maintenance organizations including MCOs that contract under section 1903(m) of the Act.

(ii) Discounted under section 340B of the PHSA.

(3) Within 30 days of the end of each quarter, a Medicaid MCO that contractually provides covered outpatient drugs dispensed to Medicaid beneficiaries must report to the State the following data:

(i) MCO identifier.

(ii) National Drug Code.

(iii) Period covered.

(iv) Product FDA list name.

(v) Total units.

(vi) Total number of prescriptions.

(vii) Amount reimbursed.

(c) *Federal offset of rebates.* States must remit to the Federal government the amount of the savings resulting from the increases in the rebate percentages.

(1) For single source or innovator multiple source drugs other than blood clotting factors and drugs approved by the 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 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 the 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 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 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 percent of the AMP (the difference between 13 percent of AMP and 11 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 of this subpart.

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

(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) of this subpart for the rebate period.

(5) A manufacturer that fails to submit a quarterly AMP to CMS for a product by the thirtieth day after the end of each rebate period will be subject to civil monetary penalties for each product not

reported on the thirty-first day of \$10,000 per day per drug.

(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 underpayments to States, or potential liability regarding those underpayments, as required by CMS or court order, or pursuant to an internal investigation, or an OIG or DOJ investigation.

(2) A manufacturer may report revisions to AMP, best price, customary prompt pay discounts, or nominal prices for a period in excess of 12 quarters from the quarter in which the data were due based on the approval of CMS for good cause.

(3) A manufacturer must report revisions to 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 DRA base date AMP to CMS within the first four 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 of this subpart.

(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 four full calendar

quarters following [publication date of the final rule].

(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 of this subpart.

(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 of this subpart, 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 price concessions using a 12-month rolling percentage to estimate the value of those discounts.

(3) *Timeframe for reporting revised monthly AMP.* A manufacturer must report to CMS revisions to monthly AMP for a period not to exceed 36 months from the month in which the data were due, 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.

(7) *Failure to report product information, monthly AMP and AMP units.* A manufacturer that fails to submit a monthly AMP and the total number of units that are used to calculate that monthly AMP to CMS for a product by the thirtieth day after the last day of each month will be subject to civil monetary penalty for each product not reported on the thirty-first day of \$10,000 per drug per day.

(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 (e)(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. This 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 of this subpart. If a specific limit has not been established under § 447.514 of this subpart, then the rule for "other drugs" set forth in paragraph (b) of this section applies.

(b) *Other drugs.* The agency payments for brand name drugs certified in accordance with paragraph (c) of this section and drugs other than multiple source drugs for which a specific limit has been established under § 447.514 of this subpart must not exceed, in the aggregate, payment levels that the agency has determined by applying the lower of the 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 of this subpart does not apply if a physician certifies in his or her own handwriting (or by an electronic alternative means approved by the Secretary) that a specific brand is medically necessary for a particular 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 the FDA has rated at least three drug products as pharmaceutically and therapeutically equivalent in its most current edition of "Approved Drug Products with Therapeutic Equivalence Evaluations" (including supplements or in successor publications). Only pharmaceutically and therapeutically equivalent formulations will be used to determine such limit, and such limit will only be applied to those therapeutically 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.* 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 drug entity 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 AMP using manufacturer submitted utilization data.

(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.* 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:

(1) A covered entity described in section 1927(a)(5)(B) of the Act.

(2) A contract pharmacy under contract with a covered entity described in section 1927(a)(5)(B) of the Act.

(3) An Indian Health Service, tribal and urban Indian pharmacy.

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

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

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

(ii) In the aggregate, its Medicaid expenditures for all other drugs are in

accordance with § 447.512 of this subpart.

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

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

(d) *Data requirements.* When proposing changes to the ingredient cost reimbursement or professional dispensing fee reimbursement, States must provide adequate data, including, but not limited to, a State or national survey of retail pharmacy providers or other reliable data which reflects the pharmacy's actual or average acquisition cost as a base to support any proposed change in ingredient cost reimbursement. 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 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 has been indicated by the FDA for human trials.

(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 payments for investigational drugs will be reimbursed in accordance with the FDA final rules at 21 CFR parts 312 and 316 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 covered outpatient drugs or fail to be listed electronically with the FDA.

(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.

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

Dated: March 16, 2011.

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

Approved: August 16, 2011.

Kathleen Sebelius,
Secretary.

Editorial Note: This document was received at the Office of the Federal Register on January 26, 2012.

[FR Doc. 2012-2014 Filed 1-27-12; 11:15 am]

BILLING CODE 4120-01-P

111TH CONGRESS }
1st Session

HOUSE OF REPRESENTATIVES

{ REPT. 111-299
Part 1

AMERICA'S AFFORDABLE HEALTH CHOICES
ACT OF 2009

R E P O R T

OF THE

COMMITTEE ON ENERGY AND COMMERCE

ON

H.R. 3200

together with

DISSENTING VIEWS



OCTOBER 14, 2009.—Ordered to be printed

U.S. GOVERNMENT PRINTING OFFICE

52-801

WASHINGTON : 2009

tail pharmacies; (5) sales directly to, or rebates, discounts, or other price concessions provided to, hospitals, clinics, and physicians, unless the drug is an inhalation, infusion, or injectable drug, or the Secretary determines under HHS administrative procedures that it is necessary to include these sales, rebates, discounts, and price concessions in order to calculate an accurate AMP for the drug; and (6) rebates, discounts, and other price concessions required under subsections (f) and (g) of section 1860D-2(f) of the Social Security Act (as added by section 1181(b) of the bill). A determination by the Secretary that it is necessary to include certain sales or price concessions to hospitals, clinics, and physicians in order to obtain an accurate AMP for a drug would not be subject to judicial review.

The bill requires manufacturers that have entered into Medicaid drug rebate agreements with the Secretary to report within 30 days after the last day of each month of a rebate period, the manufacturer's total number of units used to calculate the monthly AMP for each covered drug. The bill clarifies that manufacturers are required to submit specified AMP pricing information to the Secretary within 30 days of the end of each month of a rebate period, rather than within 30 days of the end of a rebate period.

The bill authorizes the Secretary to promulgate in an expedited manner regulations setting forth the requirements for FULs and for the determination of AMPs. These regulations could be effective on an interim final basis pending opportunity for public comment.

The bill would eliminate the current law requirement that the Secretary post on a website accessible to the public, and update on a quarterly basis, the most recently reported AMPs for single source drugs and for multiple source drugs.

Sec. 1742. Prescription drug rebates

Current Law

Medicaid law requires prescription drug manufacturers that seek to sell any of their products to State Medicaid programs to enter into a rebate agreement with the Secretary of HHS. Under these agreements, manufacturers must provide state Medicaid programs with rebates for the drugs purchased for Medicaid beneficiaries on an outpatient basis, and state Medicaid programs must cover all drugs (except certain statutorily excluded drug classes) marketed by those manufacturers. The rebates are shared by the state and federal governments in proportion to their respective shares of Medicaid drug expenditures. Certain drugs are not subject to rebates, including drugs dispensed by Medicaid managed care organizations, drugs used on an inpatient basis, and drugs dispensed in physicians' or dentists' offices.

In the case of brand-name prescription drugs, a manufacturer's rebate obligation is the sum of two components—the basic rebate and an additional rebate. The basic rebate is the greater of (1) 15.1% of the average manufacturer price (AMP) or (2) the difference between AMP and the best price. The AMP is the average price that a manufacturer receives for sales in the United States to wholesalers for drugs distributed to the retail pharmacy class of trade. The "best price" is the lowest price available from the manufacturer to any wholesaler, retailer, provider, health maintenance organization, or nonprofit or governmental entity, subject to certain

exceptions. The additional rebate is the amount by which a drug's AMP exceeds the drug's base period AMP increased by the consumer price index.

Currently, modifications to existing drugs—new dosages or formulations, such as extended release versions, sometimes referred to as product line extensions—generally are considered new products for purposes of reporting AMPs to the Secretary. As a result, manufacturers can avoid incurring additional rebate obligations by making slight alterations to existing products. When new products are released, manufacturers can set their base period AMP to any price, so they are able to set new higher prices that will not incur Medicaid's additional rebates.

Proposed Law

The bill would increase the minimum rebate percentage for single source and innovator multiple source drugs from 15.1% to 22.1%. This increase would be effective for rebate periods beginning after December 31, 2009.

The bill would apply a rebate to new formulations of existing single source or innovator multiple source drugs. Under this provision, the rebate for a line extension of a single source or innovator multiple source prescription drug that is an oral solid dosage form would be the greater of (1) the rebate as calculated under current law (e.g., basic rebate plus additional rebate) or (2) a line extension rebate calculation. The line extension rebate amount would be product of: (1) the AMP for the line extension that is an oral solid dosage form; (2) the highest additional rebate (calculated as a percentage of AMP) for any strength of the original single source or innovator multiple source drug; and (3) the total number of units of each dosage form and strength of the line extension product paid for by the state Medicaid program during the rebate period (as reported by a state). For this purpose, the term "line extension" means an extended release formulation of the drug. This provision would be effective for new formulations dispensed to Medicaid beneficiaries after December 31, 2009, regardless of when the new formulations came to market.

