DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Parts 433, 438, and 447

[CMS–2434–P]

RIN 0938–AU28

Medicaid Program; Misclassification of Drugs, Program Administration and Program Integrity Updates Under the Medicaid Drug Rebate Program

AGENCY: Centers for Medicare & Medicaid Services (CMS), Department of Health and Human Services (HHS).

ACTION: Proposed rule.

SUMMARY: This proposed rule would seek to implement policies in the Medicaid Drug Rebate Program (MDRP) related to the new legislative requirements in the Medicaid Services Investment and Accountability Act of 2019 (MSIAA), which are needed to address drug misclassification, as well as drug pricing and product data misreporting by manufacturers. Additionally, we are proposing several other program integrity and program administration provisions or modifications in this proposed rule including revising and proposing key definitions used in the MDRP. This proposed rule also designates a time limitation on manufacturers initiating audits with States; clarifies and establishes requirements for State fee-for-service (FFS) pharmacy reimbursement; codifies conditions relating to States claiming FFP for physician-administered drugs (PADs); clarifies the requirement of accumulating price concessions when determining best price; designates drug price verification and transparency through data collection; and proposes two new contracting requirements between States and their Medicaid managed care plans. In addition, this rule includes a proposal unrelated to MDRP that would make revisions to the third-party liability regulation due to Bipartisan Budget Act (BBA) of 2018. Finally, we are proposing to rescind revisions made by the December 31, 2020 final rule ''Medicaid Program; Establishing Minimum Standards in Medicaid State Drug Utilization Review (DUR) and Supporting Value-Based Purchasing (VBP) for Drugs Covered in Medicaid, Revising Medicaid Drug Rebate and Third Party Liability (TPL) Requirements'' to the Determination of Best Price and Determination of Average Manufacturer Price (AMP) sections.

DATES: To be assured consideration, comments must be received at one of the addresses provided below, by July 25, 2023.

ADDRESSES: In commenting, please refer to file code CMS–2434–P.

Comments, including mass comment submissions, must be submitted in one of the following three ways (please choose only one of the ways listed):

1. *Electronically.* You may submit electronic comments on this regulation to *https://www.regulations.gov*. Follow the ''Submit a comment'' instructions.

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–2434–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–2434–P, Mail Stop C4–26–05, 7500 Security Boulevard, Baltimore, MD 21244–1850.

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

FOR FURTHER INFORMATION CONTACT:

Ruth Blatt, (410) 786–1767, for issues related to the definitions of vaccine, noninnovator multiple-source drug, market date, and covered outpatient drug (COD).

Ginger Boscas, (410) 786–3098, for issues related to third party liability.

Michael Forman, (410) 786–2666, for issues related to physician-administered drugs.

Whitney Swears (410) 786–6543, for issues related to time limitation on audits, definition of vaccine, diagnosis on prescriptions, professional dispensing fees, definition of a manufacturer.

Christine Hinds, (410) 786–4578, for issues related to internal investigation, removal of manufacturer rebate cap, drug cost transparency in Medicaid managed care contracts, ''stacking'' when determining best price, and drug price verification through data collection.

Lisa Shochet, (410) 786–5445, for issues related to Beneficiary Identification Number and Processor Control Number (BIN/PCN) and drug misclassifications.

Terry Simananda, (410) 786–8144, for issues related to the Collection of Information and Regulatory Impact Analysis sections.

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 website as soon as possible after they have been received: *https://www.regulations.gov*. Follow the search instructions on that website to view public comments. CMS will not post on *Regulations.gov* public comments that make threats to individuals or institutions or suggest that the individual will take actions to harm the individual. CMS continues to encourage individuals not to submit duplicative comments. We will post acceptable comments from multiple unique commenters even if the content is identical or nearly identical to other comments.

I. Background

A. Introduction

Under the Medicaid program, States may provide coverage of prescribed drugs as an optional benefit 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 the case of a State that provides for medical assistance for covered outpatient drugs (CODs), as provided under section 1902(a)(54) of the Act, the State must comply with the requirements of section 1927 of the Act. Section 1927 of the Act governs the Medicaid Drug Rebate Program (MDRP) and payment for CODs, which are defined in section 1927(k)(2) of the Act. In general, for payment to be made available for CODs under section 1903(a) of the Act, manufacturers must enter into a National Drug Rebate Agreement (NDRA) as set forth in section 1927(a) of the Act. See also section 1903(i)(10) of the Act. The rebates paid by manufacturers to States help to partially offset the Federal and State costs of most outpatient prescription drugs dispensed to Medicaid beneficiaries. The MDRP provides specific requirements for manufacturer rebate agreements, drug pricing submission and confidentiality requirements, the formulas for calculating rebate payments, drug utilization reviews (DUR), and requirements for States for CODs.

With limited exceptions, if a manufacturer wants payment to be

available under Medicaid for their CODs, the manufacturer must participate (have entered into and have in effect a rebate agreement) in the MDRP, and agree to pay rebates for CODs dispensed and paid for under the State Plan. The amount of the rebate is determined by a formula set forth in section 1927(c) of the Act. Generally, the formula to calculate the rebate that applies to a particular drug depends on whether the drug is classified as (1) a single source drug (S drug) or innovator multiple source drug (I drug) (commonly referred to as a brand-name drug), or (2) other drugs, which include noninnovator multiple source drugs (N drug), commonly referred to as generic drugs, among others.

Consistent with section 1927(b)(3)(A) of the Act, a manufacturer must report and certify certain drug product and drug pricing information for CODs to CMS not later than 30 days after the last day of each month and certain drug pricing information and drug product data 30 days after the last day of each quarter of a rebate period. For example, drug pricing information that manufacturers must submit and certify includes average manufacturer price (AMP) and best price data in addition to other information consistent with section 1927(b)(3)(A) of the Act each quarter. We use the reported data to calculate an accurate unit rebate amount (URA) for each covered outpatient drug to assist States with billing manufacturers for rebates. Drug product information that is reported includes the name of the drug, its National Drug Code (NDC), drug category, and drug type, among other items. However, manufacturers ultimately remain responsible for accurately calculating the URA for their drug products. Manufacturers pay rebates to States for each unit of the drug dispensed and paid for under the State Plan on the basis of the URA.

Thus, the failure of a manufacturer to submit and certify timely monthly and quarterly pricing and drug product data for a drug may impede the States' ability to invoice and collect appropriate rebate amounts. If a manufacturer fails to submit timely information, or misreports information, we may be unable to establish accurate URAs due to the misreporting or late reporting. While we provide URAs to the States each quarter to help facilitate billing manufacturers for rebates, it is ultimately the manufacturer's responsibility to assure that accurate rebates are paid to States for their CODs.

One specific element of drug product information that is required to be submitted by manufacturers includes drug category or drug classification information. Generally, drugs classified as single source or innovator multiple source pay higher rebates than those that are classified as an ''other drug,'' such as noninnovator multiple source drugs. In accordance with section 1927(c) of the Act and 42 CFR 447.509, the rebate calculation for a particular COD may also include an additional inflationary component to account for increases in the drug's Average Manufacturer's Price from the base date AMP quarter to the current calendar quarter's AMP. That is, this additional rebate is generally calculated based on the difference between the drug's current quarter AMP and its base date AMP adjusted to the current period by the Consumer Price Index for All Urban Consumers (CPI–U).

Prior to the enactment of the Medicaid Services Investment and Accountability Act of April 2019 (MSIAA) (Pub. L. 116–16; enacted April 18, 2019), section 1927(k)(7)(A)(iv) of the Act defined a single source drug as a covered outpatient drug which is produced or distributed under an original new drug application. Section 1927(k)(7)(A)(ii) of the Act similarly defined an innovator multiple source drug as a multiple source drug that was originally marketed under an original new drug application. A noninnovator multiple source drug was defined at section 1927(k)(7)(A)(iii) of the Act as a multiple source drug that is not an innovator multiple source drug.

Prior to the 2016 Medicaid Covered Outpatient Drug final rule with comment period (COD final rule) (81 FR 5170), the regulatory definitions of a single source and an innovator multiple source drug largely mirrored the statute and defined a drug as a single source or innovator multiple source drug based on whether it was produced, distributed, or marketed under an ''original new drug application.'' The statute did not expressly define ''original NDA''. However, CMS' longstanding interpretation of the term was that an original new drug application (NDA) is an NDA approved under section 505(b)(1) or (2) of the Federal Food, Drug, and Cosmetic Act (FFDCA), as distinguished from one approved under an abbreviated NDA (ANDA) under section 505(j) of the FFDCA (Manufacturer's Release 113).

We codified new regulatory definitions of single source and innovator multiple source drugs in the COD final rule and added a narrow exception for ''certain drugs [that] might be more appropriately treated as if they were approved under an ANDA and classified as a noninnovator multiple source drug'' (81 FR 5191). The COD final rule also added a drug approved under a Biologics License Application (BLA) to the definition of single source drug (81 FR 5203).

In the COD final rule, we also introduced a process by which drug manufacturers could submit a request for a narrow exception to have us recognize individual drugs approved under an NDA as noninnovator multiple source drugs prospectively from the effective date of the COD final rule. Instructions to manufacturers regarding this process were included in Manufacturer Release #98, May 2, 2016 (*https://www.medicaid.gov/medicaid-chip-program-information/by-topics/prescription-drugs/downloads/rx-releases/mfr-releases/mfr-rel-098.pdf*). The COD final rule did not, however, excuse manufacturers from their obligation to correctly report drugs approved under an NDA as either single source or innovator multiple source drugs prior to the effective date of the COD final rule, which was April 1, 2016.

Yet, notwithstanding our interpretation of the statute, many manufacturers have disregarded our reasonable interpretation of the statute and have continued to misreport drugs marketed under an NDA as noninnovator multiple source drugs for periods prior to April 1, 2016 (Manufacturer Release #113-*https://www.medicaid.gov/prescription-drugs/downloads/mfr-rel-113.pdf*).

B. Amendments Made by the Medicaid Services Investment and Accountability Act of 2019 (MSIAA) to Section 1927 of the Act Regarding MDRP Drug Classification Enforcement and Penalties

Section 6 of the MSIAA, titled ''Preventing the Misclassification of Drugs Under the Medicaid Drug Rebate Program,'' amended sections 1903 and 1927 of the Act to specify the definitions for multiple source drug, single source drug and innovator multiple source drug, and to provide the Secretary with additional compliance, oversight and enforcement authorities to ensure compliance with program requirements with respect to manufacturers' reporting of drug product and pricing information, which includes the appropriate classification of a drug. Drug classification refers to how a drug should be classified—as a single source, innovator multiple source, or noninnovator multiple source drug for the purposes of determining the correct rebates that a manufacturer owes

the States.[1] In general, a misclassification in the MDRP occurs when a manufacturer reports and certifies its covered outpatient drug under a drug category that is not supported by the statutory and regulatory definitions of S, I, or N. A drug that is misclassified is likely paying different rebates to States than those supported by statute and regulation.

We published guidance to manufacturers regarding compliance with drug pricing and drug product information reporting under this new law in Manufacturer Release #113 on June 5, 2020. See *https://www.medicaid.gov/prescription-drugs/downloads/mfr-rel-113.pdf*. Here, although much of this law is self-implementing, we are proposing a series of regulatory amendments at §§ 447.509 and 447.510 to implement and codify the statutory changes in regulation. We propose that a misclassification of a drug under the MDRP has occurred or is occurring when a manufacturer reports and certifies to the agency a drug category or drug product information relating to that COD that is not supported by the statutory and regulatory definitions of S, I, or N. We also define a misclassification as a situation in which a manufacturer is correctly reporting its drug category or drug product information for a COD, but is paying a different rebate amount to the States than is supported by the classification.

The MSIAA also amended the Act to expressly require a manufacturer to report not later than 30 days after the last day of each month of a rebate period under the agreement, such drug product information as the Secretary shall require for each of the manufacturer's covered outpatient drugs. We are proposing a definition of ''drug product information'' for the purposes of the MDRP.

Similarly, the MSIAA amended the Act to specify that the reporting of false drug product information and data related to false drug product information would also be subject to possible civil monetary penalties (CMPs) by the HHS Office of the Inspector General (OIG), and to provide specific new authority to the Secretary to issue civil monetary penalties related to knowing misclassifications of drug product or misreported information. These new OIG authorities will not be the subject of this rulemaking.

Under the MSIAA, if a manufacturer fails to correct the misclassification of a drug in a timely manner after receiving notification from the agency that the drug is misclassified, in addition to the manufacturer having to pay past unpaid rebates to the States for the misclassified drug if applicable, the Secretary can take any or all of the following actions: (1) correct the misclassification, using drug product information provided by the manufacturer on behalf of the manufacturer; (2) suspend the misclassified drug, and the drug's status as a covered outpatient drug under the manufacturer's national rebate agreement, and exclude the misclassified drug from FFP (correlating amendments to section 1903 of the Act); and, (3) impose CMPs for each rebate period during which the drug is misclassified subject to certain limitations. The Act expressly provides that the imposition of such penalties may be in addition to other remedies, such as termination from the MDRP, or CMPs under Title XI.

The manufacturer has an affirmative legal obligation to correctly report all necessary drug product and pricing information to the agency on a timely basis as described in the statute and regulations. When issues or questions regarding a drug's classification arise, we generally rely upon various sources of information to be able to determine if a drug is misclassified in MDRP. In its oversight role, the agency will use information reported by manufacturers to us, in combination with publicly available information, to be able to make determinations of whether a drug is misclassified in the MDRP. The agency also uses manufacturer reported information, such as the COD status code, in combination with information available on the Food and Drug Administration's (FDA's) Comprehensive NDC Structured Product Labeling (SPL) Data Elements file (NSDE) *https://download.open.fda.gov/Comprehensive_NDC_SPL_Data_Elements_File.zip*, and information from FDA's drugs@fda web page *https://www.accessdata.fda.gov/scripts/cder/daf/* to be able to verify that the national drug codes (NDCs) reported to the MDRP by manufacturers are appropriately classified and reported.

Codifying these statutory amendments in our regulations provides an opportunity for the agency to give additional clarity to and guidance on the new legal authorities for ensuring oversight of, compliance with, and enforcement of the provisions of the MDRP, and ultimately, to ensure that Federal and State programs are receiving appropriate rebates and that CMS continues to be a stringent steward of the Medicaid program.

TABLE 1—HISTORY OF THE CHANGES IN THE DEFINITION OF SINGLE SOURCE DRUG AND INNOVATOR MULTIPLE SOURCE DRUG

	Statute	Regulation
Prior to April 18, 2019 MSIIA enactment.	Single Source drug Section 1927(k)(7)(A)(iv) of the Act A covered outpatient drug which is produced or distributed under an original new drug application approved by the Food and Drug Administration (FDA), including a drug product marketed by any cross-licensed producers or distributors operating under the new drug application.	

[1] Section 1927(c)(3) of the Act describes rebates for ''other drugs'' and section 1927(c)(3)(A) of the Act, more specifically describes rebates for covered outpatient drugs ''other than single source drugs and innovator multiple source drugs.'' The MDRP reporting system provides for all ''other drugs'' that are covered outpatient drugs to be classified in the system as N drugs, regardless of whether they expressly meet the definition of noninnovator multiple source drug. This reporting methodology has been in effect for the history of the program and interested parties have understood that a covered outpatient drug that was not an S or an I drug is reported in the system as an N drug. In a later section of this proposed rule, we are proposing changes to the regulatory definition of a N drug to more clearly align with the statutory definition of N drug. This is a technical change and is not intended to modify any reporting requirements.

TABLE 1—HISTORY OF THE CHANGES IN THE DEFINITION OF SINGLE SOURCE DRUG AND INNOVATOR MULTIPLE SOURCE DRUG—Continued

	Statute	Regulation
	Innovator Multiple Source Drug Section 1927(k)(7)(A)(ii) of the Act A multiple source drug that was originally marketed under an original new drug application approved by the Food and Drug Administration.	
2007 Final Rule	.....	§ 447.502 Single source drug A covered outpatient drug that is produced or distributed under an original new drug application (NDA) approved by the FDA, including a drug product marketed by any cross-licensed producers or distributors operating under the NDA. It also includes a covered outpatient drug approved under a biological license application (BLA), product license approval (PLA), establishment license approval (ELA) or antibiotic drug approval (ADA) PLA, ELA, or ADA. Innovator Multiple Source Drug A multiple source drug that was originally marketed under an original 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 PLA, ELA, or ADA.
2016 Final Rule	.....	The term ''single source drug'' means a covered outpatient drug that is produced or distributed under an original NDA approved by FDA and has an approved NDA number issued by FDA, including a drug product marketed by any cross licensed producers or distributors operating under the NDA. It also includes a covered outpatient drug approved under a BLA, PLA, ELA, or ADA. For purposes of this definition and the MDR program, an original NDA means an NDA, other than an ANDA, approved by the FDA for marketing, unless CMS determines that a narrow exception applies. The term ''innovator multiple source drug'' means a multiple source drug that was originally marketed under an original NDA approved by FDA, including an authorized generic drug. It also includes a drug product marketed by any cross-licensed producers, labelers, or distributors operating under the NDA and a covered outpatient drug approved under a BLA, ELA, or ADA. For purposes of this definition and the Medicaid drug rebates (MDR) program, an original NDA means an NDA, other than an Abbreviated New Drug Application (ANDA), approved by the FDA for marketing, unless CMS determines that a narrow exception applies.
MSIAA enactment on April 18, 2019.	Single Source drug Section 1927(k)(7)(A)(iv) of the Act The term ''single source drug'' means a covered outpatient drug, including a drug product approved for marketing as a non-prescription drug that is regarded as a covered outpatient drug under paragraph (4), which is produced or distributed under a new drug application approved by the Food and Drug Administration, including a drug product marketed by any cross-licensed producers or distributors operating under the new drug application unless the Secretary determines that a narrow exception applies (as described in 42 CFR 447.502 (or any successor regulation)). Such term also includes a covered outpatient drug that is a biological product licensed, produced, or distributed under a biologics license application approved by the Food and Drug Administration.	

TABLE 1—HISTORY OF THE CHANGES IN THE DEFINITION OF SINGLE SOURCE DRUG AND INNOVATOR MULTIPLE SOURCE DRUG—Continued

	Statute	Regulation
	Innovator Multiple Source Drug Section 1927(k)(7)(A)(ii) of the Act The term ''innovator multiple source drug'' means a multiple source drug that is marketed under a new drug application approved by the FDA, unless the Secretary determines that a narrow exception applies (as described in 42 CFR 447.502 (or any successor regulation)).	
2020 Final Rule	.....	The term ''single source drug'' means a covered outpatient drug, including a drug product approved for marketing as a non-prescription drug that is regarded as a covered outpatient drug under section 1927(k)(4) of the Act, which is produced or distributed under a new drug application [*removing 'original'*] approved by the FDA, including a drug product marketed by any cross-licensed producers or distributors operating under the new drug application unless the Secretary determines that a narrow exception applies (as described in this section), and includes a covered outpatient drug that is a biological product licensed, produced, or distributed under a biologics license application approved by the FDA. The term ''innovator multiple source drug'' means a multiple source drug that is marketed [removing 'was originally marketed'] under a new drug application [*removing 'original'*] approved by the Food and Drug Administration, unless the Secretary determines that a narrow exception applies (as described in 42 CFR 447.502 (or any successor regulation)).

C. MDRP Program Administration Proposed Changes

We are focused on increasing efficiency and economy of directing overall operations, resources, and activities of MDRP to better facilitate the needs of Medicaid beneficiaries. In that regard, we are proposing a number of new regulatory policies and clarification of existing policies.

Specifically, consistent with our statutory authorities, we are proposing to define, specify or amend the definitions for COD, internal investigation (for restatement purposes outside the 3-year time window), manufacturer (for NDRA purposes), market date, noninnovator multiple source drug, drug product information, and vaccine for the purpose of MDRP. We are also proposing to specify that the rebate provisions for a drug other than a single source drug or an innovator multiple source drug apply to an array of drugs, including those that may not satisfy the definition of multiple source drug. As noted above, based on longstanding operational processes, such drugs are properly classified as N drugs in the MDP reporting system.

Next, we are also proposing new policies, including to add a time limitation on manufacturer ability to initiate audits with States, to further clarify and establish the requirements for FFS pharmacy reimbursement, and to clarify the required collection of all National Drug Codes (NDC) for single and multiple source physician-administered drugs to receive FFP and secure manufacturer rebates.

We also propose to revise Medicaid managed care standard contract requirements to adopt a requirement for inclusion of Beneficiary Identification Number and Processor Control Number (BIN/PCN) numbers on Medicaid prescription identification cards, as well as enhance drug cost transparency by adopting specific requirements relating to the third-party administration of the pharmacy benefit.

These proposed revisions are designed to improve CMS oversight, and State administration of Medicaid pharmacy benefits by promoting greater consistency and accuracy of reporting, strengthened data, and robust stewardship of State and Federal funds. These proposals would help to strengthen and preserve the foundation of the MDRP by ensuring proper payments so Federal expenditures are spent appropriately on delivering quality, necessary care, while also ensuring sufficient access to care for Medicaid beneficiaries.

1. Proposal To Modify the Definition of Covered Outpatient Drug

Sections 1927(k)(2) and (3) of the Act provide a definition of the term ''covered outpatient drug'' (COD) and a limiting definition, which excludes certain drugs, biological products, and insulin provided as part of, or as incident to and in the same setting as, enumerated services and settings. This exclusion is subject to a parenthetical, however, which limits the exclusion to when payment may be made as part of payment for the enumerated service or setting, and not as direct reimbursement for the drug. In the COD final rule, we finalized a regulatory definition of covered outpatient drug in § 447.502 that substantially mirrors the statutory definition, and consistent with section 1927(k)(3) of the Act, the regulatory language includes a limiting clause at § 447.502 (covered outpatient drug) that excludes from the definition of COD any drug, biological product, or insulin provided as part of or incident to and in the same setting in a list of services, and for which payment may be made as part of that service instead of as a direct reimbursement for the drug.

Over the years we have received questions about when a payment is considered to be a direct reimbursement for a drug and whether identifying a

drug separately on a claim for payment may qualify as direct reimbursement for a drug, rendering the drug eligible for rebates under section 1927 of the Act, or in other words, making the limiting definition inapplicable. To provide greater clarity, we propose to amend the regulatory definition of the term covered outpatient drug at § 447.502 to clarify when a payment is considered direct reimbursement for the drug.

Additionally, we propose to more closely align the regulatory language to the statute by changing ''. . . instead of as a direct reimbursement . . .'' to ''. . . and not as direct reimbursement . . .''

2. Proposed Definition of an Internal Investigation for Purposes of Pricing Metric Revisions

In accordance with section 1927(b)(3) of the Act, § 447.510 of the applicable regulations, and the terms of the NDRA, manufacturers are required to report certain pricing and drug product information to CMS on a timely basis or could incur penalties or other compliance and enforcement measures. As explained in the ''Medicaid Program; Time Limitation on Price Recalculations and Recordkeeping Requirements Under the Drug Rebate Program'' final rule (final time limitation rule) (68 FR 51912, August 29, 2003), in an effort to improve the administration and efficiency of the MDRP and assist States and manufacturers that would otherwise be required to retain drug utilization pricing data records indefinitely, we established the 12-quarter time frame for reporting revisions to AMP or best price information.

Despite the 12-quarter time frame, we continued to receive requests from manufacturers to make revisions to their pricing data that fall outside of the 12-quarter period. Consequently, in the COD final rule (81 FR 5278) we established § 447.510(b)(1), which provides that a manufacturer must report to CMS any revision to AMP, best price, customary prompt pay discounts or nominal prices (pricing data) for a period not to exceed 12 quarters from the quarter in which the data were due unless one of a number of enumerated exceptions applies. See § 447.510(b)(1)(i) through (vi).

Section 447.510(b)(1)(v) provides an exception to the 12-quarter price reporting rule if the change is to address specific rebate adjustments to States by manufacturers, as required by CMS or court order, or under an internal investigation, or an OIG or Department of Justice (DOJ) investigation. However, as part of that rule, we did not define the term internal investigation which has led to different interpretations of the nature of an internal investigation. Therefore, we propose to add a definition of internal investigation at § 447.502 and additional clarity around the 12-quarter rule at § 447.510.

3. Proposal To Modify the Definition of Manufacturer for National Drug Rebate Agreement (NDRA) Compliance Purposes

At times, we receive requests from manufacturers to allow them to exclude a particular labeler that they may own or have a business affiliation with from participation in the MDRP, even though the labeler markets products that meet the definition of covered outpatient drug. It is our view that the statute requires that all labelers of a manufacturer that market CODs be required to participate in the MDRP to meet the statutory requirement that FFP is only available for a manufacturer's drugs if they participate in the program. That is, all the labelers of the manufacturer have to be in the program, or none of the labelers can be in the program.

We are proposing to further refine the definition manufacturer at § 447.502 to codify the requirements under section 1927(a)(1) of the Act which specifies that a manufacturer has to have entered into and have in effect a rebate agreement with the Secretary in order for payment to be available for their CODs under Medicaid. We are also proposing to codify in regulation that all labelers (with their applicable codes) that are associated or affiliated with a manufacturer must have a rebate agreement in effect in order for the manufacturer to satisfy the statutory requirement that the manufacturer have a rebate agreement in effect with the Secretary.

Additionally, we are also proposing a new paragraph (h) in § 447.510 to further specify the responsibilities of a manufacturer with respect to rebate agreements when that manufacturer acquires or purchases another labeler, acquires or purchases covered outpatient drugs from another labeler, or forms a new subsidiary or associated entity to ensure that any of a manufacturer's labeler codes that market CODs are included in the MDRP. We also specify that termination of one of the manufacturer's labelers from the program results in all labelers of that manufacturer being terminated from the program whether initiated by the manufacturer or the government. If the manufacturer is terminated for noncompliance, they can come back into the program under certain conditions, including resolving all compliance issues. However, the one-quarter delay in program re-entry provided for in section 1927(b)(4)(C) of the Act still applies unless good cause is found.

4. Proposal To Establish a Definition of Market Date for a COD for the Purposes of Determining a Base Date AMP for a COD

Section 1927 of the Act governs the MDRP and payment for CODs which are defined in section 1927(k)(2) of the Act. Manufacturers that participate in the MDRP are required to pay rebates for CODs that are dispensed and paid for under the State Medicaid plan. See section 1927(b)(1)(A) of the Act.

The rebates due by manufacturers are calculated based on statutory formulas described in section 1927(c) of the Act and consist of a basic rebate and, in some cases, an additional rebate that is applicable when an increase in the AMP, with respect to each dosage form and strength of a drug, exceeds the rate of inflation. One of the factors in the calculation of the additional rebate is the base date AMP of the drug, a value that is determined based on the market date of the drug. Manufacturers are required to report the market date of each dosage form and strength of a COD for all of its CODs.

We have received numerous inquiries regarding the determination of market date for reporting to MDRP, and some manufacturers have reported incorrect market dates for their CODs. Because the term market date has not been previously defined in regulation and it is a critical factor in the determination of base date AMP, and ultimately, the calculation of applicable rebates, we are proposing to define the term market date at § 447.502 for the purpose of the MDRP.

5. Proposal To Modify the Definition of Noninnovator Multiple Source Drug

As discussed previously in this proposed rule, section 6(c) of the MSIAA included a number of amendments to statutory definitions in section 1927 of the Act. Generally, those statutory amendments were discussed in the ''Medicaid Program; Establishing Minimum Standards in Medicaid State Drug Utilization Review (DUR) and Supporting Value-Based Purchasing (VBP) for Drugs Covered in Medicaid, Revising Medicaid Drug Rebate and Third Party Liability (TPL) Requirements'' final rule published in the December 31, 2020 **Federal Register** (the December 31, 2020 final rule) (see 85 FR 87000, 87032), where the regulatory definitions of multiple source drug, innovator multiple source (I) drug, and single source drug were amended

consistent with the MSIAA. One of the amendments to the regulatory definitions was to remove the phrase ''was originally marketed'' from the definition of an I drug and replace it with ''is marketed.''

The change in the statutory and regulatory definitions of an I drug should have prompted us to also change the regulatory definition of noninnovator multiple source (N) drug, however we neglected to do so in the December 31, 2020 final rule. We are now proposing to amend the definition of an N drug at § 447.502 to maintain the clear distinction between an I drug and an N drug.

6. Proposal To Define Vaccine for the Purposes of the MDRP Only

Section 1927(k)(2)(B) of the Act specifically excludes vaccines from the definition of COD for purposes of the MDRP. This exclusion is codified in paragraph (1)(iv) of the regulatory definition of COD at § 447.502. Section 1927 of the Act, specifically, does not define vaccine. Nor is there a definition of vaccine in Title XI, XVIII, XIX, or XXI of the Act (applicable to Medicare, Medicaid, and Children's Health Insurance Program (CHIP)), that speaks to the specific kinds of biological products that qualify as vaccines, in terms of their actions in the human body and how and when they are used.[2] Moreover, we are not aware that any authorizing statutes for any other Department of Health and Human Services agencies include such a statutory definition of the term ''vaccine.''

To date, we have not established a regulatory definition of the term vaccine as used in section 1927(k)(2)(B) of the Act for the specific purposes of the MDRP. However, given therapeutic advances that have occurred since 1990, when the original rebate statute was enacted, we believe that a regulatory definition is necessary to identify which products are considered vaccines for the purposes of the MDRP and thus, appropriately excluded from the definition of COD. We are therefore proposing a definition of vaccine at § 447.502 for the purpose of identifying products that do not satisfy the definition of COD and are therefore not subject to possible required coverage under the prescribed drugs benefit consistent with section 1927 of the Act, and applicable rebate liability under the MDRP. The regulatory definition of vaccine that is proposed to be added to § 447.502 would be established solely for the purposes of the MDRP, and be applicable only to that program. It would not apply under any title XIX statutory provisions other than section 1927(k)(2), or to separate CHIPs operating pursuant to 42 CFR 457.70(a)(1) and (d), or for purposes of the Vaccines for Children Program. Nor would it apply to any other programs within CMS or any other agencies within the Department of Health and Human Services, (for example, FDA, Centers for Disease Control and Prevention (CDC), or Health Resources and Services Administration (HRSA)). We note that these proposed changes would only specify which products are vaccines and are therefore excluded from the definition of a covered outpatient drug and are not subject to Medicaid drug rebates. This proposed policy would not apply with regard to any applicable Federal or State requirements to cover vaccines for Medicaid beneficiaries, as applicable.

7. Proposal To Accumulate Price Concessions and Discounts (''Stacking'') When Determining Best Price

Section 1927(c)(1)(C) of the Act defines the term ''best price'' to mean with respect to 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 a new drug application approved under section 505(c) of the Federal Food, Drug, and Cosmetic Act), the lowest price available from the manufacturer during the rebate period to any wholesaler, retailer, provider, health maintenance organization, nonprofit entity, or governmental entity within the United States, subject to certain exceptions and special rules.

The implementing regulations for the determination of best price are found at § 447.505, and we propose to revise § 447.505(d)(3) to add language to make clearer that the manufacturer must adjust the best price for a drug for a rebate period if cumulative discounts, rebates, or other arrangements to best price eligible entities subsequently adjust the prices available from the manufacturer, and that those discounts, rebates, or other arrangements must be stacked for a single transaction to determine a final price realized by the manufacturer for a drug. In other words, we are proposing to make clearer that manufacturers have to stack all applicable discounts that they offer on a single sale of a covered outpatient drug, including discounts or rebates provided to more than one best price eligible entity.

8. Proposal To Establish a Time Limitation for Audits Over Utilization Data With States: 12-Quarter Rebate Dispute Time Limitation

Currently, there is no time limit for a manufacturer to initiate an audit or resolve previously disputed State utilization data with respect to rebates owed, and section 1927 of the Act does not impose a specific timeframe on a manufacturer's audit authority. As a result, any dispute of State invoices arising from audits, reviews, or hearings of State information on State utilization data is not limited to current quarter rebate invoices, but may also be initiated for prior quarterly rebate invoices that have been previously paid in full. We are proposing to limit the time period for manufacturers to initiate disputes, hearing requests and audits of State-invoiced utilization data to 12 quarters from the last day of the quarter from the date of State invoice to the manufacturer. We propose to include a new paragraph (j), titled ''Manufacturer audits of State-provided information,'' at § 447.510, to limit the time a manufacturer has to initiate a dispute, hearing request or audit of State-invoiced utilization data with a State, to ensure more efficient administration of the Medicaid Drug Rebate Programs.

9. Proposal Regarding Drug Price Verification and Transparency Through Data Collection

Since the beginning of the MDRP in 1991, the Secretary has had the authority, under section 1927(b)(3)(B) of the Act, to survey wholesalers and manufacturers that directly distribute their covered outpatient drugs, when necessary, to verify manufacturer prices that are reported under section 1927(b)(3)(A) of the Act, if required to make a payment. The prices that are subject to this survey include a manufacturer's AMP, best price, Average Sales Price (ASP), and in certain cases, Wholesale Acquisition Cost (WAC) for a drug. (Note that in 2003, Congress amended section 1927(b)(3)(B) of the Act in the Medicare Prescription Drug, Improvement, and Modernization Act (MMA) of 2003 (Pub. L. 108–173, enacted December 8, 2003), to expand the original survey authority to include manufacturer's average sales prices (including wholesale acquisition cost or WAC).) These prices that are reported to the agency under section 1927(b)(3)(A) of the Act are used by various CMS programs, such as

[2] While section 1928(h) of the Act defines ''pediatric vaccine'' and ''qualified pediatric vaccine,'' those definitions do not speak to the actions of a vaccine in the human body and how and when it is used, and therefore do not help CMS determine when a product should count as a vaccine (as opposed to a drug) for purposes of the Medicaid Drug Rebate Program.

Medicare Part B and State Medicaid agencies, to pay for drugs for beneficiaries, as well as calculate rebates paid by manufacturers to States under MDRP. Thus, there is a direct connection between the prices reported to us and the payments made by Medicaid.

The types of drugs paid for by Medicaid, manufacturers' pricing structures for these drugs, as well as the methods used by manufacturers to distribute these drugs, have evolved since the enactment of the MDRP, as well as the enactment of the MMA. New highly individualized gene and cell therapy drug treatments have resulted in manufacturer launch prices that have increased dramatically, impacting the manufacturers' prices reported to CMS. In addition, manufacturers and health plans now own pharmacy benefit managers (PBMs), and manufacturers are more frequently limiting the distribution of drugs through specialty pharmacies, some of which are owned by the PBMs themselves.

All of these factors impact how manufacturers set drug pricing, and, given that these prices are used to set payment rates, it affects the payments that State Medicaid programs make for these drugs. For example, State Medicaid programs use the ASP values reported by manufacturers to make payment for many physician-administered drugs. A product's WAC has generally tracked its acquisition cost to providers for brand name drugs, and this WAC value is used by payers to reimburse them for the drug cost component of providing the drug. AMP is used to calculate Federal Upper Limits (FULs) for multiple source drugs.

While the model of distribution from manufacturer to wholesaler to provider still exists, and the predominant provider of pharmacy services remains the community-based pharmacy, there are other arrangements emerging for the production and distribution of specialty and high-cost gene therapy drugs, and pricing structures for these drugs that were not necessarily existing in the market when the MDRP was enacted.

Section 1902(a)(30)(A) of the Act requires that Medicaid payments be consistent with economy, efficiency, and quality of care to enlist enough providers so that care and services are available under the plan to Medicaid beneficiaries at least to the extent that such care and services are available to the general population in the geographic area. It is important that the Medicaid program understand the production and distribution method for these drugs, as well as the impact on prices and charges, to assure beneficiary access to these medications. Therefore, using the authority at section 1927(b)(3)(B) of the Act, which grants the Secretary the ability to survey wholesalers and manufacturers to obtain information about manufacturer's prices for a drug reported to us under section 1927(b)(3)(A) of the Act, we are proposing rules to describe those situations when it is necessary for surveys to be sent to manufacturers and wholesalers to verify prices and charges, and the information that would be requested, to verify prices or charges such that payments can be made.

10. Proposal To Clarify and Establish Requirements for FFS Pharmacy Reimbursement

In the COD final rule, we finalized regulations to move FFS pharmacy reimbursement to an actual acquisition cost-based reimbursement, under which pharmacists would be paid for the ingredient costs of the drug that was dispensed, and a professional dispensing fee (PDF) that reflected their costs of dispensing. Since that time, almost every State has made the appropriate transition, and the updated pharmacy reimbursement methodology is accurately reflected in approved amendments to their State Plans. Nonetheless, we are proposing to revise § 447.518, ''State plan requirements, findings, and assurances,'' in paragraph (d)(1) to ensure that pharmacy providers are reimbursed adequately for both their pharmacy ingredient costs and professional dispensing services costs consistent with the applicable statutory and regulatory requirements.

This regulation currently indicates that States are required to provide adequate data to support any proposed changes to either component of the reimbursement methodology (ingredient cost or PDF), such as a State or national survey of retail pharmacy providers or other reliable data other than a survey. We are proposing to provide clarity regarding adequate data so that payments are consistent with efficiency, economy, and quality of care and are sufficient to enlist enough providers so that care and services are available at least to the extent that such care and services are available to the general population in the geographic area, by expressly providing in regulation that the research and data must be based on costs and be sufficient to establish the adequacy of the pharmacy reimbursement methodology under the State Plan. In addition, we are proposing to state in regulatory text that other data, such as reimbursements that pharmacies accept from third parties, are not cost-based data, and therefore, cannot be used by States to justify PDFs.

11. Proposals Implementing Section 1927(a)(7) of the Act and Federal Financial Participation (FFP): Conditions Relating to Physician-Administered Drugs

Generally, physician-administered drugs may satisfy the definition of a covered outpatient drugs (COD) under section 1927(k)(2) of the Act, subject to the limiting definition at section 1927(k)(3) of the Act. Prior to the Deficit Reduction Act (DRA) of 2005 (Pub. L. 109–171, enacted February 8, 2006), States did not collect rebates on all physician-administered drugs when they were not identified by NDC number, because the NDC number is necessary for States to invoice manufacturers for rebates.

Section 6002 of the DRA added sections 1903(i)(10)(C) and 1927(a)(7) to the Act to require the States to collect and submit certain utilization data on certain physician-administered drugs in order for FFP to be available for these drugs, and for States to secure rebates. More specifically, in accordance with section 1927(a)(7) of the Act, titled ''Requirement For Submission Of Utilization Data For Certain Physician-Administered Drugs'', States are required to provide for the collection and submission of utilization data and coding (such as J-codes [3] and NDC numbers) for a covered outpatient drug that is a single source or a multiple source drug that is a top 20 high dollar volume physician-administered drug on a published list (based on highest dollar volume dispensed under Medicaid identified by the Secretary) that the Secretary may specify in order for payment to be available under section 1903 of the Act and for States to secure applicable Medicaid rebates.[4] This list may be modified year to year to reflect changes in such volume.

Regulations at § 447.520 were established to implement these statutory provisions in the final rule entitled ''Medicaid Program; Prescription Drugs'' (72 FR 39142, 39162) (hereinafter referred to as the July 17, 2007 final rule), specifying the conditions for FFP for physician-administered drugs.[5]

We are proposing to amend § 447.520 to require States to collect NDC information on all covered outpatient single and multiple source physician-

[3] J codes are a subset of the Healthcare Common Procedure Coding System (HCPCS) Level II code set used to primarily identify injectable drugs.

[4] *https://www.govinfo.gov/content/pkg/CFR-2007-title42-vol4/pdf/CFR-2007-title42-vol4-sec447-520.pdf.*

[5] Ibid.

administered drugs and to specify that States should be invoicing for rebates for all covered outpatient physician-administered drugs to receive FFP and secure manufacturer rebates.

