DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Parts 433, 438, and 447

[CMS–2434–F]

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: Final rule.

SUMMARY: This final rule implements 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 address drug misclassification, as well as drug pricing and product data misreporting by manufacturers. Additionally, we are finalizing several other proposed program integrity and program administration provisions or modifications in this final rule, including revising and finalizing key definitions used in the MDRP. This rule also finalizes a provision not directly related to MDRP that makes revisions to the third-party liability regulation due to amendments made by the Bipartisan Budget Act (BBA) of 2018. We also are finalizing our proposal 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'' (''the 2020 final rule'') to the Determination of Best Price and Determination of Average Manufacturer Price (AMP) sections.

DATES: These regulations are effective on November 19, 2024.

Applicability Dates: In the **SUPPLEMENTARY INFORMATION** section of this final rule, we provide a table (Table 1), which lists key changes in this final rule that have an applicability date other than the effective date of this final rule.

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

FOR FURTHER INFORMATION CONTACT:

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Lisa Shochet, 410–786–5445, *lisa.shochet@cms.hhs.gov,* for issues related to Bank Identification Number and Processor Control Number (BIN/PCN).

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Whitney Swears, 410–786–6543, *whitney.swears@cms.hhs.gov,* for issues related to time limitation on audits and the definition of manufacturer.

Cathy Traugott, 720–853–2785, *catherine.traugott@cms.hhs.gov,* for issues related to drug misclassifications, definition of vaccine, and a drug price verification process through data collection survey.

SUPPLEMENTARY INFORMATION:

I. Background

A. Introduction

Under the Medicaid program, section 1902(a)(54) of the Social Security Act (the Act) provides States with the option of providing coverage of prescribed drugs as described in section 1905(a)(12) of the Act, and to date, all States have elected to do so. Section 1903(a) of the Act provides for Federal Financial Participation (FFP) in State expenditures for these covered outpatient drugs (CODs). Coverage of CODs under the option provided by section 1902(a)(54) of the Act 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 conditioning FFP in medical assistance for drugs covered under section 1902(a)(54) on the manufacturer of the drug having an NDRA. 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 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. Generally, pursuant to section 1927 of the Act, drugs classified as single source drugs or innovator multiple source drugs pay higher rebates than those that are classified as an ''other drug,'' such as noninnovator multiple source drugs.

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 product and drug pricing information 30 days after the last day of each quarter of a rebate period. If a manufacturer fails to submit timely information, or misreports information, we may be unable to establish accurate Unit Rebate Amounts (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 ensure accurate rebates are paid to States for their CODs.

Prior to the enactment of the Medicaid Services Investment and Accountability Act of 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 (NDA). 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 NDA. 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. MSIAA made several revisions to these definitions, including adding a provision to ratify CMS' existing policy to permit certain exceptions from the definitions if a narrow exception applies, as described in § 447.502 or any successor regulation.

This narrow exception process in § 447.502 was created in the 2016 final rule entitled ''Medicaid Program; Covered Outpatient Drugs'' [1] (2016 COD final rule), under which drug manufacturers could submit a request for a narrow exception to allow individual drugs approved under an NDA to be treated as if they were approved under an abbreviated new drug application (ANDA) and classified as noninnovator multiple source drugs prospectively from the effective date of the 2016 COD final rule. Instructions to manufacturers regarding this process were included in Manufacturer Release #98, May 2, 2016.[2] The 2016 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 2016 COD final rule, which was April 1, 2016. This narrow exception process was codified into statute in MSIAA when the Congress removed the word ''original'' from the definitions of single source drug and innovator multiple source drug, thereby confirming CMS' pre 2016 interpretation.

We published the proposed rule (88 FR 34238–34296) on May 26, 2023, and provided a 60-day comment period. A total of 128 comments were received. We are now publishing the final rule. We are clarifying and emphasizing our intent that if any provision of this final rule is held to be invalid or unenforceable by its terms, or as applied to any person or circumstance, or stayed pending further action, it shall be severable from other parts of this final rule, and from rules and regulations currently in effect, and not affect the remainder thereof or the application of the provision to other persons not similarly situated or to other, dissimilar circumstances. Through this rule, we adopt provisions that are intended to and will operate independently of each other, even if each serves the same general purpose or policy goal. Where a provision is necessarily dependent on another, the context generally makes that clear.

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 MSIAA, titled ''Preventing the Misclassification of Drugs Under the Medicaid Drug Rebate Program,'' amended sections 1903 and 1927 of the Act to (1) specify the definitions for single source drug, innovator multiple source drug, and noninnovator multiple source drug, and (2) 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 drug, innovator multiple source drug, or noninnovator multiple source drug—for the purposes of determining the correct rebates that each manufacturer owes the States.

Although much of this law is self-implementing, we proposed a series of regulatory amendments at §§ 447.509 and 447.510 to implement and codify the statutory changes in regulation. We proposed that 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 drug. We also defined 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.

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 proposed a definition of ''drug product information'' for the purposes of the MDRP.