Sec. 1743. Extension of prescription drug discounts to enrollees of Medicaid managed care organizations

Current Law

Medicaid law requires prescription drug manufacturers that seek to sell any of their products to state Medicaid programs to enter into a rebate agreement with the Secretary of HHS. Under these agreements, manufacturers must provide state Medicaid programs with rebates for the drugs purchased for Medicaid beneficiaries on an outpatient basis, and state Medicaid programs must cover all drugs (except certain statutorily excluded drug classes) marketed by those manufacturers. The rebates are shared by the state and federal governments in proportion to their respective shares of Medicaid drug expenditures.

Certain drugs are not subject to rebates, including drugs dispensed by Medicaid managed care organizations (MCOs) that contract on a risk basis with state Medicaid agencies when prescription drugs are included in the capitation agreement between the

March 28, 2012

Acting Administrator Marilyn Tavenner
Centers for Medicare & Medicaid Services
Department of Health and Human Services
200 Independence Avenue SW
Washington, DC 20201

**Re: Comments on "Line Extension" Proposal in Medicaid Program; Covered
Outpatient Drugs Proposed Rule (CMS-2345-P)**

Dear Acting Administrator Tavenner:

We appreciate that patient access to pain medication must be balanced with the risk of prescription drug abuse that affects families across the United States. Our organizations have supported efforts at the federal and state level to reduce the illegal use of prescription pain-relief drugs. While the Institute of Medicine has recently issued a report on the needs of the 100 million Americans suffering from chronic pain, the White House Office of National Drug Control Policy (ONDCP) has described prescription drug abuse as the nation's fastest-growing drug problem, and has established a comprehensive plan (White House Plan), along with other federal agencies, to combat this growing crisis.

In January 2012, the Centers for Medicare & Medicaid Services (CMS) released a proposed rule, *Medicaid Program; Covered Outpatient Drugs*, which contains a proposal to increase rebates for line extension drugs, including abuse deterrent formulations (ADFs). This proposal conflicts with the White House Plan and the policies of several federal agencies, including the Drug Enforcement Agency (DEA) and HHS' own Food and Drug Administration (FDA), Centers for Disease Control and Prevention (CDC) and Substance Abuse and Mental Health Services Administration (SAMHSA), to reduce prescription drug abuse. On the one hand, CMS is overreaching by creating disincentives for ADF technologies, which are designed to both lower barriers for patient access and deter the abuse of these important medicines. On the other hand, the White House and Members of Congress are encouraging the development of ADF technologies. Ironically, CMS' proposal actually runs counter to the White House Plan and Congressional efforts by creating disincentives for manufacturers to develop ADFs for pain-relief products.

To understand the significant potential for CMS' proposal to undercut ONDCP, FDA, DEA, CDC, SAMHSA and other agencies aimed at reducing prescription drug abuse, we urge CMS to review the record. For example, the White House Plan calls for expediting financial support and giving FDA review priority to ADFs of opioid medications (pain relievers) and other drugs with abuse potential. ADFs are designed to reduce tampering and abuse of certain products. ADF drugs help to achieve the goal of the White House Plan, and are described as a "balance between our desire to minimize abuse of prescription drugs and the need to ensure access for their legitimate use." Additionally, the Deputy Director of FDA's Center for Drug Evaluation and Research (CDER), Doug Throckmorton, recently said that FDA is considering

ways to incentivize manufacturers to make ADFs of substances such as reformulated tablets that are more difficult to misuse and abuse. These reformulated tablets would include properties intended to prevent them from being cut, broken, crushed or dissolved to release more medication. Currently, FDA is reviewing ways to spur ADF development as it creates criteria for anti-abuse claims and faces continued pressure from Congress to establish these standards. Additionally, FDA is expected to release additional guidance on ADFs by the end of 2012.

Moreover, the Government Accountability Office (GAO), the non-partisan Congressional watchdog organization, studied the issue of prescription drug abuse in a December 2011 report, *Prescription Pain Reliever Abuse: Agencies Have Begun Coordinating Education Efforts, but Need to Assess Effectiveness*. The report highlighted the problem that ADFs are designed to address and emphasized the need for various federal agencies to coordinate efforts to reduce patient abuse:

[A]busers seek out drugs that can be smoked, snorted, or taken intravenously, thus providing a more rapid onset of the effects of the drug. Therefore, some manufacturers of prescription pain relievers have focused on making their products tamper resistant, so that the physical or chemical makeup or delivery system of the drug cannot be altered, with the goal of preventing users from accessing and abusing the active ingredient.

Despite the GAO report's description of the advances in ADF technologies and the White House Plan's recognition of the value of ADF drugs, CMS' proposal not only threatens patient access to ADF products, but undermines President Obama's national strategy to combat prescription drug abuse.

Specifically, CMS' proposal would increase manufacturer rebates paid to Medicaid for "line extensions" of oral solid dosage form drugs (tablets or pills). Legislative history demonstrates that Congress intended to increase rebates only for those line extensions involving merely a "slight alteration" to the manufacturer's own existing products because Congress feared that "slight alterations" could be used as a "loophole" to circumvent some Medicaid rebates. Unfortunately, CMS proposed an overly broad definition of "line extension" that fails to distinguish between a slightly-altered drug and an innovative ADF drug that is intended to benefit patients based upon significant R&D investment.

In fact, CMS chose specifically not to exclude ADF drugs from the proposed definition of line extension, despite the significant R&D investments required to develop the technology necessary to achieve the White House Plan's goal to prevent drug abuse. As highlighted in the 2011 GAO report, the development of ADF drugs requires the commitment of considerable resources. For example, the GAO found that one manufacturer spent nearly nine years developing an ADF version of a pain relief drug that was both effective and safe. These types of resource commitments already present serious challenges for manufacturers developing ADF drugs. It makes little sense for the White House, FDA, DEA, CDC, SAMHSA and other federal agencies focused on prescription drug abuse to propose policies that would lead to the expanded

availability of ADF drugs, only for CMS to undercut these important policies by penalizing ADF drug manufacturers by proposing a distorted definition of line extension.

Fortunately, there is still time for CMS to change its proposal by ensuring that ADF drugs are not exposed to higher Medicaid rebates. We strongly urge CMS to specify that the term "line extension" exclude an abuse deterrent formulation of a controlled substance for which the FDA required one or more pre- or post-approval studies or clinical trials (other than for bioequivalence or bioavailability purposes) or that meets FDA's anticipated 2012 guidance on the development of abuse deterrent formulations. This simple policy change will help to ensure that patients have continued access to the pain relief they need and will strongly contribute to the prevention of prescription drug abuse.

Sincerely,

**U.S. Pain Foundation
Wisconsin Pain Initiative
Endo Pharmaceuticals
Collegium Pharmaceuticals
American Academy of Pain Management
Purdue Pharma L.P.
Hospice & Palliative Nurses Association
Community Anti-Drug Coalitions of America (CADCA)
The National Fibromyalgia & Chronic Pain Association
Reflex Sympathetic Dystrophy Syndrome Association (RSDSA)
Pain Treatment Topics
Center for Lawful Access and Abuse Deterrence (CLAAD)
National Hospice and Palliative Care Organization
Interstitial Cystitis Association
Johnson & Johnson
Harm Reduction Coalition
Teva Pharmaceuticals
Partnership at Drugfree.Org
American Society for Pain Management Nursing
The Researched Abuse, Diversion, and Addiction-Related Surveillance System (RADARS)
Healthcare Distribution Management Association (HDMA)**

cc: The Honorable Kathleen Sebelius, Secretary of Health and Human Services
ONDCP Director R. Gil Kerlikowske
FDA Commissioner Margaret Hamburg, M.D.



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April 2, 2012

Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-2345-P
P.O. Box 8016
Baltimore, MD 21244-8016

BY ELECTRONIC DELIVERY at <http://www.regulations.gov>

Re: Submission of Comments Pursuant to CMS-2345-P — Proposed Rule: Medicaid Program; Covered Outpatient Drugs (RIN 0938-AQ41)

Dear Administrator Tavenner:

Purdue Pharma L.P. ("Purdue") is pleased to have the opportunity to comment on the proposed rule released by the Centers for Medicare & Medicaid Services ("CMS" or the "Agency") entitled *Medicaid Program; Covered Outpatient Drugs* (the "Proposed Rule"),¹ which implements provisions of the Patient Protection and Affordable Care Act ("PPACA") as amended by the Health Care and Education Reconciliation Act ("HCERA") (collectively, the "Affordable Care Act" or "ACA"). We appreciate the challenging task CMS faces in implementing the ACA provisions that are addressed in the Proposed Rule. However, as explained in detail below, we have serious concerns that CMS' line extension proposal will significantly stifle, if not halt, the development of abuse-deterrent formulations ("ADFs") of opioid analgesics.