12. Proposal Related to Suspension of a Manufacturer's Drug Rebate Agreement

We are proposing regulatory changes to further implement section 1927(b)(3)(C)(i) of the Act, which provides authority to suspend a rebate agreement for a manufacturer's failure to timely report drug pricing or drug product information to the agency, required under section 1927(b)(3)(A) of the Act, and when there is a continued failure to report after a 90-calendar day deadline for reporting of information is imposed by the agency. Specifically, the new § 447.510(i) proposes that a manufacturer who has failed to report timely information to the agency under § 447.510(a) and (d), would be imposed a 90-calendar day deadline determined by the agency, and communicated to electronically and in writing by the agency to report such information, or the manufacturer would have its rebate agreement suspended.

This section further proposes that failure to report such information to the agency after the end of the imposed 90-calendar day period would result in suspension of the rebate agreement, and that such agreement shall not be reinstated until such information is reported in full and certified, but not for a period of suspension of less than 30 calendar days. This suspension would apply to all of the manufacturer's labelers that have a rebate agreement with the Secretary, consistent with the proposed regulatory definition of ''manufacturer.''

This rule also proposes that continued suspension of the rebate agreement could result in termination for cause. During the period of time of the suspension, FFP would not be available to the States for a manufacturer's CODs. The States would be given 30 calendar days' notice before such a suspension is implemented. This would allow States to notify prescribers and beneficiaries that a specific COD or specific CODs may be unavailable for a period of time, and to allow the beneficiary to switch to a different medication, if necessary. We are proposing that the suspension would only be applicable to the manufacturer's Medicaid program participation, and would not affect manufacturer participation in Medicare Part B or the 340B Drug Pricing Program during the time the rebate agreement is suspended. However, if continued suspension results in termination, such termination could affect Medicare Part B and 340B Drug Pricing Program participation.

13. Proposals Related to Managed Care Plan Standard Contract Requirements

a. Requirement of BIN/PCN Inclusion on Medicaid Managed Care Pharmacy Identification Cards

Patients enrolled in health care plans, including in Medicaid managed care plans such as Medicaid managed care organizations (MCOs), prepaid inpatient health plans (PIHPs), or prepaid ambulatory health plans (PAHPs), generally use identification cards at the pharmacy so they can obtain prescription drug benefits, as well as allow pharmacies to process and bill claims in real time. Health plans use two codes on the card to identify a patient's prescription health insurance and benefits—the National Council for Prescription Drug Programs (NCPDP) Processing Bank Identification Number (BIN) and Processor Control Number (PCN). This information, along with a group number, can specify that a beneficiary is part of a specific patient insurance group, such as being a Medicaid managed care beneficiary.

However, it is often difficult to determine from a Medicaid managed care beneficiary's health insurance card if he or she is covered under a Medicaid managed care plan or under non-Medicaid coverage, such as an employer-sponsored group health plan or individual market insurance, offered by the same organization or entity that offers the Medicaid managed care plan. This is due to the fact that Medicaid-specific BIN, PCN, and group numbers are not always placed on Medicaid managed care plan identification cards. However, if Medicaid-specific BIN/PCN and group information were included on the card, the pharmacy could enter this information into its claims processing system which would identify that the beneficiary is enrolled in a Medicaid managed care plan. We believe it is important that unique BIN/PCN/group numbers are established for Medicaid managed care plans for several program needs, including facilitating the appropriate identification of cost sharing and ensuring claims are billed and paid for appropriately.

Use of Medicaid-specific BIN/PCN/group numbers can help States and their managed care plans identify claims for drugs paid for under the 340B Drug Pricing Program (340B Program) and avoid invoicing for rebates on 340B drugs. Section 340B(a)(5)(A) of the Public Health Service Act (the PHS Act) prohibits duplicate discounts for drugs purchased under the Medicaid drug rebate program. Section 1927(a)(5)(C) of the Act requires the establishment of a mechanism to ensure against duplicate discounts or rebates and section 1927(j)(1) of the Act provides that covered outpatient drugs are not subject the requirements of section 1927 of the Act if they are dispensed by health maintenance organizations (HMOs), including MCOs that contract under section 1903(m) of the Act, and are subject to discounts under section 340B(a)(5)(A) of the PHS Act. Certain eligible entities and hospitals are permitted to purchase drugs under the 340B Drug Pricing Program and dispense these drugs to Medicaid beneficiaries. Identifying claims where the dispensed drug has been discounted under the 340B program is necessary to avoid duplicating that discount in the MDRP.

Duplicate discounts occur when a State erroneously bills a manufacturer for a Medicaid drug program rebate involving a drug that was purchased under the 340B Drug Pricing Program. That occurs because the claim was not identified as a 340B claim before it was sent to the State. If the identification card included a unique Medicaid BIN/PCN/group number, and the State permits the use of 340B drugs at contract pharmacies for individuals enrolled in Medicaid managed care, then it would allow for the inclusion of a modifier at the point of dispensing that would identify the claim as ineligible for a Medicaid rebate. This would assist States with identifying 340B drug claims that should not be invoiced for Medicaid drug rebates.

Section 1902(a)(4) of the Act allows the Secretary to specify ''methods of administration'' that are ''found by the Secretary to be necessary for . . . proper and efficient operation.'' We believe that having States require their MCOs, PIHPs, or PAHPs that provide CODs to Medicaid beneficiaries to add unique identifiers onto the identification cards would make the Medicaid drug program run more efficiently, help avoid duplicate discounts, and improve the level of pharmacy services provided to Medicaid beneficiaries.

Therefore, under the authority of section 1902(a)(4) of the Act, as well as to ensure effective implementation of and compliance with sections 1927(a)(5)(C) and 1927(j)(1) of the Act, we are proposing to amend 42 CFR 438.3(s) to require MCOs, PIHPs, and PAHPs that provide coverage of CODs to assign and exclusively use unique Medicaid BIN, PCN, and group number identifiers for all Medicaid managed

care beneficiary identification cards for pharmacy benefits.

b. Drug Cost Transparency in Medicaid Managed Care Contracts

Medicaid managed care plans often contract with a subcontractor PBM to operate the pharmacy benefit provided to Medicaid beneficiaries. In order for a Medicaid managed care plan to appropriately calculate and report its Medical Loss Ratio (MLR) under § 438.8, the plan must know from the subcontractor certain information relating to how much of the payments made to the Medicaid managed care plan by the State was used to pay for health care services and other specific categories outlined in § 438.8. To correctly report the MLR, a Medicaid managed care plan must distinguish between expenses that are for covered benefits (such as healthcare services and drug costs) and administrative expenses, such as fees paid to its PBM for PBM services (for example, claims adjudication, processing prior authorization requests, etc.).

Therefore, we are proposing that MCOs, PIHPs, and PAHPs that provide coverage of CODs structure any contract with any subcontractor to require the subcontractor report the amounts related to the incurred claims described in § 438.8(e)(2), such as reimbursement for the covered outpatient drug, payments for other patient services, and the fees paid to providers or pharmacies for dispensing or administer a covered outpatient drug, separately from any administrative costs, fees, and expenses of the subcontractor.

14. Proposal To Rescind Revisions Made by the December 31, 2020 Final Rule to Determination of Best Price (§ 447.505) and Determination of Average Manufacturer Price (AMP) (§ 447.504) Consistent With Court Order

On May 17, 2022, the United States District Court for the District of Columbia vacated and set aside the ''accumulator adjustment rule of 2020'' in response to a complaint filed against the Secretary regarding the best-price accumulator provisions within the December 31, 2020 final rule ''Medicaid Program; Establishing Minimum Standards in Medicaid State Drug Utilization Review (DUR) and Supporting Value-Based Purchasing (VBP) for Drugs Covered in Medicaid, Revising Medicaid Drug Rebate and Third Party Liability (TPL) Requirements.'' See *Pharm. Rsch. & Mfrs. of Am.* v. *Becerra,* 1:21–cv–01395–CJN (D.D.C. May 17, 2022). This final rule had revised the conditions for excluding patient assistance from AMP at § 447.504(c)(25) through (29) and (e)(13) through (17), and best price at § 447.505(c)(8) through (12), to add language (effective January 1, 2023) that would require manufacturers to ''ensure'' the full value of the assistance provided by patient assistance programs is passed on to the consumer and that the pharmacy, agent, or other AMP or best price eligible entity does not receive any price concession. While the district court's order focused on the changes to the patient-assistance program exclusions from best-price determinations, to which it referred as the ''accumulator adjustment rule of 2020,'' for consistency, we propose to withdraw the changes to both the AMP and best-price sections made by the December 31, 2020 final rule.

As a result, the regulations would maintain the language that has been in place since 2016.

15. Proposals Related to Amendments Made by the American Rescue Act of 2021—Removal of Manufacturer Rebate Cap (100 Percent AMP)

Section 9816 of the American Rescue Plan Act of 2021 (Pub. L. 117–2, enacted March 11, 2021) sunsets the limit on maximum rebate amounts for single source and innovator multiple source drugs by amending section 1927(c)(2)(D) of Act by adding ''and before January 1, 2024,'' after ''December 31, 2009''. In accordance with section 1927(c)(3)(C)(i) of the Act and the special rules for application of provision in section 1927(c)(3)(C)(ii)(IV) and (V) of the Act, this sunset provision also applies to the limit on maximum rebate amounts for CODs other than single source or innovator multiple source drugs. Therefore, to conform § 447.509 with section 1927(c)(2)(D) of Act, as amended by the American Rescue Plan Act of 2021, and sections 1927(c)(3)(C)(i), (ii)(IV), and (ii)(V) of the Act, we are proposing to make conforming changes to § 447.509 to reflect the removal of the maximum rebate amounts for rebate periods beginning on or after January 1, 2024.

16. Request for Information—Comments on Issues Relating to Requiring a Diagnosis on Medicaid Prescriptions as a Condition for Claims Payment

Under the MDRP, a COD is generally defined as a prescribed drug that is FDA approved and used for a medically accepted indication. While the statute limits the definition of a COD to those products used for ''medically accepted indications,'' without a diagnosis on a prescription drug claims, it is difficult to determine whether a drug is being used for a medically accepted indication, and if it therefore satisfies the definition of a COD, and is rebate eligible. We are soliciting comments on the possibility and potential impact of proposing a requirement that a patient's diagnosis be included on a prescription as a condition of receiving Medicaid FFP for that prescription. We are soliciting comment on the patient care, clinical, and operational impact of requiring that a patient's diagnosis be included on a prescription as a condition of a State receiving FFP for that prescription. We are particularly interested in understanding any operational implications, privacy related concerns, the burden associated, and how to negate any foreseeable impact on beneficiaries and providers, including what steps would be needed by States to successfully implement a Medicaid requirement for diagnosis on prescriptions. This is a request for information only.

17. Background on Coordination of Benefits/Third Party Liability Regulation Due to Bipartisan Budget Act of 2018 (BBA 2018)

Medicaid is generally the payer of last resort, which means that other available resources—known as third party liability, or TPL—must be used before Medicaid pays for services received by a Medicaid-eligible individual. Title XIX of the Act requires State Medicaid programs to identify and seek payment from liable third parties, before billing Medicaid. Section 53102 of the Bipartisan Budget Act of 2018 (BBA 2018) (Pub. L. 115–123, enacted February 9, 2018) amended the TPL provision at section 1902(a)(25) of the Act.

Specifically, section 1902(a)(25)(A) of the Act requires that States take all reasonable measures to ascertain the legal liability of third parties to pay for care and services available under the plan. That provision further specifies that a third party is any individual, entity, or program that is or may be liable to pay all or part of the expenditures for medical assistance furnished under a State Plan. Section 1902(a)(25)(A)(i) of the Act specifies that the State Plan must provide for the collection of sufficient information to enable the State to pursue claims against third parties. Examples of liable third parties include: Private insurance companies through employment-related or privately purchased health insurance; casualty coverage resulting from an accidental injury; payment received directly from an individual who has voluntarily accepted or been assigned legal responsibility for the health care of one or more Medicaid recipients;

fraternal groups, unions, or State workers' compensation commissions; and medical support provided by a parent under a court or administrative order.

To update the regulation for the recent statutory changes, a final rule was published on December 31, 2020, which went into effect on March 1, 2021, to include changes as authorized under the BBA 2018. We are submitting a correction due to an omission in the regulation text to require a State to make payments without regard to TPL for pediatric preventive services unless the State has made a determination related to cost-effectiveness and access to care that warrants cost avoidance for up to 90 days.

II. Provisions of the Proposed Regulations

A. Payment of Claims (42 CFR 433.139)

In 1980, under the authority in section 1902(a)(25)(A) of the Act, we issued regulations at part 433, subpart D, establishing requirements for State Medicaid agencies to support the coordination of benefits (COB) effort by identifying third party liability.

Section 433.139(b)(3)(i) and (b)(3)(ii)(B) detail the exception to standard COB cost avoidance by allowing pay and chase for certain types of care, as well as the timeframe allowed prior to Medicaid paying claims for certain types of care. Specifically, we proposed to revise § 433.139(b)(3)(i) by adding—''that requires a State to make payments without regard to third party liability for pediatric preventive services unless the State has made a determination related to cost-effectiveness and access to care that warrants cost avoidance for up to 90 days.'' We propose to revise § 433.139(b)(3)(i) and (b)(3)(ii)(B) by adding ''within'' prior to the waiting periods Medicaid has to pay claims for preventive pediatric and medical child support claims. We also propose to revise § 433.139(b)(3)(ii)(B) by removing ''from'' and replacing it with ''after;'' and by removing ''has not received payment from the liable third party'' and adding the following language at the end of the sentence ''provider of such services has initially submitted a claim to such third party for payment for such services, except that the State may make such payment within 30 days after such date if the State determines doing so is cost-effective and necessary to ensure access to care.'' These revisions in language would permit States to pay claims sooner than the specified waiting periods, when appropriate.

B. Standard Medicaid Managed Care Contract Requirements (§ 438.3(s))

1. BIN/PCN on Medicaid Managed Care Cards

We propose to amend § 438.3(s) to add a new paragraph (s)(7) to require States that contract with MCOs, PIHPs, or PAHPs that provide coverage of CODs, to require those managed care plans to assign and exclusively use unique Medicaid-specific BIN, PCN, and group number identifiers for all Medicaid managed care beneficiary identification cards for pharmacy benefits. We propose that the managed care contracts, and thus MCOs, PIHPs and PAHPs, must comply with this new requirement no later than the next rating period for Medicaid managed care contracts, following the effective date of the final rule adopting this new regulatory provision. We believe that the delay between the effective date of the final rule and the start of the next rating period would provide both States and the affected Medicaid managed care plans with adequate time to prepare both the necessary contract terms, and finish the necessary administrative processes for creating and issuing beneficiary identification cards with these newly required Medicaid-specific BIN, PCN, and group number identifiers.

This proposal is under our authority in section 1902(a)(4) of the Act to specify ''methods of administration'' that are ''found by the Secretary to be necessary for . . . proper and efficient operation.'' Having States require their MCOs, PIHPs, or PAHPs that provide CODs to Medicaid beneficiaries to add these types of unique identifiers to the identification cards would make the Medicaid drug program run more efficiently, and improve the level of pharmacy services provided to Medicaid beneficiaries. With the inclusion of Medicaid-specific BIN/PCN and group numbers on the pharmacy identification cards issued to the enrollees of MCOs, PHIPs and PAHPs, pharmacies would be able to identify patients as Medicaid beneficiaries, and better provide pharmacy services. This would be helpful to all parties to ensure that Medicaid benefits are provided correctly, including the confirmation of accurate cost sharing amounts, along with assisting that claims are billed and paid for appropriately.

This proposed change would also help to reduce the incidence of 340B duplicate discounts. Section 340B(a)(5)(A) of the PHS Act prohibits duplicate discounts; that is, manufacturers are not required to both provide a 340B discounted price and pay the State a rebate under the Medicaid drug rebate program for the same drug. Section 1927(a)(5)(C) of the Act requires the establishment of a mechanism to ensure against duplicate discounts or rebates, and section 1927(j)(1) of the Act also provides that CODs are not subject to, among other requirements of section 1927 of the Act, MDRP rebates if: (1) they are dispensed by health maintenance organizations, including MCOs that contract under section 1903(m) of the Act, and are subject to 340B discounts and (2) the drugs are subject to 340B discounts. Therefore, CODs covered by MCOs, PIHPs, and PAHPs are within the scope of this provision designed to prevent duplicate discounts. The existing regulation at § 438.3(s)(3) already reflects the position that CODs covered by MCOs, PIHPs, and PAHPs must be identified to prevent duplicate discounts under both section 1927 of the Act and section 340B of the PHS Act. The identification of a Medicaid beneficiary at the point of dispensing can result in the pharmacy placing a code on the prescription, such as the NCPDP ''20'' submission clarification code, so that the claim will be excluded from the Medicaid rebate pool.

Medicare Part D has supported the inclusion of BIN/PCN numbers for pharmacy cards. That is, 42 CFR 423.120(c)(4) requires that Part D sponsors assign and exclusively use a unique Part D BIN or RxBIN and Part D processor control number (RxPCN) combination in its Medicare line of business. The use of the BIN/PCN ensures that a pharmacy claim can be accurately billed by the pharmacy. Medicare made the BIN/PCN unique to Part D so that a Part D sponsor clearly identifies the Medicare enrollee as part of a particular Part D plan and the pharmacy knows that Medicare statute and rules may apply, such as not allowing certain manufacturer coupons, which plan benefits apply, appeals rights, etc.

In the absence of Medicaid-specific BIN, PCN, and group numbers to identify beneficiaries as being Medicaid participants, it is difficult for pharmacies and other providers, such as physicians and hospitals that administer drugs to Medicaid beneficiaries, to determine whether the beneficiary is enrolled in a Medicaid managed care plan, since a group number alone is not sufficient for Medicaid identification. Adding unique identifiers would make the beneficiary's Medicaid managed care status distinguishable from the other lines of business offered by the same organization or entity that contracts with the State to offer an

MCO, PIHP or PAHP for Medicaid beneficiaries.

Accordingly, we propose to amend the regulatory language in § 438.3(s) to add paragraph (s)(7) to mandate that Medicaid managed care contracts require that Medicaid MCO, PIHPs, or PAHPs that provide coverage of CODs must assign and exclusively use unique Medicaid BIN, PCN, and group number identifiers for all Medicaid managed care beneficiary identification cards for pharmacy benefits. We propose that Medicaid managed care contract must include this new requirement (which would require compliance by MCOs, PIHPs, and PAHPs) no later than the next rating period for Medicaid managed care contracts, following the effective date of the final rule adopting this new provision. We are soliciting comments on the implementation time frame and other possible operational issues of requiring unique Medicaid BIN, PCN, and group numbers to be on Medicaid managed care beneficiary identification cards.

2. Drug Cost Transparency in Medicaid Managed Care Contracts

We propose that the contracts between States and MCOs, PIHPs, or PAHPs that provide coverage of CODs require those plans to structure contracts with any subcontractor for the delivery or administration of CODs, in a manner that ensures drug cost spending transparency by requiring the subcontractor to report separately certain expenses and costs. These subcontractors may include PBMs.

Most Medicaid beneficiaries receive either all or part of their health care benefits, including CODs, through Medicaid managed care plans. Because of the specialized nature of the COD benefit, many Medicaid managed care plans (that is, the MCOs, PIHPs, or PAHPs) may contract with, or have their own PBMs to administer the COD benefit.

PBMs are the middlemen of the relationship between the managed care plans and the health care (medical and pharmacy) providers that provide CODs. That is, they have contracts with both the managed care plans to administer the pharmacy benefit, as well as with the health care providers that administer or provide the drugs to patients that are enrolled in the managed care plan. Among other tasks in the marketplace, a PBM may be responsible for developing a drug formulary, collecting manufacturer rebates on behalf of the managed care plan, performing drug utilization review (DUR), adjudicating claims, and contracting with retail community pharmacies and other health care providers to develop a network of pharmacy providers that can dispense drugs to managed care enrolled patients.

The PBM also negotiates reimbursement rates on behalf of the various health plans, including managed care plans with which it contracts, and pays the pharmacy and other health care providers for the drugs that are dispensed or administered. In most cases, the pharmacy reimbursement rates are specified in the contract between the PBM and the pharmacy providers, and these include reimbursement rates for brand name and generic prescription drugs, as well as the dispensing fees paid to dispense or administer the prescription drug to the beneficiary. There are also administrative fees paid to the PBM by the managed care plans for its administration and operation of the pharmacy benefit.

PBMs' methods of reimbursing health care providers for prescription drugs may differ from those used to determine the charges to managed care plans for the dispensed prescription. That is, a PBM's set of reimbursement benchmarks can be used in one relationship, and another set of reimbursement benchmarks in another, making it difficult for health plans or Medicaid managed care plans to know how much they are paying for the actual cost of the drug compared to the fees for administering the benefit. For this reason, under Part D, CMS requires that the price the PBM pays to the pharmacy for the cost of the drug is passed through to the plan, and any ''spread'' that the PBM keeps is an administrative cost that must be reported to the plan.

Medicaid-contracted PBMs (that is, PBMs contracted with or on behalf of Medicaid managed care plans) often reimburse health care providers using methods similar to those used in the commercial and Medicare Part D markets, which are heavily dependent on drug pricing benchmarks provided by manufacturers, and published by commercial publishers of drug pricing data (that is Average Wholesale Price (AWP) or Wholesale Acquisition Cost (WAC)). The PBMs may also use a Maximum Allowable Cost (MAC) benchmark for generic drugs, which is a PBM proprietary benchmark that reimburses pharmacy providers for generics.

For PBMs' payment to contracted health care providers, reimbursement might be based on a discount off AWP, a markup on WAC, or the Maximum Allowable Cost (MAC) for generics, plus any contractually defined professional dispensing fee (PDF), which determines the total reimbursement for each COD. In contrast, the PBM might charge the managed care plans for dispensing that same COD based upon a different fixed percentage discount from AWP, or a higher percentage of WAC, either on a per-claim or aggregate spend basis. That is, a PBM's benchmarks, markups, or discount percentages may differ for the same COD. The result is that there is little to no transparency to the managed care plan as to how much the plan actually pays for the COD administered or dispensed to the patient, and how much is paid to the PBM for fees related to the administration of the COD benefit. The cost charged to the managed care plan for the COD by the PBM often includes both the amount that the PBM reimbursed the medical or pharmacy provider for the COD as well as the PBM's administrative fees for operating the benefit program.

The margin between the amount charged to a managed care plan for a COD, and the amount paid by a PBM to a pharmacy provider is referred to as the ''spread'' or ''spread pricing.'' This margin or ''spread'' may only be known by the PBM, unless a State Medicaid program or managed care plan (or other prime contractor in other contexts) specifically requires disclosure of the charge and payment data that are used to make these calculations. This information deficit results in a lack of accountability and transparency to the Medicaid program, which we believe is contrary to proper and efficient operation of the State Medicaid program and potentially creates conflicts of interest in connection with payment for CODs.

Section 1902(a)(4)(A) of the Act requires that the State Plan for medical assistance comply with methods of administration that are found by the Secretary to be necessary for the proper and efficient operation of the State Plan. Greater transparency and accountability by Medicaid managed care plans (and their subcontractors) to the States for how Medicaid benefits are paid compared to how administrative fees or services are paid are necessary for efficient and proper operation of Medicaid programs. Moreover, this lack of transparency makes it more difficult for Medicaid managed care plans to assure that the plan's MLR calculation is limited to the true medical costs associated with the provision of CODs.

Medicaid managed care regulations at § 438.8 require States, through their contracts with managed care plans, to require each managed care plan to calculate and report an annual MLR starting on or after July 2017, consistent with the requirements of the regulation

detailing the calculation, including which expenses are in the numerator and the denominator. We issued a Center for Medicaid & CHIP Services (CMCS) Informational Bulletin on May 15, 2019, for Medicaid Managed Care plans, titled ''Medicaid Loss Ratio (MLR) Requirements Related to Third Party Vendors'' (''2019 CIB'') (see *https://www.medicaid.gov/sites/default/files/Federal-Policy-Guidance/Downloads/cib051519.pdf*), regarding calculation of the MLR when a managed care plan uses subcontractors for plan activities.

MLR calculations are used to develop capitation rates paid to Medicaid managed care plans, thus their accuracy is critical in assuring that Medicaid payments are reasonable, appropriate and necessary for health care services when using a Medicaid managed care plan. Managed care capitation rates must (1) be developed such that the plan would reasonably achieve an 85 percent MLR (§ 438.4(b)(9)) and (2) are developed using past MLR information for the plan (§ 438.5(b)(5)). In addition to other standards outlined in §§ 438.4 through 438.7, these requirements for capitation rates related to the MLR are key to ensuring that Medicaid managed care capitation rates are actuarially sound. In addition, Medicaid managed care plans may need to pay remittances (that is, refund part of the capitation payments) to States should they not achieve the specific MLR target. Thus, the accuracy of MLR calculation is important to conserving Medicaid funds.

This 2019 CIB provided additional guidance regarding the calculation of the MLR when third party vendors, such as PBMs, are involved. The purpose was to assist States in ensuring that revenues, expenditures and amounts are appropriately identified and classified for the MLRs submitted by managed care plans, especially when a subcontractor is used. The 2019 CIB uses PBM spread pricing as a specific example. Several States have already implemented prohibitions or other restrictions on the PBM practice of spread pricing. Although there is not currently a Federal prohibition on using spread pricing in Medicaid, as noted, we issued the 2019 CIB regarding the impact of the lack of transparency between costs for administrative functions versus actual Medicaid services on the managed care plan's MLR calculation. The 2019 CIB is clear that when the subcontractor, in this case the PBM, is performing administrative functions, such as eligibility and coverage verification, claims processing, utilization review, or network development, the expenditures and profits on these functions are a non-claims administrative expense as described in § 438.8(e)(2)(v)(A), and should not be counted as an incurred claim for the purposes of MLR calculations.

In addition, the Medicaid managed care regulation at § 438.230(c)(1) requires, through contractual requirements in the managed care contract between the managed care plan and the State, certain agreements to be in subcontracts, including that subcontractors agree to perform the delegated activities and reporting responsibilities in compliance with the managed care plan's contract obligations. Moreover, the reporting standards at § 438.8(k)(3) specify that managed care plans must require any third-party vendor providing claims adjudication activities to provide all underlying data associated with MLR calculation and reporting. The 2019 CIB explains how these regulatory obligations mean that all subcontractors that administer claims for the managed care plan must report the incurred claims, expenditures for activities that improve health care quality, and information about mandatory deductions or exclusions from incurred claims (overpayment recoveries, rebates, other non-claims costs, etc.) to the managed care plan.

The requirements and definitions in § 438.8 for these categories of costs and expenditures must be applied to the required reporting. The reporting from the subcontractor must have sufficient detail to allow a managed care plan to accurately incorporate the expenditures associated with the subcontractor's activities into the managed care plan's overall MLR calculation. The level of detail must meet the requirements in § 438.8(k)(3) and the level of detail that is required may vary based on what is necessary to accurately calculate an overall MLR or to comply with any additional reporting requirements imposed by the State in its contract with the managed care plan.

Medicaid managed care plans are generally paid by States using single monthly capitation payments that for the plan's coverage of the health care services covered under the Medicaid managed care contract, including CODs. If the managed care plan contracts with a PBM, there are different options for the managed care plan to pay the PBM for the administrative services provided by the PBM. Payment for administrative services is made in addition to the amount the managed care plan would reimburse the PBM for the actual COD and dispensing fee costs. In general, managed care plans have paid PBMs for administrative services in one of two ways, or a mix of these approaches—either through a flat administrative fee per prescription, or, as described above, by including it in the overall COD payment (that is through ''spread pricing'').

When payments to the PBM for the administration services are included in the managed care plans' total COD payment without a clear delineation of which amount is for administrative services, it obscures how much of that total payment is actually paid to the provider for the prescription and what is paid for administrative services furnished by the PBM. In other words, it is difficult for the managed care plan to determine the proportion of the payment to the PBM that is attributable to the administrative service costs provided by the PBM.

Furthermore, incorrectly attributing administrative service costs as medical expenditures, may increase the MLR numerator, and thus increase the per-member-per-month (PMPM) revenue a managed care entity can receive while appearing to meet MLR requirements. Given this lack of transparency, the ''spread'', which has been the basis for generating significant PBM profit, obscures from Medicaid and the managed care plans the actual cost of the CODs dispensed to plan enrollees. This makes it difficult for managed care plans and State Medicaid agencies to determine whether the amount that the PBM is charging to administer the benefit is a reasonable expense to be borne by a Medicaid program. Moreover, it makes it difficult for plans to ensure that their MLR calculations appropriately classify and account for expenditures.

We provide a representative example of how spread pricing occurs in the context of Medicaid prescription drug coverage provided by a managed care plan. Specifically, in Table 2, we illustrate how a PBM might leverage a 5 percent difference in the AWP value between the amount charged to the plan and the amount paid to the pharmacy for a commonly-dispensed generic drug product, to ultimately capture 30.76 percent of the dollars spent by the managed care plan for the prescription.

TABLE 2—EXAMPLE OF SPREAD PRICING

Drug Product	NDC 1234567890, Drug 300 MG CAPSULE, 60 capsules in prescription.
Published AWP	$1.33 per capsule.
PBM Reimbursement to pharmacy (MAC)	((AWP − 90%) * 60) + $1 dispensing fee = $8.98.
Amount PBM billed to Managed care plan	((AWP − 85%) * 60) + $1 dispensing fee = $12.97.
PBM spread =	($12.97 − $8.98) = $3.99.
PBM spread percentage =	($3.99/$12.97) = 30.76% of total cost to managed care plan.

Table 2 shows that, while the pharmacy only received $8.98 in reimbursement from the PBM for the prescription, PBM charged the managed care plan $12.97, or about 31 percent more for the same prescription. Depending on the specifics of the contract that the PBM has with the managed care plan, some of this margin or spread might be used to pay the PBM for managing or administering the pharmacy benefit but in some cases, this spread may be in addition to administrative fees paid by the plan to the PBM. For example, there may already be included in the contract a specific fee that the Medicaid MCO is paying for the administration of the COD benefit. These fees would be in addition to the amounts being paid as part of the ''spread pricing.''

However, unless the managed care plan knows the amounts that the pharmacy providers are being paid by the PBM, the managed care plan is unable to assess the full scope of payments to the PBM for administrative services furnished by the PBM. As a result, the plan may not know whether the PBM is being appropriately compensated for administering the COD benefit.

While the per-prescription dollar amounts above may not appear substantial, the overall impact to a Medicaid managed care pharmacy program may be significant given generic claims represent greater than 90 percent of total pharmacy claims. For example, an analysis of Ohio's Medicaid managed care program by the Ohio Auditor of State revealed $208.4 million of spread within their managed care plan's PBM transactions for generic drug claims between April 1, 2017, and March 31, 2018.[6] For the time period analyzed, this amount of PBM spread represented 31.4 percent of total generic drug expenditures within the State's Medicaid managed care program.

CMS has determined that 11 States[7] have enacted relevant legislation related to the practice of spread pricing. Four of these States (Arkansas, Delaware, Michigan, and Oklahoma) have complete State-wide prohibitions on the practice of spread pricing for any PBM operating within the State, regardless of the payer. Five States (Kentucky, Louisiana, New York, Pennsylvania, and Virginia) prohibit the practice of spread pricing by PBMs or MCOs in Medicaid, explicitly. One State (Pennsylvania) further requires that all Medicaid MCOs include a spread pricing prohibition clause in all contracts with PBMs. Only 2 of the 11 States with spread pricing laws (Alabama and Montana) merely require disclosure of certain spread pricing information (that is, annual report of aggregate rebate information and whether the PBM engages in spread pricing). Spread pricing can increase Medicaid pharmacy program costs, reduce efficient operation of the Medicaid program, and reduce the transparency of State Medicaid expenditures within managed care programs. This makes it more difficult for managed care plans and States to discern which participants of the pharmacy supply chain retain the bulk of the COD reimbursement.

For these reasons, we are proposing to amend § 438.3(s) to require Medicaid MCOs, PIHPs, and PAHPs that provide coverage of CODs to structure any contract with any subcontractor for the delivery or administration of the COD benefit require the subcontractor to report separately the amounts related to the incurred claims described in § 438.8(e)(2), such as reimbursement for the CODs, payments for other patient services, and the dispensing or administering providers fees, and subcontractor administrative fees. The proposal would ensure that MLRs reported by MCOs, PIHPs, and PAHPs that use subcontractors in the delivery of COD coverage would be more accurate and transparent. The separate payment requirements would help States and managed care plans better understand whether they are appropriately and efficiently paying for the delivery of CODs, a significant part of which is funded by the Federal Government. We note that this proposal does not change the applicability of the 2019 CIB to PBM subcontractors or to other subcontracting arrangements used by a Medicaid managed care plan; the 2019 CIB remains CMS' position on how §§ 438.8 and 438.230 apply. This proposal would create additional requirements for MCOs, PIHPs and PAHPs that help ensure that the objectives and responsibilities outlined in the 2019 CIB are met.

The proposal requires MCOs, PIHPs, and PAHPs that cover CODs to require their subcontractors to report their costs in a way that aligns more fully with the specific categories specified in § 438.8(e)(2) regarding the MLR numerator. Fully aligning the subcontractor's reports and billing (invoices) with how the MLR regulation categorizes and treats specific costs and expenditures would make clearer for the MCOs, PIHPs, and PAHPs how its payments to a subcontractor are used that would be subject to proposed § 438.3(s)(8), and allow those managed care plans to incorporate the subcontractor's costs into the MLR reporting and calculation. However, having the subcontractor's (in particular a PBM's) expenditures and costs reported in the categories that we are proposing might not be representative of how the industry works, might require systems changes and impose burden that we have not taken into account, or might result in unintended consequences. Therefore, we are specifically soliciting comment on this point and on other alternatives for how MCOs, PIHPs, and PAHPs should require information from their subcontractors and how they should structure payment or billing arrangements to achieve the policy goals we have outlined.

We believe this new transparency requirement would assist States and Medicaid managed care plans in complying with § 438.8 and related guidance because subcontractor PBMs would be required to appropriately identify certain costs, so that the managed care plan can appropriately calculate its MLR. In particular with COD spending, the managed care plan would have to separately identify prescription drug and dispensing or administration fee claim costs when calculating the MLR, in contrast to

[6] David Yost, Ohio's Medicaid Managed Care Pharmacy Services Auditor of the State Report (2018), available at *https://tinyurl.com/mbn75c.*

[7] *https://nashp.org/comparison-of-state-pharmacy-benefit-managers-laws/.*

administrative costs. As a result, any payments for costs over and above the cost of the prescription and dispensing fee would be separately identifiable by the managed care plan and cannot be used to inappropriately inflate the MLR which may result in managed care plan capitation rates that are not actuarially sound.

C. MDRP Administrative and Program Integrity Changes

1. Proposed Definitions (§ 447.502)

a. Proposal To Modify the Definition of Covered Outpatient Drug (§ 447.502)

Sections 1927(k)(2) and (3) of the Act provide a definition of the term ''covered outpatient drug'' (COD) and a limiting definition, which excludes certain drugs, biological products, and insulin provided as part of, or as incident to and in the same setting as, enumerated services and settings from the definition of COD. This exclusion is subject to a parenthetical, however, which limits the exclusion to when payment may be made as part of payment for the enumerated service or setting, and not as direct reimbursement for the drug.

In the COD final rule, we finalized a regulatory definition of COD in § 447.502 that substantially mirrors the statutory definition. Consistent with section 1927(k)(3) of the Act, the regulatory definition includes a limiting definition in paragraph (2) of the definition of covered outpatient drug at § 447.502 that excludes from the definition of COD any drug, biological product, or insulin provided as part of or incident to and in the same setting as any one in a list of services, and for which payment may be made as part of that service instead of as a direct reimbursement for the drug.

Over the years we have received questions about when a payment is considered to be a direct reimbursement for a drug and whether identifying a drug separately on a claim for payment may qualify as direct reimbursement for a drug, rendering the drug eligible for rebates under section 1927 of the Act as a COD, or in other words, garnering the limiting definition exclusion inapplicable. If a drug and its cost can be separately identified on a claim for payment it can be considered subject to direct reimbursement. That is, if the payment to the provider includes any reimbursement for the drug and the drug is separately identified, then the reimbursement for the drug is a direct reimbursement. Additionally, if the payment to the provider is solely for the drug (and no other services), and the drug is separately identified, it is also a direct reimbursement. Therefore, direct reimbursement may be reimbursement for a drug alone, or reimbursement for a drug plus the service, in one inclusive payment, if the drug plus the itemized cost of the drug are separately identified on the claim. In other words, the payment for the drug is not required to be a separate payment in order for such payment to be considered direct reimbursement.

To provide greater clarity on this point and the application of the limiting definition, we propose to amend the regulatory definition of the term covered outpatient drug at § 447.502 to add that direct reimbursement for the drug includes when a claim for payment identifies the drug plus the itemized cost of the drug. Specifically, we propose to add to the regulatory definition of covered outpatient drug at § 447.502 that the direct reimbursement for a drug may include both reimbursement for a drug alone, or reimbursement for a drug plus the service, in one inclusive payment, if the drug and the itemized cost of the drug are separately identified on the claim.

Additionally, the limiting definition in section 1927(k)(3) of the Act includes the following parenthetical: ''. . . (and for which payment may be made under this subchapter as part of payment for [certain services] and not as direct reimbursement for the drug).'' The term covered outpatient drug is defined in § 447.502 and includes this limiting definition parenthetical at paragraph (2): ''. . . (and for which payment may be made as part of that service instead of as a direct reimbursement for the drug).''

There is no meaningful distinction between the statutory and regulatory language for purposes of the MDRP, and thus, we are proposing to make a technical change by modifying the regulatory language so that it more closely mirrors the statutory language. We propose to add ''payment for'' after ''and for which payment may be made as part of'' and to delete ''instead of as a'' in the limiting definition of covered outpatient drug and replace it with ''and not as''.

The proposed definition would then read, in significant part, as ''. . . (and for which payment may be made as part of payment for that service and not as direct reimbursement for the drug).''

b. Proposal To Define Drug Product Information (§ 447.502)

Section 6(a)(1)(A)(iv) of MSIIA amended section 1927(b)(3) of the Act by adding the words ''and drug product'' to the title of section (b)(3), and adding section (b)(3)(A)(v), to require a manufacturer to report drug product information that the Secretary shall require for each of the manufacturer's CODs no later than 30 days after the last day of each month of a rebate period. Section 1927(b)(3)(A) of the Act describes the manufacturer drug product and pricing information that is required to be reported to the agency by statute, and with respect to the pricing information, specifically provides for the reporting of such information, such as AMP and best price. To support the implementation of this new statutory requirement to report drug product information, we propose to define drug product information at § 447.502.

We currently require manufacturers to submit drug product information when the covered outpatient drug is entered into the MDP system, although there is no regulatory definition of drug product information. When initially reporting drug product data upon the execution of an NDRA, manufacturers have 30 days after the date on which they enter into an NDRA to report drug product data for their existing CODs under section 1927(b)(3)(A) of the Act. After the execution of an NDRA, manufacturers have 30 days from the end of each rebate period to report drug product data for new CODs under section 1927(b)(3)(A)(v) of the Act.

We propose to define ''drug product information'' in § 447.502 as information that includes, but is not limited to, NDC number, drug name, units per package size (UPPS), drug category (''S'', ''I'', ''N''), unit type (for example, TAB, CAP, ML, EA), drug type (prescription, over-the counter), base date AMP, therapeutic equivalent code (TEC), line extension drug indicator, 5i indicator and route of administration, if applicable, FDA approval date and application number or OTC monograph citation if applicable, market date, COD status, and any other information deemed necessary by the agency to perform accurate URA calculations.