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

Under 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, including correcting the misclassification, suspending the misclassified drug from the MDRP, imposing CMPs, or ultimately terminating the manufacturer's participation in the MDRP.

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 taxpayer monies.

C. MDRP Program Administration Proposed Changes

In order to increase efficiency and economy of directing overall MDRP operations, resources, and activities to better facilitate the needs of Medicaid beneficiaries, we proposed a number of new regulatory policies and clarifications of existing policies. Specifically, consistent with our statutory authorities, we proposed to define, specify, or amend the definitions for COD, internal investigation (for restatement purposes outside of a 3-year time window), manufacturer (for National Drug Rebate Agreement (NDRA) purposes), market date, noninnovator multiple source drug, drug product information, and vaccine for the purposes of the MDRP. We also proposed 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 noninnovator multiple source drug.

In addition, we proposed new policies, including to add a time

[1] *https://www.govinfo.gov/content/pkg/FR-2016-02-01/pdf/2016-01274.pdf.*

[2] *https://www.medicaid.gov/medicaid-chip-program-information/by-topics/prescription-drugs/downloads/rx-releases/mfr-releases/mfr-rel-098.pdf.*

limitation on manufacturers' 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 (NDCs) for single and multiple source physician-administered drugs to receive FFP and secure manufacturer rebates.

We also proposed to revise Medicaid managed care standard contract requirements to adopt a requirement for the inclusion of Bank Identification Number and Processor Control Number (BIN/PCN) numbers on Medicaid enrollee identification cards for pharmacy benefits, as well as enhance drug cost transparency by adopting specific requirements relating to the third-party administration of the pharmacy benefit. We provide additional background later in this rule.

1. Proposal To Modify the Definition of Covered Outpatient Drug

In the 2016 COD final rule (81 FR 5278), we finalized a regulatory definition of covered outpatient drug in § 447.502 that substantially mirrors the statutory definition and is consistent with section 1927(k)(3) of the Act. The definition includes a limiting definition which exempts from the COD definition, and thus from rebates, any drug, biological product, or insulin provided as part of, or as incident to and in the same setting as, (and for which payment may be made under this title as part of payment for the following and not as direct reimbursement for the drug) certain health care setting or situations described in section 1927(k)(3). However, we never clarified what the term ''direct reimbursement'' means for the purposes of defining those situations under which a State could bill a manufacturer for a rebate for a COD when the COD is part of an inclusive payment for the COD and related services. In regulation, we proposed to define the term direct reimbursement at § 447.502 so that States know those situations in which the limiting definition would not apply such that a State could bill for a rebate. CMS received several thoughtful comments on this issue, and based on these comments, we realized the proposed language did not adequately clarify the policy. Thus, we are further refining the definition to more clearly delineate the situations in which the limiting definition would not apply.

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 else they could incur penalties or other compliance and enforcement measures. In the 2016 COD final rule, 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 enumerated exceptions apply. See § 447.510(b)(1)(i) through (vi).

The existing regulation at § 447.510(b)(1)(v) provides an exception to the 12-quarter price reporting rule if the change is being made 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, up to this point, we have not defined the term internal investigation, which has led to different interpretations of the nature of an internal investigation. Therefore, we proposed to add a definition of internal investigation at § 447.502 and additional clarity around the 12-quarter price reporting rule at § 447.510. Based on comments we received, we are finalizing as proposed except we are adding the term ''possible'' to ''fraud, abuse or violation of law or regulation''.

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

We proposed to further refine the definition of manufacturer to clarify that a manufacturer includes all other manufacturers that are associated or affiliated with that manufacturer. This was intended to clarify that once a manufacturer has entered into a rebate agreement with CMS, all entities (with their applicable labeler 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.

We appreciate the thoughtful comments received on this issue, and we determined not to finalize the proposed policy at this time. We are continuing to review the input provided by commenters, which may inform future rulemaking on this topic.

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

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. A key factor in the calculation of the additional rebate is the base date AMP [3] 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 their CODs. The term market date has not been previously defined in regulation for purposes of the MDRP, and CMS has received numerous questions regarding the determination of market date. Accordingly, we proposed to define the term market date at § 447.502 for the purpose of the MDRP and are finalizing as proposed.

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

As discussed previously in the proposed rule, section 6(c) of MSIAA included a number of amendments to statutory definitions in section 1927 of the Act. One of the amendments to the statutory definitions was to remove the phrase ''was originally marketed'' from the definition of an I drug and replace it with ''is marketed.'' We also made conforming changes to the regulatory definition of an I drug in the 2020 final rule.

These amendments should have prompted a corresponding change to the regulatory definition of noninnovator multiple source (N) drug in the 2020 final rule to align with the statutory and regulatory change to the definition of an I drug, however we neglected to include the change. Therefore, we proposed to amend the definition of an N drug at § 447.502 to maintain the clear distinction between an I drug and an N drug and are finalizing as proposed.

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 does not define vaccine.