As CMS itself acknowledges in the preamble to the Proposed Rule, ADFs "have the potential to decrease abuse of prescription drugs and improve patient and public safety."² ADFs are intended to reduce tampering and abuse of pain relief drugs and have long been recognized as an important step in combating prescription drug abuse, which affects millions of families in the United States. Manufacturers such as Purdue have expended significant resources to develop ADFs, in close cooperation with the Food and Drug Administration ("FDA"). As described in a 2011 Government Accountability Office ("GAO") report identifying the challenges faced by ADF manufacturers, Purdue spent nearly *nine years* developing an ADF version of OxyContin.³ In addition, Purdue continues to conduct post-market studies required by FDA.

In these comments, we urge CMS to exclude from the definition of line extension an ADF of an opioid or other controlled substance that required significant research and development (R&D) investment by the manufacturer in connection with approval.

¹ See CMS, Proposed Rule, *Medicaid Program; Covered Outpatient Drugs*, 77 Fed. Reg. 5318 (Feb. 2, 2012).

² *Id.* at 5338.

³ GAO, *Prescription Pain Reliever Abuse: Agencies Have Begun Coordinating Education Efforts, but Need to Assess Effectiveness*, GAO-12-115 (Dec. 22, 2011) App. I, available at <http://www.gao.gov/products/GAO-12-115> (last visited Mar. 28, 2012).

Specifically, we urge CMS to exclude from the definition of line extension an ADF of an opioid or other controlled substance for which (1) FDA requires one or more pre-approval or post-approval studies or trials (other than for bioequivalence purposes or to gain approval for the extended release properties of a drug), or (2) the product meets FDA's anticipated (by the end of 2012) guidance on the development of ADFs.

As explained below, CMS' proposed definition is inconsistent with Congressional intent (which was focused on closing a loophole for slightly altered drugs, not on ADFs), Executive Branch policies (which have identified the importance of R&D on ADFs to fight prescription drug abuse and have encouraged the development of these products), and the statutory definition of line extension (which is focused on extended-release products and other slightly altered new formulations, not on ADFs). Failure to implement an appropriate exclusion for ADFs that require significant R&D investment will cause Purdue to re-evaluate the financial feasibility of continuing the development of additional ADF products currently underway. We are sure that Purdue would not be alone in re-evaluating whether or not to proceed with ADF product innovation, if CMS' line extension proposal ultimately covers ADFs. Furthermore, as discussed below, failure to exempt ADFs that reflect significant R&D investment will ultimately *raise costs for the Medicaid Drug Rebate Program* by forcing the program to employ other, less effective means to combat prescription drug abuse by individuals covered by Medicaid.

Below we explain important legal and policy considerations supporting our proposal that CMS exclude ADFs from the definition of line extension where the ADF requires significant R&D investment. We then explain in further detail the proposed test – set forth above – to assist CMS in measuring significant R&D investment based on FDA's approval for such products. We also explain why CMS' line extension proposal violates the APA and antitrust laws. Finally, in the last section of these comments, we express support for several topics covered under the comment letters of two trade associations in which Purdue is a member, the Biotechnology Industry Organization ("BIO") and the Pharmaceutical Research and Manufacturers of America ("PhRMA").

I. Line Extensions – Proposed 42 C.F.R. §§ 447.502 & 447.509(a)(4)

A. *The Legislative History and Federal Agency Policy Support an Exclusion for ADFs That Reflect Significant R&D Investment.*

Legislative history clearly demonstrates Congress' intent that the line extension rebate apply only to "new formulations" reflecting "*slight alterations*" to the initial brand name drug. Beginning in 2008, at each point where the legislative history or agency reports discuss the types of products that are the focus of the proposal that became the "line extensions" provision, the concern is that manufacturers could avoid incurring additional rebate liability by making "slight alterations" to existing products.

For example, a House Energy & Commerce Report describes the law in effect prior to the ACA as permitting manufacturers to avoid additional rebate requirements "by making *slight alterations* to existing products."⁴ As another example, on the Senate side, the Senate Finance Committee Chairman's Mark regarding the America's Healthy Future Act of 2009 ("AHFA") reflects the same concern that "drug makers can avoid incurring additional rebate obligations by making *slight alterations* to existing products, sometimes called line-extensions, while significantly increasing the price on these products."⁵ Similarly, an October 2009 Senate Finance Committee Report, which accompanied the legislative text to

⁴ H.R. Rep. No. 111-299, Pt. 1, on America's Affordable Health Choices Act of 2009, H.R. 3200, at 635 (2009) (emphasis added).

⁵ S. Comm. on Fin. Chairman's Mark: America's Healthy Future Act of 2009, at 68 (Oct 2, 2009) (emphasis added).

the AHFA reported out of the Committee, again emphasizes the focus on lawmakers' concern that manufacturers "sometimes can avoid incurring additional rebate obligations by making *slight alterations* to existing products."⁶

In addition to these numerous House and Senate Committee reports, materials from the Congressional Research Service ("CRS") contain similar descriptions emphasizing the focus on the possibility that "drug makers can avoid incurring additional rebate obligations by making *slight alterations* to existing products."⁷ Moreover, CRS further noted that only "*certain* extended release versions" reflect a slight alteration.⁸ Accordingly, CMS must limit its definition of the term "line extension" to new formulations that are slight alterations of existing products, and must exclude those new formulations that are approved based on significant R&D efforts and investments.

Congressional intent is not the only evidence that weighs in favor of limiting the definition of line extension to slightly altered products. The Congressional Budget Office ("CBO") and HHS, including the Office of Inspector General ("OIG"), all were focused on closing the perceived "loophole" that could enable manufacturers to reset the Medicaid additional rebate based merely on "slight alterations" to existing products. For example:

- A 2008 CBO Budget Options document stated that application of an additional rebate to "*new formulations*" of existing drugs "would *remove a loophole* that enables drug manufacturers to *circumvent their rebate obligations* simply by altering an existing product." This document expressly notes that the option is designed to address instances where manufacturers can "avoid incurring an additional rebate obligation by making a *slight alteration*" or "*minor change*" to an existing product.⁹
- The same 2008 CBO document states that the policy would apply only to "*a certain type of new formulation—specifically, extended-release versions.*"¹⁰
- HHS' FY 2010 Budget in Brief stated as follows about the proposal to "*Apply Medicaid Additional Rebate to New Formulations of Existing Drugs*": "Addresses the *current loophole* that *enables drug manufacturers to circumvent the additional rebate* by creating new formulations of drugs and charging higher initial prices for these drugs."¹¹
- A 2010 OIG Report stated: "*Drug manufacturers may have many valid reasons to seek approval from FDA for these new versions.* However, because the Medicaid drug rebate program calculates rebates separately for each version of a drug, manufacturers could develop new versions of existing brand-name drugs *solely* to avoid paying additional rebates when they substantially increase prices. *Without some modification to the rebate law, the risk of manufacturers taking advantage of this potential loophole may increase over time.*"¹²

⁶ S. Rep. No. 111-89, at 92 (2009) (emphasis added).

⁷ See, e.g., CRS REPORT FOR CONGRESS, MEDICAID AND CHILDREN'S HEALTH INSURANCE PROGRAM (CHIP) PROVISIONS IN AFFORDABLE HEALTH CARE FOR AMERICA ACT (H.R. 3962), at 27 (2009) (emphasis added).

⁸ *Id.* (emphasis added). Notably, this CRS report refers back to the iteration of the line extension provision in H.R. 3962, which is identical to the line extension provision as enacted in the ACA.

⁹ CBO, *Budget Options Vol. I—Health Care* (Dec. 2008), Option 76, at 143 (emphasis added).

¹⁰ *Id.* (emphasis added).

¹¹ HHS, *FY 2010 Budget in Brief* (May 7, 2009), at 62 (emphasis added).

¹² OIG, *Review of Additional Rebates for Brand-Name Drugs with Multiple Versions*, A-06-09-00033 (Mar. 2010), at ii (emphasis added).

As with the legislative history, the foregoing statements clearly reflect an intent by the Executive Branch that this provision be limited to a subset of products where a slight change to the product was made for the purpose of circumventing Medicaid rebate liability. Indeed, CMS itself has recognized that ADF technology is more than a "slight alteration." In the Proposed Rule, CMS discusses the benefits of these innovative technologies, expressly noting that, "by preventing alternate routes of administration, or employing physical barriers that resist common methods of tampering, . . . abuse deterrent formulations (ADFs) have the potential to decrease abuse of prescription drugs and improve patient and public safety."¹³

We respectfully urge CMS to recognize ADFs that reflect significant R&D investment as an excluded category. ADFs are dramatically different than extended release products and other line extensions, not only because of the unique technology involved in developing an ADF, but also because FDA requires significant testing for ADFs for approval purposes. Because ADFs alter the abuse potential of the underlying drug, ADFs have different safety profiles as compared to that of the underlying drug. A different safety profile often leads the FDA to require additional studies, beyond the relatively simple and inexpensive bioequivalence studies required for line extensions. Bioequivalence studies analyze only the rate and extent of absorption of a drug product. However, since ADFs have a different safety profile as compared to the original drug, more intensive testing is required by the FDA to ensure that the ADF is safe and achieves its' intended objective.