As previously discussed in this proposed rule, the drug category for an NDC should be single source or innovator for the entire history of the NDC if it was always produced, distributed, or marketed under an NDA, unless a narrow exception applies, or single source if marketed under a BLA. If a narrow exception has been granted by CMS, the drug category for that NDC should historically be reported as single source or innovator, and can be changed to noninnovator, effective April 1, 2016. We use the FDA ''applications.txt'' file to verify the type of application associated with an application number. The file may be accessed using the link to the Drugs@FDA download file found

on the FDA web page at *https://www.fda.gov/drugs/drug-approvals-and-databases/drugsfda-data-files*.

The only situation in which a drug that is produced or marketed under an NDA may be reported as a noninnovator drug is if a narrow exception was granted by CMS in accordance with the process established in the COD final rule. See 81 FR 5191. Definitions for these drug categories can be found at section 1927(k)(7) of the Act and at § 447.502.

Manufacturers should evaluate all of their NDCs for compliance with drug product information reporting, and if they determine corrections are required, they should contact the agency for assistance. In Manufacturer Release No. 113, we address a manufacturer's responsibility to ensure that all of their CODs are correctly classified and reported in the Drug Data Reporting system (DDR) for the history of the NDC, including such NDCs that may no longer be active: *https://www.medicaid.gov/prescription-drugs/downloads/mfr-rel-113.pdf*.

As part of a manufacturer's evaluation of their NDCs for compliance with accurate drug product information reporting, they should ensure that each NDC is reported with an accurate market date. In this proposed rule, we are proposing to add a definition for ''market date'' for the purposes of the MDRP. Please see proposed § 447.502 for that proposed definition and elsewhere in this preamble for an explanation of how market date is used to determine the quarter that establishes each drug's base date AMP.

Generally, a manufacturer cannot make the drug product information corrections in the CMS system without our intervention. To request corrections, a manufacturer should contact CMS using instructions that are available on *Medicaid.gov* (*https://www.medicaid.gov/medicaid/prescription-drugs/medicaid-drug-rebate-program/medicaid-drug-rebate-program-change-request/index.html*) to correct drug product and pricing information. If we identify a misclassified or misreported NDC as part of the review of the information submitted by the manufacturer to support these drug pricing or product information changes, and notify the manufacturer, the link to the instructions for correcting the data would generally be included as part of that notification.

For most drug product information changes, as outlined above, we would make the requested changes on behalf of the manufacturer in the CMS system, and those changes would subsequently be available for manufacturer certification. However, in some situations where monthly and/or quarterly pricing data must be updated as a result of the drug product information change, if necessary, we would notify the manufacturer that certain pricing data fields have been ''unlocked'' in the CMS system to allow the manufacturer to enter or correct required pricing information if applicable.

Regardless of whether we make a data change on behalf of a manufacturer or whether the manufacturer enters required data directly in the CMS system, manufacturers would be required to certify the information in accordance with § 447.510. If we make a data change at the request of a manufacturer, the manufacturer is not relieved of its responsibility to ensure the accuracy of such data, nor should it be inferred that we have approved a variance from the requirements of the statute.

Until certification is complete, the changes in the CMS system are not considered final and would not be used in any quarterly rebate calculations or transmitted to the States as part of the quarterly rebate files; however, the manufacturer is still responsible for correct URA calculations and rebate payments. If drug product information changes are left uncertified, the previously certified values would remain in effect; therefore, corrections made in the CMS system that remain uncertified would result in the drug continuing to be considered misclassified or misreported. We would consider this to be late reporting of product data for which a manufacturer's rebate agreement may be suspended from the MDRP under section 1927(b)(3)(C)(i) of the Act, and eventually terminated as authorized under section 1927(b)(4)(B) of the Act.

c. Proposal To Define Internal Investigation for Purposes of Pricing Metric Revisions (§§ 447.502 and 447.510)

In accordance with section 1927(b)(3) of the Act, § 447.510 of the implementing regulations, and the terms of the NDRA, manufacturers are required to report certain pricing and drug product information to CMS on a timely basis or else they could incur penalties or be subject to other compliance and enforcement measures. As explained in the final time limitation rule, in an effort to improve the administration and efficiency of the MDRP and assist States and manufacturers that would otherwise be required to retain drug utilization pricing data records indefinitely, we established the 12-quarter time frame for reporting revisions to AMP or best price information. Notwithstanding the 12-quarter time frame for reporting revisions, we continued to receive requests outside of the 12-quarter period from manufacturers to revise pricing data. These types of manufacturer requests, which could span multiple years prior to the 12-quarter timeframe, and could sometimes result in substantial recoupment of Medicaid rebates already paid to States, impede the economic and efficient operation of the Medicaid program.

Consequently, in the COD final rule (81 FR 5278) we finalized § 447.510(b)(1), which provides that a manufacturer must report to CMS any revision to AMP, best price, customary prompt pay discounts or nominal prices (pricing data) for a period not to exceed 12 quarters from the quarter in which the data were due unless one of a number of enumerated exceptions applies. See § 447.510(b)(1)(i) through (vi). Of note, § 447.510(b)(1)(v) provides an exception to the 12-quarter price reporting rule if the change is to address specific rebate adjustments to States by manufacturers, as required by CMS or court order, or under an internal investigation, or an OIG or Department of Justice (DOJ) investigation.

In a response to comment in the preamble of the COD final rule, which added § 447.510(b)(1)(v), we indicated that internal investigation is intended to mean a manufacturer's internal investigation, and we further explained that in the event that a manufacturer discovers any discrepancy with its reported product and pricing data to the MDRP that are outside of the applicable timeframes, the manufacturer should determine if the change satisfies one of the enumerated exceptions. (81 FR 5280)

However, we did not further define or give any greater explanation for the applicability of the exception to the 12-quarter rule, particularly in instances when manufacturers perform an internal investigation of the prices (AMP and best price) reported and certified in the Medicaid Drug Product systems by another manufacturer. Given the absence of a definition of internal investigation or specificity as to when this exception applies, some manufacturers have broadly interpreted the internal investigation exception to the 12-quarter rule.

Some manufacturers have requested revisions to AMP and best price outside of the 12-quarter rule based upon an internal investigation related to newly acquired products or lines of business

previously certified by the prior manufacturers without making findings that the prior manufacturer violated any law. For example, some requests from manufacturers to revise AMP or best price for drug product and drug pricing information previously reported and certified from another manufacturer were based on internal reviews that did not result in proof that the prior manufacturer misapplied the laws or regulations, or acted in a fraudulent or illegal manner.

In cases when a manufacturer requests an exception to the 12-quarter rule due to an internal investigation, we propose to specify that the manufacturer must make a finding that indicates a violation of statute or regulation made by the prior manufacturer before we consider such a request. For example, a request to restate or revise pricing outside of the 12-quarter time frame by a manufacturer to previously reported and certified data of a prior manufacturer based upon a mere disagreement with the prior manufacturer's government pricing calculations and assumptions would not be considered a valid reason to revise a prior manufacturer's pricing outside of the 12-quarter time frame. The manufacturer must make findings that include actual data as evidence that the prior manufacturer violated statute or regulation.

Manufacturers should not use the internal investigation exception to permit restatements to allow manufacturers to apply a different methodology or reasonable assumption to determine AMP and best price to its favor when the methodology originally applied was consistent with statute and regulation, and drug product and pricing information was properly reported and certified by the manufacturer at the time. To ensure clarity on when the internal investigation exception may be appropriately applied, we are proposing to define internal investigation at § 447.502 to mean a manufacturer's investigation of its AMP, best price, customary prompt pay discounts or nominal prices that have been previously certified in MDRP that results in a finding made by the manufacturer of fraud, abuse or violation of law or regulation. A manufacturer must make data available to CMS to support its finding. We are also proposing to amend § 447.510(b)(1)(v) to reference the proposed definition of internal investigation at § 447.502.

d. Proposal To Revise Definition of Manufacturer for NDRA Compliance (§ 447.502)

When Congress passed the drug rebate provisions in 1990, they established a framework for coverage and payment of covered outpatient drugs under Medicaid, and prescribed drugs, generally. Often referenced as the ''grand bargain'' between the States, the Federal Government, and manufacturers, the MDRP made clear that if manufacturers paid rebates for the covered outpatient drugs dispensed and paid for under the State Plan, States would be required to cover their covered outpatient drugs, subject to limited permissible restrictions and exclusions. These policies would help increase Medicaid beneficiaries' access to medications, while assisting States in striving to deliver an economic and efficient Medicaid program. A key piece of the coverage and payment framework the MDRP established is captured in section 1927(a)(1) of the Act, which provides that in order for payment to be available under section 1903(a) or under part B of title XVIII for covered outpatient drugs of a manufacturer, the manufacturer must have entered into and have in effect a rebate agreement with the Secretary as described in section 1927(b) of the Act.

With an effectuated rebate agreement in place, manufacturers participating in the MDRP are required to provide periodic rebates for CODs dispensed and paid for under the State Plan, and also provide certain drug price and drug product information on a monthly and/or quarterly basis to the agency. While entering into a rebate agreement is voluntary, a manufacturer that does not enter into such an agreement forgoes payment and coverage, for their covered outpatient drugs under Medicaid. It also affects coverage under the 340B Drug Pricing Program and may affect Medicare Part B reimbursement.

To implement the important requirement set forth at section 1927(a)(1) of the Act, and in an effort to prevent selective reporting of NDCs, the agency has required manufacturers to ensure that all their associated labeler codes with CODs enter into a rebate agreement to comply with the terms of the NDRA. This requirement has been included in the NDRA since the inception of the program. (See section II., Manufacturer's Responsibilities, subsection (a) of the previous NDRA, and section II., Manufacturer's Responsibilities, subsection (b) of the updated NDRA.) We also reiterated this point most recently in the preamble to the updated NDRA, 83 FR 12770 (Mar. 23, 2018). In that final notice, we explained that manufacturers are required to report all CODs under their labeler code(s) to the MDRP, and may not be selective in reporting their national drug codes (NDCs) to the program.

We continue to maintain that this requirement applies to all the manufacturer's labeler codes, including newly acquired labeler codes, newly formed subsidiaries, and labeler codes previously omitted from the original rebate agreement. 83 FR 12771; see also Manufacturer Releases #13 and #48. Thus, once we review a request for a rebate agreement and the manufacturer confirms, among other things, that all of a manufacturer's CODs are listed, a rebate agreement will be issued. Manufacturers are then responsible for paying a rebate on those CODs that were dispensed and/or paid for, as applicable, under the State Plan. These rebates are paid by manufacturers on a quarterly basis to States, and are shared between the States and the Federal Government to partially offset the overall cost of prescription drugs under the Medicaid program.

The term ''manufacturer'' was first defined in statute in 1990, when section 1927 of the Act was established, and was interpreted in regulation in 2007 at § 447.502. Section 1927(k)(5) of the Act defines the term ''manufacturer'' as any entity which is engaged in: (1) the production, preparation, propagation, compounding, conversion, or processing of prescription 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) in the packaging, repackaging, labeling, relabeling, or distribution of prescription drug products.

The regulations at § 447.502 define ''manufacturer'' to mean any entity that holds the NDC for a covered outpatient drug or biological product and meets the following criteria:

- 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
- 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.

• For authorized generic products, the term ''manufacturer'' will also include the original holder of the NDA.

• 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.

The labeler code is a unique 5-digit number within the NDC,[8] assigned by the FDA, and one manufacturer may be assigned multiple labeler codes by FDA. A manufacturer can obtain a different labeler code for each manufacturing establishment or company under the same ownership since the labeler code identifies a company marketing a drug product.[9] Some drug companies that have several divisions have more than one labeler code, and a single manufacturer may be marketing its drugs across or under multiple labeler codes. Furthermore, a manufacturer may own, operate, or be associated or affiliated with several labeler code subsidiaries, each of which makes CODs.

Consistent with the statute and regulation, our current policy is that each of these associated labeler codes would have to have an effectuated rebate agreement in order for the single manufacturer to be considered to be in compliance with the requirement under section 1927(a)(1) of the Act that a manufacturer have a rebate agreement in effect, and this has been noted in related guidance.[10] We treat each associated labeler code as part of the single manufacturer, and if any of the labeler codes of a manufacturer do not have an NDRA in effect, no FFP would be available for any of the CODs of the labeler codes of the manufacturer, and all of the labelers would be subject to potential termination from the MDRP.

We also explained in the final notice for the updated NDRA that manufacturers that wish to terminate an NDRA that have active CODs must request termination for all associated labeler codes, and provide a reason for the request (for example, all CODs under the labeler code are terminated), or if the request for termination is only for certain labeler codes, provide justification for such request (83 FR 12770, 12771). In that same final notice, we indicated that for purposes of ensuring beneficiary access to single source drugs and/or drugs that are not otherwise available in the MDRP, we may choose to grant an exception to issuing or reinstating an NDRA for certain labeler codes of a manufacturer prior to issuing an NDRA for all of the labeler codes of the manufacturer, or terminating certain labeler codes as mentioned above (83 FR 12771).

The requirement that manufacturers that enter into a rebate agreement cannot exclude any covered outpatient drug from their listings applies to all CODs associated with any of the manufacturer's labeler codes that market CODs, including newly-purchased labeler codes, and newly-formed subsidiaries. This means a manufacturer has to be ''all in'' for all its drugs, or ''all out''. Otherwise, there is a possibility that a manufacturer would create separate labeler codes for some of its drugs, and enter into a rebate agreement for some of its labeler codes, and not others. Permitting a manufacturer to do so would allow them the benefit of receiving FFP for some of their CODs, while potentially avoiding the financial obligation to pay rebates for other drugs that would otherwise qualify as CODs and be subject to rebates. If a product meets the definition of a covered outpatient drug, but the manufacturer of such drug does not have a rebate agreement in effect, that drug is not eligible for FFP and may not be claimed on the CMS–64 form, even though the drug may meet the definition of a prescribed drug. In these situations, while States would not be required to provide mandatory coverage of such drugs, a State may still elect to cover these products with State only funds.

While we believe that the overwhelming majority of manufacturers are compliant with section 1927(a)(1) of the Act, and have had all their associated labelers enter into and maintain drug rebate agreements, this issue has been challenged by a few manufacturers. In more recent times, manufacturers have suggested certain associated labelers are exempt or not required to be included in the program under the manufacturer's rebate agreement, stating that such associated companies, parent entities and brother-sister entities are distinct separate manufacturers. They have stated that the agency has not required such a policy through final regulations, but rather has articulated this policy only in program releases and preamble statements, which are subregulatory guidance that do not carry the force of law.

To codify the requirement at section 1927(a)(1) of the Act, that a manufacturer have entered into and have in effect an agreement with the Secretary to receive FFP for its CODs, we are now proposing to modify the regulatory definition of manufacturer to specify how the term ''manufacturer'' is defined for purposes of complying with this statutory requirement. To satisfy the requirement that a manufacturer have entered into and have in effect an agreement with the Secretary, we are specifying at proposed § 447.510(h) that manufacturers must provide CMS with all labeler codes for all the manufacturer's applicable drugs. More specifically, we are proposing at § 447.510(h)(2) that if any manufacturer with a signed rebate agreement in effect, acquires or purchases another labeler, acquires or purchases covered outpatient drugs from another labeler code, or forms a new subsidiary, they must ensure that a signed rebate agreement is in effect for these entities or covered outpatient drugs, consistent with the definition of manufacturer at § 447.502, within the first 30 days of the next full calendar quarter beginning at least 60 days after the acquisition, purchase, asset transfer, or formation of the subsidiary.

As first described in the ''Medicaid Program; Payment for Covered Outpatient Drugs Under Drug Rebate Agreements With Manufacturers'' proposed rule (95 FR 48442; hereinafter referenced as the ''1995 proposed rule''), we have noted our intent that each associated manufacturer's labeler codes would have to have an effectuated rebate agreement in order for the single manufacturer to be considered to be in compliance with the requirement under section 1927(a)(1) of the Act that a manufacturer have a rebate agreement in effect. This 1995 proposed rule is informative and helpful to understanding and describing the agency's initial proposed policy and intentions with the Medicaid Drug Rebate Program.[11] In this proposal, CMS proposed to interpret the term ''manufacturer'' to specify that if a corporation meets the statutory definition of manufacturer (that is, section 1927(k)(5) of the Act) and possesses legal title to the NDC, the agency would consider the term to include associated companies, including parent corporations, brother-sister corporations, and subsidiary corporations. In addition, we further proposed to interpret the term to specify that if a corporation meets the statutory definition of manufacturer, and possesses legal title to the NDC number, we would consider the term to include: (1) Any corporation that owns at least 80 percent of the total combined voting power of all classes of stock or 80 percent of the total value of shares in all

[8] See 21 CFR 207.33.

[9] Electronic Drug Registration and Listing Instructions | FDA.

[10] Manufacturer Release 013 (October 6, 1994), Manufacturer Release 048 (November 15, 2000) and 83 FR 12770, 12771 (Mar. 23, 2018).

[11] 60 FR 48447 through 48448.

classes of stock in such entity (that is a parent corporation); (2) Any other corporation in which a parent corporation of the entity owns at least 80 percent of the total combined voting power of all classes of stock or 80 percent of the total value of shares. (60 FR 48447–48448)

This policy comports with Congress' desire to maximize recipient access to medically necessary drugs, while at the same time providing a more favorable drug purchasing arrangement for State Medicaid programs.[12] When Congress passed the drug rebate provisions in 1990, they made it clear that States that elect to cover prescription drugs must, except for certain restrictions or exclusions allowed under the statute, cover the CODs of a manufacturer that enters into and complies with a drug rebate agreement. In return for such coverage, a manufacturer would be responsible for providing a rebate to the State that would give the Medicaid program the benefit of those discounts that other large public and private purchasers receive.[13]

We believe it would be directly contrary to Congressional intent to apply the definition of a manufacturer in a manner that would permit a manufacturer (that is by forming a subsidiary corporation) to exclude some of its drugs from the drug rebate program.[14] Our proposal would prevent manufacturers from manipulating the system as to select drugs by assigning separate labeler codes, without consequence to all of their CODs, and codify a longstanding policy that has faced scrutiny more recently. As such, we continue to believe that when defining a manufacturer, the term ''entity'' should be interpreted to include parent, brother-sister, or subsidiary corporations, as well as, labelers that are owned, acquired, subsidiaries, affiliates, parent companies, franchises, business segments, part of holding companies, or under common corporate ownership or control.

Therefore, to provide a clearer definition of the meaning of manufacturer with respect to section 1927(a)(1) of the Act, we are proposing to amend the regulatory definition of manufacturer at § 447.502. Consistent with the statute and our understanding of Congressional intent of the MDRP, which was increasing access to medications while at the same time helping States manage pharmacy program costs and maximizing Medicaid savings, we are proposing to include a new paragraph (5) as part of the definition of a manufacturer. This change explains that, for purposes of meeting the requirements in section 1927(a)(1) of the Act of maintaining an effectuated rebate agreement, that the term ''manufacturer'' means that all associated labeler entities of the manufacturer that sell prescription drugs, including, but not limited to, owned, acquired, affiliates, brother or sister corporations, operating subsidiaries, franchises, business segments, part of holding companies, divisions, or entities under common corporate ownership or control, must each maintain an effectuated rebate agreement in order for a manufacturer to satisfy the requirement at section 1927(a)(1) of the Act to have entered into and have in effect a rebate agreement with the Secretary.

Additionally, we are proposing a new paragraph (h), ''Participation in the Medicaid Drug Rebate Program (MDRP),'' in § 447.510 to further specify the responsibilities of a manufacturer, specifying in § 447.510(h)(1) that manufacturers participating in the MDRP must have a signed rebate agreement that complies with paragraph (5) in the definition of the manufacturer in § 447.502.

Furthermore, with respect to rebate agreements when a manufacturer acquires or purchases another manufacturer, acquires or purchases covered outpatient drugs from another manufacturer, or forms a new subsidiary, we are proposing to add § 447.510(h)(2), ''Newly purchased labeler codes and covered outpatient drugs.'' We are proposing that any manufacturer with a rebate agreement in effect that acquires or purchases another labeler code, acquires or purchases covered outpatient drugs from another labeler, or forms a new subsidiary, must have in effect a rebate agreement for these entities or covered outpatient drugs consistent with definition of manufacturer at § 447.502. The newly associated entity of the manufacturer must also have a rebate agreement in effect within the first 30 days of the next full calendar quarter beginning at least 60 days after the acquisition, purchase, asset transfer, or creation of a subsidiary has occurred. By including these provisions in regulation, we would better specify that a manufacturer must, in part, assure that a NDRA is in effect with the Secretary for all associated labeler codes and that MDRP requirements apply to all CODs of a manufacturer, including newly associated entities.

Finally, we are proposing to add a provision on termination in at § 447.510(h)(3) specifying that each associated labeler code of a manufacturer is considered to be part of the single manufacturer, and if any of the associated labeler codes as defined in paragraph (5) of the definition of manufacturer at § 447.502 do not have an NDRA in effect, or are terminated, then all of the labeler codes will be subject to termination.

e. Proposal To Define Market Date (§ 447.502)

Section 1927 of the Act governs the MDRP and payment for CODs which are defined in section 1927(k)(2) of the Act. Manufacturers that participate in the MDRP are required to pay rebates for CODs that are dispensed and paid for under the State Medicaid plan. (See section 1927(b)(1)(A) of the Act.) Section 1927 of the Act provides specific requirements for program implementation, including requirements for rebate agreements, submission of drug pricing and product information, confidentiality, the formulas for calculating rebate payments, and many others related to State and manufacturer obligations under the program. The rebates due by manufacturers are calculated based on statutory formulas described in section 1927(c) of the Act and consist of a basic rebate and, in some cases, an additional rebate that is applicable when an increase in the AMP, with respect to each dosage form and strength of a drug, exceeds the rate of inflation. This additional rebate formula is set forth in sections 1927(c)(2) and 1927(c)(3)(C) of the Act, and codified in regulation at § 447.509(a)(2) and (7).[15]

The additional rebate calculation requires a determination of the AMP for the dosage form and strength of the drug for the current rebate quarter, and a comparison of that AMP to the AMP for the dosage form and strength of that drug for a certain calendar quarter, generally referenced as the base date AMP quarter.[16] For S or I drugs, that

[12] H.R. Conf. Rept. No. 964, 101st Cong., 2d Sess. 822, 832 (1990); H.R. Rept. No. 881, 101st Cong., 2d Sess. 996 (1990).

[13] Id.

[14] Id.

[15] Section 602 of the Bipartisan Budget Act (BBA) of 2015 amended section 1927(c)(3) of the Act, to require that manufacturers pay additional rebates when their covered outpatient drugs other than single source or innovator multiple source drugs' average manufacturer prices increase at a rate that exceeds the rate of inflation. In accordance with section 1927(c)(3) of the Act, as revised by section 602 of the BBA of 2015, manufacturers must calculate these additional rebates for these drugs beginning with the January 1, 2017 quarter (that is, first quarter of 2017).

[16] Base Date AMP is defined in the National Drug Rebate Agreement (NDRA) at I.(c) as follows: ''Base

base date AMP quarter is the third quarter of 1990, for drugs that were first marketed prior to fourth quarter of 1990, or the first full calendar quarter after the day on which the drug was first marketed for drugs that were first marketed on or after October 1, 1990.[17] See sections 1927(c)(2)(A) and 1927(c)(2)(B) of the Act. For other drugs (including N drugs and other drugs reported as N), that base date AMP quarter is the third quarter of 2014 for drugs that were first marketed prior to April 1, 2013, or the fifth full calendar quarter after the day on which the drug was first marketed for drugs that were first marketed on or after April 1, 2013. See section 1927(c)(3)(C) of the Act. To determine the applicable base date AMP, and ultimately, to calculate the additional rebate for a quarter, a critical data point is the day on which the drug was first marketed. We reference this date as a COD's ''market date.'' Manufacturers are required to report to CMS the market date of each dosage form and strength of a COD for all of its CODs.

Section 1927(c)(2)(A)(ii)(II) of the Act expressly provides that the base date AMP quarter, with respect to a dosage form and strength of a drug, is established ''without regard to whether or not the drug has been sold or transferred to an entity, including a division or subsidiary of the manufacturer. . .'' This means the market date of a drug is the date that the drug was first marketed, regardless of the entity that marketed the drug. Consistent with the statute, the market date of a drug is not and cannot be based on the first date upon which a subsequent manufacturer first markets the drug, but rather the earliest date on which the drug was first marketed, by any manufacturer, or under any NDC.

A new market date cannot be established for a drug that is marketed under the same FDA-approved NDA number, ANDA number or BLA license unless the drug is a new dosage form or strength because the rebate statute requires an additional rebate amount based on the market date for each dosage form and strength of a COD.[18] Thus, if a drug is purchased or otherwise acquired from another manufacturer, the market date should not change, and should equal the market date of the drug first marketed under the approved application.

Some manufacturers have attempted to set a new market date to establish a new base date AMP for a drug by making changes to a drug already approved under an FDA application that are something other than changes to the dosage form or strength. If changes to the drug are approved under the same FDA application and do not constitute changes to the dosage form or strength, a new base date AMP is not appropriate.

Over the years, manufacturers have sporadically engaged in debate regarding the determination of a COD's market date, base date AMP quarter, and base date AMP under varied fact-driven scenarios. This proposed definition seeks to clarify the term ''market date'' as used in the MDRP and to end any further such debates.

AMP is defined in section 1927(k)(1) of the Act and the definition includes that it is ''. . . the average price paid to the manufacturer for the drug. . . .'' If there have not been any sales of the drug, there is no data upon which to determine an average price paid to the manufacturer to most accurately calculate the AMP value. Historically, in such cases where no sales may have occurred in a base date AMP quarter (because sometimes a new NDC may be available for sale during a quarter, but no sales occurred during that quarter), we have advised manufacturers to use reasonable assumptions, as appropriate, and consistent with applicable law to establish an AMP.

To assist manufacturers in reporting a more accurately calculated AMP, we are proposing to define market date based on the first sale of the drug, rather than the date the drug was first available for sale. Linking the market date determination to the date of the first sale, rather than the date the drug was first available for sale, would permit a manufacturer to establish and report a base date AMP without reliance on reasonable assumptions, and based on actual data. As a result, the URA would also be calculated more accurately because actual sales would be available for reporting.

For purposes of determining the base date AMP quarter and base date AMP, we propose that market date be based upon the earliest date on which the drug was first sold, by any manufacturer, or under any NDC, and define the term to mean the date on which the COD was first sold by any manufacturer.

We propose that first sold means any sale of the COD. We understand defining market date, for purposes of determining a COD's base date AMP, based on when the COD was first sold, may not completely eliminate a manufacturer's need to make reasonable assumptions because the first sales may include only AMP ineligible sales. For example, if all the sales during the first quarter of a drug's availability are made to entities other than retail community pharmacies or wholesalers, and are not eligible for a 5i AMP calculation, then there may not be any AMP eligible sales to use for the calculation of AMP for that quarter. In such cases, a manufacturer may still need to use reasonable assumptions to report an AMP for that quarter.

We propose that ''sold'' means that the drug has been transferred (including in transit) to a purchasing entity. We are requesting comments on this topic to determine what qualifies as ''sold'' for the purposes of determining the market date of a drug, as we have also experienced manufacturers interpreting the term ''sold'' differently across the industry.

Because the term market date has not been previously defined in regulation and it is data used in the determination of base date AMP, we are proposing a definition of market date for the purposes of the MDRP. We are proposing at § 447.502 that market date, for the purpose of establishing the base date AMP quarter, means the date on which the COD was first sold by any manufacturer.

f. Proposal To Modify the Definition of Noninnovator Multiple Source Drug (§ 447.502)

As discussed previously in this proposed rule, section 6(c) of the MSIAA included a number of amendments to statutory definitions in section 1927 of the Act. Generally, those statutory amendments were discussed in the December 31, 2020 final rule (85 FR 87000, 87032) where the regulatory definitions of multiple source drug, innovator multiple source drug, and single source drug were amended consistent with the MSIAA.

Although we made conforming changes to the regulatory definition of an I drug in the December 31, 2020 final rule, because the MSIAA did not

Date AMP'' will have the meaning set forth in sections 1927(c)(2)(A)(ii)(II) and 1927(c)(2)(B) of the Act. See also I.(l) definition of ''marketed''. Section VIII.a, provides that the agreement is subject to any changes in the Medicaid statute or regulations that affect the rebate agreement. Thus, any changes to regulations will be incorporated into rebate agreements without further action. See also Manufacturer Release 113—Misclassification of Drugs (*medicaid.gov*); *https://www.medicaid.gov/medicaid-chip-program-information/by-topics/prescription-drugs/downloads/rx-releases/mfr-releases/mfr-rel-009.pdf Manufacturer release No. 9; form 367c data definitions.*

[17] For a drug with a market date prior to October 1, 1990, the MDRP reporting system defaults to a market date of September 30, 1990. The system assigns a base date AMP quarter of fourth quarter of 1990 to such drugs as the statute defines (section 1927(c)(2)(A)(ii) of the Act).

[18] The FDA approved application (for example the NDA itself) includes all FDA approved supplements to the application.

expressly amend or clarify the statutory definition of an N drug we did not consider whether any changes to the regulatory definition of an N drug were necessary at that time. After further evaluation, we propose to amend the regulatory definition of an N drug to conform the regulatory definition of an N drug to the regulatory definition of an I drug. When we established a regulatory definition of an N drug in the July 17, 2007 final rule, we did so to distinguish between multiple source drugs approved under an ANDA (generally referenced as N drugs) and multiple source drugs approved under an NDA (that is, S or I drugs). Both I drugs and N drugs are generally multiple source drugs. The main difference between the definitions is the authority under which the drug is marketed. Generally speaking, I drugs are marketed under an NDA and N drugs are marketed under ANDA, or are unapproved.

Section 1927(k)(7)(A)(iii) of the Act, which was not expressly amended or clarified by the MSIAA, defines a noninnovator multiple source (N) drug as a multiple source drug that is not an I drug. As noted, the MSIAA amended the statutory definition of an I drug by removing ''was originally marketed'' and adding ''is marketed,'' and we made conforming changes to the regulatory definition of an I drug in the December 31, 2020 final rule. When we modified the regulatory definition of an I drug to replace ''was originally marketed'' with ''is marketed'', we neglected to make a corresponding change to the definition of an N drug to maintain the clear distinction between an I drug, which is marketed under an NDA, and an N drug, which is not marketed under an NDA. Paragraph (3) of the regulatory definition of an N drug, codified at § 447.502, continues to refer to a COD that entered the market before 1962 that was not originally marketed under an NDA.

To maintain the clear distinction between an I drug and an N drug, we propose to amend paragraph (3) of the definition of an N drug at § 447.502 by removing ''was not originally marketed'' and inserting in place ''is not marketed.'' As amended, the regulatory definition of an N drug would, in relevant part, have the same structure as the statutory and regulatory definitions of an I drug and distinguish between a multiple source drug approved under an ANDA (that is, an N drug) and a multiple source drug approved under an NDA (that is, an S or I drug) based on the authority under which the drug is marketed, not how the drug was originally marketed.

Accordingly, we propose to amend § 447.502 by revising paragraph (3) of the definition of an N drug to read, a COD that entered the market before 1962 that is not marketed under an NDA. We believe this to be a technical correction to the regulatory text.

g. Proposal To Define Vaccine for Purposes of the MDRP Only (§ 447.502)

States that opt to cover prescribed drugs under section 1905(a)(12) of the Act in their State Plan are required to do so consistent with section 1927 of the Act, as set forth at section 1902(a)(54) of the Act. With limited exceptions, if a manufacturer wants payment to be available under Medicaid for their CODs, the manufacturer must participate (have entered into and have in effect a rebate agreement) in the MDRP, and agree to pay rebates for CODs dispensed and paid for under the State Plan. States are then required to cover the drugs of a manufacturer participating in the MDRP, if the drug satisfies the definition of COD, and then are required to invoice manufacturers for rebates on those CODs that are dispensed and paid for under the State Plan. If a particular drug or biological product of a participating manufacturer is excluded from or does not satisfy the definition of COD, then with limited exceptions, a State is not required to cover the product under the prescribed drugs benefit nor would it be subject to section 1927 of the Act. Moreover, those drugs or biological products are not eligible for rebate invoicing, even though a State may cover them and seek FFP.

Section 1927(k)(2)(B) of the Act specifically excludes vaccines from the definition of COD for purposes of the MDRP. This exclusion is codified in paragraph (1)(iv) of the regulatory definition of COD at § 447.502. Section 1927 of the Act, specifically, does not define vaccine. Nor is there a definition of vaccine in Title XI, XVIII, XIX, or XXI of the Act (applicable to Medicare, Medicaid, and CHIP), that speaks to the specific kinds of biological products that qualify as vaccines, in terms of their actions in the human body and how and when they are used. Moreover, we are not aware that any authorizing statutes for any other Department of Health and Human Services agencies include such a statutory definition of the term ''vaccine.'' We have not established a regulatory definition of vaccine for purposes of the MDRP, and we are not aware of any other statutory or regulatory definition of vaccine (that speaks to the actions of a product in the human body and how and when it is used) that would be applicable for purposes of the MDRP. However, for the reasons discussed in this section, we believe that a regulatory definition of vaccine is necessary for the purposes of the MDRP to specify which products are considered vaccines and thus excluded from the definition of COD.[19]

Generally, drugs and biological products that are used to treat a disease fall into one of the categories of CODs set forth at section 1927(k)(2) of the Act. Since Congress excluded vaccines from the definition of COD in the original 1990 law, and vaccines that were licensed at that time have a different intended use than therapeutics, we believe that vaccines were excluded because of their unique characteristics among medical products marketed at the time of preventing disease by inducing an immune response.

When the MDRP statute was enacted as part of the Omnibus Budget Reconciliation Act of 1990 (Pub. L. 101–508, enacted November 5, 1990), the term ''vaccine'' referred to a product administered to provide active immunity to a person to prevent an infectious disease.[20] At the time, it was generally understood that vaccines are administered prophylactically, to prevent the development of an infectious disease, not to treat an existing non-infectious disease (such as a cancer). Although we have not found any legislative history specifically indicating why Congress chose to exclude vaccines from the definition of COD, it is likely Congress understood the term ''vaccine'' to refer to preventive vaccines only (that is, we do not believe that Congress understood the term to

[19] Currently, for vaccines other than COVID–19 vaccines, Medicaid coverage of vaccines and vaccine administration for adults is generally optional for States. Coverage of certain vaccinations recommended by the Advisory Committee on Immunization Practices (ACIP) is required for children and youth under age 21 who are eligible for the Early and Periodic Screening, Diagnostic, and Treatment (EPSDT) benefit and for beneficiaries receiving Medicaid coverage through an Alternative Benefit Plan. Additionally, to receive a one percentage point increase in the Federal medical assistance percentage for certain expenditures, States must cover certain services, including approved adult vaccinations recommended by the Advisory Committee on Immunization Practices (ACIP), without cost-sharing. See *https://www.medicaid.gov/state-resource-center/downloads/covid-19-vaccine-toolkit.pdf* for more information. Beginning October 1, 2023, under section 11405 of the Inflation Reduction Act of 2022, States are required to cover approved adult vaccines recommended by the ACIP, and their administration, for many adults enrolled in Medicaid and the CHIP program, without cost sharing.

[20] See *https://purplebooksearch.fda.gov/*. The database at this link provides information about all FDA-licensed biological products, including the date on which they were licensed. All the vaccines listed in the ''Purple Book'' are licensed to prevent an infectious disease.

include therapeutic vaccines) because all licensed vaccines at the time the law was enacted shared those characteristics.

As the science of immunology has become more advanced, drugs and biological products have been, and continue to be, developed that treat diseases using immunotherapy, such as immunotherapy used to treat certain cancers. Some manufacturers refer to such products as ''therapeutic'' vaccines. While both preventive vaccines and ''therapeutic vaccines'' work by creating an immune response, each type of product has a unique role in health care.

In general, a preventive vaccine provides active immunity to a disease, that is, it causes the body's immune system to produce an antigen-specific immune response (for example, antibodies and/or a cellular immune response) to antigens of the disease-causing organism.[21] A preventive vaccine is generally administered to induce immunity and a ''memory'' response to a particular infectious disease-causing organism so that in the event an individual is later exposed to that disease, the body will recognize the disease and respond before the disease has a chance to manifest or to reduce the severity of illness. There are also situations in which a preventive vaccine may be administered to an individual who has already been exposed to a disease-causing organism but the disease has not yet developed and may be prevented by a timely and robust vaccine-induced immune response (for example, rabies and anthrax vaccines).

In contrast, ''therapeutic vaccines'' are generally biological products that are intended to induce an antigen specific immune response to treat an already established disease (for example, treatment of cancer by inducing a specific immune response to the tumor). This type of product is generally intended to be a treatment modality similar to other forms of immunotherapy such as the checkpoint inhibitors or strategies that are based on the transfer of a preformed immune response (for example, transfer of antibodies or immune effector cells.)

If ''therapeutic vaccines'' were considered vaccines that are excluded from the definition of COD at section 1927(k)(2)(B) of the Act, a Medicaid beneficiary's access to these products under the prescribed drugs benefit could be limited because States would not be required to cover them under that benefit. Moreover, coverage of such a product under other benefits might only be available if the CDC's Advisory Committee on Immunization Practices (ACIP) issued a recommendation for such a product. This potential lack of access to important therapies for Medicaid beneficiaries is a critical concern. Clinical research into ''therapeutic vaccines'' has been increasing and several have been licensed by FDA that offer treatments for diseases that previously had limited or no effective treatment available. Similarly, if products that provide passive immunity, such as immune globulins, were excluded from the definition of a COD, because they were identified as vaccines, such treatments may not be made available to Medicaid beneficiaries.

Thus, with the increasing development and availability of products that use immunology to treat diseases, and because sometimes these products are referred to as ''therapeutic vaccines'', we believe that adopting an MDRP regulatory definition of ''vaccine'' that reflects Congress' likely intent at the time of the enactment of section 1927 of the Act is imperative to ensure that only the appropriate products are excluded from the definition of a COD. This would ensure manufacturers are able to report their drug product and drug pricing data for all CODs accurately, pay appropriate rebates to States, and most critically, that Medicaid beneficiaries have access to these important therapies under the prescribed drugs benefit.[22]

Therefore, we are proposing to define ''vaccine'' at § 447.502 for the specific purposes of the MDRP, so that manufacturers understand which products are considered vaccines under the MDRP and are excluded from the definition of COD, and not subject to rebates. The definition would be applicable only to the MDRP and would not be applicable to any other agencies or agency program implementation, including FDA, CDC, and HRSA. The proposed definition of vaccine would not apply under any Title XIX statutory provisions other than section 1927(k)(2), or to separate CHIPs operating pursuant to § 457.70(a)(1) and (d), or for purposes of the Vaccines for Children Program. The definition would apply to the MDRP for purposes of Medicaid expansion CHIPs, pursuant to § 457.70(c)(2). This proposed policy would not alter any applicable Federal or State requirements to cover immunizations for Medicaid beneficiaries, as applicable. Specifically, we are proposing to define ''vaccine'' to mean a product that is administered prophylactically to induce active, antigen-specific immunity for the prevention of one or more specific infectious diseases and is included in a current or previous FDA published list of vaccines licensed for use in the United States.

We are including in the proposed definition that a vaccine must be administered prophylactically—that is, to prevent a disease and not to treat a disease—because we believe that States should generally not exclude from coverage, under the prescribed drugs benefit, drugs or biologicals that treat disease. We are also proposing that a vaccine must be administered to induce active, antigen-specific immunity because that is a characteristic of preventive vaccines.