[3] The terms ''base date AMP,'' ''baseline AMP,'' and ''base AMP'' are used interchangeably within this document.

We proposed 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. We noted that the regulatory definition of vaccine is intended to be established solely for the purposes of the MDRP and is intended to be applicable only to that program and Medicaid expansion CHIP programs (that is, CHIP programs operating pursuant to 42 CFR 457.70(a)(2) and (c)). It is not intended to 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 (VFC) Program. Nor is it intended to apply to any other programs within CMS or any other agencies within HHS (for example, the Food and Drug Administration (FDA), Centers for Disease Control and Prevention (CDC), or Health Resources and Services Administration (HRSA)). Rather, we stated that the proposed changes would only specify which products are vaccines and are therefore excluded from the definition of a COD under the MDRP and thus are not subject to section 1927, including to MDRP rebate liability; the proposed changes would not apply to any applicable Federal or State requirements to cover vaccines for Medicaid beneficiaries, as applicable. We appreciate the thoughtful comments we received on this issue. At this time, we are not finalizing the proposed regulatory definition. We are continuing to review the input provided by commenters, which may inform future rulemaking on this topic.

7. Proposal To Account for Stacking When Determining Best Price

We proposed 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. CMS received a number of thoughtful comments on this issue, and we have determined not to finalize the proposed regulation changes at this time. We are continuing to review the input provided by commenters. We intend to collect information through a separate Paperwork Reduction Act (PRA) request to collect additional information related to manufacturers' stacking methodologies, which may inform future rulemaking on this topic.

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. We proposed to limit the time period during which manufacturers may initiate disputes, hearing requests, and audits of State-invoiced utilization units to 12 quarters from the last day of the quarter from the date of State invoice to the manufacturer. Upon reviewing comments, we believe referencing the invoice postmark date instead of the date of the State invoice offers the same clarity for both States and Manufacturers on the timeline initiation and would align with previous DP policy. Therefore, we are finalizing as proposed, with the exception of referencing ''postmark date'' instead of ''the date of the State invoice''.

9. Proposal Regarding Drug Price Verification Through Data Collection

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 under section 1927(b)(3)(A) of the Act. Under this authority, we proposed rules to describe those situations when it would be considered ''necessary'' for such surveys to be sent to manufacturers and wholesalers, and the information that would be requested to use in order to verify the reported prices at issue.

We appreciate the thoughtful comments we received on this issue, and we determined not to finalize the proposed policy at this time. We are continuing to review the input provided by commenters, which may inform future rulemaking on this topic.

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

In the 2016 COD final rule, we finalized at § 447.518 moving 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. We proposed to revise § 447.518, ''State plan requirements, findings, and assurances,'' in paragraph (d)(1) to clarify State requirements regarding pharmacy ingredient costs and professional dispensing fees to be consistent with the applicable statutory and regulatory requirements, specifying in particular that any dispensing fee surveys must be based on actual pharmacy dispensing costs data and not market research data. We are finalizing as proposed.

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

In accordance with section 1927(a)(7) of the Act, for payment to be available under section 1903 of the Act, and for States to secure applicable Medicaid rebates, States are to provide for the collection and submission of utilization data and coding (such as J-codes [4] and NDC numbers) for a COD that is a physician-administered single source drug as determined by the Secretary, or that is a multiple source drug that is determined by the Secretary to be a top 20 high dollar volume PAD dispensed under Medicaid (as identified on a published list).[5] 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 2007 final rule), specifying the conditions for FFP for PADs.[6]

We proposed to amend § 447.520 to require States to collect NDC information on all covered outpatient single and multiple source PADs and to specify that States must invoice for rebates for all covered outpatient PADs to receive FFP and secure manufacturer rebates. We are finalizing as proposed but have added a discussion of our statutory authority for extending this requirement by regulation beyond the top 20 multiple source drugs already required by statute.

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

[5] *https://www.medicaid.gov/medicaid/prescription-drugs/state-prescription-drug-resources/physician-administered-drugs-pad/index.html.*

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

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

We proposed 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, when there is a continued failure to report after a 90-calendar day deadline is imposed by the agency. Specifically, we proposed in § 447.510(i) that a manufacturer must report information required under § 447.510(a) and (d), and the failure to report such information to the agency after the end of an imposed 90-calendar day period would result in suspension of the manufacturer's rebate agreement, and that such agreement would not be reinstated until such information was reported in full and certified, but not for a period of suspension of less than 30 calendar days. We are finalizing as proposed.

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 enrollee 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 identifier, can specify that a patient is covered by a specific insurance group, such as being a Medicaid managed care enrollee.

Without the BIN, PCN, and group number identifiers, it is often difficult to determine from a Medicaid managed care enrollee's identification 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.

While the use of Medicaid-specific BIN, PCN, and group number identifiers does not assist in identifying claims for drugs purchased under the 340B Drug Pricing Program (340B Program), it may help States and their managed care plans avoid invoicing for rebates on 340B drugs by identifying which plans are covered under Medicaid. Section 340B(a)(5)(A) of the Public Health Service Act (the PHS Act) prohibits duplicate discounts for drugs purchased under the MDRP. Identifying claims where the dispensed drug has been discounted under the 340B Program is necessary to avoid duplicating that discount in the MDRP.