For example, CMS states that ADFs may include "combination oral formulation products with an opioid agonist and opioid antagonist" and "prodrugs." Combination oral formulation products with an opioid agonist and opioid antagonist are products with two active pharmaceutical ingredients and, as such, the FDA would require studies well beyond inexpensive bioequivalence studies. The addition of the opioid antagonist to a formulation with an opioid agonist is not a change that would merely require a bioequivalence study. Additionally, prodrugs, which are distinct products converted to an active pharmaceutical ingredient through metabolism require expensive and time consuming R&D well beyond bioequivalence studies.

Accordingly, we believe CMS possesses the authority to exclude ADFs that reflect significant R&D investment from the definition of line extension. Below we explain why the Agency should do so based on the legislative history and important Executive Branch policies, and propose a bright-line test that would identify such products.

Failure to implement the standard proposed above would also result in a conflict with the White House Office of National Drug Control Policy's ("ONDCP") plan to combat prescription drug misuse and abuse, and other important Federal agency policy. Indeed, the White House's 2011 Response to the Prescription Drug Epidemic includes two action items focused specifically on encouraging and expediting further R&D on ADFs, including priority New Drug Application review by the FDA, and the FDA is granting such priority reviews to applications involving ADF technologies.¹⁴

Likewise, the Drug Enforcement Administration ("DEA") and other HHS agencies, including the FDA, Centers for Disease Control and Prevention ("CDC"), and Substance Abuse and Mental Health Services Administration ("SAMHSA"), have identified the importance of R&D on ADFs of prescription

¹³ 77 Fed. Reg. at 5338.

¹⁴ See Office of National Drug Control Policy, *The Administration's Response to the Prescription Drug Epidemic: Action Items* (2011), Action Items 1.k & 1.m, available at http://www.whitehouse.gov/sites/default/files/ondcp/issues-content/action_items_response_to_the_prescription_drug_epidemic.pdf (last visited Mar. 28, 2012).

pain medications.¹⁵ For example, in an October 2010 presentation on the “Regulatory History of Development of Abuse-Deterrent Formulations,” a speaker from FDA’s Center for Drug Evaluation and Research (“CDER”) noted that “FDA encourages manufacturers to develop new formulations with abuse-deterrent features” and discussed strategies, public campaigns, and other collaborations among DEA, SAMHSA, ONDCP, CDC, FDA, and other agencies and organizations to mitigate the risk of prescription drug abuse and misuse.¹⁶ CMS’ proposal to include ADFs in the definition of line extension undercuts these important Executive Branch policies and initiatives.

B. *ADFs That Reflect Significant R&D Investment are Not Line Extensions Based on the Plain Language of the Statute.*

CMS’ proposed definition of “line extension” fails to exclude ADFs, citing lack of statutory authority as its basis. However, not only does CMS plainly possess, based on the statutory definition of “line extension,” the necessary authority to exclude from the definition of line extension those ADFs that are more than slight alterations of existing products, it *must* do so to carry out Congress’ intent with respect to the line extension provision and current Federal policy to deter prescription drug abuse. Beginning with the statutory definition, Congress defined the term “line extension” as a drug that is “a *new formulation, such as* an extended-release formulation, of a single source drug or an innovator multiple source drug.”¹⁷ This language clearly states that only new formulations “such as” extended release products can be line extensions.

The question then becomes: What new formulations are sufficiently distinct from extended release products to justify CMS excluding the product or product category from the definition of “line extension”? Key to this analysis is that not all products that are new formulations are “line extensions.” Indeed, the plain text of the statutory definition *necessitates* that CMS identify categories of new formulations that are *not* line extensions; otherwise, the Agency would render the “such as” phrase meaningless. The Supreme Court has found that “[s]tatutes must be interpreted, if possible, to give each word some operative effect.”¹⁸ Accordingly, because ADFs are dramatically different from extended-release products for the reasons explained above, CMS should exclude from the definition of line extension ADFs of opioids or other controlled substances that reflect significant R&D investment in connection with approval.

C. *Absent an Appropriate Exclusion for ADFs from CMS’ Proposed Definition of Line Extension, ADF Innovation Will Surely Decline.*

Purdue’s focus on the need for an exemption for ADFs that reflect significant R&D investment is not merely theoretical in nature. At stake is the future of ADF innovation itself. Absent an appropriate exemption for ADFs from the regulatory definition of line extension, ADF innovation will surely decline.

¹⁵ See, e.g., Slide Presentation, “Regulatory History of Development of Abuse-Deterrent Formulations” (Oct. 2010), Larissa Lapteva, CDER/FDA, Deputy Director for Safety, Division of Anesthesia & Analgesia Products, at 6-7.

¹⁶ *Id.*

¹⁷ 42 U.S.C. § 1396r-8(c)(2)(C)(iii) (added by PPACA § 2501(d) as amended by HCERA § 1206) (emphasis added).

¹⁸ *Walters v. Metropolitan Educational Enterprises, Inc.*, 519 U.S. 202, 209 (1997); see also, *United States v. Nordic Village, Inc.*, 503 U.S. 30, 36 (1992) (it is “a settled rule that a statute must, if possible, be construed in such fashion that every word has some operative effect”) (statute in question now superseded); *Mountain States Telephone & Telegraph Co. v. Pueblo of Santa Ana*, 472 U.S. 237, 249 (1985) (it is an “elementary canon of construction that a statute should be interpreted so as not to render one part inoperative”); *Connecticut National Bank v. Germain*, 503 U.S. 249, 253, 254 (1992) ([w]e have stated time and again that courts must presume that a legislature says in a statute what it means and means in a statute what it says there”).

This, in turn, would negatively affect patients' access to improved therapies. As mentioned above, Purdue currently has additional products in development that incorporate ADF technology. Unfortunately, Purdue will be forced to reconsider whether to continue to develop these products if CMS' line extension proposal covers ADFs. We are confident we would not be alone, and that other developers of ADFs would undertake a similar financial analysis.

By imposing this difficult financial position on manufacturers that seek to develop ADFs, CMS' proposal, if finalized, would reduce patient and provider access to important new drugs. This further demonstrates the proposal's conflict with the policies of the Executive Branch, as demonstrated by the White House ONDCP's recognition that, "while we must ensure better access to prescription drugs to alleviate suffering, it is also vital that we do all we can to reduce the diversion and abuse of pharmaceuticals."¹⁹ CMS' proposed definition undercuts both of those important goals. Thus, to protect patient access, deter prescription drug abuse, and encourage the continued development of ADFs, we urge CMS to adopt an appropriate exclusion for ADFs of opioids or other controlled substances that reflect significant R&D investment in connection with approval.

D. *Absent an Appropriate Exclusion for ADFs from the Regulatory Definition of Line Extension, the Costs to the Medicaid Program Will Increase.*

On March 22, 2012, just 11 days before our submission of these comments, the Senate Finance Committee's Health Care Subcommittee held a hearing entitled, "Prescription Drug Abuse: How are Medicare and Medicaid Adapting to the Challenge?" During the hearing, Subcommittee members and witnesses discussed the "epidemic" of prescription drug abuse and its very significant costs for individuals, families, and the health care system. Subcommittee Chairman Jay Rockefeller recognized that "prescription drugs can and do work wonders for millions of people" and "can be a godsend" for "people with conditions like chronic pain and severe mental illness;" however, he added, "the availability of powerful prescription drugs has in some ways gotten ahead of our ability to prescribe them safely."²⁰ Notably, Subcommittee members and witnesses urged the implementation of safeguards in the Medicaid and Medicare programs to help reduce prescription drug abuse within these programs. On this point, Subcommittee Ranking Member Charles Grassley noted that, "[a]s health care payers, Medicare and Medicaid have a significant role to play in guiding solutions to this growing problem;" however, he added that "states have overwhelmingly confirmed that *CMS has been an absent partner* in helping to lower prescription drug abuse in Medicaid."²¹

CMS' role in advancing these safeguards and initiatives is crucial because, as the Subcommittee members and hearing witnesses recognized, prescription drug abuse increases costs to the Medicaid and Medicare programs, not only with respect to inappropriately dispensed and / or diverted prescriptions and the costs associated with patients seeking prescriptions from multiple physicians, but also with respect to the medical costs associated with treatment of overdoses and other complications and consequences related to prescription drug abuse. As one witness noted, "[w]hile regulations and other approaches

¹⁹ ONDCP, Fact Sheet, *A Response to the Epidemic of Prescription Drug Abuse* (Apr. 2011), at 1, available at http://www.whitehouse.gov/sites/default/files/ondcp/Fact_Sheets/prescription_drug_abuse_fact_sheet_4-25-11.pdf (last visited Mar. 28, 2012).

²⁰ Written Statement of Sen. Jay Rockefeller, S. Fin. Comm. Subcomm. On Health Care Hearing: "Prescription Drug Abuse: How Are Medicare and Medicaid Adapting to the Challenge?" (Mar. 22, 2012).