Finally, we are proposing to limit the definition of vaccine to those products that satisfy the conditions of being administered prophylactically, to prevent a disease, and induce active antigen-specific immunity, that also appear on a current or previous list compiled by FDA. FDA publishes a list of vaccines licensed for use in the United States.[23] As FDA is the agency responsible for licensing vaccines, we believe that if a product satisfying the previously described conditions appears on this list, it should be treated as a vaccine for the purposes of the MDRP. We seek comment on whether the proposed definition of vaccine, for purposes of the MDRP only, appropriately distinguishes between preventive vaccines (which would satisfy the definition of vaccine and, therefore, not satisfy the definition of a covered outpatient drug and would not be eligible for statutory rebates), and therapeutic vaccines (which would not satisfy the definition of vaccine and therefore could satisfy the definition of a covered outpatient drug and could therefore be eligible for statutory rebates).

Additionally, while we propose to cabin this definition to the MDRP, we seek comment on whether this definition might result in indirect consequences for Medicaid benefits other than the prescribed drugs benefit. We are also requesting comment about the consequences for Medicaid of ACIP recommending immunization with a

[21] CDC describes active immunity as a long-lasting immunity that develops by triggering antibody production. Conversely, they describe passive immunity as a short-term immunity provided by the administration of antibody-containing products. See *https://www.cdc.gov/vaccines/vac-gen/immunity-types.htm*.

[22] Even if a ''therapeutic vaccine'' product is required coverage under other Medicaid benefits, this proposal would help to ensure that manufacturers report product and pricing data accurately and pay rebates to States, as applicable.

[23] Vaccines Licensed for Use in the United States.

product that would not qualify as a vaccine under this definition.

D. Proposal To Account for Stacking When Determining Best Price—(§ 447.505)

Section 1927(c)(1)(C) of the Act defines the term ''best price'' to mean with respect to 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 a new drug application approved under section 505(c) of the Federal Food, Drug, and Cosmetic Act), the lowest price available from the manufacturer during the rebate period to any wholesaler, retailer, provider, health maintenance organization, nonprofit entity, or governmental entity within the United States, subject to certain exceptions and special rules. The implementing regulations for the determination of best price are at § 447.505.

In the COD final rule, we addressed a comment to our proposal to make revisions to the determination of best price, and specify which prices are included in best price. The comment requested that CMS further adopt a policy with regard to the practice of a manufacturer stacking two different price concessions provided to two different entities, such that under these circumstances, the best price for a drug should reflect all rebates and payments associated with a transaction of a covered outpatient drug to a particular customer. (See 81 FR 5252.) In response to the commenter's request, we indicated that a manufacturer is responsible for including all price concessions that adjust the price realized by the manufacturer for the drug in its determination of best price. We also explained that if a manufacturer offers multiple price concessions to two entities for the same drug transaction, such as rebates to a PBM where the rebates are designed to adjust prices at the retail or provider level, in addition to discounts to a retail community pharmacy's final drug price, all discounts related to that transaction which adjust the price available from the manufacturer should be considered in the final price of that drug when determining best price (81 FR 5252 through 5253).

In the COD final rule with comment, we made minor revisions to the regulatory text at § 447.505(b) by deleting the reference to ''associated'' rebate and discounts and inserting a reference to ''applicable discounts, rebates'' so that it presently reads that the best price for CODs includes all prices, including applicable discounts, rebates or other transactions that adjust prices either directly or indirectly to the best price-eligible entities listed in § 447.505(a).

We addressed the question regarding stacking in the response to comments in the COD final rule, specifying that if multiple price concessions are provided to two entities for the same drug transaction, all discounts related to that transaction which adjust the price available from the manufacturer should be considered when determining best price. However, we did not revise or propose to revise the regulation text at § 447.505(d)(3) to address stacking in such detail. Section 447.505(d)(3) currently indicates that the manufacturer must adjust the best price for a rebate period if cumulative discounts, rebates or other arrangements subsequently adjust prices available, to the extent that such cumulative discounts, rebates or other arrangements are not excluded from the determination of best price by statute or regulation.

However, in the case *United States ex rel. Sheldon* v. *Allergan Sales, LLC.,* a relator alleged that a drug manufacturer failed to aggregate discounts provided to separate customers for purposes of determining best price, and the manufacturer argued that the stacking requirement was not sufficiently clear. The district court granted Allergan's motion to dismiss, ruling that relator failed to plausibly allege either falsity or knowledge because Allergan's interpretation ''is objectively reasonable'' and CMS' rule had not specifically warned against it. On appeal, a panel of the United States Court of Appeals for the Fourth Circuit stated that, in that case, the drug manufacturer had not been ''warned . . . by the authoritative guidance from CMS'' and that CMS had ''failed to clarify'' the stacking issue.[24] The Government filed an amicus brief supporting the relator's petition for rehearing en banc, which the Fourth Circuit granted. Following argument, the Fourth Circuit issued its decision with no substantive opinion that vacated the prior panel decision and affirmed the district court by an equally divided court.

As noted, section 1927(c)(1)(C) of the Act defines the term ''best price'' to mean with respect to 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 a new drug application approved under section 505(c) of the Federal Food, Drug, and Cosmetic Act), the lowest price available from the manufacturer during the rebate period to any wholesaler, retailer, provider, health maintenance organization, nonprofit entity, or governmental entity within the United States. We interpreted this section expansively as the statute refers to a manufacturer's lowest price ''available'' ''to any'' entity on this statutory list. That is, if a manufacturer provides a discount to a wholesaler, then a rebate to the provider who dispensed the drug unit, and then another rebate to the insurer who covered that drug unit, CMS has concluded that ''best price'' must include (or ''stack'') all the discounts and rebates associated with the final price, even if the entity did not buy the drug directly from the manufacturer. By stacking, best price reflects the lowest realized price at which the manufacturer made that drug unit available. We also note that manufacturers are required to take rebates into account for multiple entities when calculating AMP, and for logical reasons, best price should do so as well, since including them in AMP and not accounting for them in best price could result in AMP being lower than best price.

Therefore, to remove any potential doubt prospectively, we are proposing to revise § 447.505(d)(3) to add to the existing regulatory statement that the manufacturer must adjust the best price for a covered outpatient drug for a rebate period if cumulative discounts, rebates or other arrangements to best price eligible entities subsequently adjust the price available from the manufacturer for the drug. We are adding the clarifying statement that cumulative discounts, rebates or other arrangements must be stacked to generate a final price realized by the manufacturer for a covered outpatient drug, including discounts, rebates or other arrangements provided to different best price eligible entities.

E. Proposal To Rescind Revisions Made by the December 31, 2020 Final Rule to Determination of Best Price (§ 447.505) and Determination of Average Manufacturer Price (AMP) (§ 447.504) Consistent With Court Order

Pharmaceutical manufacturers have provided purported financial assistance payments (for example, in the form of copay coupons) to patients for purposes of paying the patient cost obligation of certain drugs.

[24] *United States ex rel. Sheldon* v. *Allergan Sales, LLC,* 24 F.4th 340, 351, 354 (4th Cir. 2022), *reh'g en banc granted,* No. 20–2330, 2022 WL 1467710 (4th Cir. May 10, 2022).

On June 19, 2020, CMS proposed regulations to address the effect of PBM accumulator adjustment programs on best price calculations (85 FR 37286) in relation to these purported manufacturer financial assistance payments by instructing manufacturers on how to consider the implementation of such programs when determining best price and AMP for purposes of the Medicaid Drug Rebate Program (MDRP). In particular, CMS proposed revising its regulations to provide that the exclusions for manufacturer's financial assistance payments ''apply only to the extent the manufacturer ensures the full value of the assistance or benefit is passed on to the consumer or patient'' (85 FR 37299). On December 31, 2020, CMS finalized its proposed revisions (85 FR 87000, 87048 through 87055, and 87102 through 87103). The final rule codified the proposed language to require that ''the manufacturer ensures that the full value'' of the assistance or benefit is passed on to the consumer or patient to exclude that assistance or benefit to an insured patient from the manufacturer's best price calculation and AMP. The final rule also delayed the effective date of the change until January 1, 2023, to ''give manufacturers time to implement a system that will ensure the full value of assistance under their manufacturer-sponsored assistance program is passed on to the patient.''

In May 2021, the Pharmaceutical Research and Manufacturers of America (PhRMA) filed a complaint against the Secretary asking the court to vacate these amendments to § 447.505(c)(8) through (11) (85 FR 87102 and 87103), as set forth in the 2020 final rule (referred to by the Court as ''the accumulator adjustment rule of 2020''). On May 17, 2022, the United States District Court for the District of Columbia ruled in favor of the plaintiff and ordered that the accumulator adjustment rule of 2020 be vacated and set aside.

In response to this court order, we propose to withdraw the changes made to best price and to also withdraw the changes to AMP to apply consistent rules for determining best price and AMP. Therefore, we propose to remove the language added to these sections as part of the 2020 final rule: §§ 447.504(c)(25) through (29) and (e)(13) through (17) and 447.505(c)(8) through (12). *See* 85 FR 87102 and 87103. Specifically, we would remove ''the manufacturer ensures'' from these provisions. As a result, these regulations would maintain the language that has been in place since 2016. To be clear, the changes to these regulations made by the 2020 final rule on January 1, 2023, were not effective as a result of the court's order.

F. Drug Classification; Oversight and Enforcement of Manufacturer's Drug Product Data Reporting Requirements—Proposals Related to the Calculation of Medicaid Drug Rebates and Requirements for Manufacturers (§§ 447.509 and 447.510)

1. Medicaid Drug Rebates (MDR) and Penalties (§ 447.509)

Section 6 of the MSIAA, titled ''Preventing the Misclassification of Drugs Under the Medicaid Drug Rebate Program,'' amended sections 1903 and 1927 of the Act to clarify the definitions for multiple source drug, single source drug and innovator multiple source drug, and to provide the Secretary with additional compliance, oversight and enforcement authorities to ensure compliance with program requirements with respect to manufacturers' reporting of drug product and pricing information, which includes the appropriate classification of a drug. Drug classification refers to how a drug should be classified—as a single source, innovator multiple source, or noninnovator multiple source drug—for the purposes of determining the correct rebates that a manufacturer owes the States.[25] When manufacturers misclassify their drugs in the rebate program, it can result in manufacturers paying rebates to States that are different than those that are supported by statute and regulation, and in some cases, can result in the manufacturer paying a lower per-unit rebate amount to the States.

Specifically, section 1927(c)(4)(A) of the Act, ''Recovery of Unpaid Rebate Amounts due to Misclassification of Drugs,'' was added to the statute to provide new authorities to the agency to identify and correct a manufacturer's misclassification of a drug, as well as impose other penalties on manufacturers that fail to correct their misclassifications. In general, a misclassification in the MDRP occurs when a manufacturer reports and certifies its covered outpatient drug under a drug category, or uses drug product information, that is not supported by the statutory and regulatory definitions of S, I, or N.

We published guidance to manufacturers regarding compliance with drug pricing and drug product information reporting under this new law in Manufacturer Release #113 on June 5, 2020. See *https://www.medicaid.gov/prescription-drugs/downloads/mfr-rel-113.pdf*.

Although much of this law is self-implementing, we are proposing a series of regulatory amendments at §§ 447.509 and 447.510 to implement and codify the statutory changes in regulation. We propose that a misclassification of a drug under the MDRP has occurred or is occurring when a manufacturer reports its drug under a category that is not supported by the statutory and regulatory definitions of S, I, or N. A misclassification can also occur when a manufacturer's drug is appropriately classified, but the manufacturer is paying rebates at a different amount than required by the statute, or where the drug manufacturer's certified drug product information for the COD is also inconsistent with statute and regulation.

The MSIAA also amended the Act to expressly require a manufacturer to report not later than 30 days after the last day of each month of a rebate period under the agreement, such drug product information as the Secretary shall require for each of the manufacturer's covered outpatient drugs. In a separate section, we are proposing a definition of ''drug product information'' for the purposes of the MDRP.

Similarly, the MSIAA amended the Act to clarify that the reporting of false drug product information and data related to false drug product information would also be subject to possible CMPs by the HHS Office of the Inspector General (OIG), and to provide specific new authority to the Secretary to issue civil monetary penalties related to knowing misclassifications of drug product or misreported information. These new OIG authorities will not be the subject of this rulemaking.

Under the MSIAA, if a manufacturer fails to correct the misclassification of a drug in a timely manner after receiving notification from the agency that the drug is misclassified, in addition to the manufacturer having to pay past unpaid rebates to the States for the misclassified drug if applicable, the Secretary can take any or all of the following actions: (1) correct the misclassification, using drug product information provided by the manufacturer on behalf of the manufacturer; (2) suspend the misclassified drug, and the drug's status as a covered outpatient drug under the

[25] Note that section 1927(c)(3) of the Act describes rebates for covered outpatient drugs other than single source and innovator multiple source drugs in section 1927(c)(3) of the Act as ''rebates for other drugs.'' The MDRP reporting system provides for all ''other drugs'' that are covered outpatient drugs to be classified in the system as N drugs, regardless of whether they expressly meet the statutory definition of noninnovator multiple source drug. This reporting methodology has been in effect for the history of the program and interested parties have understood that a covered outpatient drug that was not an S or an I drug is reported in the system as an N drug.

manufacturer's national rebate agreement, and exclude the misclassified drug from FFP (correlating amendments to section 1903 of the Act); and, (3) impose civil monetary penalties (CMP) for each rebate period during which the drug is misclassified subject to certain limitations. The Act expressly provides that the imposition of such penalties may be in addition to other remedies, such as termination from the MDRP, or CMPs under Title XI.

In § 447.509, we propose to include a new paragraph (d), ''Manufacturer misclassification of a covered outpatient drug and recovery of unpaid rebate amounts due to misclassification and other penalties,'' to implement additional penalty and compliance authorities outlined in section 6 of the MSIAA, which amended sections 1903 and 1927 of the Act. As some manufacturers may continue to misclassify drug products, we believe these proposed penalties are necessary so that manufacturers do not neglect to correct and certify their information, to assure that States receive the rebates that they deserve, to assure that public MDRP data are accurate, to protect the integrity of the MDRP, and to ensure the efficient and economic administration of the Federal Medicaid program.

Under the MDRP, a drug should be classified as a single source, innovator multiple source, or noninnovator multiple source drug for the purposes of determining the correct rebates that a manufacturer owes the States. We propose that a misclassification in the MDRP occurs when a manufacturer reports and certifies its covered outpatient drug under a drug category or other drug product data related to a COD that is not supported by the statutory and regulatory definitions of S, I, or N. We also propose to define as a misclassification a situation in which the manufacturer accurately reports and certifies its COD under a drug category or other related drug product data for a COD, but is paying a different rebate amount than that required by the statute and regulations. The statute expressly indicates at section 1927(d)(4) of the Act that a misclassification can occur without regard to whether the manufacturer knowingly made the misclassification or should have known that the misclassification was being made.

It is the legal responsibility of the manufacturer to report and certify the correct classification of its covered outpatient drugs to the agency, and the drug product information related to a COD. The agency does not as a routine matter review or verify the drug category classifications and related drug product information reported and certified by the manufacturer. However, in its oversight role, the agency will review the classification and other drug product and pricing information reported by the manufacturer for a drug to determine its accuracy, as needed. For example, when questions arise, the agency will generally review the drug product and pricing information reported and certified by a manufacturer. To this end, we generally rely upon various sources of information to determine if a drug is misclassified in the MDRP. This includes information reported by manufacturers to CMS in combination with publicly available information in making determinations of whether a drug is misclassified in the MDRP. The agency also uses manufacturer reported information, such as the COD status code, in combination with information available on the FDA's Comprehensive NDC SPL Data Elements file (NSDE) *https://download.open.fda.gov/Comprehensive_NDC_SPL_Data_Elements_File.zip,* and information from FDA's Drugs@FDA web page *https://www.accessdata.fda.gov/scripts/cder/daf/* to verify that the national drug codes (NDCs) reported to the MDRP by manufacturers are appropriately classified and reported to MDRP.

Therefore, we propose in the new § 447.509(d), the following process to identify, notify and correct a manufacturer's drug category misclassifications, and impose other penalties, while at the same time notifying the HHS OIG and/or other governmental agencies about possible violations of MDRP requirements.

a. Identification and Notification to Manufacturer To Correct Misclassification (§ 447.509(d)(1) Through (4))

We are proposing in new paragraphs (d)(1) through (4) of § 447.509, requirements relating to the process by which the agency would identify when a misclassification of a drug has occurred in MDRP, subsequently notify a manufacturer that we have determined that a drug is misclassified in MDRP, indicate the penalties that may be imposed on the manufacturer, as well that the manufacturer may owe past due rebates.

We propose to define what constitutes a misclassification in paragraph (d)(1). As proposed at § 447.509(d)(1)(i), misclassification in the MDRP occurs when a manufacturer reports and certifies to the agency its drug category or drug product information related to a covered outpatient drug that is not supported by applicable statute or regulation. For example, a drug is misclassified by the manufacturer if it is reported as a noninnovator multiple source drug when the correct classification for the COD, as determined by the agency, is a single source drug or an innovator multiple source drug, based on application of relevant statutes and regulations. In such an example, it is likely that the manufacturer has paid or is paying a lower per unit rebate amount to a State as a result of the misclassification, and the agency would notify the manufacturer as part of the communication regarding the misclassification that rebates are owed to the States.

However, there may be circumstances where a manufacturer is reporting its drug as a S or I drug, when the appropriate category is a N drug. For example, a manufacturer may be categorizing a non-prescription drug as a brand drug, when it should be classified as a noninnovator drug for the purposes of MDRP. These situations would be considered misclassifications as well. These situations may result in States needing to pay rebates back to the manufacturer, which creates recordkeeping and fiscal issues for the States, as well as the need for the States to request FFP from the Federal Government to pay its share of the rebates that are due back to the manufacturer. There are two-year timely claims filing deadlines under section 1132(A) of the Act, which may prohibit States from claiming FFP in these situations.

A manufacturer may also have reported and certified an incorrect base date AMP to calculate its inflation penalty rebates, thus paying overall lower rebates to the States. This example would also be considered a misclassification under paragraph (d)(1)(i), as the incorrect drug product information related to a COD is being used by the manufacturer.

We also propose in § 447.509(d)(1)(ii) that a misclassification includes a situation where a manufacturer has correctly reported and certified its drug classification as well its drug product information for a COD, but is paying rebates to States at a level other than that supported by statute and regulation applicable to the reported and certified data. For example, if a manufacturer is correctly reporting and certifying a COD as an S or I drug, but paying rebates that would be expected for that of an N drug, we would consider that to be a misclassification as well. Note that while the statute and regulations specify that rebates are paid to States based on classifications of CODs as S, I, or ''other

drugs'', the MDP system only allows for the classification of CODs as S, I, or N. The N category would include any drug that is not an S or I, which may include non-prescription drugs. Manufacturers should assure that those drugs that are classified as N in the MDP system are drugs other than S or I drugs.[26]

We propose at § 447.509(d)(2) that if the agency makes a determination of a misclassification, the agency would send a written and electronic notification to the manufacturer that misclassified a drug of such misclassification, and any past rebates due, and the manufacturer would have 30 calendar days from date of the notification to submit to the agency the drug product and pricing information necessary to correct the misclassification or the incorrect product information, and calculate rebate obligations. If the manufacturer misclassified the drug as an N when it should have been an S or I, then the data submitted to the agency must include the drug's ''best price'' data for the period or periods during which it was misclassified. Once the information is changed in the MDP, the manufacturer must certify the data.

Upon receipt from the manufacturer of the requested corrected information as proposed in § 447.509(d)(2), we propose in § 447.509(d)(4) to review the information submitted by the manufacturer in response to the notice sent under proposed § 447.509(d)(2) to ensure consistency with published drug product information, and if the manufacturer fails to correct the misclassification, fails to certify applicable pricing and product data, and/or fails to pay rebates due as a result of misclassification in the timeframes proposed, we propose the enforcement actions the agency may further take. Upon notification by CMS that the manufacturer's information was updated in the system, we propose that the manufacturer certify the applicable price and drug product data. The proposed time period the manufacturer has to correct the misclassification, and respond to the agency's request to certify the information in the system, is 30 calendar days from the date of the original notification to the manufacturer of the misclassification.

The determination made by CMS and notification provided by CMS to the manufacturer as a result of the process proposed in § 447.509(d) regarding misclassification is limited by the information available to CMS and is specific to the facts and circumstances for each scenario. It does not release the manufacturer from any additional liabilities, or preclude actions against manufacturers by HHS, OIG, DOJ, or otherwise.

b. Manufacturer Payment of Unpaid Rebates Due to Misclassification (§ 447.509(d)(3))

As required in section 1927(c)(4)(A) of the Act, the manufacturer is required to pay unpaid rebates to the State for a misclassified drug in an amount equal to the product of the difference of the URA paid to the State for the period, and the URA that the manufacturer would have paid to the State for the period, as determined by the agency, if the drug had been correctly classified or correctly reported by the manufacturer, or the drug product information had been reported correctly, and the total units of the drug paid for under the State Plan in the rebate period(s).

Therefore, once we determine that a misclassification has occurred in § 447.509(d)(1) and notify the manufacturer of the misclassification in accordance with the proposed process steps at § 447.509(d)(2), we are proposing in § 447.509(d)(3) the process by which manufacturers would pay unpaid rebates to the States resulting from a misclassification of a drug in the MDRP.

Specifically, we propose at § 447.509(d)(3) that when the agency determines that a misclassification of COD occurs as proposed under § 447.509(d)(1), and notification has been provided to the manufacturer as proposed under § 447.509(d)(2), a manufacturer shall pay to each State an amount equal to the sum of the products of the difference between: the per URA paid by the manufacturer for the COD to the State for each period during which the drug was misclassified, and the per URA that the manufacturer would have paid to the State for the COD for each period, as determined by the agency based on the data provided by the manufacturer under proposed paragraph (d)(2), if the drug had been correctly classified by the manufacturer, multiplied by the total units of the drug paid for under the State Plan in each period.

Consistent with section 1927(d)(4)(A) of the Act, we are proposing regulatory text in § 447.509(d)(3)(i) that requires manufacturers to pay these unpaid rebates amounts. We are also proposing to codify at § 447.509(d)(3) the time frame by which the manufacturer shall pay such unpaid rebates to the States for the period or periods of time that such COD was misclassified, based upon the proposed URA provided to the States by the agency for the unpaid rebate amounts. We are proposing to include a regulatory provision that requires such rebates be paid to the States by the manufacturer within 60 calendar days of the date of the notice that is sent by the agency to the manufacturer indicating that the drug is misclassified, and specifies that it is the manufacturer's burden to contact the States and pay the rebates that are due. We are also proposing that a manufacturer would be required to provide documentation to the agency that all past due rebates have been paid to the States within the 60 calendar day timeframe.

c. Agency Authority To Correct Misclassifications and Additional Penalties for Drug Misclassification (§ 447.509(d)(4))

Consistent with section 1927(c)(4)(B) of the Act, which provides the authority to the Secretary to correct drug misclassifications in the system and impose other penalties, we propose to add § 447.509(d)(4), allowing CMS to correct the drug's misclassification on behalf of the manufacturer, as well as provide a plan of action for enforcement against the manufacturer. Specifically, we propose at § 447.509(d)(4) that the agency would review the information submitted by the manufacturer based on the notice sent under proposed paragraph (d)(2), and if a manufacturer fails to correct the misclassification within 30 calendar days from the date of the notification of the misclassification by the agency to the manufacturer, fails to certify applicable pricing and drug product data, and/or fails to pay the rebates that are due to the States as a result of the misclassification within 60 calendar days of receiving such notification, the agency may do any or all of the following:

- Correct the misclassification of the drug in the system, using any pricing and drug product information that may have been provided by the manufacturer, on behalf of the manufacturer;
- Suspend the misclassified drug, and the drug's status as a COD under the manufacturer's rebate agreement from the MDRP, and exclude the

[26] Since the beginning of the MDRP, the term noninnovator multiple source drug, and its abbreviation (N), has been used very generally to identify a covered outpatient drug other than a single source drug or an innovator multiple source drug. The rebate is calculated using the same formula for all drugs other than a single source drug or an innovator multiple source drug, including both those that satisfy the definition of noninnovator multiple source drug and those that do not. Therefore, manufacturers are to report all of their drugs other than a single source drug or an innovator multiple source drug and identify them with the drug category of N, regardless if they satisfy the statutory definition of noninnovator multiple source drug.

misclassified drug from FFP in accordance with section 1903(i)(10)(E) of the Act;

• Impose a Civil Monetary Penalty (CMP) for each rebate period during which the drug is misclassified, not to exceed an amount equal to the product of:

++ The total number of units of each dosage form and strength of such misclassified drug paid for under any State Plan during such a rebate period; and

++ 23.1 percent of the AMP for the dosage form and strength of such misclassified drug for that period.

Also, we propose at § 447.509(d)(4)(iv) to indicate that, in addition to the actions described previously in this proposed rule, we may take other actions or seek additional penalties that are available under section 1927 of the Act (or any other provision of law), against manufacturers that misclassify their drugs including referral to the HHS OIG and termination from the MDRP. Section 1927(b)(4)(B)(i) of the Act provides that the Secretary may terminate a manufacturer from the program for violation of the rebate agreement or other good cause. Furthermore, section 1927(c)(4)(D) of the Act indicates that other actions and penalties against a manufacturer for misclassification of a drug include termination from the program.

Therefore, we propose that a manufacturer is subject to termination from the program if it fails to meet agency's specifications for participation in the MDRP program as proposed when it is in violation of section 1927(b)(4)(B)(i) or 1927(c)(4)(D) of the Act, which includes failing to correct misclassified drugs as identified to the manufacturer by the agency, and continuing to have one or more drugs suspended from MDRP because of the lack of certification of the correct drug classification data in the system.

We note that as provided in section 1927(b)(4)(C) of the Act, a manufacturer with a terminated NDRA is prohibited from entering into a new NDRA for a period of not less than one calendar quarter from the effective date of the termination until all of the above or any subsequently discovered violations have been resolved, unless the Secretary finds good cause for an earlier reinstatement. In accordance with section 1927(b)(4)(B)(ii) of the Act, and section VII.(e) of the NDRA, termination shall not affect the manufacturer's liability for the payment of rebates due under the agreement before the termination effective date. Consequently, invoicing by States may continue beyond the manufacturer's termination from the program for any utilization that occurred prior to the effective date of the termination.

In addition to affecting Medicaid coverage of a manufacturer's drugs, the termination of the manufacturer's NDRA may impact the coverage of the drugs under the Medicare Part B program as well as the 340B Drug Pricing Program. Alternatively, we propose that suspension of a drug under this section as a COD would not affect its status as a reimbursable drug under the 340B Drug Pricing Program or Medicare Part B.

d. Transparency of Manufacturer Misclassification (§ 447.509(d)(5))

Section 1927(c)(4)(C)(i) and (ii) of the Act requires information on CODs that have been identified as misclassified be reported to Congress on an annual basis, and that the annual report be made available to the public on a public website. Therefore, we propose to add new paragraph (d)(5) to § 447.509 to indicate that the agency would make available on a public website an annual report as required under section 1927(d)(4)(C)(ii) of the Act on the COD(s) that were identified as misclassified during the previous year. This report would include a description of any steps taken by the agency with respect to the manufacturer to reclassify the drugs, ensure the payment by the manufacturer of unpaid rebate amounts resulting from the misclassifications, and disclose the use of the expenditures from the fund created in section 1927(b)(3)(C)(iv) of the Act.

2. Proposed Requirements for Manufacturers Relating to Drug Category—Requirements for Manufacturers (§ 447.510)

To implement section 1927(c)(4) of the Act, we propose to rename § 447.510 as ''Requirements and penalties for manufacturers''.

a. Suspension of Manufacturer NDRA for Late Reporting of Pricing and Drug Product Information (§ 447.510(i))

In accordance with section 1927(b)(3)(C)(i) of the Act, we propose to add paragraph (i) to § 447.510 to describe the process by which the suspension of a manufacturer's NDRA would occur when a manufacturer fails to report timely information, which includes drug pricing and drug product information, as described in section 1927(b)(3)(A) of the Act, which also includes the reporting timeframes for such information. This drug product and pricing information includes, but is not limited to AMP, best price, and drug product information as described in the proposed definition of drug product information included in this rule.

Specifically, the new paragraph § 447.510(i)(1) proposes that if a manufacturer fails to provide timely information required to be reported to the agency under § 447.510(a) and (d) of this section, the agency would provide written notice to the manufacturer of the failure to provide timely information. If such information is not reported within 90 calendar days of a deadline determined by the agency, and communicated to the manufacturer electronically and in writing by the agency, it shall result in suspension of the manufacturer's rebate agreement for all CODs furnished after the end of the 90-calendar day period for purposes of Medicaid and the MDRP only, and the rebate agreement shall remain suspended for Medicaid until such information is reported in full and certified, but not for a period of suspension of less than 30 calendar days. This section also proposes that continued suspension of the rebate agreement could result in termination for cause.

During the period of the suspension, the CODs of the manufacturer are not eligible for Medicaid coverage or reimbursement and Medicaid FFP. However, the manufacturer must continue to offer its CODs for purchase by 340B eligible entities, and reimbursement availability for such drugs under Medicare Part B would not change because, while suspended for purposes of the MDRP, the Medicaid drug rebate agreement with the manufacturer would remain in effect for purposes of Medicare Part B reimbursement and the 340B Drug Pricing Program.

Under proposed § 447.510(i)(2), the agency would notify the States 30 calendar days before the effective date of the manufacturer's suspension, which is 60 calendar days after the notice is sent to the manufacturer that the data are late. If a manufacturer fails to report and certify the complete information within this 30-calendar day period before the suspension begins, they would continue to be suspended from the program until such information is reported and certified, and would be subject to termination of the manufacturer rebate agreement.

We understand that suspension of a manufacturer's agreement, and loss of the availability of FFP for a period of time, would likely mean that these manufacturers' drugs would not be available to Medicaid beneficiaries during the period of the suspension. We would give States sufficient time before

the suspension begins—30 calendar days—to work with beneficiaries and their prescribers to transition to other covered outpatient drugs that would meet the clinical needs of the beneficiaries during the suspension period. We believe that the intermediate step of suspension rather than termination should be sufficient incentive to manufacturers to report pricing and product information within the statutory and regulatory requirements, without initially resorting to termination, which means that a manufacturer's drug could be unavailable to beneficiaries for a possible longer period of time.

We believe this proposed process provides clearer implementation of the statutory authority to suspend a manufacturer's rebate agreement in the event of a failure to provide timely information, and would hopefully incentivize manufacturers to ensure the timely reporting of pricing and drug product information, which would further the efficient and economic operation of the MDRP.

For example, every month it is common that several manufacturers either do not report or only partially report their AMP data to the agency, which are used to calculate the Federal Upper Limits (FULs) for multiple source drugs, among other purposes. Such conduct reduces the agency's ability to set FULs on Medicaid payment for certain drugs, which means States may spend more money on multiple source drugs than they otherwise should. As a standard practice, we already notify these manufacturers that they are late in reporting or only have partially reported their information, and we also provide information about late reporting by manufacturers to OIG for possible imposition of CMPs. We consider partial reporting of information to also be late reporting, as the information that was not reported is late.

Consistent with the proposed clarification to the definition of manufacturer, the proposed suspension of the manufacturer's NDRA would be applied to all the associated labeler rebate agreements of the manufacturer.

G. Proposals Related to Amendments Made by the American Rescue Act of 2021—Removal of Manufacturer Rebate Cap (100 Percent AMP)

Section 9816 of the American Rescue Plan Act of 2021 sunsets the limit on maximum rebate amounts for single source and innovator multiple source drugs by amending section 1927(c)(2)(D) of Act by adding ''and before January 1, 2024,'' after ''December 31, 2009''. In accordance with section 1927(c)(3)(C)(i) of the Act and the special rules for application of provision in sections 1927(c)(3)(C)(ii)(IV) and (V) of the Act, this sunset provision also applies to the limit on maximum rebate amounts for CODs other than single source or innovator multiple source drugs.

Section 2501(e) of the Affordable Care Act amended section 1927(c)(2) of the Act by adding a new subparagraph (D) and established 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. This limit on maximum rebate amounts was codified at § 447.509(a)(5) for single source and innovator multiple source drugs, effective January 1, 2010. This limit was later extended to apply to drugs other than single source or innovator multiple source drugs by section 602 of the Bipartisan Budget Act of 2015 (Pub. L. 114–74, enacted November 2, 2015) (BBA 2015), which amended section 1927(c)(3) of the Act to require that manufacturers pay additional rebates on such drugs if the AMPs of the drug increase at a rate that exceeds the rate of inflation. This provision of BBA 2015 was effective beginning with the January 1, 2017 quarter, and the limit on maximum rebates for drugs other than single source or innovator multiple source drugs was added at § 447.509(a)(9).

Therefore, to conform § 447.509 with section 1927(c)(2)(D) of the Act, as amended by the American Rescue Plan Act of 2021, and sections 1927(c)(3)(C)(i), (ii)(IV), and (ii)(V) of the Act, we are proposing to make conforming changes to § 447.509 to reflect the removal of the maximum rebate amounts for rebate periods beginning on or after January 1, 2024. Specifically, we propose to amend § 447.509(a)(5) and (9) to state that the limit on maximum rebate amounts applies to certain time frames, which for all drugs, ends on December 31, 2023. That is, no maximum rebate amount would apply to rebate periods beginning on or after January 1, 2024.

H. Proposal To Clarify § 447.509(a)(6), (7), (8), and (9) and (c)(4) With Respect to ''Other Drugs''

Section 1927(c) of the Act describes how the unit rebate amount (URA) is determined for a covered outpatient drug. There is a defined calculation of the applicable basic rebate and additional rebate for a covered outpatient drug that is either a single source drug or innovator multiple source drug at sections 1927(c)(1) and (2) of the Act, and a different defined calculation for ''other drugs,'' that is, a covered outpatient drug that is a drug other than a single source drug or an innovator multiple source drug at section 1927(c)(3) of the Act.

Section 1927(c)(3) of the Act, titled ''Rebate for other drugs,'' describes in subsections (c)(3)(A) and (B) the basic rebate calculation for covered outpatient drugs other than single source drugs and innovator multiple source drugs. Section 1927(c)(3)(C) of the Act describes the additional rebate calculation for a covered outpatient drug other than a single source drug or an innovator multiple source drug. Thus, the statute makes it clear that rebates are applicable to all covered outpatient drugs, whether they are single source drugs, innovator multiple source drugs, or drugs other than such drugs.

Manufacturers are required to report all of their covered outpatient drugs in our MDRP reporting system and must select the appropriate drug category for each (that is, S, I, or N). Since the beginning of the MDRP, the term noninnovator multiple source drug, and its abbreviation (N), have been used very generally to identify a covered outpatient drug other than a single source drug or an innovator multiple source drug in our system for operational purposes. Choosing N in our reporting system thus can result in capturing drugs that satisfy the statutory definition of an N drug, but also other drugs that are not single source or innovator multiple source drugs. Because manufacturers are to report all of their covered outpatient drugs and identify the applicable drug category, all covered outpatient drugs other than a single source drug or an innovator multiple source drug should be identified with the drug category of N, regardless if they satisfy the definition of noninnovator multiple source drug.

In the July 17, 2007 final rule, we finalized a definition for ''noninnovator multiple source drug'' to clarify the distinction between multiple source drugs approved under an abbreviated new drug application (ANDA) and multiple source drugs approved under a new drug application (NDA). We also finalized that the term includes a drug that entered the market prior to 1962 that was not originally marketed under an NDA (72 FR 39162).

Over the years, interested parties too have used the term ''noninnovator multiple source drug'' synonymously with ''a covered outpatient drug that is a drug other than a single source drug or an innovator multiple source drug.'' However, the statute specifically defines ''noninnovator multiple source drug'' at section 1927(k)(7)(iii) of the Act as a multiple source drug that is not an

innovator multiple source drug. The regulatory definition of noninnovator multiple source drug goes beyond this statutory definition but does not capture every covered outpatient drug that is something other than a single source drug or an innovator multiple source drug because not every ''other drug'' is a multiple source drug. As a result, ''other drugs'' and ''noninnovator multiple source drugs'' are not synonymous. While the terms are not synonymous, they are treated so for purposes of reporting the COD in the MDRP system, as ''other drugs'' should be classified as N, if not an S or I drug.

As noted previously, the statute makes it clear that rebates apply to all covered outpatient drugs, regardless if they are single source drugs, innovator multiple source drugs or something other than a single source drug or innovator multiple source drug. To align our longstanding policy and practices of identifying ''other drugs referenced in section 1927(c)(3) of the Act as N drugs, for purposes of the MDRP, we are proposing to modify language in § 447.509 by replacing each appearance of ''noninnovator multiple source drug(s)'' with ''drug(s) other than a single source drug or an innovator multiple source drug.'' [27]

We propose to delete each appearance of ''noninnovator multiple source drug(s)'' in § 447.509 and replace it with ''drug other than a single source drug or innovator multiple source drug(s).'' The clarification is proposed to be made in § 447.509(a)(6), (7), (8), and (9) and (c)(4), and the language would change as set out in the proposed regulatory text at the end of the document.

- In paragraph (a)(8), we would specify the ''total rebate''. Specifically, the total rebate amount for a drug other than a single source drug or innovator multiple source drug is equal to the basic rebate amount plus the additional rebate amount, if any.
- In paragraph (a)(9), we would specify the ''limit on rebate''. Specifically, in no case would the total rebate amount exceed 100 percent of the AMP for a drug other than a single source drug or innovator multiple source drug.
- In paragraph (c)(4), we would specify that for a drug other than a single source drug or innovator multiple source drug, the offset amount is equal to 2.0 percent of the AMP (the difference between 13.0 percent of AMP and 11.0 percent of AMP).

[27] Drugs other than single source drugs and innovator multiple source drugs should continue to be reported in the MDRP system with the drug category of ''N''.

I. Proposal To Establish a 12-Quarter Rebate Audit Time Limitation (§ 447.510)

In accordance with sections 1927(b)(1) and 1927(c) of the Act, and section II. (b) of the NDRA, manufacturers are required to pay quarterly rebates to States for the CODs dispensed and paid for under the State Plan for the rebate period. Section 1927(b)(2)(B) of the Act provides that a manufacturer may audit the rebate billing information provided by the State as set forth under section 1927(b)(2)(A) of the Act on the total number of units of each dosage form, strength and package size of each COD dispensed and paid for under the State Plan during a rebate period, and authorizes that adjustments to rebates shall be made to the extent that the information provided by States indicates that utilization was greater or less than the amount previously specified. The statute does not impose a specific timeframe on a manufacturer's audit authority or limit when adjustments to rebates may occur.

For the purposes of this proposed regulation, audit authority is intended to refer to any process a manufacturer is using to seek an adjustment to utilization data under section 1927(b)(2)(B) of the Act. That audit authority encompasses many processes for seeking adjustments in utilization data, including disputes, assessments, reviews and hearings, and may involve paper procedures, informal phone calls, and emails or other mechanisms. This proposed provision is intended to provide a 12-quarter timeline for any of those processes related to initiation of audits.

Section V. of the NDRA describes how the agency operationalizes the manufacturer audit authority; that is, it describes the procedures for dispute resolution once an audit identifies a dispute with the utilization data (that is, number of units for any given quarter) for which States are requesting rebates using a rebate invoice. A manufacturer can dispute State utilization on an original invoice or initiate a dispute on utilization that was previously paid. See section V, Dispute Resolution, ''Medicaid Program: Announcement of Medicaid Drug Rebate Program National Rebate Agreement,'' Final Notice, 83 FR 12770 (Mar. 23, 2018). The audit/dispute resolution processes are further discussed in a number of manufacturer releases (State Release 177,[28] State Release 181,[29] Manufacturer Release 95,[30] Manufacturer Release 105,[31] and Manufacturer Release 115 [32]).