Therefore, under the authority of section 1902(a)(4) of the Act, to ensure effective implementation of and compliance with sections 1927(a)(5)(C) and 1927(j)(1) of the Act, we proposed to amend § 438.3(s) to require States to require (via standard contract requirements) 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 enrollee identification cards for pharmacy benefits. Based on comments received, we are changing the requirement to be a unique BIN/PCN combination with a group number identifier, as well as the effective date.

b. Drug Cost Transparency in Medicaid Managed Care Contracts

Medicaid managed care plans often contract with a subcontractor Pharmacy Benefit Manager (PBM) to operate the pharmacy benefit provided to Medicaid beneficiaries. 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 were 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 incurred claims for health care services and drug costs) and administrative expenses, such as fees paid to its PBM for PBM services (for example, claims adjudication and processing prior authorization requests).

Therefore, we proposed that MCOs, PIHPs, and PAHPs that provide coverage of CODs require any subcontractor to report the amounts related to the incurred claims described in § 438.8(e)(2) separately from any administrative costs, fees, and expenses of the subcontractor. Based on comments received, we are finalizing as proposed, with a few clarifying changes. We are adding ''MCO, PIHP or PAHP'' in a few places to be consistent with other paragraphs in 42 CFR 438.3(s) and are adding a subsection to include an effective date, which will be the first rating period for contracts beginning on or after 1 year following the effective date of the rule.

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 accumulator provisions within the 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.'' 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, for consistency, we proposed to withdraw the changes related to patient assistance to both the AMP and best price sections made by the 2020 final rule so that the regulations would revert back to the language that has been in place since 2016. We are finalizing this provision as proposed.

15. Proposals Related to Amendments Made by the American Rescue Plan Act of 2021—Removal of the 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 the Act to add ''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 the 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 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 proposed to make conforming changes to § 447.509 to reflect the removal of the limit on maximum rebate amounts for rebate periods beginning on or after January 1, 2024. We are finalizing this provision as proposed.

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

We solicited comments 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 were particularly interested in understanding any operational implications, privacy related concerns, associated burden, and approaches 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.

We appreciate the thoughtful comments we received on this issue, and we determined we are not moving forward with any proposed regulations regarding this topic at this time.

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 certain 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.

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 submitted 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.

D. Applicability and Compliance Timeframes

Generally, we are finalizing that this rule, including the proposals being finalized herein, will be effective 60 days after publication of this final rule, with the exception of two provisions in the Standard Medicaid Managed Care Contract Requirements section. We are including Table 1 with these provisions and relevant timing information and dates. We encourage all interested parties to confirm the applicability dates indicated in this final rule for any changes from the proposed.

TABLE 1—APPLICABILITY DATES

Regulation text	Applicability date
§ 438.3(s)(7)	First rating period for contracts with MCOs, PIHPs, and PAHPs beginning on or after 1 year following November 19, 2024.
§ 438.3(s)(8)	First rating period for contracts with MCOs, PIHPs, and PAHPs beginning on or after 1 year following November 19, 2024.

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

The proposed rule to implement regulatory 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 address drug misclassification, as well as drug pricing and product data misreporting by manufacturers, was published on May 26, 2023 (88 FR 34238). As discussed in the proposed rule, we also made proposals to enhance program integrity and improve program administration for the MDRP. The proposals included a time limitation on manufacturers initiating audits with States, clarifications and requirements for State fee-for-service (FFS) pharmacy reimbursement, and the establishment of conditions relating to States claiming Federal Financial Participation (FFP) for physician-administered drugs (PADs). Other proposals included two new requirements for contracts between States and their Medicaid managed care plans in connection with coverage of covered outpatient drugs (CODs). In addition, the rule included a proposal not directly related to the MDRP that would modify the third-party liability regulation based on the Bipartisan Budget Act of 2018 (BBA of 2018). Finally, the proposed rule solicited comments related to the issues, benefits, and challenges of requiring the inclusion of diagnoses on Medicaid prescriptions.

We received 128 comments from drug manufacturers, membership organizations, law firms, pharmacy benefit managers (PBMs), State Medicaid agencies, advocacy groups, not-for-profit organizations, consulting firms, health care providers, employers, health insurers, health care associations, and individuals. The comments ranged from general support or opposition to the proposed provisions to very specific questions or comments regarding the proposed changes.

We also received public comments on this regulation that were out of scope for this rulemaking, and, therefore, are not being addressed in this rule. The following summarizes comments about the proposed rule in general or about specific issues that are not addressed in this final rule.