²¹ Written Statement of Sen. Chuck Grassley, S. Fin. Comm. Subcomm. On Health Care Hearing: "Prescription Drug Abuse: How Are Medicare and Medicaid Adapting to the Challenge?" (Mar. 22, 2012) (emphasis added).

involving Medicare and Medicaid cannot solve this problem alone, they can certainly play an important role.”²²

Importantly, witnesses at the hearing discussed a number of potential solutions to help combat prescription drug abuse by the Medicaid and Medicare population and control program and State and Federal enforcement costs related to such abuse. Among the solutions offered was the development of newer, safer versions of addictive drugs, in addition to expanded use of monitoring programs, better utilization data and coordination with law enforcement and other groups. It is clear that a combination of solutions must be employed to have an impact on the problem.

Finding ways to deter abuse will be an important step to help reduce those long-term costs and the tragic effects that prescription drug abuse has on American families. If CMS fails to create an appropriate exemption for ADFs that reflect significant R&D investment, the long-term costs to the Medicaid and other Federal health care programs will inevitably increase, as will the costs—both financial and social—to society as a whole. To avoid this result, we urge CMS to adopt the bright-line test discussed in the next section.

E. *Purdue’s Proposed Bright-Line Test for Excluding Appropriate ADFs Strikes the Right Balance.*

For all the reasons noted above, we urge CMS to adopt an appropriate bright-line test to identify ADFs of an opioid or other controlled substance that reflect significant R&D investment in connection with approval.

Specifically, we urge CMS to exclude from the definition of line extension an ADF of an opioid or other controlled substance for which (1) FDA requires one or more pre-approval or post-approval studies or trials (other than for bioequivalence purposes or to gain approval for the extended release properties of a drug), or (2) the product meets FDA’s anticipated (by the end of 2012) guidance on the development of ADFs.

This is a workable, common sense test that will exempt those ADFs that the White House and FDA and other government agencies are working hard to encourage, while allowing CMS to effectuate Congress’ intent to close the rebate loophole on slightly-altered new formulations, such as extended release products.

F. *CMS’ Line Extension Proposal Violates the APA and Antitrust Laws.*

1. *CMS’ Proposed Line Extension Test—Based on Chemical Types—Is Contrary to Statute and Would Be Arbitrary and Capricious If Finalized.*

CMS’ proposed and exceedingly broad test to identify line extensions clearly contradicts this statutory definition and is thus invalid under the Administrative Procedure Act (“APA”).²³ Specifically, in addition to Chemical Type 3 (new formulation), CMS has proposed to include all of the following in the line extension definition: Chemical Type 2 (new ester, salt, or other noncovalent derivative),

²² Written Testimony of Jeffrey Coben, MD, Director of the W, Va. Univ. Injury Control Research Center, before the S. Fin. Comm. Subcomm. On Health Care (Mar. 22, 2012).

²³ 5 U.S.C. § 706(2)(A) (stating that a reviewing court shall hold unlawful and set aside agency action that is “not in accordance with law”).

Chemical Type 4 (new combination), and Chemical Type 6 (new indication).²⁴ Based on the plain meaning of the descriptions that FDA has assigned to these designations, however, Chemical Types 2, 4, and 6 clearly are not “new formulations.” For that reason, it is not appropriate as a matter of statutory interpretation to include Chemical Type 2, 4, or 6 in the regulatory definition of a line extension.

Because it is the “unambiguously expressed intent of Congress”²⁵ to limit the alternative rebate to “new formulations,” and because Chemical Types 2, 4, and 6 are not “new formulations,” any rule applying the line extension rebate to those Chemical Types would be contrary to statute. Moreover, CMS’ proposal to include Chemical Types 2, 4, and 6 as line extensions would, if adopted in the final rule, be arbitrary and capricious under the APA.²⁶ Congress intended for the alternative rebate to apply only to “new formulations” that reflect “slight alterations” to existing products,²⁷ but the inclusion of Chemical Types 2, 4, and 6 would extend the alternative rebate to new versions, new combinations, and new indications which not only are not “new formulations” but also may have required significant investment and may represent substantial product changes and advancements. Failure to consider these fundamental issues and the implications of this result would render the rule arbitrary and capricious.²⁸

In addition, the Agency’s perfunctory explanations as to why its proposal includes these Chemical Types—explanations which note only that these types represent changes to existing products, without any explanation as to which changes are appropriate to include under the statutory text²⁹—offer only the sort of conclusory statements that, under applicable APA precedents, do not fulfill CMS’ obligation to offer a “satisfactory explanation for its action.”³⁰ Further, CMS’ stated reasoning with respect to Chemical Types 6 and 8 is internally inconsistent³¹ and thus constitutes an unreasonable interpretation that is arbitrary and capricious under the APA.³²

2. CMS’ Line Extension Proposal Raises Serious Antitrust and Other Legal Concerns.

We note with serious concern CMS’ proposal that manufacturers be responsible for ensuring that “all necessary product and pricing data, whether such information is for the initial brand name listed drug

²⁴ 77 Fed. Reg. at 5338–5339.

²⁵ *Chevron, U.S.A., Inc. v. NRDC, Inc.*, 467 U.S. 837, 842–43 (1984).

²⁶ 5 U.S.C. § 706(2)(A).

²⁷ *See supra* § I(B).

²⁸ *Motor Vehicle Mfrs. Ass’n v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 43 (1983) (holding that a rule is arbitrary and capricious if the agency “entirely failed to consider an important aspect of the problem”).

²⁹ 77 Fed. Reg. at 5339.

³⁰ *State Farm*, 463 U.S. at 43. *See, e.g., AT&T Corp. v. FCC*, 236 F.3d 729, 737 (D.C. Cir. 2001) (“[C]onclusory statements cannot substitute for the reasoned explanation that is wanting in this decision.” (quoting *Arco Oil & Gas Co. v. FERC*, 932 F.2d 1501, 1504 (D.C. Cir. 1991))); *Gen. Chem. Corp. v. United States*, 817 F.2d 844, 855 (D.C. Cir. 1987) (per curiam) (stating that the agency’s analysis “was so incomplete and conclusory as to fall below the standard of reasoned decisionmaking”).

³¹ Specifically, CMS acknowledges that, when there is “no new formulation” of the initial brand name listed drug, there is no line extension; indeed, under this exact reasoning, the Agency has declined to include Chemical Type 8 products, over-the-counter switch products, in its proposed line extension definition. 77 Fed. Reg. 5339 (“[W]e do not propose to consider this Chemical Type [8] as a line extension because there is no new formulation of the initial brand name listed drug.”). It would be wholly inconsistent, arbitrary, and capricious to apply different reasoning with respect to Chemical Type 6 products, which likewise involve “no new formulation” of the drug.

³² *See Gen. Chem. Corp.*, 817 F.2d at 857 (finding agency action “arbitrary and capricious” because the supporting analysis was “internally inconsistent and inadequately explained”), *cited in Portland Cement Ass’n v. EPA*, 665 F.3d 177, 187 (D.C. Cir. 2011).

or the line extension drug, are exchanged between the manufacturer of the initial brand name listed drug and the manufacturer of the line extension drug to accurately calculate the URA for the line extension drug and provide rebates in accordance with the statute.”³³ This language suggests the possibility that a single source drug manufactured by one manufacturer could be treated as a “line extension” of another manufacturer’s single source or innovator multiple source drug for purposes of the additional rebate provision. This proposal is troubling for a number of reasons.

First, the concept of a “line extension” as used in the statute and legislative history (discussed above in Section I(A)) suggests that Congress intended to eliminate the incentive for a manufacturer to make slight alterations *to its own* existing products in order to avoid increased rebates. It would therefore be inconsistent with the statute’s text and purpose to create a rule under which one manufacturer’s product could trigger the line extension rebate for another manufacturer. This also makes sense as a matter of policy and a practice, because, absent a licensing agreement or other similar financial arrangement, the manufacturer of the new formulation would have no control or influence over the prices set by the other manufacturer, and the other manufacturer stands to gain nothing from the introduction of the new formulation. In other words, there is no loophole to close.

Second, exchange of sensitive cost and price information between direct competitors raises significant antitrust issues under the Sherman Act, which CMS previously recognized when finalizing pricing regulations in the 2007 Medicaid Final Rule. In that rule, CMS ultimately rejected, for this very reason, its proposal for primary manufacturers of authorized generics to obtain quarterly AMP data from a secondary manufacturer and calculate a blended AMP based on sales in the market of a secondary manufacturer. In making that decision, CMS noted that “[s]everal commenters expressed concern that our proposed policy would require the primary manufacturer and the secondary manufacturer to share confidential pricing information that may result in anti-trust violations,” and stated that the Agency therefore had “revised the authorized generics provision” in a manner intended to “avoid any anti-trust concerns that could potentially arise as a result of pricing data being exchanged between manufacturers.”³⁴ CMS should exercise equal caution in its implementation of the line extension provision and must avoid an interpretation that would clearly implicate antitrust laws.