As provided at section 1927(b)(2)(A) of the Act, no later than 60 days of the end of each quarter, States invoice manufacturers for rebates based on utilization of the manufacturer's drugs in that quarter (§ 447.511(a)). Consistent with section 1927(b)(2)(B) of the Act, manufacturers may audit State utilization data for their covered outpatient drugs reported under section 1927(b)(2)(A) of the Act to determine if the data are accurate and appropriate. If a manufacturer's review of a quarterly State invoice determines that no adjustments are necessary, and that the total quarterly rebate amount can be paid as reflected on the invoice, the manufacturer pays the total invoiced amount in full. The manufacturer will use identifying documentation about payment from the State's records which may include, for example, the labeler code, the labeler name, the quarter and applicable Federal program(s) covered by the payment, or any other such pertinent information that would help identify from whom the rebate payment is being sent and for which quarter and Federal program the payment applies.

In the event a potential discrepancy with State drug utilization data on the rebate invoice is discovered for a current period, the manufacturer will submit a Reconciliation of State Invoice (ROSI) form to the State, or if such a discrepancy is discovered for a prior rebate period's invoice after that rebate period has already been invoiced and paid, the manufacturer will submit a Prior Quarter Adjustment Statement (PQAS) to the State. When completing the ROSI or the PQAS, manufacturers must enter the appropriate code(s) to explain the bases or reasons for any adjustments. Both forms assist in standardizing data exchange elements and improving communication between manufacturers and States. Consistent with section 1927(b)(2)(B) of the Act, adjustments to rebates are made to the extent that the audit results in information indicating that utilization was greater or less than the amount previously specified by the State in its rebate invoice, and can result in manufacturers owing additional rebate

[28] *https://www.law.cornell.edu/definitions/index.php.*

[29] *https://www.cbo.gov/system/files/2020-03/PDPRA-SFC.pdf.*

[30] *https://www.medicaid.gov/medicaid-chip-program-information/by-topics/prescription-drugs/downloads/rx-releases/mfr-releases/mfr-rel-095.pdf.*

[31] *https://www.medicaid.gov/prescription-drugs/downloads/mfr-rel-113.pdf.*

[32] *https://www.accessdata.fda.gov/scripts/cder/daf/.*

amounts to the States, or the States owing credits to manufacturers.

In State Release 56 and Manufacturer Release 20, we explained an adjustment is a correction in the number of units for any given NDC, or a correction to the unit rebate amount (URA) by the labeler for any given NDC. We clarified a dispute to mean ''a disagreement between the labeler and the State regarding the number of units the State invoiced for any given quarter.'' Consistent with section 1927(b)(2)(B) of the Act, all disputes must be resolved on a unit basis only, and not on any other factor (for example, monetary amounts, percentages, etc.) (State Release 181).

State Release Number 45 sets forth the Dispute Resolution Process for manufacturers and States to follow when engaged in a dispute. In that release, we specified that the manufacturer should notify a State of the disputed data no later than 38 days after the State utilization data is sent. However, we have been made aware that manufacturers initiate disputes far past this suggested timeline. For example, States have reported receiving new disputes on claims from more than 30 years ago.

Previous OIG reports indicated that manufacturers have initiated disputes dating back many years. Although the rebate agreement notes that States and manufacturers should strive to resolve disputes within a reasonable timeframe, there is no mention of how far back a dispute can be initiated once a manufacturer receives an invoice.[33] While section V. of the NDRA, along with several CMS-issued program releases address dispute resolution procedures for when a manufacturer identifies State drug utilization data (SDUD) discrepancies based on the audit authority at section 1927(b)(2)(B) of the Act, no law or regulation, provides a specific time limitation for initiating a dispute over drug utilization data.[34]

Section V of the NDRA describes the dispute resolution processes available to manufacturers and States when a manufacturer discovers a potential discrepancy with State drug utilization data on the rebate invoice, when the manufacturer and State in good faith are unable to resolve prior to the payment due date. As noted above, manufacturers use the ROSI or PQAS process, and shall use their best efforts to resolve a dispute within a reasonable timeframe, and if they are not able to resolve the dispute within a reasonable time frame, CMS will employ best efforts to ensure the State makes available to manufacturers (in accordance with § 447.253(e)) and as explained in State Release 181, the same State hearing mechanism available to providers for Medicaid payment disputes. The State hearing option is available to both States and manufacturers when they have reached an impasse through the normal dispute resolution process, or when one of the parties is not being responsive to another's efforts to engage in dispute resolution. Once a hearing has taken place and a finding is issued, States and manufacturers are expected to act in accordance with the finding. We believe having an unlimited timeframe to initiate such disputes on rebates can result in manufacturer, State and Federal resources being spent to adjudicate excessively old disputes and is not an efficient use of resources.

Given the lack of timeframe for dispute resolution, both States and manufacturers have requested greater CMS involvement in resolving disputes.[35] More specifically, States have requested we establish a time limit for when a manufacturer may initiate a dispute. Establishing a time limit for manufacturers to initiate a dispute concerning State utilization data on the rebate invoice would promote the timely identification of outstanding disputes. Having an unlimited period to initiate disputes is not consistent with the proper and efficient operation of the rebate program. Due to recalculations involving hundreds of millions of State and Federal Medicaid dollars involving years of paperwork, we believe it is essential that a standard timeframe be established within which disputes are permitted.

We propose to use our authority under sections 1102 and 1902(a)(4) of the Act to require efficient handling of disputes by limiting the period for manufacturers to initiate disputes, hearing requests and audits concerning State-specified COD utilization data to 12 quarters from the last day of the quarter from the date of the State invoice. Section 1102 of the Act requires the Secretary to ''make and publish such rules and regulations, not inconsistent with this Act, as may be necessary to the efficient administration of the functions with which [he or she] is charged'' under the Act.

Consistent with this authority, and with the authority found in section 1902(a)(4) of the Act, which allows the Secretary to specify such methods necessary for the proper and efficient operation of the plan, we are proposing to establish a 12-quarter time limit for manufacturers to initiate disputes, hearing requests, and audits for State-invoiced units on current rebates as well as to initiate disputes, hearing requests, and audits on rebates that have been paid in full. We are proposing a time limitation to help ensure that discrepancies are timely identified and resolved, thereby providing increased financial certainty to manufacturers and States and promoting the efficient operation of the MDRP. This limitation would only apply to disputes regarding State drug utilization data on State rebate invoices. We would continue to work with manufacturers to process appropriate change requests (for example: COD Status change requests, Market Date change requests, Base Date AMP change requests, and 5i Drug Indicator change requests).

We understand this proposal implicates the authority at section 1927(b)(2)(B) of the Act, and would result in adding a time limitation to a manufacturer's authority to audit information provided by States under section 1927(b)(2)(A) of the Act. However, we believe that this proposal and implications to the authority to audit comport with our policy goals and the authority bestowed by Congress to ensure the proper and efficient operation of the program.

In considering an approach that is fair for both States and manufacturers, we believe that a regulation adopted in 2003 provides a way forward. The ''Medicaid Program; Time Limitation on Price Recalculations and Recordkeeping Requirements Under the Drug Rebate Program'' final rule with comment period, 68 FR 51912 (August 29, 2003), set forth a 12-quarter time limitation during which manufacturers must report changes to average manufacturer price and best price for purposes of reporting data to CMS.[36] Establishing a 12-quarter time limitation for manufacturers to initiate disputes concerning State-invoiced utilization data would align with the timelines for manufacturers to report changes to data elements relevant to the calculation of

[33] United States, Congress, Office of Inspector General. Medicaid Drug Rebate Dispute Resolution Could Be Improved, OEI–05–11–00580. Available at *https://oig.hhs.gov/oei/reports/oei-05-11-00580.pdf.*

[34] *https://www.ncpdp.org/NCPDP/media/pdf/WhitePaper/Medicaid-Drug-Rebate-Program-Challenges-Across-the-Industry.pdf?ext=.pdf.*

[35] United States, Congress, Office of Inspector General. Medicaid Drug Rebate Dispute Resolution Could Be Improved, OEI–05–11–00580. Available at *https://oig.hhs.gov/oei/reports/oei-05-11-00580.pdf.*

[36] As stated in current regulation in § 447.510(b), manufacturers 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, with limited exceptions.

MDRP rebate amounts and for manufacturers to initiate disputes concerning State-supplied utilization data also necessary to the rebate calculation (§ 447.510(b)(1)), and would allow for more efficient administration of State operated drug rebate programs. This 12-quarter timeframe would also assist States that would otherwise be required to retain their drug utilization data indefinitely to verify changes in rebate amounts resulting from retroactive manufacturer recalculations. We would also like to specify, whenever we refer to a 3-year timeframe for disputes, we are interpreting it as 12 quarters from the last day of the quarter from the date of the State invoice.

We recognize the potential burden for States and manufacturers to comply with a 38-day dispute initiation timeframe as mentioned in State Release Number 45; however, we believe that a 12-quarter timeframe is reasonable because it comports with requirements for maintenance of records on State Medicaid expenditures at § 433.32. It also mirrors the manufacturer's timeline for reporting revisions to monthly AMP at § 447.510(d)(3). We also understand that there are two-year timely claims filing deadlines under section 1132(A) of the Act, and regulations at 45 CFR 95.7, which may prohibit States from claiming FFP in these situations, unless under a good cause waiver. Therefore, consistent with our authority at sections 1102 and 1902(a)(4) of the Act, we propose to ensure the efficient handling of rebate disputes, by limiting the period for manufacturers to initiate disputes, hearing requests or audits concerning State utilization data submitted pursuant to section 1927(b)(2)(A) of the Act to 12 quarters from the last day of the quarter from the date of the State invoice.

Accordingly, we are proposing a new paragraph (j), titled ''Manufacturer audits of State-provided information,'' at § 447.510, specifying that a manufacturer may, within 12 quarters from the last day of the quarter from the State invoice date, initiate a dispute, request a hearing or seek an audit with a State for any discrepancy with State drug utilization data reported under section 1927(b)(2)(A) of the Act on the State rebate invoices.

J. Proposal To Establish a Drug Price Verification Survey Process of Certain Reported CODs (§ 447.510)

In this section of the proposed regulation, we describe the legal basis, rationale, and process we propose to survey manufacturers and wholesalers that directly distribute their CODs using our authority at section 1927(b)(3)(B) of the Act to obtain information about the prices they are reporting to us under section 1927(b)(3)(A) of the Act and in accordance with § 447.510. The purpose of this survey is to verify prices reported under section 1927(b)(3)(A) of the Act to assure that Medicaid payments and applicable rebates for CODs can be made, and that Medicaid payments are economical and efficient, as well as sufficient, to provide access to care.

Currently, there is no centralized collection of specific data from manufacturers (or wholesalers) used by CMS to verify prices manufacturers reported to us under section 1927(b)(3)(A) of the Act. Our proposal to survey manufacturers for certain information on specific CODs and our proposal to make certain manufacturer information publicly available (unless it is proprietary), would allow States to access this information and understand the derivation of a COD's price so that States may establish and negotiate payment for Medicaid CODs consistent with section 1902(a)(30)(A) of the Act. For example, transparency into a manufacturer's costs and process for establishing a drug price via the survey, along with other factors, would give States the ability to better negotiate supplemental rebates, and better understand the impact of the drug on its budget as supplemental rebates are negotiated.

The proposed drug price verification survey is not intended to limit or deny access to any of the CODs included on the survey list, assess cost effectiveness of such drugs, or supplant findings from the applicable FDA approval process. That is, we would not be using the survey data to further assess either the clinical or cost effectiveness of the COD. Furthermore, neither the selection of CODs subject to the survey, nor the information collected in response to a survey under this proposal, would impact coverage of a COD consistent with section 1927 of the Act, or supplant any of the Federal requirements established under section 1927 of the Act and the implementing regulations at 42 CFR part 447, subpart I. Section 1902(a)(30)(A) of the Act (42 U.S.C. 1396a(a)(30)(A)) requires that States have a State Plan that provides methods and procedures to ensure that payments are consistent with efficiency, economy, and quality of care and are sufficient to enlist enough providers so that care and services are available at least to the extent that such care and services are available to the general population in the geographic area. In turn, the agency has an overarching obligation under section 1902(a)(30)(A) of the Act to ensure that Medicaid payments are made in an economical and efficient, as well as sufficient, manner to provide access to care.

Section 1927(b)(3)(B) of the Act authorizes the Secretary to survey wholesalers and manufacturers that directly distribute their CODs, when necessary, to verify manufacturer prices reported to us under section 1927(b)(3)(A) of the Act. We are proposing to interpret this language broadly to provide authority to verify prices and charges from wholesalers and manufacturers that distribute their own drugs, including when the manufacturer distributes drugs directly to pharmacies and other providers. In other words, we believe it is meant to allow the Secretary to verify prices reported in both situations in which a manufacturer sells to wholesalers and/or distributes them directly on their own. The statute expressly provides at section 1927(b)(3)(B) of the Act the authority to verify ''manufacturer prices and manufacturer's average sales prices (including wholesale acquisition cost)'' and that requests for information may span ''charges or prices.'' We discuss later in this section which charges and prices we may request to verify the reported manufacturer prices.

The meaning of the term ''verify,'' as set forth in the Oxford English Dictionary means ''make sure or demonstrate that (something) is true, accurate, or justified''. Viewing the authority provided under section 1927(b)(3)(B) of the Act through the lens of section 1902(a)(30)(A) of the Act obligations, we are proposing the following: (1) to describe the criteria by which we would develop a list of CODs (identified by NDC) that may be subject to a survey, and the manufacturers to whom the agency intends to send such a survey, to obtain additional information from said manufacturers or wholesalers to verify prices or charges of certain CODs that are reported to us under section 1927(b)(3)(A) of the Act; and, (2) the information that manufacturers and wholesalers would be required to report to satisfy the verification survey request.

Under our proposal, a process would be established such that once the agency determines that a manufacturer and its COD would be subject to verification, the prices or charges that would be subject to verification may include those that are described in section 1927(b)(3)(A) of the Act and reported by manufacturers, including a manufacturer's AMP, best price, ASP, and WAC for a drug. We note that WAC is generally available through public sources, while the manufacturer reported AMP, best price, and ASP for

CODs are generally not available through public sources.

The CODs to which this verification survey would apply would be limited to those for which manufacturers that have a National Drug Rebate Agreement in place with the Secretary of HHS, as required under section 1927(a)(1) of the Act. Only these manufacturers would report applicable product and pricing data under section 1927(b)(3)(A) of the Act and proposed § 447.510. We note this rulemaking does not address the separate authority to conduct surveys under section 1847A(f)(2) of the Act to verify prices reported under section 1847A(f)(2).

We note that participating manufacturers are required to report and certify certain product and pricing data for each of their CODs on a monthly and quarterly basis to CMS. The COD pricing and product information is primarily used for the determination of the quarterly Medicaid drug rebates paid by participating manufacturers, but also serves as the basis for Medicaid payment for CODs. For example, the AMPs that are reported to the agency are used in the calculation of the Medicaid Federal Upper Limits (FULs) for payment of certain multiple source CODs under section 1927(e)(5) of the Act. The 340B Drug Pricing Program uses the AMP and the Unit Rebate Amount (which is the amount calculated to determine the Medicaid rebate for each dosage form and strength of a COD, and is based in part on AMP) to calculate the 340B ceiling price. Many States require that 340B entities are paid no more than the 340B ceiling price for CODs dispensed by 340B entities. Additionally, many State Medicaid programs use the ASP (as defined in section 1847A(b)(4)(A) of the Act) and the Wholesale Acquisition Cost (as defined in section 1847A(b)(4)(B) of the Act) for Medicaid payment for physician administered drugs, such as those administered in hospital outpatient departments and physician offices.

Since the aforementioned pricing data that manufacturers report to us under section 1927(b)(3)(A) of the Act (AMP, ASP, WAC) are often used by States for reimbursement under Medicaid, serve as a basis for payment to providers for CODs, including physician administered drugs, and thus have a significant impact on how much the Federal Government pays for CODs under Medicaid, CMS must ensure, in accordance with section 1902(a)(30)(A) of the Act, that Medicaid payments for CODs based on these reported prices, are made in an economical and efficient, as well as sufficient manner, to provide access to care.

To provide additional background on the need for the agency to use this survey authority, we note that Medicaid pays for CODs under both FFS programs and through Medicaid managed care plans. State Medicaid programs and their contracted managed care plans have been successful in managing the costs of the pharmacy benefit programs through the implementation of various drug cost containment strategies. The primary mechanisms used by States and managed care plans to manage their pharmacy program spending consist of manufacturer rebates that are collected under the MDRP, the use of lower-cost generic or multiple source drugs, prior authorization, and preferred drug lists, which allow States to leverage crowded therapeutic classes to negotiate supplemental rebates with manufacturers. Manufacturer rebates collected by the States totaled $42.9 billion on a total drug spending of $77.6 billion for the four-quarter period Q1 2022 through Q4 2022 or 55.3 percent of total drug spending.

We also finalized regulations in the COD final rule that require that reimbursement for drugs dispensed through retail pharmacies be based on a two-part formula which consists of: (1) the ingredient cost of the drug based on actual acquisition costs (AAC); and, (2) a professional dispensing fee (PDF) for the drug based on the pharmacy's cost of professional dispensing. See §§ 447.502, 447.512, and 447.518. States establish reimbursement methodologies for these two components based on actual acquisition cost data and costs associated with dispensing. To further assist States to pay for CODs, the agency publishes the National Average Drug Acquisition Cost (NADAC) file on a monthly basis, which is based on community pharmacy invoice prices for CODs. The NADAC is one source States can use to support their ingredient cost AAC-based portion of pharmacy reimbursement. This methodology provides greater transparency into Medicaid payment for prescription drugs dispensed through community pharmacies, and most States use this file to help assure that pharmacies are paid for the cost of the drug that is dispensed and the professional dispensing costs. No such survey process, however, exists for CODs paid for by Medicaid that are not traditionally dispensed through retail pharmacies, such as many physician-administered drugs and gene therapy drugs, which are not required to follow the regulations noted above with regard to pharmacy reimbursement and AAC and PDF requirements.

Thus, while Medicaid has implemented policies that generally provide effective management of traditional retail community pharmacy drug spending, while creating greater transparency around payment for drugs dispensed by retail community pharmacies, there are fewer effective policies in place for management of COD purchasing and reimbursement to non-retail health care providers.

Substantial growth in non-retail community pharmacy drug spending is expected to continue. In March 2022, we estimated that for CY 2022, drugs that may require special handling or inpatient or outpatient hospitals stays will account for about 50 percent of the drug supply chain spending.[37] Additionally, Medicaid expenditures for CODs dispensed in non-retail community pharmacy settings continue to experience similar growth. Based on an analysis of CMS State utilization data from 2012 to 2019, total Medicaid non-retail community pharmacy drug expenditures as a percentage of total Medicaid drug expenditures grew from 28 percent to 47 percent, and total Medicaid non-retail community pharmacy dispensed drug expenditures grew from $10.58 billion to $30.70 billion.[38]

Thus, it is evident that the evolution in the types of drugs paid for by Medicaid, manufacturers' pricing structures for these drugs, as well as the methods used by manufacturers to distribute these drugs, have changed since the enactment of the MDRP, as well as the enactment of the MMA. While the model of distribution from manufacturer to wholesaler to provider still exists, and the predominant provider of pharmacy services remains the community-based pharmacy, there are other distribution and pricing arrangements for certain drugs, including high-cost gene therapy drugs that were not necessarily in existence in the market when the MDRP was enacted.

In some of these situations, there is a need for more information or verification regarding how certain prices or charges reported to us for these high-cost CODs are calculated in order to make payment under Medicaid. For example, there is little or no public information available about the factors

[37] Iqvia, National Sales Perspective, February 2022. Presentation given by Doug Long at Asembia, May 2022.

[38] Myers and Stauffer LC, Specialty Drugs Spend Trend 2012–2019 (2020) (unpublished analysis) (on file with Agency) (this analysis reviewed FFS and MCO combined spend for specialty drugs included on the Myers and Stauffer LC specialty list, based upon eight years of CMS National Utilization Data).

that influence the pricing of drugs dispensed in non-retail community pharmacy settings in Medicaid, the prices that pharmacies or wholesalers pay for these CODs, whether the prices or charges bear any relationship to the cost components of the COD, or whether the costs of distribution or preparation methods are included in the prices reported to us.

States do not have access to invoice data of manufacturers or purchasers, or information as to how manufacturers have arrived at the prices they charge wholesalers or direct distributers. Therefore, States may assume that manufacturer prices reflect the manufacturer's cost inputs such as research, development, and production costs. However, States do not know how those costs relate to the prices available from the manufacturer. Manufacturers may also consider the relative value of that drug to the patient/payer versus other treatments for similar conditions when developing their prices. As such, States may assume that the manufacturer prices its drug(s) at a certain value because it either has the potential to cure the patient or substantially reduce other medical costs (for example, reduces a patient's need for higher cost inpatient hospital care). However, these assumptions may not be accurate since how the manufacturer arrives at its price is generally opaque.

We believe our proposed drug price verification survey process, along with the NADAC that we publish for retail community pharmacy costs, should provide CMS and the States a clearer understanding into a manufacturer's pricing for its covered outpatient drug to verify those prices and charges, and ensure that Medicaid payments are made in an economical and efficient, as well as sufficient manner, to provide access to care. A lack of current understanding of manufacturer pricing bears directly on whether payments can be made consistent with section 1902(a)(30)(A) of the Act. Moreover, Medicaid managed care plans may be able to use such public information about the prices or charges that are collected under this process to determine the appropriateness of their payments to PBMs, or for States and managed care plans to determine the appropriateness of the drug spending component of the overall Medicaid managed care capitation rate attributable to pharmacy services.

For the foregoing reasons, and as described below, we propose to use the statutory authority in section 1927(b)(3)(B) of the Act, coupled with that in section 1902(a)(30)(A) of the Act, and this proposed regulatory process, to collect additional charges and pricing information from manufacturers to verify the prices reported to us for CODs. We believe this verification is extremely important given the significant number of high cost drugs and biologics, including cell and gene therapy drugs entering the market; the prices associated with new and different distribution channels; and the continued use of WAC as a pricing metric in instances when actual acquisition cost data are not available. Gene and cell therapy drugs especially, while transformative in terms of therapeutic benefits, are being priced in the millions of dollars. States, with their limited budgets, are concerned about how they would be able to afford these medications as they are generally required to pay for these drugs that are CODs as part of the prescribed drugs benefit in accordance with the requirements of section 1927 of the Act and the Medicaid drug rebate program. As stated earlier in this rule, our proposal to survey manufacturers to verify price(s) and charge(s) involves collecting certain information on specific CODs, and our proposal to make certain manufacturer information publicly available (unless it is proprietary), would give States an additional tool to negotiate payment for Medicaid CODs consistent with section 1902(a)(30)(A) of the Act. For instance, while the survey would be used by CMS to verify prices, the access to certain non-proprietary data via the survey, for example, patient outcomes of the covered outpatient drug, could give States the ability to negotiate supplemental rebates with a full understanding of the impact of the drug on its budget and Medicaid patient population. This is important, particularly in light of the limited ability of States to negotiate additional supplemental rebates because of the few novel products in a particular drug class.

We have also seen pricing-related issues relating to the production methods for these drugs, and query whether and how such methods should factor into the prices that are reported to us under section 1927(b)(3)(A) of the Act. For example, there are new preparation methods that modify or treat a patient's own cells, which are then placed back into the body to treat the patient's condition. This type of preparation method, while novel, raises issues of how such costs are included in the prices that are reported to us. We have also observed that certain manufacturers are using limited-distribution specialty pharmacies to distribute their drugs to providers and patients. Certain closed-door specialty pharmacies may have access to limited-distribution specialty drugs due to specific arrangements with pharmaceutical manufacturers or special monitoring provisions required by FDA.[39] Of the drugs approved by FDA in 2020 that were distributed through specialty pharmacies, 96 percent were for limited-distribution drugs.[40]

In addition to retail community and closed-door specialty pharmacies, other provider types may dispense and/or administer drugs dispensed in non-retail community pharmacy settings to Medicaid beneficiaries. These providers include, but are not limited to, physicians, home infusion pharmacies, hemophilia treatment centers, and clinics. In these situations, there may be questions regarding how a manufacturer calculates its AMP and best price that are reported to us under section 1927(b)(3)(A) of the Act, and how those data points compare to the actual invoice cost of the drug to the pharmacy. This directly affects Medicaid payments and rebates.

Manufacturers are also using innovative versions of third-party logistic arrangements to distribute their drugs, which include specialty pharmacies, under which the title of the drug does not transfer to the pharmacy. Questions have been raised by States as to how such arrangements work with respect to the Medicaid program's payment to the pharmacy, as well as the calculation of the covered outpatient drug's AMP and best price that are reported to us under section 1927(b)(3)(A) of the Act and used for purposes of calculating Medicaid rebates.

And we note that many States and Medicaid programs continue to use WAC as the basis for reimbursement of many drugs dispensed in a non-retail community pharmacy setting—because of the lack of availability of acquisition cost data. However, we have observed that there may be a trend in Medicaid by some manufacturers with recently-marketed high cost CODs to increase their WACs at a rate faster than their AMPs, especially for specialty drugs. We have not identified this trend with respect to long-marketed drugs covered by Medicaid and dispensed at retail community pharmacies based upon a

[39] Erin M. Turingan, et al., *Financial Effect of a Drug Distribution Model Change on a Health System.* 52 Hosp. Pharm. 422 (2017).

[40] Anton Health, *2020 Specialty Approvals—96% Via Limited Distribution,* Anton RX Report (Jan. 15, 2021), *https://antonhealth.com/2020-specialty-pharmacy-approvals/.*

May 2023 CMS comparison research of changes to invoice prices vs. changes in WAC. This comparison showed consistent changes in invoice pricing and WAC. We believe consistent changes in invoice pricing and WAC also occur for drugs covered by Medicare Part D and dispensed at retail community pharmacies. Generally, when manufacturers increase their WACs at a rate faster than their AMPs, the higher the WAC for the COD, the greater the spread between the Medicaid reimbursement and the actual acquisition cost. This trend could affect whether Medicaid payments are consistent with sections 1927 and 1902(a)(30)(A) of the Act, as discussed previously in this proposed rule. That is, the use of WAC by the State for reimbursement purposes for certain drugs, such as high cost specialty drugs, may result in States overspending for a drug and manufacturers underpaying in rebates because of the much lower reported AMP for the drug.

For example, based on an agency analysis of the relationship between WAC and AMP for a specific high-cost specialty drug, we found in 2018 that there was an 8.5 percent difference between the WAC and the AMP. Based on the latest data available, that difference is now 23 percent. Thus, States that use WAC that is reported to us under section 1927(b)(3)(A) of the Act to pay providers may significantly overspend for specialty drugs, given that AMP has traditionally been considered a closer proxy for the approximate revenues received by the manufacturer from sales of the drugs in the non-retail community pharmacy setting.

Given these situations, we propose that significant enough changes have occurred in the marketplace to warrant the use of the Secretary's authority to survey manufacturers and wholesalers in certain situations with respect to the prices and charges reported to us under section 1927(b)(3)(A) of the Act to make payment. Specifically, section 1927(b)(3)(B) of the Act gives the Secretary the authority to survey wholesalers and manufacturers that directly distribute their CODs, when necessary, to verify manufacturer prices and manufacturer's average sales prices (including wholesale acquisition cost) if required to make payment reported under section 1927(b)(3)(A) of the Act.

Therefore, we propose at § 447.510(k)(1) to use the authority granted to the Secretary under section 1927(b)(3)(B) of the Act to survey manufacturers with rebate agreements in effect with the Secretary to verify prices or charges for certain CODs for which drug product and pricing information is submitted under section 1927(b)(3)(A) of the Act and § 447.510, to make payment for the COD.

We do not believe it is required or necessary that we survey every manufacturer's price or charge submitted under section 1927(b)(3)(A) of the Act, as the authority to verify via a survey of the prices under section 1927(b)(3)(B) of the Act indicates that the Secretary ''may'' verify. Notably, we propose to exclude those CODs that are subject to certain CMS drug pricing program(s) or initiatives under which participating manufacturers negotiate the COD's price directly with CMS. For example, under the Medicare Drug Price Negotiation program established under sections 11001 and 11002 of the Inflation Reduction Act of 2022, or potentially certain CMMI models that are developed in response to the President's Executive Order 14087 (see HHS response at *https://innovation.cms.gov/data-and-reports/2023/eo-rx-drug-cost-response-report*), participating manufacturers will negotiate and collaborate with CMS on prices for certain CODs. This being the case, we propose to exclude CODs subject to these programs and initiatives from the survey verification, as CMS may have already successfully negotiated lower prices for the Medicare and/or Medicaid programs with these manufacturers. We intend to include a list of CMS drug pricing programs and initiatives under which manufacturers directly negotiate with CMS on a public website and would expect to update that list to reflect any future CMS drug pricing programs and initiatives that result in manufacturers' directly negotiating COD pricing with CMS.

We further note that under section 1927(c)(1)(C)(ii)(V) of the Act, maximum fair prices (MFPs) that are negotiated for selected drugs under the Medicare Drug Price Negotiation Program would be included in the Medicaid best price; thus, State Medicaid programs will benefit from the MFPs negotiated under Medicare Part B and Part D to the extent that such drugs are CODs. In other words, the MFP negotiated for these drugs could potentially lower the best price and potentially increase the Federal Medicaid drug rebate. Furthermore, it is unlikely that CODs with an MFP would be selected for the proposed drug price verification survey under section 1927(b)(3)(B) of the Act because we expect that our proposal would verify drug prices that are more recently marketed high cost drugs not typically dispensed at non-retail community pharmacies, while drugs for which an MFP has been negotiated must have been approved for at least 7 years, in the case of drugs approved and marketed under section 505(c) of the FFDCA, or licensed for at least 11 in the case of biological products that are licensed and marketed under section 351 of the PHS Act. Moreover, as noted previously in this proposed rule, we do not believe the trend of WACs increasing at a rate faster than their AMPs is relevant for the types of drugs for which MFP likely will be negotiated. Therefore, in this rule, we are proposing to survey manufacturers to verify price (or prices) and/or charges regarding specific CODs based on a three-step process.

The first step would use objective measures related to Medicaid spending to identify CODs with the highest drug spending per claim, highest total Medicaid drug spending, highest 1 year price increase, or highest launch price, as determined and explained below. Specifically, we propose at § 447.510(k)(2) that CMS, on an annual basis, would compile a list of single source CODs that may be subject to a survey based on one or more of the criteria proposed at § 447.510(k)(2)(i) through (iv).

The proposed measures in § 447.510(k)(2)(i) (highest drug spending per claim) and (ii) (highest total Medicaid drug spending) would use Medicaid drug spending data as reported from States to CMS in accordance with the State drug utilization data (SDUD) reporting (*https://www.medicaid.gov/medicaid/prescription-drugs/state-drug-utilization-data/index.html*). We note that the per claim Medicaid spending data used in § 447.510(k)(2)(i) is not reduced by Federal rebates since such rebates are not reported at the claim level. Further, the supplemental rebate data are reported in the aggregate to CMS from States on a quarterly basis, thus it is difficult to identify individual State supplemental rebate data to net State supplemental rebates from per claim Medicaid spending. However, we would review the reported annual total Medicaid spending at § 447.510(k)(2)(ii) as reported by the States net of Federal rebates when determining if a COD spend is greater than 0.5 percent of total annual Medicaid drug spend, net of Federal rebates.

For proposed measure § 447.510(k)(2)(iii), we would look at published WACs to determine when a COD's price increase falls in the top 1 percent of CODs with the highest median WAC increase over a 12-month period.

In proposed measure § 447.510(k)(2)(iv), we propose to look at the highest launch price, which we

propose to do by estimating whether or not the covered outpatient drug's cost would be in the top 5th percentile of Medicaid spending by comparing a manufacturer's published launch price (available as a published WAC or published by the manufacturer) to Medicaid per claim spending or if treatment costs are greater than $500,000 (indexed for inflation using the CPI–U).

We expect application of the measures proposed at § 447.510(k)(2)(i) through (iv) would capture an initial set of high-cost CODs that could significantly impact Medicaid covered outpatient drug spending. From a process standpoint, in subregulatory guidance, we would provide the applicable time periods that CMS would review the data in order to determine the initial list of CODs, which we propose to be finalized in April following publication of this final rule, and each April thereafter. We expect that we would use data from the prior calendar year or Federal fiscal year. The list of CODs as a result of this analysis would not be made public.

We propose at § 447.510(k)(3) to further refine this initial survey list of CODs in the second step by considering additional criteria such as a manufacturer's willingness to negotiate further rebates either through a CMS-authorized supplemental rebate, or a manufacturer's participation in a CMS drug pricing program or initiative under which participating manufacturers negotiate directly with CMS (see discussion above about proposal to exclude drugs under a CMS drug pricing program or initiative). At § 447.510(k)(3)(i), CMS proposes to exclude the CODs of manufacturers that participate in any CMS pricing program or initiative under which participating manufacturers negotiate a COD's price directly with CMS.

CMS believes that a manufacturer's willingness to negotiate also may be demonstrated by the manufacturer's level of effort to work with States to make the identified COD more affordable, especially considering States' limited budgets. Therefore, by way of a State survey to determine a manufacturer's level of effort, we propose at § 447.510(k)(3)(ii) to further exclude covered outpatient drugs of manufacturers that have negotiated CMS-authorized supplemental rebates with at least 50 percent of the States, that when in combination with the Federal rebate results in a total (State and Federal) rebate for the drug of interest to total Medicaid spend (State and Federal) for the drug of interest, that is greater than the total Medicaid rebates (State and Federal) to total Medicaid drug spend for States that cover CODs only through fee-for-service, as reflected in the most recent Medicaid Financial Management Report (FMR).[41] The FMR reflects annual State expenditures collected on the CMS–64 report.[42] We propose to use the Federal fiscal year Medicaid FMR and analyze the rebates for those States that currently provide coverage of covered outpatient drugs only through fee-for-service (fee-for-service States). Specifically, we would determine total computable prescribed drugs expenditures for the States that cover CODs only through fee-for-service (currently 10 States) and determine the percentage of prescribed drug expenditures that are offset by State and Federal drug rebates. We propose to consider only States that cover CODs entirely through fee-for-service because the prescribed drugs expenditures in the FMR do not include COD expenditures made by managed care entities, while the rebate lines do include the managed care rebate offset. In other words, the denominator in the comparison of rebates to total expenditures would be understated, resulting in a higher percentage, if we included managed care COD expenditures and rebates in the calculation. Based upon the Federal fiscal year 2021 Medicaid FMR, the total Federal and State rebates range from 38 percent to 72 percent of total prescribed drug expenditures based upon analysis of eight States that pay for CODs entirely through fee-for-service (2 of the 10 such States had insufficient data reported for Federal fiscal year (FFY) 2021). We request comment on this proposal to refine the list of covered outpatient drugs to be surveyed, based upon a manufacturer's level of effort at reducing the price for the identified high cost drugs (that is, those drugs identified by applying measures proposed at § 447.510(k)(2)).

We also propose § 447.510(k)(3)(iii)(A) that if after application of § 447.510(k)(3)(i) and (ii), more than 10 CODs still remain, CMS would proceed to the third step and consider soliciting State-specific Medicaid program information as to the manufacturer's level of effort to lower drug price for the Medicaid program, such as a manufacturer offering other programs to lower the cost of the drug to the State such as subscription models, VBP arrangements under the multiple best price approach, or other special arrangements. We do not intend these examples of manufacturer effort to lower drug prices in § 447.510(k)(3)(iii)(A) to be exclusive or to encourage or discourage specific pricing approached; CMS recognizes that the pharmaceutical pricing market is fluid and States and manufacturers may pursue or negotiate arrangements not specifically listed in regulation. Additionally, we propose at § 447.510(k)(3)(iii)(B) that we would consider narrowing the list based on the highest cost CODs based on the factors outlined under § 447.510(k)(2) of this section, and before application of § 447.510(k)(3). We propose to collect the information in § 447.510(k)(3)(ii) and (k)(3)(iii)(A) using a State survey tool that we would develop if the rule is finalized as proposed. Once CMS determines a final list of CODs to be verified after the application of 447.510(k)(3), we would send a letter to the manufacturers of the identified drugs sometime in August, as discussed further below.

While currently not proposed in regulation at § 447.510(k)(2) and (3), we also invite comments on whether CMS should consider surveying manufacturers of certain CODs that are identified under the proposed criteria at § 447.510(k)(2)(i) through (iv) that are also granted accelerated approval by FDA. The approval of a COD using the accelerated approval pathway relies on demonstrating an effect on surrogate or intermediate endpoint(s) that is reasonably likely to predict clinical benefit. Drug sponsors have been required by the FDA to conduct confirmatory trials after approval to verify and describe the predicted clinical benefit. However, the HHS OIG[43] found that drug sponsors do not always complete trials promptly, which can result in drugs staying on the market—often at high prices with limited competition—and being administered for years with unverified clinical benefit. Subjecting accelerated approval drugs to the drug price verification survey process would not supplant any determination made by the FDA. However, CMS surveying manufacturers for verification of prices may be warranted by recent trends of high costs of some of these therapies, particularly in view of some manufacturers' noncompliance with FDA's requirement for further confirmatory trials. Accordingly, we seek comments regarding whether CODs included on the list under the proposed

[41] *https://www.medicaid.gov/medicaid/financial-management/state-expenditure-reporting-for-medicaid-chip/expenditure-reports-mbescbes/index.html.*

[42] *https://www.medicaid.gov/medicaid/financial-management/state-expenditure-reporting-medicaid-chip/index.html.*

[43] *https://oig.hhs.gov/oei/reports/OEI-01-21-00401.asp.*

§ 447.510(k)(2) that are approved under the FDA accelerated approval pathway should be surveyed when a manufacturer has failed to demonstrate the clinical benefits of the drug through further confirmatory trials required by the FDA.

We propose at § 447.510(k)(4) that after a survey list of CODs is compiled after the application of the criteria in § 447.510(k)(2) and (3), the agency would post on a publicly accessible, government website the letter sent to the manufacturer indicating the name of the COD to be surveyed and the request for completion of the drug price verification survey.

In proposed § 447.510(k)(5), we propose that such survey to a manufacturer or wholesaler would request in a standard reporting format specific information that would include the information proposed at § 447.510(k)(5)(i) through (iv). The survey tool would be developed after the publication of the final rule, if this proposal is finalized.

In § 447.510(k)(5)(i), we propose to collect information on the pricing, charges, distribution and utilization for the COD. We propose to collect these utilization and pricing metrics from manufacturers to verify that the prices reported at section 1927(b)(3)(A) of the Act do not have the potential to negatively impact State budgets to the extent States are not able to cover the drugs, thus impeding Medicaid beneficiary access to treatment.

In § 447.510(k)(5)(ii), we propose to collect product and clinical information for the COD described in the proposed regulation text at § 447.511(k)(5)(ii)(A) through (E) to understand the clinical benefits and risks of the covered outpatient drug to verify that the price reported fairly represents the benefits and/or risks of the COD.

In § 447.510(k)(5)(iii), we propose to collect information on the costs of production, research, and marketing of the COD. We believe it is important to understand the costs to the manufacturer of researching, producing, and marketing of the drug and how those costs are accounted for in the prices and charges they report. We also note in this proposed subparagraph that research and development costs of a line extension drug shall not include the research and development costs of the initial single source or innovator multiple source covered outpatient drug.

In § 447.510(k)(5)(iv), we propose to collect other information as determined by the Secretary specific to the particular COD in question that would help inform CMS and States with their verification of drug prices. This additional information would likely be specific to each individual covered outpatient drug and may include additional requests associated with changes to the pharmaceutical marketplace. We may consider issuing additional guidance on the nature and scope of the other information we may request.