Comment: Several commenters submitted comments that were outside of the scope of the proposed rule. Examples of out-of-scope comments include but are not limited to whether Medicaid accepts JW/JZ modifiers when billing radiopharmaceuticals at free-

standing radiology offices, the amount charged for a specific drug per month, and comments on CMS' ''Medicare Part D Drug Inflation Rebates Paid by Manufacturers: Initial Memorandum, Implementation of Section 1860D–14B of Social Security Act, and Solicitation of Comments,'' that CMS issued on February 9, 2023.

Response: We appreciate commenters' interest in these topics. However, because these comments are outside of the scope of the proposed rule, we are not addressing them in this final rule.

Comment: A commenter stated that Federal agencies must align their rules and proposals to ensure compatibility. The commenter believes there are a variety of currently proposed, pending, or expected rules from CMS and the Office of the National Coordinator for Health Information Technology (ONC) that are not completely independent from each other; they noted, in some cases, there may be components of different rules that contradict each other, and in other cases, they may be written in ways that unnecessarily increase the burden on one or more parties subject to the rule. Specifically, the commenter mentioned CMS discusses requiring NDC codes for medications in this rule, but the recent ONC Health Data, Technology, and Interoperability: Certification Program Updates, Algorithm Transparency, and Information Sharing (HTI–1) Proposed Rule discusses the possibility of deprecating support for NDC codes in its certification programs in favor of always requiring use of RxNorm for medications. Concerns were raised that the rules were not coordinated so that their requirements are compatible and executable without placing additional burden on individuals or organizations that need to implement more than one rule.

Response: We appreciate the request for Federal agencies to align their rules to ensure compatibility. We are addressing only those proposals that were part of the proposed rule (88 FR 34238 through 34296). See also the discussion in section II.L., Federal Financial Participation (FFP): Conditions Relating to Physician Administered Drugs related to the HTI–1 final policy and CMS and ONC collaboration.

Comment: A commenter requested CMS postpone finalizing the proposals in the proposed rule. The commenter encouraged CMS to actively seek additional feedback from interested parties, including individuals and advocacy organizations who represent those most affected by Medicaid coverage challenges.

Response: Through the rulemaking process, the proposed rule was published, and the public was provided the opportunity to comment on the proposed rule's provisions. We have reviewed and addressed public comments and will proceed with finalizing the rule as noted herein.

A. Payment of Claims (42 CFR 433.139)

In the proposed rule, we included regulatory revisions that would make technical changes to the process for making payment of Medicaid claims. As background, we noted that in 1980, under the authority in section 1902(a)(25)(A) of the Act, we issued regulations at part 433, subpart D, that established requirements for State Medicaid agencies to support the coordination of benefits (COB) effort by identifying third party liability. We pointed out that § 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.

To better align our regulations with statute, 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 also proposed 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. Additionally, we proposed 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.

We received two public comments on this proposal. The following is a summary of the comments we received and our response.

Comment: The commenters stated that they were in support of our proposed regulation changes.

Response: We appreciate the support on this section.

After consideration of public comments on these provisions, we are finalizing as proposed.

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

1. BIN/PCN on Medicaid Managed Care Enrollee Identification Cards

In the proposed rule, we included a provision 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 enrollee identification cards for pharmacy benefits. Although not required to issue enrollee identification cards, it is a standard business practice for the MCOs, PIHPs, and PAHPs to routinely issue such cards for pharmacy benefits for Medicaid enrollees. We proposed that the States' managed care contracts with MCOs, PIHPs, and PAHPs must comply with this new requirement no later than the beginning of the State's next rating period for Medicaid managed care contracts following the effective date of the final rule adopting this new regulatory provision. A rating period is defined in § 438.2 as a period of 12 months selected by the State for which the actuarially sound capitation rates are developed and documented in the rate certification submitted to CMS, and typically begins with a calendar year or a State's fiscal year. We indicated 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 enrollee identification cards with these newly required Medicaid-specific BIN, PCN, and group number identifiers.

This proposal was made 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 enrollees to add these types of unique identifiers to the enrollee identification cards would make the Medicaid drug program run more efficiently and improve the level of pharmacy services provided to Medicaid enrollees. With the inclusion of Medicaid-specific BIN, PCN, and group number identifiers on the enrollee

identification cards issued to the enrollees of MCOs, PIHPs, and PAHPs, pharmacies would be able to identify patients as Medicaid enrollees, and better provide pharmacy services. This would be helpful to all parties to ensure that Medicaid benefits are provided correctly, including confirming any accurate cost sharing amounts, along with helping to ensure that claims are billed and paid for appropriately.

This proposed change may help to reduce the incidence of 340B Program duplicate discounts by identifying Medicaid managed care plans. 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.

Accordingly, we proposed to amend the regulatory language in § 438.3(s) to add paragraph (s)(7) to mandate that Medicaid managed care contracts require that Medicaid MCOs, PIHPs, and PAHPs that provide coverage of CODs assign and exclusively use unique Medicaid BIN, PCN, and group number identifiers for all Medicaid managed care enrollee identification cards for pharmacy benefits. We proposed that Medicaid managed care contracts 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 received public comments on these proposals. The following is a summary of the comments we received and our responses.