Third, to anticipate possible additional rebate liability when setting a price for the line extension, a manufacturer of the new product would need access, at the very least, to the other manufacturer’s AMP information, which is typically considered confidential under the Medicaid Drug Rebate Statute.³⁵

Finally, under the proposal, manufacturers would be required to rely upon and certify pricing data obtained from other manufacturers. This would be problematic from an operational and legal perspective, and it may require manufacturers to negotiate costly indemnification agreements—which could cover only civil, and not potential criminal, liability. Disturbingly, the proposal also creates the incentive for original manufacturers to raise their prices so that line extension manufacturers (who are their competitors) are penalized with even greater Medicaid rebate liability.

³³ 77 Fed. Reg. at 5341.

³⁴ 72 Fed. Reg. 39,142, 39,201 (Jul. 17, 2007); *see also, id.* at 39,200 (“[I]n light of the comments we have received . . . , we believe that to require the primary manufacturer to include sales of the secondary manufacturer within its calculation would be problematic from an administrative accounting and anti-trust perspective.”); *id.* (“At this time, based on concerns raised by the commenters, primary manufacturers would not be required to incorporate the sales of the authorized generic in the AMP of the brand drug; instead, [t]he primary manufacturer and secondary manufacturer would be responsible for separately calculating their own AMP”).

³⁵ *See* 42 U.S.C. § 1396r-8(b)(3)(D).

For these important legal, policy, and practical reasons, we strongly urge CMS to clarify that a drug manufactured by one manufacturer will not be treated as a "line extension" of another manufacturer's single source or innovator multiple source drug absent a licensing or similar financial relationship between the two manufacturers.

II. Support of BIO and PhRMA Comments.

In addition to CMS' line extension proposal, for which Purdue – as an ADF manufacturer – has a unique perspective, there are other topics addressed in the Proposed Rule about which Purdue has significant concern. These topics are of general concern to many manufacturers and are addressed in the comment letters submitted by two industry trade groups – BIO and PhRMA – in which Purdue is a member. We express our general support for BIO and PhRMA's comments on these topics, particularly with respect to the topics listed below. In one instance, we have provided threshold comments to the comments submitted by BIO and PhRMA.

- A. *CMS Should Not Expand the Definition of "States" and "United States" to Include the Territories – Proposed 42 C.F.R. § 447.502.*
- B. *CMS Should Retain the Presumed Inclusion Approach to the AMP Calculation – Proposed 42 C.F.R. § 447.504.*
- C. *CMS Should Clarify that the Best Price ("BP") Exclusion for Bona Fide Service Fees ("BFSFs") Applies to BFSFs Paid to any BP-eligible Entity, Such as Pharmacy Benefit Managers – Proposed 42 C.F.R. §§ 447.502 & 447.505(c)(16).*
- D. *We Have Serious Concerns with the Proposed 5i Calculation and the Associated "Not Generally Dispensed" Determination – Proposed 42 C.F.R. §§ 447.504(d) & 447.507.*
 - a. *CMS Should Allow Manufacturers to Apply a Qualitative Approach to the "Not Generally Dispensed Determination," Based on Reasonable Assumptions.*

Purdue suggests that, in lieu of the proposed 90/10 quantitative approach, CMS should permit manufacturers to make reasonable assumptions on whether a particular product is subject to the 5i AMP calculation. This approach would allow manufacturers to evaluate their products and plan accordingly for the relevant calculations, based on a reasonable and fair assessment of the product and relevant sales data. We believe this approach would balance appropriately CMS' desire to provide a reasonably definitive meaning to the "not generally dispensed" standard,³⁶ while at the same time enhancing manufacturers' ability to plan accordingly for their calculations and, moreover, mitigating administrative complexities for both manufacturers as well as the Agency.

- b. *The "Not Generally Dispensed" Determination for 5i Drugs Should Be Made on An Annual Basis.*
- E. *CMS Should Clarify that Goods Returned in Good Faith Are Excluded from AMP and BP – Proposed 42 C.F.R. §§ 447.504(c)(16) & 447.505(c)(14).*

³⁶ See 77 Fed. Reg. at 5335.

- F. *CMS Should Clarify the Proposed Smoothing Methodology to Treat Lagged Units the Same as in the ASP Context – Proposed 42 C.F.R. § 447.510(d)(2)(iii).*
- G. *CMS Should Clarify the Exclusion for Prices Under the 340B Drug Pricing Program So That Covered Entity Compliance Does Not Affect the BP Calculation – Proposed 42 C.F.R. § 447.505(c)(2).*
- H. *CMS' Grossly Underestimates the Costs to Manufacturers For Coming into Compliance with the Proposed Rule, Particularly with Respect to the Proposed Build-Up Method.*

* * *

Thank you for considering the issues discussed above.

Sincerely,



LaDonna L. Steiner
Associate General Counsel

cc: The Honorable Kathleen Sebelius, Secretary, U.S. Department of Health and Human Services
R. Gil Kerlikowske, Director, White House Office of National Drug Control Policy
Margaret Hamburg, M.D., Commissioner, U.S. Food and Drug Administration

United States Senate
WASHINGTON, DC 20510

August 10, 2012

Hon. Kathleen Sebelius
Secretary
U.S. Department of Health and Human Services
200 Independence Avenue, SW
Washington, DC 20201

Dear Secretary Sebelius:

We write to share our concern about a proposed rule issued by the Centers for Medicare & Medicaid Services (CMS) in January 2012 entitled *Medicaid Program; Covered Outpatient Drugs*, which implements provisions of the Patient Protection and Affordable Care Act, as amended (PPACA). We believe that, as written, the CMS proposal with regard to the definition of "line extensions" would take away a significant incentive for the development of abuse deterrent formulations (ADFs) of opioid drugs.

As you know, the White House's Office of National Drug Control Policy (ONDCP) has described prescription drug abuse as the nation's fastest-growing drug problem and has established a comprehensive plan, along with other federal agencies, to combat this growing crisis. Drug manufacturers have a critical role to play in this effort, specifically by developing abuse deterrent formulations that are more difficult to misuse and abuse. The development of ADFs will result in drugs that cannot be easily cut, broken, crushed, or dissolved to release more medication; but this frontier of medical research will require a significant investment of time and resources by manufacturers.

We are concerned that the definition of "line extension" in the proposed rule would create unnecessary hurdles for the companies that we are relying on to develop these abuse-deterrent formulations. In order to avoid creating such barriers, we respectfully request that you revise the proposed definition of "line extension" to exclude an abuse deterrent formulation of a controlled substance for which the U.S. Food and Drug Administration (FDA) required one or more pre- or post-approval studies or clinical trials (other than for bioequivalence or bioavailability purposes) or meets FDA's anticipated (by the end of 2012) guidance on the development of abuse deterrent formulations.

We believe that this narrow policy change would impact only a small number of products being developed as ADFs but would have a tremendous impact on national

efforts to combat prescription drug abuse, without impeding congressional action to close a loophole in Medicaid rebate policy. We appreciate your attention to this important matter and look forward to the opportunity to discuss this issue with you in more detail.

Sincerely,

A handwritten signature in blue ink, appearing to read "Joe Lieberman", written over a horizontal line.

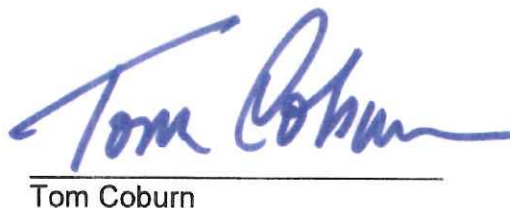
Joseph I. Lieberman

A handwritten signature in blue ink, appearing to read "Mike Crapo", written over a horizontal line.

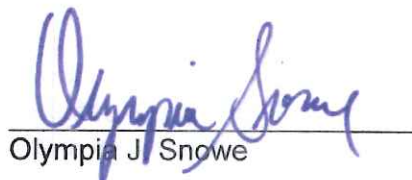
Mike Crapo

A handwritten signature in black ink, appearing to read "R. Burr", written over a horizontal line.

Richard Burr

A handwritten signature in blue ink, appearing to read "Tom Coburn", written over a horizontal line.

Tom Coburn

A handwritten signature in blue ink, appearing to read "Olympia Snowe", written over a horizontal line.

Olympia J. Snowe

A handwritten signature in blue ink, appearing to read "Tom Carper", written over a horizontal line.

Thomas Carper

Congress of the United States
Washington, DC 20515

October 31, 2012

Hon. Kathleen Sebelius
Secretary
U.S. Department of Health and Human Services
200 Independence Avenue, SW
Washington, DC 20201

Dear Secretary Sebelius:

We write to share our concern about a proposed rule issued by the Centers for Medicare & Medicaid Services (CMS) in January 2012 entitled *Medicaid Program; Covered Outpatient Drugs*, which implements provisions of the Patient Protection and Affordable Care Act (PPACA). We believe that, as written, the CMS proposal with regard to the definition of "line extensions" would take away a significant incentive for the development of abuse deterrent formulations (ADFs) of opioid drugs.