The agency understands that some of the data proposed to be collected would be confidential and likely protected under section 1927(b)(3)(D) of the Act, in addition to other privacy and confidentiality provisions, including the Trade Secrets Act.

Although the statute does not prescribe a method to verify prices or charges, we propose in § 447.510(k)(6) that CMS may post non-proprietary information provided by the manufacturer and wholesaler in response to the verification survey. By posting the non-proprietary information on our website, the public, beneficiaries, State Medicaid agencies, other Federal Government agencies and other affected interested parties would be afforded the opportunity to comment on public information as part of the verification process to ensure that those Medicaid payments are economical and efficient, as well as sufficient, to provide access to care and are sufficient to enlist enough providers so that care and services are available at least to the extent that such care and services are available to the general population in the geographic area.

Finally, section 1927(b)(3)(B) of the Act allows the Secretary to impose a civil monetary penalty in an amount not to exceed $100,000 on a wholesaler, manufacturer, or direct seller, if the wholesaler, manufacturer, or direct seller of a covered outpatient drug refuses a request for information about charges or prices by the Secretary in connection with a survey as proposed under § 447.510(k) or knowingly provides false information. The provisions of section 1128A of the Act (other than subsections (a) (with respect to amounts of penalties or additional assessments) and (b)) shall apply to a civil money penalty (CMP) under this subparagraph in the same manner as such provisions apply to a penalty or proceeding under section 1128A(a) of the Act. The civil monetary penalty authority set forth in section 1927(b)(3)(B) of the Act has been delegated to OIG. We would provide information obtained through, and in connection with, this survey to OIG for the purposes of potential imposition of CMPs for failure to report information in connection with a survey or for knowingly providing false information. Therefore, we propose at § 447.510(k)(7) that if a manufacturer or wholesaler refuses a request for information pursuant to a drug price verification survey within 90 calendar days of CMS' request, or knowingly provides false information, the manufacturer or wholesaler would be referred to OIG for possible imposition of civil monetary penalties (CMPs) as set forth in section 1927(b)(3)(B) of the Act and section IV of the National Drug Rebate Agreement.

K. Proposals Related to State Plan Requirements, Findings, and Assurances (§ 447.518)

Section 1902(a)(30)(A) of the Act requires that States include in their State Plan, methods and procedures to ensure that payments to providers are consistent with efficiency, economy, and quality of care and are sufficient to enlist enough providers so that care and services are available to the general population in the geographic area. Under that authority, the Secretary issued Federal regulations at §§ 447.502, 447.512, and 447.518 that further elaborate that generally, payments to pharmacies for drugs that they dispense, and are paid for under the State Plan, are to be based on a two-part formula which consists of: (1) the ingredient cost of the drug that is dispensed based on the actual acquisition cost (AAC); and, (2) a professional dispensing fee (PDF) for the drug based on the pharmacy's cost of dispensing, that is, the cost of the pharmacist's professional services for ensuring that the appropriate COD is dispensed or transferred to a Medicaid beneficiary.

AAC is defined at § 447.502 to mean the agency's determination of the pharmacy providers' actual prices paid to acquire drug products marketed or sold by specific manufacturers. As discussed in the COD final rule implementing this definition of AAC, a State can implement an AAC model of reimbursement based on various pricing methodologies for the ingredient cost of the drug so long as the ingredient cost represents the actual, current ingredient cost of the drug and is calculated based on the amounts that pharmacies pay for the drug (§ 447.518).

We also discussed our view that the definition of AAC requires that States establish payment rates based on pharmacies' actual prices paid to acquire drug products, and explained that the expectation is that those prices would reflect current prices (see 81 FR 5176). In accordance with § 447.502, the professional dispensing fee is incurred at the point of sale or service and pays for pharmacy costs in excess of the

ingredient cost of a COD each time a COD is dispensed. The fee includes, but is not limited to, reasonable costs associated with delivery, special packaging and overhead associated with maintaining the facility and equipment necessary to operate the pharmacy. Costs also include a pharmacist's time spent checking the computer for information about an individual's coverage, performing drug utilization review (DUR) and preferred drug list review activities, measuring or mixing, filling the prescription, counseling a beneficiary; and physically providing the completed prescription to the Medicaid beneficiary.

Under § 447.518, States are required to ensure that pharmacy providers are reimbursed adequately for both their pharmacy ingredient costs and professional dispensing services in accordance with the requirements of section 1902(a)(30)(A) of the Act. The State Plan must comprehensively describe the agency's payment methodology for prescription drugs, including the agency's payment methodology for drugs and the professional dispensing fee. As provided under § 447.518(d)(1), when proposing changes to either AAC (ingredient cost reimbursement) or PDF reimbursement, States are required to evaluate their proposed changes consistent with section 1927 of the Act, and must consider both parts of the reimbursement formula to ensure that total reimbursement under the proposed changes are consistent with section 1902(a)(30)(A) of the Act.

These reimbursement formulas and any proposals to change either or both components of the reimbursement formula are subject to review and approval by CMS through the State Plan Amendment (SPA) process. In their SPA submission, States must provide adequate data such as a State or national survey of retail pharmacy providers or other reliable data (other than a survey) to support any proposed changes to either or both of the components of the reimbursement methodology.

While States are afforded the flexibility to adjust their professional dispensing fees through the SPA process in accordance with the requirements of sections 1902(a)(30)(A) and 1927 of the Act, they must substantiate how their reimbursement to pharmacy providers reasonably reflects the actual cost of the ingredients used to dispense the drug, and the actual costs of dispensing the drug, consistent with the regulatory definitions of AAC and professional dispensing fee. We review each State's proposed reimbursement methodology to assure it meets Federal requirements under sections 1902(a)(30)(A) and 1927 of the Act, and the implementing regulations, specifically at §§ 447.502, 447.512, and 447.518.

More recently, we have seen States submit proposed changes to either or both of the components of the reimbursement methodology without adequate supporting data that reflects current drug acquisition cost prices or actual costs to dispense. This is inconsistent with applicable law because the data submitted should reflect the actual cost of dispensing, consistent with Federal requirements under sections 1902(a)(30)(A) and 1927 of the Act and the implementing regulations, specifically at §§ 447.502, 447.512 and 447.518.

The professional dispensing fee should be based on pharmacy cost data, and not be based on a market-based review, such as an assessment or comparison of what other third-party payers may reimburse pharmacies for dispensing prescriptions. A State's periodic review and examination of market-based research for a comparison of what other payers reimburse for dispensing costs is an insufficient basis for determining or proposing changes to professional dispensing fees because it does not reflect actual costs to pharmacies to dispense prescriptions. The State must submit adequate cost data to CMS as part of its SPA process to justify its professional dispensing fee amounts. We are proposing that the data submitted cannot solely rely on the amounts that pharmacies are accepting from other private third-party payers.

Similarly, with respect to reimbursement of drug ingredient costs, which must be consistent with AAC, States must support determinations or proposed changes for ingredient cost reimbursement with adequate cost based data. With respect to the AAC, we discussed in the preamble of the COD final rule our view that the definition of AAC requires that States establish payment rates based on pharmacies' actual prices paid to acquire drug products, and explained that the expectation is that those prices would reflect current prices. (See 81 FR 5176.)

Pharmacy purchase prices for drugs are subject to many external factors and market conditions which can cause purchase prices to go up or down. Many of these factors are out of the control of the purchasing pharmacy. We explained various ways States could establish pharmacy reimbursement methodologies, noting that the pricing benchmarks CMS provide to States, for example, the weekly NADAC files, and the weekly and monthly AMP are updated regularly to reflect current prices.

After the COD final rule was issued, we issued further guidance to States in the State Medicaid Directors Letter, SHO #16–001, dated February 11, 2016, and Frequently Asked Questions (FAQs), dated July 6, 2016. In that SHO, CMS provided further detail on ways States can implement an AAC model of reimbursement, including utilizing a nationwide survey, like the NADAC files (which are published on a monthly basis and updated weekly, and are designed to represent a current national pricing methodology based upon a simple average of voluntarily-submitted retail pharmacy acquisition costs for most covered outpatient drugs), a State survey of retail community pharmacy providers' pricing, published compendia prices, or average manufacturer price-based pricing. In each of these instances, the ingredient cost represents the actual, current ingredient cost of the drug and is calculated based on the amounts that pharmacies pay for the drug.

Freezing AAC rates and establishing a static provider reimbursement would not be consistent with applicable laws and regulations. Reduced beneficiary access to medically necessary drugs can result if pharmacy providers are unable to purchase drugs at a rate reflective of current market conditions. Pharmacies are not likely to purchase and dispense a covered outpatient drug to a Medicaid beneficiary if the reimbursement for the drug is not sufficient. Certain pharmacies, such as small rural pharmacies, rely primarily on revenue from prescriptions. When reimbursement rates for drugs do not adapt to changing market conditions, pharmacies may stop filling prescriptions for Medicaid beneficiaries, or, depending on the number of Medicaid prescriptions they fill, could have to permanently go out of business. This can result in reduced access to medications and negatively impact health equity, as Medicaid beneficiaries may have to go to multiple pharmacies to obtain the medication, or may not be able to obtain it at all. This can also result in the need for other costlier medical interventions, such as hospitalization.

In this proposed rule, we are proposing to clarify the data requirements that States must submit to establish the adequacy of both the current ingredient cost and the professional dispensing fee reimbursement. Furthermore, we are specifying professional dispensing fees cannot simply be determined by a market-based review of what other

third-party payers may reimburse for dispensing prescriptions. That is, we are proposing to clarify in regulatory text that in a State's periodic review of the rates being paid to pharmacies, the examination of market-based research data used to justify dispensing costs is an inappropriate basis for determining professional dispensing fees. A State cannot rely on the amounts that pharmacies are accepting from other third-party payers as a means of determining professional dispensing costs. The data that are acceptable could be a State's own survey, a neighboring States' survey, or other credible survey data, but it must be adequate and must reflect the current cost of dispensing a prescription in the State (81 FR 5311).

To pay based on costs, States need to periodically assess whether current rates being paid to pharmacies to reflect current costs. There is no specific requirement as to how often and when States have to review their current fees. However, any State currently reimbursing pharmacy providers a professional dispensing fee that does not reflect the pharmacy's actual acquisition cost and cost of dispensing must come into compliance.

Therefore, in consideration of ensuring that payments to providers are consistent with efficiency, economy, and quality of care and are sufficient to enlist enough providers, we believe an update to the regulatory text is necessary so that care and services continue to be available to the general population. Accordingly, we are proposing to update § 447.518(d) heading as ''Data requirements'' and to include paragraph (d)(1) as set out at in the regulatory text at the end of this document.

Updating this language would assure that States provide adequate data to establish pharmacy reimbursement for ingredient costs and professional dispensing fees, and that such reimbursement is based on current actual costs.

L. Federal Financial Participation (FFP): Conditions Relating to Physician-Administered Drugs (§ 447.520)

Generally, physician-administered drugs (PADs) may satisfy the definition of a covered outpatient drugs (COD) under section 1927(k)(2) of the Act, subject to the limiting definition at section 1927(k)(3) of the Act, and manufacturer rebates can be collected on these PADs.

Prior to section 6002 of the DRA of 2005, which added sections 1927(a)(7) and 1903(i)(10)(C) to the Act to require the States to collect and submit certain utilization data on certain PADs in order for FFP to be available for these drugs, and for States to secure rebates, many States did not collect rebates on PADs when they were not identified by a National Drug Code (NDC) number because the NDC number is necessary for States to bill manufacturers for rebates. The NDC identifies the specific manufacturer, product, and package size.

In the past, many PADs were classified by Healthcare Common Procedure Coding System (HCPCS) [44] codes (commonly referred to as J-codes), which group together different manufacturers of the same drug in the same code. These broad codes cannot be used to bill for rebates, as they do not identify the specific manufacturer. Many providers were submitting only these HCPCS codes to the States, rather than the NDC code of the specific drug, making it difficult for the State to bill for rebates.

In its report titled ''Medicaid Rebates for Physician Administered Drugs'' (April 2004, OEI–03–02–00660),[45] the OIG reported that, by 2003, 24 States either required providers to bill using NDC numbers or identified NDC numbers using a HCPCS-to-NDC crosswalk for PADs to collect rebates. Four of the 24 States were able to collect rebates for all PADs, both single source and multiple source drugs (one State only collected these rebates from targeted providers).

To address this situation, and to increase the rebates being invoiced by States for PADs, section 6002 of the DRA added sections 1927(a)(7) and 1903(i)(10)(C) to the Act to require the States to collect and submit certain utilization data on certain PADs in order for FFP to be available for these drugs, and for States to collect manufacturer rebates. More specifically, these provisions required that for payment to be available under section 1903(a) of the Act for a COD that is a PAD, States had to provide for the collection and submission of utilization data and coding (such as J-codes and NDC numbers) for a PAD that is a single source (after January 1, 2006) or a multiple source drug (after January 1, 2008) that is a top 20 high dollar volume PAD on a published list (based on highest dollar volume dispensed under Medicaid identified by the Secretary, after January 1, 2007) that the Secretary may specify in order for payment to be available under section 1903 of the Act and for States to secure applicable Medicaid rebates.

This list of the top 20 multiple source drugs may be modified year to year to reflect changes in such volume. (See section 1927(a)(7)(B)(i) of the Act.) The statute also required that only NDCs be used after January 1, 2007 for billing for all PADs that are CODs, unless the Secretary authorized that another alternative coding system be used. If States are not collecting NDCs and submitting the appropriate utilization data for these drugs, States should not receive Federal matching payments. In addition, States would be foregoing available rebates for these drugs.

Regulations at § 447.520 were established to implement these statutory provisions in the 2007 Medicaid Program; Prescription Drugs; Final Rule, specifying the conditions for FFP for PADs (72 FR 39142). Section 447.520(a) specifies that no FFP is available for PADs if the State has not required the submission of codes from its providers that allow it to appropriately bill manufacturers for rebates for PADs. For single source PADs, the requirement to submit appropriate coding went into effect as of January 1, 2006, and specifies under § 447.520(a)(1) that States must require providers to submit claims for single source PADs using HCPCS or NDC codes to secure rebates. Section 447.502(a)(2) further specifies that as of January 1, 2007, a State must require providers to submit claims for single source and the top 20 multiple source PADs identified by the Secretary, using NDC codes.

Under § 447.520(b), as of January 1, 2008, a State must require providers to submit claims for the top 20 multiple source drugs identified by the Secretary as having the highest dollar volume using NDC numbers to secure rebates, and § 447.520(c) provided the opportunity for States that require additional time to comply with the requirements of the applicable laws and regulations to apply for an extension to comply with the requirements. We proposed to retain this current regulatory language without modification in the 2012 COD proposed rule (77 FR 5367) and since no comments were received on that proposal, the current regulations were finalized without any modifications in the 2016 COD final rule. See 81 FR 5322.

We propose to update the regulatory language at § 447.520 to more

[44] HCPCS is a collection of standardized codes that represent medical procedures, supplies, products and services. The codes are used to facilitate the processing of health insurance claims by Medicare and other insurers. HCPCS is divided into two subsystems, Level I and Level II. Level I is comprised of Current Procedural Terminology codes (HCPT). Level II HCPCS codes identify products, supplies, and services not included in CPT.

[45] *https://oig.hhs.gov/oei/reports/oei-03-02-00660.pdf.*

specifically and accurately conform with the statutory requirements captured at section 1927(a)(7) of the Act. In proposed § 447.520(a)(1) through (3) we specify the conditions under which FFP is available for States, as they relate to the codes they must require providers to use in order for the State to secure rebates for PADs that are CODs. The proposed language clarifies that rebates are only due for PADs that are CODs, and provides the conditions that data must be submitted by providers in the State in order for States to receive FFP and secure applicable rebates. We are proposing at § 447.520(b) a State require providers to submit claims for all covered outpatient drug single source and multisource physician-administered drugs using NDC numbers to collect FFP and secure rebates.

States also need to ensure that their managed care plans report required drug utilization data in order for States to invoice manufacturers for rebates for CODs, consistent with § 438.3(s)(2) and (3), which were adopted in the 2016 Medicaid Managed Care final rule.[46] Per § 438.3(s)(2) and (3), an MCO, PIHP or PAHP that covers CODs under its Medicaid managed care contract must (1) report drug utilization data to the State that is necessary for the State to bill manufacturers for rebates under section 1927 of the Act using NDC numbers for all CODs, including all single and multiple source PADs; and, (2) establish procedures to exclude utilization data for covered outpatient drugs that are subject to discounts under the 340B Drug Pricing Program from those reports if the State does not require submission of managed care drug claims data from covered entities directly to the State.

Additionally, we are proposing at § 447.520(c) to continue to publish the top 20 list of multiple source PADs on an annual basis, as statutorily required, but it is our expectation that States would invoice rebates for all multiple source physician-administered drugs that are CODs. This section would make it clear that States are required to invoice for rebates for multiple source PADs on this list to receive Federal matching funds and to secure rebates. The proposed regulation would specify to States that they should invoice for rebates for all multiple source PADs that are CODs, and not limit such rebate invoicing to the top 20 high dollar volume list. As technology and systems are currently in place, this proposed regulation would reduce the administrative burden of monitoring any revisions to the top 20 multiple source PADs and allow States to secure rebates for these PADs that are CODs.

M. Request for Information on Requiring a Diagnosis on Medicaid Prescriptions

Generally, a COD is a prescribed drug approved under section 505(c) or 505(j) of the FFDCA or section 351 of the Public Health Service (PHS) Act when used for a medically accepted indication. The term ''medically accepted indication'' is defined in statute at section 1927(k)(6) of the Act and means any use for a COD which is approved under the FFDCA or the use of which is supported by one or more citations included or approved for inclusion in compendia described in section 1927(g)(1)(B)(i) of the Act, which is the American Hospital Formulary Service–Drug Information (AHFS–DI), Drugdex, or United States Pharmacopoeia–Drug Information (USP–DI). Medicaid COD claims do not currently require a diagnosis code as a condition for payment. When reviewing claims, without a diagnosis, it is difficult to determine whether a drug is indeed being used for a medically accepted indication, and appropriately satisfies the definition of a COD, and therefore, is rebate eligible. Despite statutory language limiting Medicaid payment for covered outpatient drugs to when used for a ''medically accepted indication,'' there are not systems in place for States to determine whether a patient's outpatient prescription drug use is in fact for a medically accepted indication, or in other words, there is no mechanism to cross-reference a prescription drug use with a Medicaid patient's medical diagnoses to ensure a drug is being used for a medically accepted indication.

In 2011, the OIG discovered in a Medicare audit that without a diagnosis, it is difficult for Part D sponsors to determine whether a drug claim is medically appropriate.[47] OIG stated that without access to diagnosis information, Part D sponsors cannot determine the indications for which drugs were used. Although this audit referenced Medicare, the same issue is applicable to Medicaid prescriptions. If States are not aware of the diagnosis for which the medication is being used, they are unable to determine if the drug is being used for a medically accepted indication and cannot determine if they should bill for rebates or if coverage is mandatory. Additionally, an article written by then Principal Deputy Inspector General (and now current Inspector General) and Chief Medical Officer from OIG. recently advocated for a new mandate that physicians include a diagnosis code with prescriptions.[48] In 2011, CMS did not concur with OIG's finding, stating that diagnosis information is not a required data element of pharmacy billing transactions, nor is it generally included on prescriptions.

Since 2011, automation of prescribing has grown significantly, and in 2020 an estimated 84 percent of all prescriptions were e-prescriptions.[49] Electronic prescribing has increased so much so that in early 2021, most prescriptions for controlled substances under Medicare Part D must be transmitted electronically.[50]

There are several instances in which a diagnosis on a prescription could help States implement certain Medicaid programs in which they are eligible for enhanced Federal matching funds, or for which they must implement a mandatory benefit. Federal funds support States in responding to the increased need for services, such as testing and treatment during the COVID–19 public health emergency, family planning, or allows States to provide innovative treatment services. For certain conditions, an increase in States' Federal medical assistance percentage (FMAP) leverages Medicaid's existing financing structure and allows enhanced Federal funds to treat that condition. For example, to be eligible for enhanced Federal funds in certain instances, such as when birth control drugs are used for family planning as opposed to other indications such as acne, moderate to severe abnormal vasomotor function, or postmenopausal osteoporosis the State needs to document when expenditures are being used to treat that condition. Without access to diagnosis information, States cannot accurately determine the indications for which drugs were used, especially when drugs have multiple indications, making identification of these costs very difficult, if not impossible, and very resource intensive. For example, if a family planning drug has multiple indications, and the family planning indication is eligible for enhanced Federal matching, then the State will only know when the drug is

[46] 86 FR 27498, May 6, 2016 (*https://www.govinfo.gov/content/pkg/FR-2016-05-06/pdf/2016-09581.pdf*).

[47] *https://oig.hhs.gov/oei/reports/oei-07-08-00150.pdf*.

[48] STAT Op-Ed by Christi A. Grimm & Julie K. Taitsman | Office of Inspector General | Government Oversight | U.S. Department of Health and Human Services (*hhs.gov*).

[49] E-prescription rate U.S. 2020 | Statista available at *https://www.statista.com/statistics/864380/share-of-us-e-prescriptions/?msclkid=a1c545e9b44d11ec81f5391e8e8d23cb*.

[50] E-Prescribing | CMS available at *https://www.cms.gov/Medicare/E-Health/Eprescribing?msclkid=27a13cf3b44e11ecb30d5dd85675d203*.

being used for birth control if there is a related diagnosis on the prescription. A requirement of diagnosis on prescriptions would allow States to easily and accurately identify drug expenditures qualifying for these enhanced Federal matching funds. State programs will be able to better determine if prescriptions meet payment requirements and can more accurately capture expenditures required for Federal matching.

There are additional benefits for adding diagnosis on prescriptions for both providers and beneficiaries. For example, practitioners and beneficiaries benefit from systematic authorizations that are diagnosis based. Vulnerable groups, such as pregnant women, or specific diagnoses (COVID–19) can be easily exempt from out-of-pocket costs and copayments for certain services or conditions. Diagnosis information on prescriptions can help pharmacists identify safety issues and helps supplement prior DUR standards under section 1927(g) of the Act in ensuring prescriptions are appropriate, medically necessary, and not likely to result in adverse medical results. Adding diagnosis to prescriptions can contribute to safer prescribing, improved patient outcomes and medication use in multiple, synergistic ways. Including diagnosis on prescriptions may be a way to ensure drugs are being only used for FDA approved indications. State Medicaid programs may also be able to better manage drug utilization by mandating diagnosis codes on drug claims to ensure payments are limited to drugs with medically accepted indications as required by statute.

Finally, we believe, if such a provision were implemented, that the design and implementation of any adjudication specifications would be left to the States' discretion to meet State-specific needs. Given this flexibility, States can continue to monitor and fine-tune program specifics as they determine what works best for their population's health and well-being. For continuity of care among programs, if this provision was implemented in the future, we envision all Medicaid managed care programs would be included in this requirement, including MCOs, PIHPs, or PAHPs.

There are many interested parties that would have views on this requirement to include diagnosis on a prescription: patients, prescribers, pharmacists, States, and drug manufacturers. We are specifically soliciting comments on this topic, its impact on beneficiaries, providers, States, Medicaid, and any operational implications. We are particularly interested in understanding the burden with such a proposal and seeking comments on how to negate any foreseeable impact on beneficiaries and providers and steps which would be needed by States to successfully implement a Medicaid requirement for diagnosis on prescriptions as a condition of FFP. We are requesting comments regarding the potential impact of supporting such a policy to require Medicaid diagnoses on prescriptions on payment, health care quality, stigma and access to care, and program integrity. We are also requesting comments on what steps we should take to protect beneficiary access to commonly used, medically accepted, compendia supported, off-label prescriptions if we propose to implement such a policy. We are seeking comments from all interested parties on potential approaches and invite all comments on this topic.

III. Collection of Information Requirements

Under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501 *et seq.*), 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. For the purposes of the PRA and this section of the preamble, collection of information is defined under 5 CFR 1320.3(c) of the PRA's implementing regulations.

To fairly evaluate whether an information collection should be approved by OMB, section 3506(c)(2)(A) of the PRA requires that we solicit comment on the following issues:

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

We are soliciting public comment (see section III.D. of this proposed rule) on each of these issues for the following sections of this document that contain collection of information requirements. Comments, if received, will be responded to within the subsequent final rule.

A. Wage Estimates

To derive average costs, we used data from the U.S. Bureau of Labor Statistics' (BLS') May 2021 National Occupational Employment and Wage Estimates for all salary estimates (*http://www.bls.gov/oes/current/oes_nat.htm*). In this regard, Table 3 presents BLS' mean hourly wage, our estimated cost of fringe benefits and other indirect costs (calculated at 100 percent of salary), and our adjusted hourly wage.

TABLE 3—NATIONAL OCCUPATIONAL EMPLOYMENT AND WAGES ESTIMATES

Occupation title	Occupation code	Mean hourly wage ($/hr)	Fringe benefits and other indirect costs ($/hr)	Adjusted hourly wage ($/hr)
Operations Research Analyst	15–2031	46.07	46.07	92.14

As indicated, we are adjusting our hourly wage estimates by a factor of 100 percent. This is necessarily a rough adjustment, both because fringe benefits and other indirect costs vary significantly from employer to employer, and because methods of estimating these costs vary widely from study to study. Nonetheless, we believe that doubling the hourly wage to estimate the total cost is a reasonably accurate estimation method.

B. Proposed Information Collection Requirements (ICRs)

1. ICRs Regarding Identification and Notification to Manufacturer To Correct Misclassification (§ 447.509(d)(1) Through (4))

As discussed in section II.F.1.a. of this proposed rule, we are proposing to add

new paragraphs (d)(1) through (4) to § 447.509 that would add new requirements relating to the process by which CMS would identify when a misclassification of a drug has occurred in MDRP and subsequently notify the manufacturer of the misclassified drug. As such, a manufacturer's efforts to address the misclassification is currently approved by OMB under control number 0938–0578 (CMS–367). This package currently takes into account the time and cost incurred by manufacturers when compiling and reporting, or changing, Medicaid drug product and price information on a monthly, quarterly, and on an as-needed basis. The burden, however, is subject to a regulatory impact analysis which can be found in section V. of this proposed rule.

2. ICRs Regarding Definitions (§ 447.502)

As discussed in section II.C.1.d. of this proposed rule, we are proposing to modify the definition of manufacturer for NDRA purposes. The modification would establish a regulatory definition of manufacturer for purposes of satisfying the requirement that a manufacturer maintain an effectuated rebate agreement with the Secretary consistent with section 1927(a)(1) of the Act. Specifically, we are proposing that the term ''manufacturer'' means that all associated labeler entities of the manufacturer that sell CODs, including, but not limited to, owned, acquired, affiliates, brother or sister corporations, operating subsidiaries, franchises, business segments, part of holding companies, divisions, or entities under common corporate ownership or control, must each maintain an effectuated rebate agreement. The preparation and maintenance of an effectuated rebate agreement has been a long-standing requirement that we propose to codify in this rule. The effectuated rebate agreement requirement and burden are currently approved by OMB under control number 0938–0578 (CMS–367). This rule's proposed actions have no impact on our currently approved requirements and burden estimates and assumptions, including the universe of manufacturers. Consequently, we are not making any changes under that control number.

Additionally, we do not believe any of the following new terms and definition modifications and clarifications would require any effort or impose burden on any public or private entities: (1) proposal to modify the definition of ''covered outpatient drug (§ 447.502), (2) proposal to define ''drug product information'' (§ 447.502), (3) proposal to define ''market date'' (§ 447.502), (4) proposal to modify the definition of ''noninnovator multiple source drug'' (§ 447.502), (5) proposal to clarify § 447.509(a)(6) through (9) and (c)(4) with respect to ''other drugs'', and (6) proposal to define ''vaccine for purposes of the MDRP only'' (§ 447.502). Consequently, none of the definition changes are subject to the requirements of the PRA.

3. ICRs Regarding Proposals Related to State Plan Requirements, Findings, and Assurances (§ 447.518)

As discussed in section II.K. of this proposed rule, we are proposing to specify in § 447.518(d)(1) that the professional dispensing fee (PDF) must be based on pharmacy cost data, and that it cannot be solely determined or supported by a market-based review or by an assessment or comparison of what other payers may reimburse pharmacies for dispensing prescriptions. The clarification also specifies the type of supporting data that we would accept as adequate to support a change to the PDF. The proposed clarification would not add any new or revised requirements or burden. If a State chooses to revise their State Plan for any updates to include a modification to their PDF, a SPA can be submitted to CMS for review and approval. The burden for such SPA submissions is currently approved by OMB under control number 0938–0193 (CMS–10398 #179 under attachment 4.19–B pertaining to the: methods and standards used for the payment of certain services, and methods and standards used for establishing payment rates for prescribed drugs). Since the proposed clarification would not add any new or revised requirements or burden, we are not making any changes under that control number.

4. ICRs Regarding Federal Financial Participation (FFP): Conditions Relating to Physician-Administered Drugs (§ 447.520)

We propose to update § 447.520 to make it consistent with section 1927(a)(7) of the Act, and to codify the requirement that States must collect NDC information on all single and multiple source physician-administered drugs that are CODs for the purposes of invoicing manufacturers for rebates, and ensuring that FFP is available, as appropriate. We are proposing to require that States must be invoicing for rebates for all physician-administered drugs that are CODs. We propose to continue to publish the top 20 high dollar volume list of multiple source physician-administered drugs, as statutorily required, to provide a means of prohibiting Federal matching funds, as necessary, if States are not requiring the use of NDC codes, and invoicing for rebates on these drugs. This proposal would be applicable to all 50 States and the District of Columbia; however, we believe that this proposal would have no additional burden because States, based on their State Drug Utilization Data (SDUD) reported to CMS, are currently collecting NDC numbers for all CODs, including all single and multiple source physician-administered drugs and invoicing manufacturers for rebates as applicable under OMB control number 0938–1026 (CMS–10215). Since the proposed provisions would not add any new or revised requirements or burden, we are not making any changes under that control number.

5. ICRs Regarding Verification Survey of Reported CODs Through Data Collection (§ 447.510)

We are proposing at § 447.510(k) a process to survey wholesalers and manufacturers to verify prices and charges for certain CODs by requesting and collecting certain information about such prices and charges for a drug reported to us under section 1927(b)(3)(A) of the Act. The proposed survey instruments will be submitted to OMB for review after this proposed rule is finalized and our survey instruments (one for requesting information from States as proposed under § 447.510(k)(3)) and another for surveying manufacturers) have been developed. The tools are not ready yet, but will be made available to the public for its review under the standard non-rule PRA process which includes the publication of 60- and 30-day **Federal Register** notices. The CMS ID number for that package is CMS–10822 (OMB control number 0938–TBD 1). Since this would be a new collection of information request, the OMB control number has yet to be determined. OMB would issue that number upon its approval of the non-rule collection of information request. We are however setting out our preliminary burden figures (see below) as a means of scoring the impact of the proposed provisions.

Since the beginning of the MDRP in 1991, the Secretary has had the authority, under section 1927(b)(3)(B) of the Act, to survey wholesalers and manufacturers that directly distribute their covered outpatient drugs, when necessary, to verify manufacturer prices, such as AMP and ASP, including wholesale acquisition cost (WAC), reported under section 1927(b)(3)(A) of

the Act, if required to make payment. Furthermore, section 1902(a)(30)(A) of the Act (42 U.S.C. 1396a(a)(30)(A)) requires that States have a State Plan that provides methods and procedures to ensure that such payments are consistent with efficiency, economy, and quality of care and are sufficient to enlist enough providers so that care and services are available at least to the extent that such care and services are available to the general population in the geographic area. Therefore, the agency has an overarching obligation under section 1902(a)(30)(A) of the Act to ensure that Medicaid payments are made in an efficient, economical, as well as sufficient manner to provide access to care.

We have never used the section 1927(b)(3)(B) of the Act authority to survey manufacturers or wholesalers, nor have we interpreted this statutory section in regulation. Therefore, we are proposing at § 447.510(k) to identify a process to survey wholesalers and manufacturers to verify prices and charges for certain CODs by requesting and collecting certain information about such prices and charges for a drug reported to us under section 1927(b)(3)(A) of the Act. As part of the drug price verification survey process, CMS proposes to post the survey's non-proprietary information on its website.

In addition to the manufacturer survey, CMS also proposes to collect information from States to determine which drugs would be surveyed under § 447.510(k)(3). The simplified State survey would ask States whether or not manufacturers meet any of the criteria for excluding drugs from the list from application of § 447.510(k)(2) from such drug verification surveys, such as the level of manufacturer's effort in accordance with proposed § 447.510(k)(3)(ii). That is, the survey will ask a State if they were able to negotiate with the manufacturer a CMS-authorized supplemental rebate that when in combination with the Federal rebate results in a total (State and Federal) rebate that is greater than the average percentage of total national average Medicaid rebates (State and Federal) to total Medicaid drug spend as reflected in the most recent Medicaid Financial Management Report.

With regard to the State survey, we estimate that once a year, 52 respondents consisting of: the 50 States, the District of Columbia, and one territory participating in the Medicaid drug rebate program (Puerto Rico), would be surveyed to determine if manufacturers of high cost drugs are participating in negotiating supplemental rebates and any additional State Medicaid input under § 447.510(k)(3)(iii)(A). At this time, we estimate that the simplified State survey would take 15 minutes at $92.14/hr for an operations research analyst to complete. In aggregate, we estimate an annual burden of 13 hours ((52 surveys × 0.25 hr/survey) at a cost of $1,198 (13 hr × $92.14/hr). While CMS may seek additional information via non-standardized follow-up questions, the burden associated with such a request is not subject to the requirements of the PRA as described under 5 CFR 1320.3(h)(9).

With regard to the manufacturer survey, there are currently 792 labelers participating in the MDRP. While there is no way to know the exact number of labeler codes used by these manufacturers, most manufacturers have at least 2 labeler codes, so we are estimating approximately selecting from a universe of 396 (792 labelers/2 labeler codes) manufacturers could potentially be subject to completing a verification survey. However, the proposed requirement to survey would be limited to only when the Secretary determines it is necessary, such as when the drug prices reported under section 1927(b)(3)(A) of the Act exceed a proposed criteria. While we anticipate that there is the potential that 396 manufacturers may be eligible to receive a survey, we estimate that based upon the criteria proposed at § 447.510(k) for when a COD would be identified and selected and a manufacturer would be surveyed with respect to that drug, we would likely to undertake a minimum of three manufacturer surveys per year, with a maximum of ten surveys per year, taking 5 hours at $92.14/hr for an operations research analyst to complete the survey. So as to not under estimate the impact of this rule's proposed provisions, we are using the maximum of ten manufacturers surveyed per year. In aggregate, we estimate an annual burden of 50 hours (10 surveys × 5 hr/survey) at a cost of $4,607 (50 hr × $92.14/hr). While CMS may seek additional information via non-standardized follow-up questions, the burden associated with such a request is not subject to the requirements of the PRA as described under 5 CFR 1320.3(h)(9).

Through this proposed rule we are soliciting comments to help us develop the manufacturer survey and the State survey.

6. ICRs Regarding Standard Medicaid Managed Care Contract Requirements (§ 438.3(s))

The following proposed changes regarding drug cost transparency in Medicaid managed care contracts will be submitted to OMB for review under control number 0938–TBD 2 (CMS–10855).

We are proposing to amend § 438.3(s) to require MCOs, PIHPs, and PAHPs that provide coverage of covered outpatient drugs to assign and exclusively use unique Medicaid-specific BIN, PCN, and group number identifiers on all issued Medicaid managed care beneficiary identification cards for pharmacy benefits. It is a usual and customary business practice for the MCOs, PIHPs, and PAHPs to routinely issue identification cards for pharmacy benefits, as they do routinely for all of their lines of business across the industry, to include commercial/private and public sector programs, such as Medicare and Medicaid. Since we believe that this is a usual and customary business practice that is exempt from the PRA (see 5 CFR 1320.3(b)(2)), we are not setting out such burden for managed care entities to program the new codes onto the cards and to issue such cards under this section of the preamble. The burden, however, is subject to a regulatory impact analysis which can be found in section V. of this proposed rule.

Additional proposed amendments to § 438.3(s) would require that MCOs, PIHPs, and PAHPs that provide coverage of covered outpatient drugs structure any contract with any subcontractor for the delivery or administration of the covered outpatient drug benefit to require the subcontractor to report separately the amounts related to:

(1) The incurred claims described in § 438.8(e)(2) such as reimbursement for the covered outpatient drug, payments for other patient services, and the fees paid to providers or pharmacies for dispensing or administering a covered outpatient drug; and

(2) Administrative costs, fees and expenses of the subcontractor.

We estimate that the proposed reporting requirements would affect 282 managed care plans in the country and 40 States. We further estimate that it would take an operations research analyst at the State level, 25 hours at $92.14/hr to restructure 282 managed care contracts to require those plans to structure their subcontracts to require the subcontractor to separately report incurred claims expenses described in § 438.8(e)(2) from fees paid for administrative activities. In aggregate, we estimate a one-time burden of 1,000 hours (40 State responses × 25 hr/response) at a cost of $92,140 (1,000 hr × $92.14/hr).

For the same contract changes between the MCOs and the subcontractors (mainly PBMs), we also estimate a one-time private sector burden of 7,050 hours (282 managed care plans × 25 hr/response) at a cost of $649,587 (7,050 hr × $92.14/hr).

With respect to the reporting burden, we estimate that 282 PBMs of those 282 managed care plans to separately report incurred claims expenses described in § 438.8(e)(2) from fees paid for administrative activities would take approximately 2 hours to identify these costs separately and report separately to the managed care plans. In aggregate we estimate an annual burden of 564 hours (282 PBMs × 2 hr/response) at a cost of $51,967 (564 hr × $92.14/hr).

C. Summary of Proposed Burden Estimates

In Table 4, we present a summary of this rule's proposed collection of information requirements and associated burden estimates.

TABLE 4—SUMMARY OF PROPOSED BURDEN ESTIMATES

Regulatory section(s) under title 42 of the CFR	OMB control No. (CMS ID No.)	Number of respondents	Total number of responses	Time per response (hr)	Total time (hr)	Labor cost ($/hr)	Total cost ($)
§ 447.510	0938–TBD 1 (CMS–10822)	52 States	52	0.25	13	92.14	1,198
§ 447.510	0938–TBD 1 (CMS–10822)	10 manufacturers	10	5	50	92.14	4,607
§ 438.8(e)(2) ..	0938–TBD 2 (CMS–10855)	40 States	40	25	1,000	92.14	92,140
§ 438.8(e)(2) ..	0938–TBD 2 (CMS–10855)	282 managed care plans	282	25	7,050	92.14	649,587
§ 438.8(e)(2) ..	0938–TBD 2 (CMS–10855)	Subcontractor PBMs of the 282 managed care plans.	282	2	564	92.14	51,967
Total	344	(52 States + 10 manufacturers + 282 managed care plans).	666	Varies	8,677	92.14	799,499

D. Submission of PRA-Related Comments

We have submitted a copy of this proposed rule's information collection requirements to OMB for their review. The requirements are not effective until they have been approved by OMB.

To obtain copies of the supporting statement and any related forms for the proposed collections discussed above, please visit the CMS website at *https://www.cms.gov/regulations-and-guidance/legislation/paperworkreductionactof1995/pra-listing,* or call the Reports Clearance Office at 410–786–1326.

We invite public comments on these potential information collection requirements. If you wish to comment, please submit your comments electronically as specified in the **DATES** and **ADDRESSES** sections of this proposed rule and identify the rule (CMS–2434–P), the ICR's CFR citation, and OMB control number.

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. Regulatory Impact Analysis

A. Statement of Need

The intent of this proposed rule is to implement several new legislative requirements relating to the operation of the MDRP and other program integrity, and program administration proposals.