Comment: Many commenters supported the use of unique Medicaid-specific BIN, PCN, and group number identifiers for managed care enrollees to ensure proper enrollee identification, application of benefits, and claims and billing processes, which would aid in reducing uncertainty and ambiguity with Medicaid prescribed drug claims. Commenters believe that this will help pharmacies identify patients as Medicaid managed care enrollees and support administration of appropriate Medicaid benefits. Some commenters also noted that many States report that they either already require unique BIN, PCN, and group identifier numbers or believe that this would be feasible to implement.

Response: We appreciate the support and agree that unique BIN, PCN, and group number identifiers on Medicaid managed care pharmacy identification cards will be helpful in supporting the administration of the Medicaid program.

Comment: Several commenters supported adding the requirement that Medicaid managed care enrollee identification cards contain BIN and PCN numbers but suggested that the requirement should be for a BIN and PCN group combination, instead of requiring unique identifiers separately. These commenters recommended that CMS clarify that the requirement would be met by the inclusion of a unique combination of BIN, PCN, and group number identifiers on Medicaid enrollee identification cards to identify a patient as a Medicaid enrollee with coverage through a specific Medicaid managed care plan contract. Other commenters suggested that requiring unique BIN and PCN combinations for managed care Medicaid enrollees would be more effective.

Response: We agree that separate, unique BIN and PCN numbers would not be as effective as having a unique Medicaid-specific BIN and PCN combination, along with a group number identifier, to be issued for Medicaid managed care identification purposes. We understand that without having a unique BIN and PCN combination requirement, there could potentially be thousands of separate, individual new BINs and PCNs. Therefore, as we noted in the response to the previous comment, we are finalizing this requirement and are adding the term ''combination'' in this final rule so that a unique BIN and PCN combination, along with a group number identifier, will be assigned for Medicaid managed care enrollees' identification cards.

Comment: Several commenters suggested that a list of unique Medicaid-specific BIN and PCNs with effective dates be publicly published and updated in a timely manner. One commenter requested that CMS publish the list by surveying States for unique BIN and PCN numbers used for Medicaid managed care enrollees and publishing a list of all such BIN and PCN numbers, similar to how HHS publishes lists of BIN and PCN numbers used to identify Medicare Part D beneficiaries. Additionally, one commenter suggested that Medicare and Medicaid standardize the process by which the BIN and PCN numbers are published, along with the publication of an up-to-date list of the unique BIN and PCN numbers.

Other commenters suggested that the States publish the lists on their websites, since they currently cannot be found in a centralized location. One of these commenters believes that the creation of a publicly published list of numbers would aid States' monitoring and oversight efforts for this plan requirement. This commenter also recommended CMS provide guidance on pharmacy point of sale (POS) operations to aid associated State monitoring and oversight.

Another commenter recommended that the BIN and PCN numbers be published on a list in machine readable form, mirroring how CMS publishes BIN and PCN numbers for Medicare Part D beneficiaries via various CMS web pages, such as the page entitled ''Part D Information for Pharmaceutical Manufacturers.'' [7]

Response: We appreciate the recommendations from the commenters concerning the publication of a list with unique BIN and PCN identification numbers; however, we decline to adopt these suggestions. Because States have the option of publishing a listing of their MCOs, PIHPs, and PAHPs with the related BIN and PCN combinations, along with the group number identifiers in any format on their websites, CMS defers to States to determine if they believe this would improve operations to include this information in one centralized location.

Comment: One commenter requested clarification on whether this requirement for unique BIN, PCN, and group number identifies is applicable to Title XXI CHIP, State-funded programs in addition to Title XIX Medicaid.

Response: This regulation applies to Medicaid and CHIP managed care programs subject to the requirements in 42 CFR part 438 in Title XIX (Medicaid). This regulation does not apply to the separate CHIP programs operating pursuant to 42 CFR 457 in Title XXI (State Children's Health Insurance Program). States may also choose at their option to consider a similar standard for State-funded programs.

Comment: Several commenters recommended changes to the applicability date for the requirement to include unique BIN, PCN, and group number identifiers on Medicaid managed care enrollee identification cards for pharmacy benefits. These commenters expressed concern with the proposed applicability date as they did not believe it was feasible to implement this requirement by the next rating period for Medicaid managed care contracts following the effective date of the final rule. Commenters indicated additional time was needed for necessary operational changes including

[7] *https://www.cms.gov/medicare/coverage/prescription-drug-coverage/part-d-information-pharmaceutical-manufacturers.*

information system development, configuration and testing as well as the creation of new enrollee identification cards and associated distribution to enrollees. Commenters varied in the recommended delay with timeframes with recommendations ranging from 12 to 18 months.

One commenter recommended that the applicability date be accelerated to implement the inclusion of BIN, PCN, and group number identifiers before the next contract rating period for managed care plans as the commenter believes this could prevent 340B duplicate discounts.