As you know, the White House's Office of National Drug Control Policy (ONDCP) has described prescription drug abuse as the nation's fastest-growing drug problem and has established a comprehensive plan, along with other federal agencies, to combat this growing crisis. Drug manufacturers have a critical role to play in this effort, specifically by developing abuse deterrent formulations that are more difficult to misuse and abuse. The development of ADFs will result in drugs that cannot be easily cut, broken, crushed, or dissolved to release more medication; but this frontier of medical research will require a significant investment of time and resources by manufacturers.

We are concerned that the definition of "line extension" in the proposed rule would create unnecessary hurdles for the companies that we are relying on to develop these abuse-deterrent formulations. In order to avoid creating such barriers, we respectfully request that you revise the proposed definition of "line extension" to exclude an abuse deterrent formulation of a controlled substance for which the U.S. Food and Drug Administration (FDA) required one or more pre- or post-approval studies or clinical trials (other than for bioequivalence or bioavailability purposes) or meets FDA's anticipated (by the end of 2012) guidance on the development of abuse deterrent formulations.

We believe that this narrow policy change would impact only a small number of products being developed as ADFs but would have a tremendous impact on national efforts to combat

prescription drug abuse, without impeding congressional action to close a loophole in Medicaid rebate policy. We appreciate your attention to this important matter and look forward to the opportunity to discuss this issue with you in more detail.

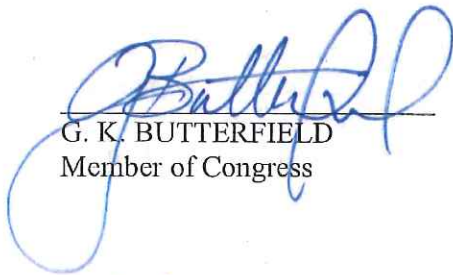
Sincerely,



BRETT GUTHRIE
Member of Congress



EDOLPHUS TOWNS
Member of Congress



G. K. BUTTERFIELD
Member of Congress



MICHAEL BURGESS, M.D.
Member of Congress



MARSHA BLACKBURN
Member of Congress



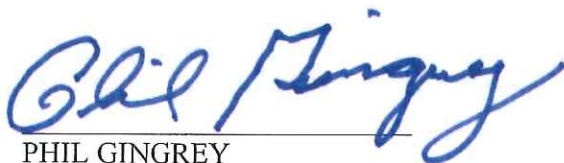
MIKE ROSS
Member of Congress



JOHN CARTER
Member of Congress



PETE OLSON
Member of Congress



PHIL GINGREY
Member of Congress

RENEE L. ELLMERS
2ND DISTRICT, NORTH CAROLINA

426 CANNON HOUSE OFFICE BUILDING
WASHINGTON, DC 20515
(202) 225-4531

ENERGY AND COMMERCE
SUBCOMMITTEE ON
COMMUNICATIONS AND TECHNOLOGY

SUBCOMMITTEE ON
HEALTH

SUBCOMMITTEE ON
OVERSIGHT AND INVESTIGATIONS

Congress of the United States
House of Representatives

Washington, DC 20515-3302

September 17, 2014

The Honorable Sylvia Burwell
Secretary
U.S. Department of Health and Human Services
200 Independence Avenue, SW
Washington, DC 20201

Dear Secretary Burwell:

We want to share our ongoing interest in the February 2012 Centers for Medicare & Medicaid Services (CMS) proposed rule entitled *Medicaid Program; Covered Outpatient Drugs* (CMS-2345-P).

The proposed rule implements provisions of the Patient Protection and Affordable Care Act, as amended (ACA). Unfortunately, the proposal's "line extension" provisions create a strong disincentive for companies to develop abuse deterrent formulations (ADFs) for opioid drugs to curb abuse of prescription drugs. The White House's Office of National Drug Control Policy (ONDCP) has found prescription drug abuse to be our nation's fastest-growing drug problem. ONDCP and other federal agencies established a comprehensive strategy to fight this crisis, which includes encouraging pharmaceutical manufacturers to develop ADF technology.

Congress, the Congressional Budget Office (CBO), HHS Office of Inspector General (OIG), and the Executive Branch all were focused on closing the "loophole" that could enable manufacturers to "reset" the Medicaid rebate based on slight alterations to existing products. CMS itself has recognized that ADF technology is more than a slight alteration. The February 2012 Proposed Rule highlights the advantages of ADF technologies, by observing that, "preventing alternate routes of administration, or employing physical barriers that resist common methods of tampering, . . . abuse deterrent formulations (ADFs) have the potential to decrease abuse of prescription drugs and improve patient and public safety." Despite this observation, CMS proposed to apply line extension penalties to medicines that required extensive research to develop.

We understand that the final rule will not be released any time in the near future. We are extremely frustrated by the continuing delay because it is unreasonable for companies developing ADF technology to have continuing uncertainty on how their products will be classified. Categorizing them as mere "line extensions" of current products discourages companies from developing these drugs. In fact, it will be more costly for manufacturers to offer Medicaid rebate for products with ADF technology than if they were "new" drugs—even though manufacturers' development costs for ADF are sizable. In its proposed rule, CMS argued that an ADF is an "extended release" formulation, so it is merely a line extension. We respectfully disagree and believe that CMS misinterpreted both the definition of line extension and the intent of the provision as contemplated by Congress, the Administration, the HHS OIG and CBO.

The Food and Drug Administration (FDA) has created a high standard for new technology development, making it immensely difficult to integrate abuse deterrent properties into an extended release formulation. ADF products are unique because the extended release formulation delivers an active drug substance, while at the same time creates barriers to prevent abuse of that same active drug substance.

Drug manufacturers play a crucial role in this undertaking, specifically by developing formulations of drugs that are more difficult to abuse. This type of cutting-edge technology is not easy to create and requires considerable investment of both time and resources by manufacturers.

We also believe that the proposed rule's definition of "line extension" goes beyond the intent of the statute, creating needless and counterproductive hurdles for companies working on formulations with abuse-deterrent properties. To prevent such barriers, we ask that controlled substances with abuse deterrent formulations be excluded from the proposed definition of "line extension" in the final rule.

The exclusion should be applied when that product is one for which FDA required one or more pre- or post-approval studies or clinical trials (other than for bioequivalence or bioavailability purposes) or meets the comprehensive requirements set out in FDA's 2012 draft guidance on the development of abuse deterrent formulations. This definitional change would be consistent with congressional intent and would only affect a limited number of products, specifically those being developed as ADFs. It also would have a tremendous positive impact on efforts to combat prescription drug abuse without interfering with congressional action to close a loophole in Medicaid rebate policy. Therefore, we urge CMS to move quickly to exempt these products from any definition of "line extension" in any Final Rule or agency communication.

We appreciate your attention to this critical issue and look forward to working with you in order to ensure that congressional intent is followed.

Sincerely,



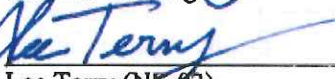
Renee Ellmers (NC-02)
Member of Congress



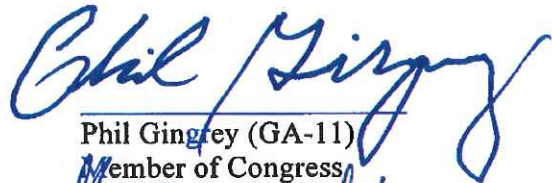
Pete Olson (TX-22)
Member of Congress



Michael Burgess (TX-26)
Member of Congress



Lee Terry (NE-02)
Member of Congress



Phil Gingrey (GA-11)
Member of Congress



Marsha Blackburn (TN-07)
Member of Congress



G.K. Butterfield (NC-01)
Member of Congress

United States Senate

WASHINGTON, DC 20510

December 9, 2014

The Honorable Sylvia Burwell
Secretary
U.S. Department of Health and Human Services
200 Independence Avenue, SW
Washington, DC 20201

Dear Secretary Burwell:

We write with respect to the proposed rule issued by the Centers for Medicare and Medicaid Services (CMS) in 2012 entitled, "Medicaid Program: Covered Outpatient Drugs (CMS-2345-P)." If finalized, this rule would include abuse-deterrent formulations of existing drugs as "line extensions," and we are concerned that such a policy outcome would be a strong disincentive for manufacturers to develop these potentially life-saving technologies.

Prescription opioid overdose continues to be a major public health concern nationwide. The increased use of abuse-deterrent properties in prescription opioids presents a promising path forward in combating this epidemic as these tools make manipulation of these drugs for abuse and misuse more difficult. In fact, the U.S. Food and Drug Administration (FDA) has stated it "considers the development of these products a high public health priority."¹ However, creating abuse-deterrent formulations requires significant research investment. The FDA has also indicated that these technologies must go through additional clinical analysis, which will add to the overall cost of their development. These hurdles generally distinguish abuse-deterrent formulations from other changes to existing drugs considered in the definition of "line extension," such as adding extended-release formulations, which present varying levels of investment, regulatory review, and ultimately, regulatory burden.