For example, section 6 of the MSIAA was signed into law on April 18, 2019. Section 6 of the MSIAA amended sections 1903 and 1927 of the Act to grant the Secretary additional authorities needed to address drug misclassification, drug pricing, and product data misreporting by manufacturers for purposes of the MDRP. This proposed rule includes policies to implement these new statutory authorities, as required.

This proposed regulation also aims to implement a provision in section 9816 of the American Rescue Plan Act of 2021, which amended section 1927(c)(2)(D) of the Act, by inserting a sunset date on the limitation on the maximum rebate amount for single source and innovator multiple source drugs, and other drugs.

We are also proposing several important MDRP program administration and integrity policies, which include the following: clarifying the definition of manufacturer for NDRA purposes; adopting a regulatory definition of vaccine for MDRP purposes; and, implementing a time limitation on manufacturer disputes and audits with States regarding rebates. This proposed rule also proposes to specify a number of existing policies, including: requirements for manufacturers for determining their best price for a covered outpatient drug; the requirements for State reimbursement for prescribed drugs, and the conditions relating to payment of FFP for PADs that are CODs dispensed and paid for under the State Plan.

We are proposing to include two new requirements for the contracts between States and their Medicaid managed care plans, specifically MCOs, PIHPs, and PHAPs. That is, States would be required to include in their contracts with MCOs, PIHPs, and PHAPs a requirement that each Medicaid enrollee's identification card used for pharmacy benefits would include a unique Medicaid-specific BIN/PCN. This inclusion of this unique Medicaid-specific BIN/PCN on these cards would have to be effective no later than the next rating period for Medicaid managed care contracts, following the effective date of the final rule adopting this new regulatory requirement. This requirement would assist providers in identifying patients as Medicaid beneficiaries.

In addition, we are proposing that Medicaid managed care plans that subcontract with a pharmacy benefit administrator or pharmacy benefit manager require the subcontractor to provide specific details to the Medicaid managed care plans about the various pharmacy and non-pharmacy (administrative) costs associated with providing the pharmacy benefit, so the managed care plan can appropriately calculate its Medicaid managed care MLR.

Moreover, we are also proposing additional program integrity and administration policies including: amending the regulatory definition of noninnovator multiple source drug; adding regulatory definitions of a manufacturer's internal investigation; drug product information; market date; and, modifying the definition of COD. There is also included a proposal

unrelated to MDRP; that, is a proposed revision to third party liability regulation resulting from statutory changes in the BBA 2018.

We are solicitating comments relating to the issues, benefits and challenges of requiring a patient's diagnosis be included on Medicaid prescriptions, and the patient care and operational aspects of such a requirement. We are particularly interested in understanding the burden with such a proposal and seeking comments on how to mitigate any foreseeable impact on beneficiaries and providers, and steps which would be needed by States to successfully implement a Medicaid requirement for diagnosis on prescriptions.

On May 17, 2022, the United States District Court for the District of Columbia vacated and set aside the ''accumulator adjustment rule of 2020'' in response to a complaint filed against the Secretary regarding the accumulator provisions within the December 31, 2020 final rule.

The December 31, 2020 final rule had revised the various the regulatory patient assistance program exclusions from AMP and best price at §§ 447.504(c)(25) through (29) and (e)(13) through (17) and 447.505(c)(8) through (12), to add language (effective January 1, 2023), such that they would require manufacturers to ''ensure'' the full value of the assistance provided by these patient assistance programs is passed on to the consumer and that the pharmacy, agent, or other AMP or best price eligible entity does not receive any price concession, before excluding such amounts from the determination of best price or AMP. In response to the district court's order, we propose to withdraw the changes made to these sections by the December 31, 2020 final rule.

B. Overall Impact

We have examined the impacts of this proposed 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). Section 3(f) of Executive Order 12866 defines a ''significant regulatory action'' as an action that is likely to result in a rule: (1) having an annual effect on the economy of $200 million or more in any 1 year, or adversely and materially affecting a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or State, local, or tribal governments or communities; (2) creating a serious inconsistency or otherwise interfering with an action taken or planned by another agency; (3) materially altering the budgetary impacts of entitlement grants, user fees, or loan programs or the rights and obligations of recipients thereof; or (4) raising legal or policy issues or which centralized review would meaningfully further the President's priorities or the principles set forth in the Executive order.

Based on our estimates, OMB's Office of Information and Regulatory Affairs has determined this rulemaking is significant per section 3(f)(1) as measured by $200 million or more in any 1 year. Therefore, OMB has reviewed this proposed rule, and the Departments have provided the following assessment of their impact.

C. Detailed Economic Analysis

There is a need for greater clarity regarding some of the administrative policies of the MDRP, and this proposed rule aims to establish regulations to provide guidance to States, manufacturers and other related parties. This proposed rule addresses these policy issues after considering the evolution of the pharmaceutical marketplace since the development of the MDRP, and the economic, social and other factors affecting Medicaid providers and beneficiaries. At the same time, this proposed rule is mindful of the impact of changes in regulations on affected interested parties, and the degree of compliance promulgated by the agency. Therefore, for these reasons, we prepared the economic impact estimates utilizing a baseline of ''no action,'' comparing the effect of the proposals against not proposing the rule at all.

If the proposals in this rule are not implemented, there would be no specific policies in place in the MDRP related to the new legislative requirements in the MSIAA, and no clear policies to address drug misclassification, drug pricing and product data misreporting by manufacturers. Accordingly, this proposed rule would address other situations in which manufacturers are paying fewer rebates to States than are supported by the pricing and product data that they are currently reporting to MDP. While we believe that most of the drugs in MDP are appropriately classified, we do not know an exact number of those which may be misclassified. For this reason, a robust analytical framework, with baseline scenarios and benchmarks, cannot be conducted at this time.

Additionally, if these proposals are not implemented, there would be no regulatory policies for addressing the authority for the American Rescue Plan Act to sunset the date on the limitation on the maximum rebate amount paid by manufacturers for single source and innovator multiple source drugs, in addition to noninnovator multiple source drugs.

At this time, program integrity and program administration provisions need to be proposed or specified to address the definitions for: covered outpatient drug (COD); drug product information; internal investigation; manufacturer; market date; noninnovator multiple source drug; and vaccine. Moreover, at this time there is a need to: establish a time limitation on manufacturer rebate disputes and audits with States; refine State requirements for State reimbursement for prescribed drugs; specify conditions relating to payment for PAD; specify the process for manufacturer to accumulate price concessions and discounts (''stacking'') when determining best price; establish a drug price verification survey process through data collection. The reasons and rationales for these provisions were detailed in the preamble section of this proposed rule. The economic impacts of these provisions are detailed below.

We are solicitating comments relating to the issues, benefits and challenges of requiring a diagnosis be included on Medicaid prescriptions, as well as any current data and estimates that could be used to develop an analytical framework for the proposals in this rule.

1. Benefits

The provision requiring that PBAs and PBMs report specific categories of drug expenditures to their contracted managed care entity would benefit States and Medicaid managed care plans, since it can help assure a more accurate calculation of their MLRs and managed care plan capitation rates, resulting in more accurate Medicaid spending. Some States have already eliminated ''spread pricing'' in their managed care contracts, meaning that the State requires the PBM pays the

pharmacy the same price that the managed care plan is charged for the prescription, such that there would be no ''spread'' or difference between the two prices. That is, the PBM would not be allowed to charge the managed care plan a higher price than the amount paid to the pharmacy. This removes the ''spread'' or the difference of which is traditionally kept by the PBM to pay for administrative and other fees. Instead, such administrative fees would have to be separately identified by the PBM for the managed care plan. While this shift in policy has begun in many States, this benefit cannot be quantified at the national level as we do not have data on which States do this now versus States that would need to implement this because of the proposed rule.

However, a March 2020 Congressional Budget Office (CBO) estimate of the Federal proposal [51] to require pass through pharmacy pricing finds the spread pricing provision would produce Federal savings of $929 million over 10 years, which translates to a less than 1 percent drop in Federal Medicaid prescription drug spending. It is unclear what analysis or assumptions went into these estimates, but they are highly dependent on assumptions or understanding of the extent to which spread pricing currently exists in Medicaid. We are soliciting comments relating to this provision.

In regards to Medicaid Drug Rebates (MDR) and penalties with respect to manufacturer misclassification of drugs, benefits also include monetary and non-monetary penalties, which are not quantifiable at this time. For example, these provisions would implement the existing statute and would benefit States as they would be receiving any past rebates that are due to them as a result of a manufacturer's misclassification of drugs. That is, the manufacturers would be finally paying the appropriate amount in past due rebates.

The overwhelming majority of drugs are appropriately classified in the manufacturer discount program (MDP) at this time, but there may be some manufacturers that continue to list their drug as a noninnovator multiple-source drug in MDP, when the drug should be listed as a single-source drug or an innovator multiple source drug. The provision allows us to also pursue penalties against manufacturers that will not change their classification as a result of the denial of their narrow exception request, and would also allow us to impose penalties on manufacturers that pay a different amount in rebates to States than is supported by the product and pricing data that they are reporting to MDP.

For example, manufacturers have the opportunity to request that certain drugs be classified in the MDP as a noninnovator multiple source drug instead of a single source or innovator multiple source drug. If this request is denied, and the manufacturer will not change the classification, CMS can use the authority under the misclassification provisions of the statute to change the classification. Moreover, we have had instances of manufacturers who have decided to take it upon themselves to pay fewer rebates to States, even though the product and pricing information they report to MDP would support a different rebate amount, in most cases, a higher rebate than they are paying to States. This provision would allow us to consider both these situations to be misclassifications, subject to the penalties that are identified in the statute, and that we further describe in the proposed regulation.

Modifying the definition of covered outpatient drug would benefit the manufacturers, States, and CMS. The provision would support the States' ability to collect rebates on drugs administered in certain settings when a drug and its reimbursement amount are separately identified on a claim billed. It would benefit manufacturers by providing clarity on drugs that would satisfy the definition of covered outpatient drug and for which compliance with section 1927 of the Act is required. This is currently not quantifiable because we do not know how many drugs this would affect.

Defining internal investigation for purposes of pricing metric revisions would benefit States and manufacturers. It would benefit manufacturers because it would provide a clear definition of what CMS views as an internal investigation for purposes of requesting CMS consideration of recalculation of AMP, best price, and customary prompt pay outside of the 12-quarter rule as permitted under § 447.510. Additionally, defining this term would benefit States because it would deter manufacturers from submitting to CMS a request for restatement of AMP, best price, and customary prompt pay discounts outside of the 12-quarter timeframe, which could trigger manufacturers seeking to collect overpaid rebates unexpectedly. This benefit is not quantifiable as it is not known how many manufacturers would be deterred from submitting the request to restate outside of the 12-quarter timeframe. However, we do not get these requests frequently.

Revising the definition of manufacturer for greater NDRA compliance would benefit CMS and States, as well as manufacturers, by providing greater clarity, codifying existing policy, and specifying direction on an area of statutory and regulatory compliance that some manufacturers previously interpreted as ambiguous. Manufacturers would now know, with certainty, that all of their associated labeler codes with CODs must enter into a rebate agreement to comply with section 1927(a)(1) of the Act and the terms of the NDRA. The benefit is not quantifiable as we do not know how many manufacturers are not reporting all of their CODs because they do not have rebate agreements in effect for all of their associated labeler codes. However, we believe the majority of manufacturers have entered into a rebate agreement for all of their associated labeler codes.

The States also benefit as noncompliant manufacturers must now enter into the rebate program and pay rebates on all their CODs. While the clear majority of manufacturers are compliant with this provision, any manufacturer that is noncompliant must ensure that every labeler code that satisfies the definition of manufacturer has a rebate agreement in effect and that the manufacturer pays rebates on all of their CODs for all labeler codes. Rebates are paid by drug manufacturers on a quarterly basis to States and are shared between the States and the Federal Government. These outstanding manufacturers' rebates would be paid to the States and shared with the Federal Government to offset the overall cost of prescription drugs under the Medicaid program. This requirement helps ensure program integrity and prevents future underpayments of rebates by noncompliant manufacturers. As previously stated, the benefit is not quantifiable as we do not know how many manufacturers are not reporting all of their CODs because they do not have rebate agreements for all of their associated labeler codes. However, we believe the majority of manufacturers have entered into a rebate agreement for all of their associated labeler codes.

The proposal to define market date using the date of first sale, rather than the date first available for sale, would benefit some manufacturers, CMS, and States. Manufacturers would not be required to report AMP information until they have actual data to report. They will appreciate not having to rely on reasonable assumptions to report AMP without actual data on which to

[51] *https://www.kff.org/medicaid/issue-brief/costs-and-savings-under-federal-policy-approaches-to-address-medicaid-prescription-drug-spending/#:~:text=This%20estimate%20is%20based%20in,between%20states%20and%20the%20federal.*

base the AMP. CMS and States would also benefit because we would now have regulatory support for the longstanding policy of determining the baseline information for a drug based on the date the drug was first sold by any manufacturer. Some manufacturers have been incorrectly interpreting that the market date of their drug is the date on which their NDC was first sold or marketed, regardless of any prior manufacturer's marketing or sale of the same drug. That is, some manufacturers believe that they can reset the baseline information for a drug once they purchase the drug.

States are likely to benefit from the proposal to establish a 12-quarter rebate manufacturer dispute, hearing, and audit time limitation in § 447.510(j). While the NDRA addresses rebate disputes, the lack of policy on audit and dispute-initiation timeframes has been interpreted as there being no timeline on initiation of disputes on drug utilization data, unreasonably burdening State rebate programs. We have heard from States that manufacturers are initiating rebate audits and disputes on claims greater than 30 years old. Some States have even stated that there have been repeated disputes on the same paper claim over the years. With this provision, States would no longer have to look back at and research paper claims dating back to as early as 1991 and the origin of the Medicaid Drug Rebate Program. We estimate this proposal would reduce the amount of time it would take States to research disputes on rebate claims since manufacturer disputes, hearing requests, and audits initiated after 12-quarters from the last day of the quarter from the date of State invoice would no longer be considered.

In regards to the proposed regulatory revisions regarding Federal Financial Participation for conditions relating to physician-administered drugs, these provisions would benefit States and the Federal Government. By revising the regulations to be consistent with the statute, States would gain a better understanding of the requirement that they must invoice for all covered outpatient single and multiple source physician-administered drugs. This proposed rule would assure Federal financial participation and provide additional rebate collection to increase State and Federal revenue. This benefit is not quantifiable because PAD utilization and costs vary among all State programs, but we believe that most if not all States are already billing for rebates for all PADs.

The proposal for inclusion of a BIN/PCN on Medicaid Managed Care Cards would benefit States, the Federal Government, providers and manufacturers. With the inclusion of Medicaid-specific BIN/PCN and group numbers on the pharmacy identification cards issued to the enrollees of MCOs, PHIPs and PAHPs, pharmacies would be able to identify patients as Medicaid beneficiaries. This would be helpful to all parties to ensure that Medicaid benefits are applied appropriately. This would also help avoid duplicate discounts between Medicaid and the 340B Drug Pricing Program, which occurs when a State bills for a Medicaid rebate on a discounted 340B drug, by providing notice to the provider that the claim should be identified as being for a 340B drug. This benefit is not quantifiable because it is currently unknown how often patients are not identified as Medicaid beneficiaries. However, we do believe that a significant number of duplicate discounts can be avoided through better identification of a 340B eligible individual at the time the prescription is being filled.

The provision for drug cost transparency in Medicaid Managed Care Contracts would benefit States and the Federal Government. It would assist Medicaid managed care plans in complying with Federal regulations regarding MLRs and guidance by effectively requiring subcontractors to appropriately identify and classify certain costs, so that the managed care plan can appropriately calculate their MLR.

In particular, we propose that managed care plans that provide coverage of covered outpatient drugs must structure any contract with any subcontractor for the delivery or administration of the covered outpatient drug benefit to require the subcontractor to report separately the amounts related to the incurred claims described in § 438.8(e)(2) (such as reimbursement for the covered outpatient drug, payments for other patient services, and the fees paid to providers or pharmacies for dispensing or administering a covered outpatient drug) from administrative costs, fees and expenses of the subcontractor. By receiving reports that separately identify fees that are outside of the prescription and dispensing fee costs of a drug, the MCO, PIHP, or PAHP would be able to accurately calculate and report its MLR.

MLR calculations are used to develop capitation rates paid to Medicaid managed care plans, thus their accuracy is critical in assuring that Medicaid payments are reasonable, appropriate and necessary for health care services when using a Medicaid managed care plan. Managed care capitation rates must (1) be developed such that the plan would reasonably achieve an 85 percent MLR (§ 438.4(b)(9)) and (2) are developed using past MLR information for the plan (§ 438.5(b)(5)). In addition to other standards outlined in §§ 438.4 through 438.7, these requirements for capitation rates related to the MLR are key to ensuring that Medicaid managed care capitation rates are actuarially sound. In addition, Medicaid managed care plans may need to pay remittances (that is, refund part of the capitation payments) to States should they not achieve the specific MLR target. Thus, the accuracy of MLR calculation is important to conserving Medicaid funds.

The payment of claims provision would benefit States, the Federal Government, providers, and beneficiaries. This provision would benefit both the Federal Government and States as it corrects omissions in regulatory language to align with statutory language, permitting Medicaid to remain the payer of last resort. These revisions would also benefit beneficiaries and providers as it permits States to pay claims sooner than the specified waiting period, when doing so is cost-effective and necessary to ensure access to care.

The proposal to account for manufacturer stacking of discounts when determining best price would benefit the States and Federal Government. It would remove any potential doubt prospectively that when determining the best price for a COD, the manufacturer should aggregate discounts such that cumulative discounts, rebates or other arrangements must be stacked to generate a final price realized by the manufacturer for a covered outpatient drug, including discounts, rebates or other arrangements provided to different best price eligible entities.

The proposal regarding verification of manufacturer drug prices for certain CODs through data collection would benefit the States, Federal Government, consumers, and insurers. The impact is that it would allow the Federal Government to verify prices by obtaining from the manufacturer various related information used by the manufacturer to determine a drug's list price and, when permissible, share the non-proprietary information submitted by the manufacturer with the general public. This would benefit States in that it could help them negotiate further rebates with manufacturers for certain

high cost or high spending Medicaid CODs.

2. Costs

a. Medicaid Drug Rebates (MDR) and Penalties

In regards to the costs associated with this provision, if CMS identifies a drug misclassification, or other situations that would fall under the misclassification provisions, the manufacturer would be responsible for paying back past rebates to the States as a result of the misclassification. This would mean that the manufacturers would have to determine which prices to use to calculate the past due rebates, and for which units rebates are owed, and pay the States for these rebates. They would also have to proactively determine that all States that are due rebates are subsequently paid. In some cases, the States may have to pay rebates back to the manufacturer if the manufacturer's misclassification resulted in overpayment of rebates to the States.

This provision will not impose new costs on States, rather it will help assure that manufacturers are accurately paying rebates to States, thus benefitting the States. However, the amount of rebates that would be recovered because of these new misclassification provisions cannot be estimated. While there are several validation checks, we cannot predict how many, if any, drugs are or would be misclassified especially since the amount would also include penalties for misclassification of future drugs that have yet to be released to market.

b. Suspension of Manufacturer NDRA for Late Reporting of Pricing and Drug Product Information

This provision would implement existing statute and is being implemented to encourage manufacturer adherence with program requirements and enhance administrative efficiency. Manufacturers that are not reporting their pricing or product information in a timely manner per statutory and regulatory requirements would have their rebate agreement (and those of their associated labelers) suspended for purposes of Medicaid and the MDRP. This means that States would not have to cover or pay for the drugs of the manufacturer during the period of the suspension. Lack of timely reporting by manufacturers can also reduce rebates that are owed to States by a manufacturer, and can affect the number of multiple source drugs for which Federal Upper Limits (FULs) can be established. Thus, this suspension authority would serve as an incentive for manufacturers to report their product and pricing information timely so that drugs of the manufacturer would continue to be covered under Medicaid and the drug rebate program.

This provision would have minimal cost to the States as their only responsibility would be to notify prescribers and patients that a drug is not available under the MDRP for the period of the suspension. Similar to §§ 431.211 and 435.917, we are requiring that States notify beneficiaries at least 30 days before a drug is no longer available because of a suspension of a manufacturer's drug rebate agreement. Since States may choose their preferred method of notification of beneficiaries including through email, form letters, list serves, or Medicaid portals, we are requesting comments on how to develop a cost estimate.

c. Modify the Definition of Covered Outpatient Drug

This proposed provision may increase manufacturers' rebate liability to the States because it would clarify those CODs that could be billed for rebates. At this time, we cannot determine an estimate of burden for manufacturers regarding this item because we do not have an estimate of the number of drugs that could potentially be billed for rebates as result of this clarification. States only have to report utilization of drugs for which rebates are invoiced. If States were not invoicing for rebates for certain types of claims previously, we do not have quantifiable information about the additional rebates that may be now collected. Additionally, States may need to educate their providers on billing procedures. We believe this would be involve minimal burden, as States could inform their providers as part of their regular communications.

d. Define Internal Investigation for Purposes of Pricing Metric Revisions

The cost of this new proposed definition would be the amount of time that needs to be taken by manufacturers' personnel to determine how to apply the definition of internal investigation when considering submitting a request to CMS for a recalculation. Furthermore, this legal analysis would not apply to every manufacturer or to every drug of the manufacturer. It would only apply if the manufacturer wants to submit a request for CMS to consider recalculation outside of 12-quarters for one or more of its CODs. At this time, we have received only a minimal number of such requests from manufacturers. We assume the time to perform legal analysis is 5 hours. Using the May, 2021 mean (average) wage information from the BLS for lawyers (Code 23–1011), we estimate that the cost of reviewing this provision is $142.34 per hour, including fringe benefits and other indirect costs (*https://www.bls.gov/oes/current/oes231011.htm*) with a total cost of ($142.34 × 5) is $711.70 for each manufacturer. We estimate that only one percent of manufacturers would submit a request for a recalculation annually outside of the 12-quarters. One percent of 792 manufacturers is approximately 8 manufacturers, with a total one-time cost of $5,693.60 (8 × $711.70). We estimated one percent because currently only one manufacturer has submitted such a request. This proposed provision will not impose substantial costs on the State.

e. Revise Definition of Manufacturer for NDRA Compliance

To better assess current manufacturer compliance with the requirement that all associated labeler codes of a manufacturer have a rebate agreement in effect, several analyses and reviews were performed. Our initial analysis identified 24 instances of related-party manufacturers and labelers that appear to have included some, but not all, of their product line within the MDRP representing 144 products, approximately 0.3 percent of all products in MDRP.

Additionally, if a manufacturer is noncompliant, the manufacturer would be responsible for having associated entities sign a rebate agreement and agree to participate in MDRP. That is, the manufacturers would have to determine which labelers are not currently participating in the program, submit rebate agreements, and pay the States for rebates for CODs of those labelers. For this reason, we are estimating a collection burden to allow manufacturers time to review and ensure compliance with this requirement. Manufacturers would need to review their respective labeler codes in the CMS-hosted online information technology system and ensure the list is complete.

We estimate that the burden associated with the proposed modification to the definition of manufacturer is a one-time cost of $43,884.72, estimating it would take 792 manufacturers 0.5 hours at $110.82 per hour, including fringe benefits and other indirect costs, for an operations manager to log onto the CMS system and review associated labeler codes. This provision will not impose substantial costs on States. States would receive additional monetary rebates if a noncompliant manufacturer comes into compliance.

While this policy has already been specified in guidance and preambles, codifying the requirement is necessary to ensure compliance and eliminate ambiguity.

f. Define Market Date

In regards to costs associated with defining market date, if manufacturers have not provided CMS with accurate market dates, they may need to develop a methodology to determine the accurate dates. In addition, going forward, manufacturers will have to identify when their first sales of the COD occur to accurately identify the market date of the COD. At this time, we cannot determine cost estimates associated for this provision. This provision will not impose substantial costs on States.

g. Modify the Definition of Noninnovator Multiple Source Drug

This provision proposes a technical correction to the regulatory text to conform the language in the definition of an N drug to the language in the definition of an I drug. We do not anticipate any impact on interested parties.

h. Define Vaccine for Purposes of the MDRP Only

In regards to costs associated with the provision, if a manufacturer has not been reporting and paying rebates on a product because it believed the product was a vaccine, and the proposed definition would result in the product being a COD, not a vaccine, then the manufacturer would have both reporting and rebate liability on that product if the proposed definition is finalized. At this time, we cannot determine an estimate for this item. This provision would not impose substantial costs on the State.

i. Proposal To Establish a 12-Quarter Rebate Audit Time Limitation

We are estimating a decrease in burden associated with this proposal. After contacting several States, we estimate that per State, between 10 and 80 disputes are initiated routinely in a quarter on rebate claims greater than 3 years old, and those disputes on average take an Operations Research Analyst between 30 minutes to 4 months to resolve, depending on the complexity of the dispute and how long ago the claim was paid. For our best estimate of the quantifiable impact, with all 50 States, the District of Columbia, and Puerto Rico being affected, we estimate it would take 52 Operations Research Analysts (1 for each State) 7 hours to resolve a dispute at $92.14/hr (*https://www.bls.gov/oes/current/oes152031.htm*) $644.98 ($92.14 × 7) (for 45 outstanding disputes [(10 disputes + 80 disputes)/2] per State for claims greater than 3 years old. We, therefore, estimate a one-time decreased burden reduction of $6,037,012.80 (45 disputes × $644.98 hr/dispute × 52 States × 4 quarters (1 year)). Once this rule is finalized, manufacturers will only have the ability to dispute claims for up to 12-quarters, from the last day of the quarter from the date of State invoice.

j. Proposals Related to State Plan Requirements, Findings, and Assurances

This proposed clarification is necessary so payments to pharmacy providers are consistent with efficiency, economy, and quality of care, and are sufficient to provide access to care equivalent to the general population. Pharmacists must be accurately reimbursed by the State for drug ingredient costs and professional dispensing services under § 447.518.

All but one State, are currently in compliance with the PDF requirements. We have not included time and cost burdens for individual State dispensing fee surveys in this proposed rule because we cannot accurately determine whether a State would choose to conduct a State-specific cost of dispensing survey or use another State's survey. As such, this is an unquantifiable cost to States and therefore, we have not included an estimate. States have several options when reviewing and adjusting their professional dispensing fee (including using a neighboring State's survey results, conducting their own survey, or using survey data from a prior survey).

In this proposed rule, we specify that the type of data that States must submit to justify their professional dispensing fees must be based on actual costs of dispensing.

k. Federal Financial Participation: Conditions Relating to Physician-Administered Drugs

All States currently have an existing process in place to collect and invoice for covered outpatient single source and the top 20 high volume multiple source physician-administered drugs in accordance with regulatory language in § 447.520, which may limit the additional burden associated with collecting and invoicing NDC information for all covered outpatient single and multiple source physician-administered drugs.

It is difficult to quantify a specific dollar value for the expected revenue increase at this time. PAD utilization and costs vary among all State programs; however, once implemented, and all States are collecting rebates for all single and multiple source COD PADs, a baseline can be established. All States currently have this process well established pursuant to regulatory language in § 447.520.

These provisions clarity the existing statute to ensure Federal financial participation and rebate collection for all covered outpatient single and multiple source physician-administered drugs.

l. BIN/PCN on Medicaid Managed Care Cards

The cost is limited to the time the Medicaid managed care entities need to program the new codes onto the cards.

m. Drug Cost Transparency in Medicaid Managed Care Contracts

The costs associated with this change is the cost to managed care plans and their subcontractors to negotiate and revise contracts to ensure administrative fees are separately identifiable from reimbursement for CODs, dispensing fee costs and other patient costs that need to be captured as incurred claims under § 483.8(e)(2). As discussed in the section III. of this proposed rule, we estimate that these requirements would affect 282 managed care plans and their subcontractors (mainly PBMs) in the country and 40 States. We estimate it would take an Operations Research Analyst (Code 15–2031) 25 hours at $92.14 per hour, including fringe benefits and other indirect costs, to renegotiate and restructure 282 Medicaid managed care contracts to require the MCO, PIHP or PAHP to require its subcontractors to separately report information on incurred costs (as described in § 438.8(e)(2)) and fees paid to the subcontractor for administrative services. We, therefore, estimate that the burden associated with the proposed dispute timeline limitation would be a one-time cost for each managed care plan of $2,303.50 or $649,587 for all managed care plans. There are 40 States with Medicaid managed care plans, therefore, we estimate the State's Operations Research Analyst (Code 15–2031) 25 hours at $92.14 per hour including fringe benefits and other indirect costs to restructure State contracts for a one-time cost per State of $2,303.50 or $92,140 for all 40 States.

Federal savings may be captured by an estimate associated with a statutory change to eliminate PBM spread pricing

at $929 Million over 10 years.[52] A March 2020 CBO *estimate* for the Federal proposal to require pass through pricing finds the spread pricing provision would produce Federal savings of $929 million over 10 years, which translates to a less than 1 percent drop in Federal Medicaid prescription drug spending. It is unclear what analysis or assumptions went into these estimates, but they are highly dependent on assumptions or understanding of the extent to which spread pricing currently exists in Medicaid.

There is not currently a Federal prohibition on using spread pricing in Medicaid. As noted, we issued guidance in 2019 regarding the impact of the lack of transparency between costs for administrative functions versus actual costs for Medicaid-covered benefits on the managed care plan's MLR calculation. The 2019 CIB is clear that when the subcontractor, in this case the PBM, is performing administrative functions such as eligibility and coverage verification, claims processing, utilization review, or network development, the expenditures and profits on these functions are a non-claims administrative expense as described in § 438.8(e)(2)(v)(A), and should not be counted as an incurred claim for the purposes of MLR calculations.

If a subcontractor incorrectly categorizes these administrative fees as incurred claims under § 438.8(e)(2), it increases the MLR numerator, and thus increases the per-member-per-month (PMPM) revenue a managed care entity can receive from the State while still appearing to meet MLR requirements. By proposing to require that managed care plans require subcontractors to separately report their administrative fees (that is, separately identified from incurred claims such as reimbursement for covered outpatient drugs, dispensing fees, and other patient services), the managed care plan is better able to ensure the accuracy of MLR, which sets the PMPM revenue for Medicaid managed care plans, and accurately reflects only medical expenditures, thus generating savings to the Medicaid program. For those States that may not already have this requirement as part of its contract with the managed care plan, this provision would be a cost to the State to revise managed care plan contracts. It provides transparency to the State and the managed care plan as to which subcontractor costs are incurred claims under § 438.8(e)(2) (costs of CODs and dispensing fees) versus administrative fees.

n. Proposals Related to Amendments Made by the American Rescue Act of 2021—Removal of Manufacturer Rebate Cap (100 Percent AMP)

This provision is a direct result of a statutory change to remove the cap on Medicaid drug rebates (the maximum rebate amount). Medicaid savings would be generated by the increased rebates due to the removal of the cap on rebates with an estimate of an average of $14.21 billion over 10 years.[53] [54] By removing the cap on the amount manufacturers would be required to pay for Medicaid drug rebates, Medicaid rebate revenue would increase thus producing savings to the Federal Government (Table 6 includes the savings which are CBO estimates from when statute was amended). The costs associated with this requirement are to manufacturers. Manufacturers would also need to make minor changes to their systems to address the removal of the cap. As stated previously in this proposed rule, States would realize some savings because of the increase in rebates; however, it is not known if manufacturer drug prices to Medicaid would decrease because of the removal of the cap as manufacturers adjust pricing to reflect the increase in Medicaid drug rebates.

o. Payment of Claims

At this time, there is no need to determine cost estimates for this item. The December 31, 2020 final rule revised the regulations and captured cost estimations and collection of information. This revision would add omitted statutory language to the existing regulation. This change would not produce new burden not already captured in final rule CMS–2482–F.

p. Requests for Information on Requiring a Diagnosis on Medicaid Prescriptions

This provision is a request for information only. We are seeking comments on how to negate any foreseeable impact on beneficiaries and providers and steps which would be needed by States to successfully implement a Medicaid requirement for diagnosis on prescriptions.

q. Proposal To Account for Stacking When Determining Best Price

When calculating the lowest price realized by a manufacturer by aggregating discounts and rebates across all best price eligible entities, the Medicaid drug rebate to the State and Federal Government increases. At this time, we cannot determine cost estimates for this item.

r. Proposal Regarding Drug Price Verification Survey Through Data Collection

The costs for States to determine which manufacturers would be included in the State survey would be 0.25 hours per State for an Operations Research Analyst (Code 15–2031) at $92.14 an hour, including fringe benefits and other indirect costs, or $23.04 per State. We estimate that the Federal Government would survey 52 States (including the District of Columbia and Puerto Rico) annually for a cost of $1,198.08 (52 States × $23.04 per State).

The costs for the manufacturer/wholesaler who are selected for completing the survey would be 50 hours per manufacturer for an Operations Research Analysts (Code 15–2031) at $92.14 an hour, including fringe benefits and other indirect costs, or $4,607.00 per manufacturer (50 hrs × $92.14/hr). Federal Government would survey a minimum of three manufacturers per year, with a maximum of ten surveys per year, for an annual cost of $46,070.00 ($4,607.00 × 10 surveys), using the maximum of ten surveys per year. Savings is not quantifiable because we do not know if manufacturers would revise pricing in the event they are requested to verify their drug prices.

s. Proposal To Rescind Revisions Made by the December 31, 2020 Final Rule to Determination of Best Price (§ 447.505) and Determination of Average Manufacturer Price (AMP) (§ 447.504) Consistent With Court Order

In the December 31, 2020 final rule, CMS revised the various patient assistance program exclusions from AMP and best price at §§ 447.504(c)(25) through (29) and (e)(13) through (17) and 447.505(c)(8) through (12) to add language that would require manufacturers ''to ensure'' the assistance provided by these patient assistance programs is passed on to the consumer, to the pharmacy, to the agent, or to other AMP or best price eligible

[52] *https://www.kff.org/medicaid/issue-brief/costs-and-savings-under-federal-policy-approaches-to-address-medicaid-prescription-drug-spending/#:~:text=This%20estimate%20is%20based%20in,between%20states%20and%20the%20federal.*

[53] *https://www.kff.org/medicaid/issue-brief/costs-and-savings-under-federal-policy-approaches-to-address-medicaid-prescription-drug-spending/#:~:text=This%20estimate%20is%20based%20in,between%20states%20and%20the%20federal.*

[54] *https://www.macpac.gov/wp-content/uploads/2019/06/Next-Steps-in-Improving-Medicaid-Prescription-Drug-Policy.pdf.*

entity who does not receive any price concession.

As part of the December 31, 2020 final rule, the impact analysis for the exclusions to ensure such patient assistance is passed on to the patient is discussed at length (see 85 FR 87098 through 87100). We concluded at that time that based upon the studies noted in the analysis, the value of patient assistance programs are being eroded by PBM copay accumulator programs because the patient assistance is accumulating to the economic benefits of health plans, not to patients, given that the health plans' spending on drugs for patient decreases. We also believed even with the changes in the rule, that manufacturers would continue to offer patient assistance because the infrastructure was there to ensure, in accordance with the regulation, the patient assistance accrued to the patient, rather than the plan. Therefore, we believed that patients would not be significantly impacted by the modifications that the manufacturers may have needed to do to ensure the pass through of the patient assistance to the patient consistent with section 1927 of the Act.

In May 2021, the Pharmaceutical Research and Manufacturers of America (PhRMA) filed a complaint against the Secretary asking the court to vacate these amendments to § 447.505(c)(8) through (11) (85 FR 87102 and 87103), as set forth in the 2020 final rule (referred to by the Court as ''the accumulator adjustment rule of 2020''). On May 17, 2022, the United States District Court for the District of Columbia ruled in favor of the plaintiff and ordered that the accumulator adjustment rule of 2020 be vacated and set aside.

In response to the order made by the United States District Court for the District of Columbia to vacate the ''accumulator adjustment rule of 2020,'' we are proposing to withdraw the changes made to these sections and, for consistency, withdraw revisions to regulations addressing AMP made by the accumulator adjustment rule. At the time of the December 31, 2020 final rule, we could not quantify to what degree the changes would impact manufacturers or patients. Therefore, we cannot quantify the impact on manufacturers and patients because of the rescinding of this rule.

TABLE 5—SUMMARY OF THE ONE-TIME QUANTITATIVE COSTS AND BENEFITS

Line item	Cost	Entity	Timeframe
Regulatory review	$851,977.32	Manufacturers, States, Trade Association.	One-time cost.
Define manufacturer internal investigation	5,693.60	Manufacturers	One-time cost.
Modify definition of manufacturer/labeler	43,884.72	Manufacturers	One-time cost.
Establish a 12-Quarter Rebate Audit Time Limitation.	(6,037,012.80)	States and Federal Government	One-time cost savings.
Restructure State Contracts	92,140.00	States	One-time cost.
Total	(5,043,317.16)		

TABLE 6—SUMMARY OF THE ANNUAL QUANTITATIVE COSTS AND BENEFIT

Line item	Cost	Entity	Timeframe
Federal Government Survey for States	$1,198.08	Federal Government	Annually over 10 years.
Federal Government Survey for Manufacturers	46,607.00	Federal Government	Annually over 10 years.
Drug cost transparency in Medicaid managed care contracts.	(929,000,000.00)	Federal Government	Annually over 10 years.
Removal of manufacturer rebate cap (100% of AMP).	(14,211,000,000.00)	Federal and State Governments	Annually over 10 years.
Total	(15,139,952,731.92)		

3. Regulatory Review Cost Estimation

If regulations impose administrative costs on private entities, such as the time needed to read and interpret this proposed rule, we should estimate the cost associated with regulatory review. Due to the uncertainty involved with accurately quantifying the number of entities that will be directly impacted and will review this proposed rule, we assume that the total number of unique commenters are based on the current 792 manufacturers participating in the MDRP. While there is no way for CMS to specify the exact number of how many labeler codes are associated with each other, most manufacturers have at least 2 labeler codes. Nevertheless, we are estimating that the current 792 manufacturers would need to review the proposed rule.

Furthermore, we anticipate one medical and health service manager (Code 11–9111) from each of the 50 States, the District of Columbia, and Puerto Rico that cover prescription drugs under the MDRP, will review this proposed rule. Additionally, we estimate that 19 trade organizations may review the proposed rule. This estimate of trade organizations is based on a previous rule pertaining to the MDRP, in which 19 formal comments were received from trade organizations. It is possible that not all commenters or drug manufacturers will review this proposed rule in detail, and it is also possible that some reviewers will choose not to comment on the proposed rule. In addition, we assume that some entities will read summaries from trade newsletters, trade associations, and trade law firms within the normal course of keeping up with current news, incurring no additional cost. Therefore, we assume that approximately 863 (792 manufacturers + 52 States + 19 trade associations) entities may review the proposed rule. For these reasons, we thought that the number of commenters would be a fair estimate of the number of reviewers who are directly impacted by this proposed rule. We are soliciting comments on this assumption.

We also recognize that different types of entities are in many cases affected by mutually exclusive sections of this proposed rule. However, for the purposes of our estimate, we assume

that each reviewer reads 100 percent of this proposed rule.