A few commenters were in support of unique BIN, PCN, and group number identifiers for each enrollee on Medicaid managed care enrollee identification cards but suggested that this requirement apply prospectively only to new Medicaid managed care plan contracts entered into or renewed after the effective date, as requiring mid-term contractual amendments would be disruptive and burdensome. They requested additional time sufficient for systems development, configuration, testing, PBM support, and card development. A commenter stated that many State Medicaid programs enter into multi-year contracts with managed care plans that may still be in effect by the time this rule is finalized.

Another commenter requested that as CMS finalizes an applicability date for this provision that it considers the need to update industry specifications that go through substantive, formal approval processes prior to a formal adoption by a standards-setting authority. The commenter suggested using existing standards and processes, when possible, for consistency between Medicare Advantage and Medicaid in the way these numbers are presented, if possible.

Response: We appreciate the issues raised concerning the timeframe for including Medicaid-specific BIN and PCN combinations, along with group number identifiers on enrollee identification cards for Medicaid managed care enrollees. We agree that additional time may be needed for all MCOs, PIHPs, or PAHPs to implement these requirements.

Therefore, we are finalizing the applicability date for this provision to be the first rating period for contracts with managed care plans beginning on or after 1 year following the effective date of this final rule.

Comment: A few commenters stated that the BIN definition, format, and field used in pharmacy claims transactions would be changing as of the next version of the Telecommunication Standards named under HIPAA. One commenter noted that CMS recently proposed to update the NCPDP Telecommunication Standard in a proposed rule. The commenter stated that the proposal has not yet been finalized but is expected soon and will most likely require health plans to distribute new member enrollee identification cards during the implementation period. The commenter recommended that CMS should consider any unintended administrative impacts that could occur due to the timing of rule implementation and the resulting need to reissue enrollee identification cards.

Response: We appreciate the information that was shared regarding the upcoming changes to the Telecommunication Standards. As stated previously, we are extending the applicability date in this final rule for this provision to be the first rating period for contracts with managed care plans beginning on or after 1 year following the effective date of this final rule. We believe this additional time will allow States and managed care plans additional time to undertake the operational activities associated with this requirement, including any changes to the Telecommunication standards.

Comment: Multiple commenters supported the unique BIN, PCN, and group number identifier requirements and suggested additional policies to be developed to eliminate 340B Program duplicate discounts. Commenters believe that this provision will not fully address the risk of 340B duplicate discounts in Medicaid managed care and urged CMS to consider additional policies designed to avoid Medicaid and 340B Program duplicate discounts, including, but not limited to, a ''carve out'' approach, wherein drugs purchased under the 340B Program may not be furnished to Medicaid enrollees, a claim-level identification approach, and requiring the usage of 340B Program claims modifiers. Another commenter believes that if 340B covered entities disclosed to insurers when drugs administered to their enrollees (or prescriptions filled in contracted pharmacies) were purchased via the 340B Program, this would assist with the prohibition on duplicate discounts. Other commenters suggested that CMS should not allow providers to submit Medicaid claims until after completing a 340B eligibility screening and requiring States to provide detailed claim-level utilization data to manufacturers. One commenter recommended that comparable identifiers be used for medical benefit products.

A few commenters suggested requiring pharmacies to enter BIN, PCN, and group number identifiers at the point of sale, so that having the identification of a Medicaid managed care enrollee can signal to the pharmacy to append the NCPDP ''20'' submission clarification code so that the claim can be excluded from States' invoices to manufacturers for Medicaid rebates. Other commenters stated that there are challenges with requiring a point-of-sale modifier for contract pharmacies. Other commenters noted that 340B determination of a prescription drug claim is not always known at the point of sale. They stated that 340B determination is often made retrospectively based on several factors, such as the replenishment model and batch reporting to a clearinghouse.

Multiple commenters stated that they oppose pharmacies being required to identify 340B claims either prospectively or retroactively, but support an alternative solution where third-party administrators provide 340B data to CMS. They also stated that there remains no requirement for pharmacies to implement a system to flag a claim as Medicaid.

Several commenters recommended clarity on the dispute resolution process to determine if the State or the covered entity is responsible for remedying a duplicate discount in a particular situation. Commenters suggested that CMS issue guidance to States to establish a transparent and consistent dispute resolution process to resolve issues regarding duplicate Medicaid/340B discounts between manufacturers and State Medicaid agencies. Commenters also stated that Medicaid managed care plans contracting with States, to help assure accountability on duplicate discounts, should be required to share data with manufacturers to permit identification of claims for which the drug was purchased under the 340B Program.

Other commenters encouraged CMS to work with the Health Resources and Services Administration (HRSA) to ensure that Medicaid managed care plan utilization is added to the Medicaid Exclusion File (MEF) as a way to establish a mechanism to track and avoid duplicate discounts on Medicaid managed care plan utilization. A few commenters suggested that it would be more appropriate for HRSA to require that ''340B patients'' receive enrollee identification cards for their 340B prescription drug benefits with this type of plan identifier information through their 340B covered entities.