We again underscore our concern that the definition of "line extension" in the proposed rule would create unnecessary hurdles for companies that we are relying on to develop abuse-deterrent formulations. In order to avoid creating such barriers, we respectfully request that you review the proposed definition of "line extension" to exclude an abuse-deterrent formulation of a controlled substance for which the FDA required one or more pre- or post-approval studies or clinical trials (other than bioequivalence or bioavailability purposes) or meets FDA's guidance on the development of abuse-deterrent formulations.

¹ Food and Drug Administration, "Abuse-Deterrent Opioids – Evaluation and Labeling – Draft," January 2013; <http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/ucm334807.htm>.

Thank you in advance for your attention to this issue. We look forward to working with you to advance innovations, including abuse-deterrent technologies, as part of combating prescription drug abuse.

Sincerely,



Tom A. Coburn, M.D.
U.S. Senator



Richard Burr
U.S. Senator



THE SECRETARY OF HEALTH AND HUMAN SERVICES
WASHINGTON, D.C. 20201

DEC 16 2014

The Honorable Renee Ellmers
U.S. House of Representatives
Washington, DC 20515

Dear Representative Ellmers:

Thank you for your letter regarding the Centers for Medicare & Medicaid Services' (CMS) proposed rule titled "Medicaid Program; Covered Outpatient Drugs." I appreciate hearing from you about this important regulation. You expressed concern with the proposal to include abuse deterrent formulations (ADFs) in the definition of line extension. You requested that the final rule exclude controlled substances from the definition of line extension if they meet the requirements in the Food and Drug Administration's (FDA) 2013 draft guidance on the development of abuse deterrent formulations or if the drug is an ADF product for which FDA required one or more pre-or post-approval studies or clinical trials (other than for bioequivalence or bioavailability purposes).

CMS received comments on the proposed line extension drug provisions that echoed these concerns and is closely reviewing all of the comments. I assure you that we will take this feedback into consideration as we continue work on the final rule. HHS shares your concerns about prescription drug abuse, including the misuse and abuse of opioid analgesics, which has resulted in many injuries and deaths across the United States. Agencies across HHS are committed to partnering with states to address this public health crisis, as evidenced by the 50-state meeting we convened on this topic earlier this year.

Thank you for sharing your thoughts on this matter. I will also provide this response to the co-signers of your letter.

Sincerely,

Sylvia M. Burwell

Option 1

The Committee is concerned about the national epidemic of prescription drug abuse, particularly the abuse of opioid-based pain medications. It is the Committee's understanding that the Department's Centers for Medicare and Medicaid Services may not be following Congressional intent in its interpretation of the term "line extension" in ACA (PL 111-148 Section 2501) when it published Covered Outpatient Drugs Proposed Rule (CMS-2345-P) over 3 years ago. Congressional intent was clear that it was defining a "line extension" to target those new formulations that are merely "slight alterations" of existing products. See the House Energy and Commerce Committee Report 111-299, Part I on America's Affordable Health Choices Act of 2009, Section 1742, p. 635 (2009). It appears that CMS' interpretation may be in conflict with FDA's approval of New Drug Applications (NDA) for pain medications containing abuse deterrent properties. It seems inconsistent that an NDA that meets the FDA's January 2013 Draft Guidance for Industry: Abuse Deterrent Opioids - Evaluation and Labeling can be approved by FDA and yet still potentially be considered a "line extension" for purposes of determining Medicaid rebates. The committee is concerned that applying "line extension" Medicaid rebates to these drugs will discourage the further development of abuse deterrent formulations for medications that can be abused.

Q: Will the Secretary commit to reviewing the "line extension" definition in the proposed rule and do a comparison analysis with FDA of new drug approvals for opioid-based drugs containing abuse deterrent properties?

Option 2

I am concerned about the national epidemic of prescription drug abuse, particularly the abuse of opioid-based pain medications. Opioids with abuser deterrent properties are proving to be one tool in combating the misuse of these medicines. Congressional intent was clear that it was defining a "line extension" to target those new formulations that are merely "slight alterations" of existing products. See the House Energy and Commerce Committee Report 111-299, Part I on America's Affordable Health Choices Act of 2009, Section 1742, p. 635 (2009).

Q1: What is the status of the Covered Outpatient Drug Proposed Rule (CMS-2345-P) first proposed over 3 years ago?

Q2: Is the Department concerned that CMS' interpretation in the draft rule may be a disincentive to the research, development and market introduction of medications with abuse deterrent properties?

Q3: While FDA held a two day hearing in October 2014 on how to incentivize the development of drugs with abuse deterrent properties, and FDA is encouraging manufacturers to develop these drugs, how can the Department consider production of opioids containing a combination of previously approved formulations and new abuse deterrent technologies as "line extensions"?

Q4: Has the Department consulted with the FDA concerning the process for formulating drugs with new abuse deterrent properties when determining the definition of line extension?

Q5: Will the Secretary commit to reviewing the "line extension" definition in the proposed rule and do a comparison analysis of new drug approvals for opioid-based drugs containing abuse deterrent properties?



CLAAD

Center for Lawful Access
and Abuse Deterrence

September 10, 2015

The Honorable Sylvia Mathews Burwell
Secretary
Department of Health and Human Services
200 Independence Avenue, SW
Washington, D.C. 20201

Howard Shelanski, Administrator
Office of Information and Regulatory Affairs
Office of Management and Budget
725 17th Street, NW
Washington, D.C. 20503

Dear Secretary Burwell and Administrator Shelanski:

On behalf of patients, providers and manufacturers, we are writing today to strongly recommend against including medications with abuse-deterrent formulations (ADF) in the line extension definition proposed in the February 2012 Centers for Medicare & Medicaid Services (CMS) proposed rule entitled *Medicaid Program; Covered Outpatient Drugs* (CMS-2345-F). It is our understanding that the proposed Final Rule is currently under review by the Office of Management and Budget (OMB). Without modifications to the proposed rule, manufacturers of ADF products would be subject to additional rebate obligations under the Medicaid program, which would serve as a major disincentive to developing ADF products.

We appreciate that patient access to pain medication must be balanced with the risk of prescription drug abuse, which is a serious public health crisis in too many communities across this nation. Indeed, opioid analgesics have been implicated in soaring rates of drug overdose deaths over the last decade. In response, a number of national and federal initiatives are tackling this challenge head-on, most recently the July announcement by the Department of Health and Human Services (HHS) of a new opioid initiative focused on opioid prescribing practices, expanded use of naloxone and expanded use of Medication-Assisted Treatment.

We enthusiastically support HHS' initiative and many of us will be active participants in its implementation. However, we must not lose sight of the fact that these drugs are critical for modern pain management, especially for patients with cancer and other serious conditions. As such, we have supported long-standing efforts by the Food and Drug Administration (FDA) and industry to develop newer formulations of opioid analgesics that may deter abuse and misuse. As one tangible outcome of this effort, in April 2015, the FDA finalized the "Abuse-Deterrent Opioids — Evaluation and Labeling Guidance for Industry." This guidance clarified the rigorous development pathway for ADF products, which requires a significant investment of time and resources by manufacturers. A number of agencies within HHS, including the National Institute of Drug Abuse at the National Institutes of Health and the Substance Abuse and Mental Health Services Administration, as well as the Office of National Drug Control Policy at the White House, are very supportive of ADF science and drug development.

In contrast, CMS' proposed line extension policy is not supportive and would seriously threaten industry incentive to create ADF products. Further, the CMS policy does not reflect the significant advances in the underlying science nor the development of robust regulatory frameworks, which have been underway for nearly a decade. Many stakeholders have expressed

Center for Lawful Access and Abuse Deterrence

1000 Potomac St., NW, Suite 150-A · Washington, DC 20007 · 202-599-8435 · www.claad.org · @claad_coalition

concern with CMS' Proposed Rule, including senior members of Congress who have sent letters to HHS leadership stating this policy runs afoul of Congressional intent.

Again, we strongly request that medications with abuse-deterrent formulations (ADF) not be included in the line extension definition for outpatient drugs in CMS' Final Rule. We would like to discuss with you this matter in more detail as soon as possible, and will be in contact to request a meeting to this end.

Sincerely,

Center for Lawful Access and Abuse Deterrence
American Academy of Pain Management
American Society for Pain Management Nursing
Atlantic Pharma
Chronic Pain Research Group, University at Buffalo School of Pharmacy and
Pharmaceutical Sciences
Collegium Pharmaceuticals
Community Anti-Drug Coalitions of America (CADCA)
Egalet Corporation
Elysium Therapeutics
Endo Pharmaceuticals
Gatekeeper Innovation, Inc.
Grünenthal USA, Inc.
Healthcare Distribution Management Association
Inspirion Delivery Technologies
Interstitial Cystitis Association
Johnson & Johnson
Kem Pharm
National Fibromyalgia & Chronic Pain Association
National Hospice and Palliative Care Organization
Pain Connection-Chronic Pain Outreach Center, Inc.
Partnership for Drug-Free Kids
Pernix Therapeutics
Project Lazarus
Purdue Pharmaceuticals
Reflex Sympathetic Dystrophy Syndrome Association
Teva Pharmaceuticals
The Pain Community
Wisconsin Pain Initiative
U. S. Pain Foundation