Using the May 2021 mean (average) wage information from the BLS for medical and health service managers (Code 11–9111), we estimate that the cost of reviewing this proposed rule is $115.22 per hour, including fringe benefits and other indirect costs (*https://www.bls.gov/oes/current/oes119111*). Assuming an average reading speed of 250 words per minute, we estimate that it would take approximately 230 minutes (3.833 hours) for the staff to read this proposed rule, which is approximately 57,500 words. For each medical and health service manager (Code 11–9111) that reviews the proposed rule, the estimated cost is (3.833 × $115.22) or $441.64. In part, we estimate that the cost of reviewing this proposed rule by medical and health service managers is $381,133.82 ($441.64 × 863 reviewers). Additionally, there is also a lawyer who will review this proposed rule. Using the May, 2021 mean (average) wage information from the BLS for lawyers (Code 23–1011), we estimate that the cost of reviewing this proposed rule is $142.34 per hour, including fringe benefits and other indirect costs (*https://www.bls.gov/oes/current/oes231011.htm*). Assuming an average reading speed of 250 words per minute, we estimate that it would take approximately 230 minutes (3.833 hours) for the staff to review this proposed rule, which is approximately 57,000 words. For each lawyer (Code 23–1011) that reviews the proposed rule, the estimated cost is (3.833 × $142.34) or $545.59. In part, we estimate that the cost of reviewing this proposed rule by lawyers is $470,843.50 ($545.59 × 863 reviewers). In total, we estimate the one-time cost of reviewing this proposed rule is $851,977.32 ($381,133.82 + $470,843.50).

We acknowledge that these assumptions may understate or overstate the costs of reviewing this proposed rule.

D. Alternatives Considered

Some provisions are directly linked to statute and therefore alternatives cannot be considered. Nevertheless, alternatives which we have considered are detailed below.

We are proposing to modify the definition of manufacturer for purposes of satisfying the requirement at section 1927(a)(1) of the Act which requires a manufacturer to have entered into and have in effect a NDRA. While this policy has already been specified in guidance and preambles, codifying the requirement is necessary to ensure compliance and eliminate ambiguity. We have reiterated this point several times in subregulatory guidance; however, some manufacturers still challenge our policy. We do not permit manufacturers to selectively report CODs which would allow a manufacturer to benefit from the coverage of some of their CODs, while avoiding their financial obligation to pay rebates.

Therefore, we considered an alternative to retain the current definition of manufacturer for the NDRA, however, we believe the term ''manufacturer'' needs to be updated in regulation to ensure legal compliance with this requirement.

In regards to proposing to define vaccine, we could have refrained from defining the term and relied on manufacturers to make their own determination. At this time, we are only aware of one manufacturer who is making a claim that a product that would not be a vaccine under the proposed definition should be treated as a vaccine for the purposes of the Medicaid Drug Rebate Program. However, we are endeavoring to prevent future disputes of this type given that there may be more products coming to market for which this definition might help provide clarity.

We are proposing to specify the time limitation on manufacturers initiating disputes, hearings, or audits with States. While the NDRA addresses dispute resolution, it provides no guidance on whether a timeline applies to the initiation of such disputes, hearings or audits. There have been reports of new disputes being initiated on claims dating back several decades to paper claims, which is placing unnecessary burden on many State rebate programs. Implementation of this provision is necessary to ensure administrative efficiency. An alternative considered was to not clarify this provision; however, then disputes initiated on claims would continue to be disputed ongoing for any defined time-period, causing undue strain, work hours and costs on rebate programs, which directly counters the purpose of the program to offset the Federal and State costs of most outpatient prescription drugs dispensed to Medicaid patients.

E. Accounting Statement and Table

As required by OMB Circular A–4 (available at *https://www.whitehouse.gov/wp-content/uploads/legacy_drupal_files/omb/circulars/A4/a-4.pdf*), we have prepared an accounting statement in Table 7 showing the classification of the impact associated with the provisions of this proposed rule.

TABLE 7—ACCOUNTING STATEMENT: CLASSIFICATION OF ESTIMATED COSTS/SAVINGS

Category	Estimates	Units		
		Year dollar	Discount rate (%)	Period covered
Costs/Savings:				
Annualized Monetized ($million/year)	($0.67)	2021	7	2024–2034
	(0.57)	2021	3	2024–2034
Costs/Savings	−1,328.91	2021	7	2024–2034
Annualized Monetized ($million/year)	−1,433.49	2021	3	2024–2034

F. Regulatory Flexibility Act (RFA)

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, we estimate that almost all Pharmaceutical and Medicine manufacturers are small entities, as that term is used in the RFA (including small businesses, nonprofit organizations, and small governmental jurisdictions). 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 (SBA) definition of a small business (having employees of less than 1,250 in any 1 year) for businesses classified in the Pharmaceutical and Medicine

Manufacturing industries. Note, the SBA does not provide any revenue data at this time as a measure of size for these industries.

According to the SBA's website at *https://www.sba.gov/content/small-business-size-standards,* the drug manufactures referred to in this proposed rule fall into both NAICS 325412, Pharmaceutical Preparation Manufacturing and NAICS 325414, Biologic Product (except Diagnostic) Manufacturing. The SBA defines small businesses engaged in Pharmaceutical and Medicine Manufacturing as businesses having less than 1,250 employees annually each for Pharmaceutical Preparation Manufacturing and Biologic Product (except Diagnostic) manufacturing industries. Table 8 presents the total number of small businesses in each of the two industries mentioned.

TABLE 8—NAICS 32541 PHARMACEUTICAL AND MEDICINE MANUFACTURING SIZE STANDARDS

NAICS (6-digit)	Industry subsector description	SBA size standard/ small entity threshold	Total small businesses
325412	Pharmaceutical Preparation Manufacturing	1,250 Employees	2,722
325414	Biologic Product (except Diagnostic)	1,250 Employees	587

Source: 2019 Economic Census.

TABLE 9—CONCENTRATION RATIOS (NAICS 325412) PHARMACEUTICAL PREPARATION

Firm size (by number of employees)	Firm count	Percentage of small firms (%)	Total employees	Employee per firm to total employee (%)
Small Firms:	2,722	100	93,181	100
02: <5 employees	390	14	633	0.679
03: 5–9 employees	159	6	1,058	1.135
04: 10–14 employees	65	2	752	0.807
05: 15–19 employees	48	2	766	0.822
06: <20 employees	662	24	3,209	3.444
07: 20–24 employees	25	1	535	0.574
08: 25–29 employees	25	1	648	0.695
09: 30–34 employees	19	1	587	0.630
10: 35–39 employees	21	1	700	0.751
11: 40–49 employees	30	1	1,329	1.426
12: 50–74 employees	45	2	2,600	2.790
13: 75–99 employees	31	1	2,439	2.617
14: 100–149 employees	49	2	5,292	5.679
15: 150–199 employees	27	1	3,793	4.071
16: 200–299 employees	42	2	6,853	7.355
17: 300–399 employees	22	1	6,204	6.658
18: 400–499 employees	13	0	3,907	4.193
19: <500 employees	1,011	37	38,096	40.884
20: 500–749 employees	19	1	6,514	6.991
21: 750–999 employees	10	0	3,635	3.901
22: 1,000–1,499 employees	9	0	3,631	3.897
Large Firms:				
Employees >1,499	68	NA	94,707	NA

Source: 2019 Economic Census.

TABLE 10—CONCENTRATION RATIOS (NAICS 325414) BIOLOGIC PRODUCT (EXCEPT DIAGNOSTIC) MANUFACTURING

Firm size (by number of employees)	Firm count	Percentage of small firms (%)	Total employees	Employee per firm to total employee (%)
Small Firms:	587	100	21,789	100
02: <5 employees	71	12	141	0.65
03: 5–9 employees	42	7	282	1.29
04: 10–14 employees	13	2	145	0.67
05: 15–19 employees	13	2	224	1.03
06: <20 employees	139	24	792	3.63
07: 20–24 employees	12	2	261	1.20
08: 25–29 employees	7	1	167	0.77
09: 30–34 employees	6	1	184	0.84
11: 40–49 employees	6	1	247	1.13
12: 50–74 employees	13	2	624	2.86
13: 75–99 employees	5	1	384	1.76
14: 100–149 employees	8	1	799	3.67
15: 150–199 employees	6	1	720	3.30
16: 200–299 employees	8	1	1,561	7.16

TABLE 10—CONCENTRATION RATIOS (NAICS 325414) BIOLOGIC PRODUCT (EXCEPT DIAGNOSTIC) MANUFACTURING—Continued

Firm size (by number of employees)	Firm count	Percentage of small firms (%)	Total employees	Employee per firm to total employee (%)
18: 400–499 employees	5	1	1,758	8.07
19: <500 employees	219	37	8,012	36.77
20: 500–749 employees	4	1	1,293	5.93
21: 750–999 employees	5	1	1,868	8.57
22: 1,000–1,499 employees	5	1	2,327	10.68
Large Firms:				
Employees >1,499	41	NA	42,822	NA

Source: 2019 Economic Census.
Note: data are not available for businesses with 1,500 to 2,500 employees.

As can be seen in Tables 9 and 10, the economic impacts are disproportionate for small firms. Tables 9 and 10 show the employees for each of the size categories and the employee impact per small entity. For example, in Table 9, 390 of the smallest firms employ only 0.68 percent of the employees in its industry; while, in Table 10, 71 of the smallest firms employ only 0.65 percent of the employees in its industry.

Therefore, as can be seen in Tables 9 and 10, almost all Pharmaceutical and Medicine Manufactures are small entities as that term is used in the RFA. Additionally, Tables 9 and 10 show the disproportionate impacts among firms, and between small and large firms. In Tables 9 and 10, each industry, Pharmaceutical Preparation Manufacturing and Biologic Product (except Diagnostic) manufacturing (by employment), firm count, percentage of small firms, total employee and percentage of total employee per firm size to total employees of the small firms were estimated separately to determine the Pharmaceutical and Medicine manufacturer concentration ratios.

For purposes of the RFA, approximately 98 percent of Pharmaceutical Preparation Manufacturing (2,722/2,790 firms) and approximately 93 percent of Biologic Product (except Diagnostic) (587/628) firms are considered small businesses according to the SBA's size standards with total employee of 1,250 in any one year.

At this time, revenue data are not currently available. However, 2012 revenue data from the U.S. Economic Census was used to obtain a proxy for revenue earned in the Pharmaceutical Preparation Manufacturing industry. Therefore, as of 2012, the total annual receipts for small establishments in the Pharmaceutical Preparation Manufacturing industry, earning less than $45 million accounted for approximately 3.1 percent of the revenue. Similarly, according to the 2012 data, total annual receipts for small establishments in the Biologic Product (except Diagnostic) accounted for approximately 3.5 percent of the revenue in its industry.

Individuals and States are not included in the definition of a small entity. This proposed rule will not have a significant impact measured change in revenue of 3 to 5 percent on a substantial number of small businesses or other small entities. As its measure of significant economic impact on a substantial number of small entities, HHS uses a change in revenue of more than 3 to 5 percent. At this time, we do not believe that this threshold will be reached by the requirements in this proposed rule. Therefore, the Secretary has certified that this proposed rule will not have a significant economic impact on a substantial number of small entities.

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

G. Unfunded Mandates Reform Act (UMRA)

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 2023, that threshold is approximately $177 million.

This proposed rule imposes mandates that would result in anticipated costs to State, local, and Tribal governments or private sector, but the transfer costs will be less than the threshold. Some of the costs that the States may incur for the requirements of reimbursement for prescribed drugs is the cost of conducting an individual State survey as an optional tool. This proposed rule would result in multiple benefits to the States including assuring that rebates would be paid accurately and timely to the States. States would receive additional monetary rebates from manufacturers brought into compliance with drug misclassification, would limit the timeframe manufacturers have to dispute rebates, identify patients to the pharmacist as Medicaid beneficiaries, provide transparency to the State as to which PBM costs are true services costs (costs of prescriptions and dispensing fees) versus administrative costs, and permit States to pay claims sooner than the specified waiting period, when doing so is cost-effective and necessary to ensure access to care.

As a result, this proposed rule would not impose a mandate that would result in the expenditure by State, local, and Tribal Governments, in the aggregate, or by the private sector, of more than $165 million in any 1 year.

H. Federalism

Executive Order 13132 establishes certain requirements that an agency

must meet when it promulgates a proposed rule that imposes substantial direct requirement costs on State and local governments, preempts State law, or otherwise has federalism implications. This proposed rule will not have a substantial direct effect on State or local governments, preempt States, or otherwise have a federalism implication, therefore the requirements of Executive Order 13132 are not applicable.

Chiquita Brooks-LaSure, Administrator of the Centers for Medicare & Medicaid Services, approved this document on May 2, 2023.

List of Subjects

42 CFR Part 433

Administrative practice and procedure, Child support, Claims, Grant programs—health, Medicaid, Reporting and recordkeeping requirements.

42 CFR Part 438

Citizenship and naturalization, Civil rights, Grant programs—health, Individuals with disabilities, Medicaid, Reporting and recordkeeping requirements, Sex discrimination.

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 433—STATE FISCAL ADMINISTRATION

■ 1. The authority citation for part 433 continues to read as follows:

Authority: 42 U.S.C. 1302.

■ 2. Amend § 433.139 by revising paragraphs (b)(3)(i) and (b)(3)(ii)(B) to read as follows:

§ 433.139 Payment of claims.

* * * * *

(b) * * *

(3) * * *

(i) The claim is for preventive pediatric services, including early and periodic screening, diagnosis and treatment services provided for under part 441, subpart B, of this chapter, that are covered under the State Plan that requires a State to make payments without regard to third party liability for pediatric preventive services except that the State may, if the State determines doing so is cost-effective and will not adversely affect access to care, only make such payment if a third party so liable has not made payment within 90 days after the date the provider of such services has initially submitted a claim to such third party for payment for such services; or

(ii) * * *

(B) For child support enforcement services beginning February 9, 2018, the provider certifies that before billing Medicaid, if the provider has billed a third party, the provider has waited up to 100 days after the date of the service and provider of such services has initially submitted a claim to such third party for payment for such services, except that the State may make such payment within 30 days after such date if the State determines doing so is cost-effective and necessary to ensure access to care.

* * * * *

PART 438—MANAGED CARE

■ 3. The authority citation for part 438 continues to read as follows:

Authority: 42 U.S.C. 1302.

■ 4. Amend § 438.3 by adding paragraphs (s)(7) and (8) to read as follows:

§ 438.3 Standard contract requirements.

* * * * *

(s) * * *

(7) Assign and exclusively use unique Medicaid-specific Beneficiary Identification Number (BIN), Processor Control Number (PCN), and group number identifiers for all Medicaid managed care beneficiary identification cards for pharmacy benefits, beginning no later than the State's next rating period for the applicable Medicaid managed care contract, following [effective date of final rule].

(8) Structure any contract with any subcontractor for the delivery or administration of the covered outpatient drug benefit to require the subcontractor to report separately the amounts related to:

(i) The incurred claims described in § 438.8(e)(2) such as reimbursement for the covered outpatient drug, payments for other patient services, and the fees paid to providers or pharmacies for dispensing or administering a covered outpatient drug; and,

(ii) Administrative costs, fees and expenses of the subcontractor.

* * * * *

PART 447—PAYMENTS FOR SERVICES

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

Authority: 42 U.S.C. 1302 and 1396r–8.

■ 6. Amend § 447.502 by—

■ a. In the definition of ''Covered outpatient drug'':

■ i. In the introductory text, adding ''*(COD)*'' immediately following ''Covered outpatient drug''; and

■ ii. Revising paragraph (2) introductory text;

■ b. Adding the definitions of ''Drug product information'' and ''Internal investigation'' in alphabetical order;

■ c. In the definition of ''Manufacturer,'' adding paragraph (5);

■ d. Adding the definition of ''Market date'' in alphabetical order;

■ e. In the definition of ''Noninnovator multiple source drug,'' revising paragraph (3); and

■ f. Adding the definition of a ''Vaccine'' in alphabetical order.

The revisions and additions read as follows:

§ 447.502 Definitions.

* * * * *

Covered outpatient drug (COD) * * *

(2) A covered outpatient drug does not include any drug, biological product, or insulin provided as part of or incident to and in the same setting as any of the services in paragraphs (2)(i) through (viii) of this definition (and for which payment may be made as part of payment for that service and not as direct reimbursement for the drug). Direct reimbursement for a drug may include both reimbursement for a drug alone, or reimbursement for a drug plus the service, in one inclusive payment if the drug and the itemized cost of the drug are separately identified on the claim.

* * * * *

Drug product information includes but is not limited to National Drug Code (NDC), drug name, units per package size (UPPS), drug category (''S'', ''I'', ''N''), unit type (for example, TAB, CAP, ML, EA), drug product type (prescription, over-the-counter), base date AMP, therapeutic equivalent code (TEC), line extension indicator, 5i indicator and route of administration, if applicable, FDA approval date, FDA application number or OTC monograph citation as applicable, market date, COD status, and any other information deemed necessary by the agency to perform accurate unit rebate amount (URA) calculations.

* * * * *

Internal investigation means a manufacturer's investigation of its AMP,

best price, customary prompt pay discounts or nominal prices that have been previously certified in the Medicaid Drug Rebate Program (MDRP) that results in a finding made by the manufacturer of fraud, abuse, or violation of law or regulation. A manufacturer must make data available to CMS to support its finding.

* * * * *

Manufacturer * * *

(5) For the purposes of maintaining an effectuated rebate agreement consistent with section 1927(a)(1) of the Social Security Act, the term ''manufacturer'' means that all associated entities of the manufacturer that sell prescription drugs, including, but not limited to, owned, acquired, affiliates, brother or sister corporations, operating subsidiaries, franchises, business segments, part of holding companies, divisions, or entities under common corporate ownership or control, must each maintain an effectuated rebate agreement.

Market date, for the purpose of establishing the base date AMP quarter, means the date on which the covered outpatient drug was first sold by any manufacturer.

* * * * *

Noninnovator multiple source drug * * *

(3) A covered outpatient drug that entered the market before 1962 that is not marketed under an NDA;

* * * * *

Vaccine means a product that is administered prophylactically to induce active, antigen-specific immunity for the prevention of one or more specific infectious diseases and is included in a current or previous FDA published list of vaccines licensed for use in the United States.

* * * * *

■ 7. Amend § 447.504 by revising paragraphs (c)(25) through (29) and (e)(13) through (17) to read as follows:

§ 447.504 Determination of average manufacturer price.

* * * * *

(c) * * *

(25) Manufacturer coupons to a consumer redeemed by the manufacturer, agent, pharmacy or another entity acting on behalf of the manufacturer, but only to the extent that the full value of the coupon is passed on to the consumer and the pharmacy, agent, or other AMP-eligible entity does not receive any price concession.

(26) Manufacturer-sponsored programs that provide free goods, including but not limited to vouchers and patient assistance programs, but only to the extent that: The voucher or benefit of such a program is not contingent on any other purchase requirement; the full value of the voucher or benefit of such a program is passed on to the consumer; and the pharmacy, agent, or other AMP eligible entity does not receive any price concession.

(27) Manufacturer-sponsored drug discount card programs, but only to the extent that the full value of the discount is passed on to the consumer and the pharmacy, agent, or other AMP eligible entity does not receive any price concession.

(28) Manufacturer-sponsored patient refund/rebate programs, to the extent that the manufacturer provides a full or partial refund or rebate to the patient for out-of-pocket costs and the pharmacy, agent, or other AMP eligible entity does not receive any price concessions.

(29) Manufacturer copayment assistance programs, to the extent that the program benefits are provided entirely to the patient and the pharmacy, agent, or other AMP eligible entity does not receive any price concession.

* * * * *

(e) * * *

(13) Manufacturer coupons to a consumer redeemed by the manufacturer, agent, pharmacy or another entity acting on behalf of the manufacturer, but only to the extent that the full value of the coupon is passed on to the consumer and the pharmacy, agent, or other AMP eligible entity does not receive any price concession.

(14) Manufacturer-sponsored programs that provide free goods, including, but not limited to vouchers and patient assistance programs, but only to the extent that the voucher or benefit of such a program is not contingent on any other purchase requirement; the full value of the voucher or benefit of such a program is passed on to the consumer; and the pharmacy, agent, or other AMP eligible entity does not receive any price concession.

(15) Manufacturer-sponsored drug discount card programs, but only to the extent that the full value of the discount is passed on to the consumer and the pharmacy, agent, or other AMP eligible entity does not receive any price concession.

(16) Manufacturer-sponsored patient refund/rebate programs, to the extent that the manufacturer provides a full or partial refund or rebate to the patient for out-of-pocket costs and the pharmacy, agent, or other AMP eligible entity does not receive any price concessions.

(17) Manufacturer copayment assistance programs, to the extent that the program benefits are provided entirely to the patient and the pharmacy, agent, or other AMP eligible entity does not receive any price concession.

* * * * *

■ 8. Amend § 447.505 by revising paragraphs (c)(8) through (12) and (d)(3) to read as follows:

§ 447.505 Determination of best price.

* * * * *

(c) * * *

(8) Manufacturer-sponsored drug discount card programs, but only to the extent that the full value of the discount is passed on to the consumer and the pharmacy, agent, or other entity does not receive any price concession.

(9) Manufacturer coupons to a consumer redeemed by a consumer, agent, pharmacy, or another entity acting on behalf of the manufacturer; but only to the extent that the full value of the coupon is passed on to the consumer, and the pharmacy, agent, or other entity does not receive any price concession.

(10) Manufacturer copayment assistance programs, to the extent that the program benefits are provided entirely to the patient and the pharmacy, agent, or other entity does not receive any price concession.

(11) Manufacturer-sponsored patient refund or rebate programs, to the extent that the manufacturer provides a full or partial refund or rebate to the patient for out-of-pocket costs and the pharmacy, agent, or other entity does not receive any price concession.

(12) Manufacturer-sponsored programs that provide free goods, including but not limited to vouchers and patient assistance programs, but only to the extent that the voucher or benefit of such a program is not contingent on any other purchase requirement; the full value of the voucher or benefit of such a program is passed on to the consumer; and the pharmacy, agent, or other entity does not receive any price concession.

* * * * *

(d) * * *

(3) The manufacturer must adjust the best price for a drug for a rebate period if cumulative discounts, rebates, or other arrangements to best price eligible entities subsequently adjust the price available from the manufacturer. Cumulative discounts, rebates, or other arrangements must be stacked to determine a final price realized by the manufacturer for a covered outpatient drug, including discounts, rebates, or

other arrangements provided to different best price eligible entities.

■ 9. Amend § 447.509 by—

■ a. Revising paragraphs (a)(5), (a)(6) introductory text, (a)(7) introductory text, (a)(8) and (9), and (c)(4); and

■ b. Adding paragraph (d).

The revisions and addition read as follows:

§ 447.509 Medicaid drug rebates (MDR).

(a) * * *

(5) *Limit on rebate.* For a rebate period beginning after December 31, 2009, and before January 1, 2024, in no case will the total rebate amount exceed 100 percent of the AMP of the single source or innovator multiple source drug.

(6) *Rebate for drugs other than a single source drug or innovator multiple source drug.* The amount of the basic rebate for each dosage form and strength of a drug other than a single source drug or innovator multiple source drug will be equal to the product of:

* * * * *

(7) *Additional rebate for drugs other than a single source drug or innovator multiple source drug.* In addition to the basic rebate described in paragraph (a)(6) of this section, for each dosage form and strength of a drug other than a single source drug or innovator multiple source drug, the rebate amount will be increased by an amount equal to the product of the following:

* * * * *

(8) *Total rebate.* The total rebate amount for a drug other than a single source drug or innovator multiple source drug is equal to the basic rebate amount plus the additional rebate amount, if any.

(9) *Limit on rebate.* For a rebate period beginning after December 31, 2014, and before January 1, 2024, in no case will the total rebate amount exceed 100 percent of the AMP for a drug other than a single source drug or innovator multiple source drug.

* * * * *

(c) * * *

(4) For a drug other than a single source drug or innovator multiple source drug, the offset amount is equal to 2.0 percent of the AMP (the difference between 13.0 percent of AMP and 11.0 percent of AMP).

(d) *Manufacturer misclassification of a covered outpatient drug and recovery of unpaid rebate amounts due to the misclassification and other penalties—* (1) *Definition of misclassification.* A misclassification in the MDRP has occurred when a manufacturer has:

(i) Reported and certified to the agency its drug category or drug product information related to a covered outpatient drug that is not supported by the statute and applicable regulations; or,

(ii) Reported and certified to the agency its drug category or drug product information that is supported by the statute and applicable regulations, but pays rebates to States at a level other than that associated with that classification.

(2) *Manufacturer notification by the agency of drug misclassification.* If the agency determines that a misclassification has occurred as described in paragraph (d)(1) of this section, the agency will send written and electronic notification of this misclassification to the manufacturer of the covered outpatient drug, which may include a notification that past rebates are due. The manufacturer has 30 calendar days from the date of notification to:

(i) Provide the agency such drug product and drug pricing information needed to correct the misclassification of the covered outpatient drug and calculate rebate obligations due, if any pursuant to paragraph (d)(3) of this section. The required pricing data submitted by the manufacturer to the agency shall include the best price information for the covered outpatient drug, if applicable, for the rebate periods for which the manufacturer misclassified the covered outpatient drug; and,

(ii) Certify applicable price and drug product data after entered into the system by the agency.

(3) *Manufacturer payment of unpaid rebates due to misclassification determined by agency.* (i) When the agency has determined that a manufacturer has misclassified a covered outpatient drug as described in paragraph (d)(1) of this section, such that rebates are owed to the States, and notification has been provided to the manufacturer as provided under paragraph (d)(2) of this section, a manufacturer must pay to each State an amount equal to the sum of the products of:

(A) The difference between:

(*1*) The per URA paid by the manufacturer for the covered outpatient drug to the State for a period during which the drug was misclassified; and

(*2*) The per URA that the manufacturer would have paid to the State for the covered outpatient drug for each period, as determined by the agency based on the data provided and certified by the manufacturer under paragraph (d)(2) of this section, if the drug had been correctly classified by the manufacturer; and,

(B) The total units of the drug paid for under the State Plan in each period.

(ii) Manufacturers must pay such rebates to the States for the period or periods of time that such covered outpatient drug was misclassified, based on the formula described in this section, within 60 calendar days of notification by the agency to the manufacturer of the misclassification, and provide documentation to the agency that the States were contacted by the manufacturer, and that such payments were made to the States within the 60 calendar days.

(4) *Agency authority to correct misclassifications and additional penalties for drug misclassification.* The agency will review the information submitted by the manufacturer based on the notice sent under paragraph (d)(2) of this section. If a manufacturer fails to comply with paragraph (d)(2) of this section within 30 calendar days from the date of the notification by the agency of the misclassification to the manufacturer under paragraph (d)(1) of this section, fails to pay the rebates that are due to the States as a result of the misclassification within 60 calendar days from the date of the notification, if applicable, and/or fails to provide to the agency such documentation that such rebates have been paid, as described in paragraph (d)(3) of this section, the agency may do any or all of the following:

(i) Correct the misclassification of the drug in the system on behalf of the manufacturer, using any pricing and drug product information that may have been provided by the manufacturer.

(ii) Suspend the misclassified drug and the drug's status as a covered outpatient drug under the manufacturer's rebate agreement from the MDRP, and exclude the misclassified drug from FFP in accordance with section 1903(i)(10)(E) of the Act.

(iii) Impose a civil monetary penalty (CMP) for each rebate period during which the drug is misclassified, not to exceed an amount equal to the product of:

(A) The total number of units of each dosage form and strength of such misclassified drug paid for under any State Plan during such a rebate period; and

(B) 23.1 percent of the AMP for the dosage form and strength of such misclassified drug for that period.

(iv) Other actions and penalties available under section 1927 of the Act (or any other provision of law), including referral to the HHS Office of the Inspector General and termination from the MDRP.

(5) *Transparency of manufacturers' drug misclassifications.* The agency will make available on a public website an annual report as required under section 1927(c)(4)(C)(ii) of the Act on the covered outpatient drug(s) that were identified as misclassified during the previous year, any steps taken by the agency with respect to the manufacturer to reclassify the drugs and ensure the payment by the manufacturer of unpaid rebate amounts resulting from the misclassifications, and a disclosure of the expenditures from the fund created in section 1927(b)(3)(C)(iv) of the Act.

■ 10. Amend § 447.510 by—

■ a. Revising the section heading and paragraph (b)(1)(v);

■ b. Adding paragraphs (h) through (k).

The additions and revision read as follows:

§ 447.510 Requirement and penalties for manufacturers.

* * * * *

(b) * * *

(1) * * *

(v) The change is to address specific rebate adjustments to States by manufacturers, as required by CMS or court order, or under an internal investigation as defined at § 447.502 or an Office of Inspector General (OIG) or Department of Justice investigation.

* * * * *

(h) *Participation in the Medicaid Drug Rebate Program (MDRP).* Manufacturers that participate in MDRP must meet the following requirements:

(1) *Signed rebate agreement with the Secretary.* Manufacturers participating in the MDRP must have a signed rebate agreement in effect that complies with paragraph (5) in the definition of *manufacturer* in § 447.502.

(2) *Newly purchased labeler codes and covered outpatient drugs.* Any manufacturer with a signed rebate agreement in effect that acquires or purchases another labeler, acquires or purchases covered outpatient drugs from another labeler code, or forms a new subsidiary, must ensure that a signed rebate agreement is in effect for these entities or covered outpatient drugs, consistent with the definition of *manufacturer* at § 447.502, within the first 30 days of the next full calendar quarter beginning at least 60 days after the acquisition, purchase, asset transfer, or formation of the subsidiary.

(3) *Termination.* Each associated labeler code of a manufacturer is considered to be part of the single manufacturer. If any of the associated labeler codes as defined in paragraph (5) in the definition of *manufacturer* at § 447.502 do not have a National Drug Rebate Agreement (NDRA) in effect, or are terminated, all of the labeler codes will be subject to termination.

(i) *Suspension of manufacturer's NDRA for late reporting of drug pricing and drug product information.* (1) If a manufacturer fails to timely provide information required to be reported to the agency under section 1927(b)(3)(A) of the Act, and paragraphs (a) and (d) of this section, the agency will provide written notice to the manufacturer of failure to provide timely information. If such information is not reported within 90 calendar days of the date of the notice communicated to the manufacturer electronically and in writing by the agency, such failure by the manufacturer to report such information in a timely manner shall result in suspension of the manufacturer's rebate agreement for all covered outpatient drugs furnished after the end of the 90-day calendar period. The rebate agreement will remain suspended until the date the information is reported to the agency in full and certified, and the agency reviews for completeness, but not for a period of fewer than 30 calendar days. Continued suspension of the rebate agreement could result in termination for cause. Suspension of a manufacturer's rebate agreement under this section applies for Medicaid purposes only, and does not affect manufacturer obligations and responsibilities under the 340B Drug Pricing Program or reimbursement under Medicare Part B during the period of the suspension.

(2) During the period of the suspension, the covered outpatient drugs of the manufacturer are not eligible for FFP. The agency will notify the States 30 calendar days before the beginning of the suspension period for the manufacturer's rebate agreement and any applicable associated labeler rebate agreements.

(j) *Manufacturer audits of State-provided information.* A manufacturer may only initiate a dispute, request a hearing, or seek an audit of a State regarding State drug utilization data, during a period not to exceed 12 quarters from the last day of the quarter from the date of the State invoice.

(k) *Verification survey of reported covered outpatient drug pricing*—(1) *Survey of manufacturers.* CMS may survey a manufacturer with a rebate agreement with the Secretary under this section, or a wholesaler as defined in § 447.502, to verify prices or charges for a covered outpatient drug identified through paragraphs (k)(2) and (3) of this section, reported to the agency under section 1927(b)(3)(A) of the Act and this section, to make payment for the covered outpatient drug.

(2) *Identification of covered outpatient drugs potentially subject to price verification.* On an annual basis, CMS will compile a list of single source covered outpatient drugs that may be subject to a survey based on one or more of the following criteria (further refined based upon criteria in paragraph (k)(3) of this section). This list will identify drugs that have:

(i) The highest Medicaid drug spend per claim, which is when the claim is in the top 5th percentile of Medicaid spending per claim;

(ii) The highest total Medicaid drug spend, which is when the annual Medicaid drug spend, net of Federal Medicaid drug rebates, is greater than 0.5 percent of total annual Medicaid drug spend, net of Federal Medicaid drug rebates;

(iii) The highest 1-year price increase among single source covered outpatient drugs, which is when the covered outpatient drug falls in the top 1 percent of covered outpatient drugs with the highest median Wholesale Acquisition Cost (WAC) increase over 12 months; or

(iv) The highest launch price, which is a launch price estimated to be in the top 5th percentile of Medicaid spending per claim, or a launch price that is estimated to result in a total annual treatment price that is greater than $500,000 (indexed annually for inflation using the Consumer Price Index for all Urban Consumers (CPI–U)).

(3) *Selection of covered outpatient drugs for price verification.* The survey list compiled under paragraph (k)(2) of this section will be further refined by excluding covered outpatient drugs of manufacturers that have:

(i) Participated in any CMS drug pricing program or initiative under which participating manufacturers negotiate a covered outpatient drug's price directly with CMS; or,

(ii) Negotiated CMS-authorized supplemental rebate with at least 50 percent of States, that when in combination with the Federal rebate results in a total (State and Federal) rebate for the drug of interest to total Medicaid spend (State and Federal) for the drug of interest, that is greater than the total Medicaid rebates (State and Federal) to total Medicaid drug spend for States that cover CODs only through the FFS delivery system, as reflected in the most recent Medicaid Financial Management Report.

(iii) If after application of the criteria in paragraphs (k)(3)(i) and (ii) of this section more than 10 covered outpatient drugs remain on the survey list, CMS

will consider narrowing the list based on:

(A) State-specific Medicaid program input regarding manufacturer effort to lower drug price (including through mechanisms such as subscription models, value-based purchasing arrangements under the multiple best price approach, or other purchasing arrangements favorable to the Medicaid program); or,

(B) Highest cost covered outpatient drugs based on the factors outlined under paragraph (k)(2) of this section, and before application of paragraph (k)(3) of this section.

(4) *Posting of survey request.* After a survey list is compiled based on the application of the criteria in paragraphs (k)(2) and (3) of this section, the agency will post on a publicly accessible, government website, the letter sent to the manufacturer indicating the name of the covered outpatient drug to be surveyed and the request for completion of the drug price verification survey.

(5) *Covered outpatient drug price verification survey.* Such survey to a manufacturer or wholesaler will request in a standard reporting format specific information that will include:

(i) *Pricing, charges, distribution, and utilization.* (A) WAC of the covered outpatient drug, including the types of discounts available to purchasers on the commercial market, or for a wholesaler or pharmacy affiliated with a manufacturer or wholesaler, the invoice price for the drug;

(B) Calculated average price of the drug from the manufacturer to wholesalers and other direct purchasers for sales outside of the U.S.;

(C) Actual or expected utilization of the covered outpatient drug in the United States, including among the Medicare and Medicaid populations;

(D) Public prices for the drug to other Federal agencies, such as the Department of Veterans Affairs; and,

(E) Information relating to the costs of distribution of the covered outpatient drug.

(ii) *Product and clinical information.* (A) Characteristics of the covered outpatient drug, including route and setting of administration, dosing frequency, duration of therapy, side effects, interactions and contraindications, and potential for misuse or abuse.

(B) Manufacturer information regarding the clinical efficacy, effectiveness and outcomes of the drug.

(C) Therapeutic benefits to the patient including information such as the:

(*1*) Seriousness and prevalence of the disease or condition that is treated by the covered outpatient drug.

(*2*) The extent to which the covered outpatient drug addresses an unmet medical need.

(*3*) The extent to which the use of the covered outpatient drug will reduce or eliminate the need for other health care services.

(*4*) Whether there are therapeutic equivalents and the number of such equivalents available for the covered outpatient drug.

(D) Whether there are other existing therapies (pharmacological and non-pharmacological) available to a patient to address the indicated medical condition and the estimated costs of such other therapies to the patient compared to the price of the covered outpatient drug.

(E) If the drug is approved using FDA's accelerated approval pathway in section 506(c) of the FFDCA, any additional post-market studies required by FDA.

(iii) *Costs of production, research, and marketing.* (A) Manufacturer expenditures on materials and manufacturing for such covered outpatient drug, any costs of purchasing or acquiring the covered outpatient drug, and other processes needed to obtain, manufacture or license the covered outpatient drug.

(B) Research and development costs, including total public funds used for such research and development. If the covered outpatient drug is a line extension of a single source or innovator multiple source drug, manufacturers shall not include the research and development costs of the initial single source or innovator multiple source covered outpatient drug.

(C) Total expenditures of the manufacturer associated with marketing and advertising for the applicable covered outpatient drug.

(D) Total revenue and net profit generated from the covered outpatient drug for each calendar year since drug approval, if applicable.

(iv) *Secretary information.* Any other information as determined by the Secretary to verify the price or charge of the covered outpatient drug reported under section 1927(b)(3)(A) of the Act and this section.

(6) *Posting of manufacturer/wholesaler information from survey for further verification.* To further verify the prices and charges submitted by the manufacturer for a covered outpatient drug, CMS may post publicly non-proprietary information provided by the manufacturer and wholesaler in response to the verification survey. CMS may request that a manufacturer address the non-proprietary information specified in paragraph (k)(6) of this section in a public forum. CMS will seek comments from the public, beneficiaries, State Medicaid agencies, other governmental agencies, and other affected interested parties on the information posted.

(7) *Civil monetary penalties (CMPs).* A manufacturer or wholesaler that refuses a request for information pursuant to the drug price verification survey within 90 calendar days of CMS' request for such information, or knowingly provides false information, will be referred to the OIG for possible imposition of CMPs as set forth in section 1927(b)(3)(B) of the Act and section IV of the National Drug Rebate Agreement.

■ 11. Amend § 447.518 by adding a heading to paragraph (d) and revising paragraph (d)(1) to read as follows:

§ 447.518 State plan requirements, findings, and assurances.

* * * * *

(d) *Data requirements.* (1) When proposing changes to either the ingredient cost reimbursement or professional dispensing fee reimbursement, States are required to evaluate their proposed changes in accordance with the requirements of this subpart, and States must consider both the ingredient cost reimbursement and the professional dispensing fee reimbursement when proposing such changes to ensure that total reimbursement to the pharmacy provider is in accordance with requirements of section 1902(a)(30)(A) of the Act. States must provide adequate cost-based data, such as a State or national survey of retail pharmacy providers or other reliable cost-based data other than a survey to support any proposed changes to either or both of the components of the reimbursement methodology. States must submit to CMS the proposed change in reimbursement and the supporting data through a State Plan Amendment formal review process. Research and data must be based on pharmacy costs and be sufficient to establish the adequacy of both current ingredient cost reimbursement and professional dispensing fee reimbursement. Submission by the State of data that are not based on pharmacy costs, such as market-based research (for example, third party payments accepted by pharmacies) to support the professional dispensing fee would not qualify as supporting data.

* * * * *

■ 12. Revise § 447.520 to read as follows:

§ 447.520 Federal Financial Participation (FFP): Conditions relating to physician-administered drugs.

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

(1) *Single source drugs.* For a covered outpatient drug that is a single source, physician-administered drug, administered on or after January 1, 2006, a State must require providers to submit claims for using National Drug Code (NDC) numbers to secure rebates and receive FFP.

(2) *Multiple source drugs.* For a covered outpatient drug that is a multiple source, physician-administered drug on the list published by CMS described in paragraph (c) of this section, administered on or after January 1, 2008, a State must require providers to submit claims using NDC numbers to secure rebates and receive FFP. States are required to invoice for rebates for all multiple source physician-administered drugs that are CODs, and not limit such rebate invoicing to the top 20 multiple source physician-administered drug list.

(b) *Required coding.* As of January 1, 2007, a State must require providers to submit claims for a covered outpatient drug that is described in paragraph (a)(1) or (2) of this section (any covered outpatient drug that is a physician-administered drug) using NDC numbers.

(c) *Top 20 multiple source physician-administered drug list.* The top 20 multiple source physician-administered drug list, identified by the Secretary as having the highest dollar volume of physician administered drugs dispensed under the Medicaid program, will be published and may be modified from year to year to reflect changes in such volume.

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

Dated: May 18, 2023.

Xavier Becerra,

Secretary, Department of Health and Human Services.

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