Response: We believe that the new requirement for the inclusion of a

unique Medicaid-specific BIN and PCN combination, along with a group number identifier, may help States and their managed care plans avoid invoicing for rebates on 340B drugs by identifying which plans are covered under Medicaid. While we appreciate the comments received for additional ways to improve the operations of the 340B Program, these suggestions are outside of the scope of this final rule.

Comment: A few commenters expressed opposition to the exclusive use of unique Medicaid-specific identifiers on enrollee identification cards. Reasonings include that the addition of exclusive BIN and PCN numbers is insufficient policy action to reduce or eliminate 340B duplicate discounts and that the action is unduly burdensome and unlikely to have a meaningful impact on 340B duplicate discounts. One commenter requested that CMS allow for continued use of the existing identification numbers.

Another commenter stated that the inclusion of identifiers on enrollee identification cards could make it easier to engage in discriminatory reimbursement for 340B covered entity providers. They stated that such discriminatory reimbursement could have a negative effect on certain 340B covered entities. Other commenters requested that CMS not implicate pharmacies in the process of identifying and reconciling 340B claims.

One commenter was opposed to this BIN, PCN and group number identifier requirement since they believe the main purpose was to help States and managed care plans identify claims for drugs paid for under the 340B Program to help avoid duplicating discounts or rebates via the MDRP. For their managed care delivery system in which Medicaid managed care enrollees primarily access care from plans and contracted providers that do not participate in 340B, the commenter stated that there would be a significant operational burden to deploy new enrollee identification cards with BIN, PCN, and group number identifiers without a corresponding benefit.

Another commenter also stated that creating a unique BIN and PCN for each managed care plan would be unduly burdensome. They recommended amending this proposal such that this requirement would only apply to unique group number identifiers, and not BIN and PCN, on Medicaid managed care enrollee identification cards for pharmacy benefits. Other commenters recommended that Medicaid be consistent with the policy requiring Medicare Part D plan to use unique BIN and PCN combination identifiers, and not include group number identifiers, to identify enrollees.

Response: We appreciate the concerns raised by the commenters but believe that mandating that States require their MCOs, PIHPs, and PAHPs that provide CODs to Medicaid enrollees to include a unique Medicaid-specific BIN and PCN combination, and group number identifiers, on the enrollee identification cards would make the Medicaid drug program run more efficiently, help avoid 340B duplicate discounts, and improve the level of pharmacy services provided to Medicaid beneficiaries.

Pharmacies' identification of patients as Medicaid enrollees based on the inclusion of Medicaid-specific BIN, PCN, and group number identifiers on the enrollee identification cards must not be used in any way to discriminate in the provision of healthcare services, and such alleged behavior may be referred to HHS' Office for Civil Rights or other authorities.

After considering the comments raised by the commenters, we are finalizing § 438.3(s) with some changes to the proposed regulatory text. We will modify § 438.3(s)(7) by: adding ''combination,'' so that a unique BIN and PCN combination, and group number identifiers, will be assigned and used on enrollee identification cards; removing the comma after ''(BIN)'' and replacing it with ''and'' for grammatical correctness; and replacing ''beneficiary'' with ''enrollee'' to accurately acknowledge that enrollee identification cards are provided to a Medicaid beneficiary enrolled in a managed care plan in a given managed care program. Furthermore, we are revising the applicability date for this provision to be the first rating period for contracts with MCOs, PIHPs, and PAHPs beginning on or after 1 year following the effective date of the final rule. To accomplish this, we are removing the proposed applicability date from § 438.3(s)(7) and establishing § 438.3(w) with this applicability date.

2. Drug Cost Transparency in Medicaid Managed Care Contracts

In the proposed rule, we included a provision that would require that the contracts between States and MCOs, PIHPs, and PAHPs that provide coverage of CODs require these managed care plans to structure contracts with any subcontractor, which may include 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. As part of our proposal, we noted that these subcontractors may include PBMs.

As stated in the preamble of the proposed rule, PBMs are intermediaries in the relationship between the managed care plans and the health care (medical and pharmacy) providers that provide CODs. That is, PBMs have contracts with both the managed care plans to administer the pharmacy benefit, as well as with the health care providers that administer or dispense 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 providers that can dispense or administer drugs to managed care enrolled patients.

PBMs also may negotiate pharmacy reimbursement rates on behalf of the various health plans, including Medicaid managed care plans with which it contracts, to pay the pharmacy and other health care providers for the CODs 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 pharmacy reimbursement rates for brand name and generic prescription drugs, as well as the dispensing fees paid to dispense or administer the prescription drug. In addition, there are also administrative fees paid to the PBM by the managed care plans for its administration and operation of the pharmacy benefit.

The margin between the amount charged by the PBM to a managed care plan for a COD and the amount paid by the PBM to a pharmacy provider is referred to as the ''spread,'' and this construct is referred to as ''spread pricing.'' A detailed description and example of how spread pricing works and how it may affect Medicaid spending for prescription drugs was included in the proposed rule at 88 FR 34250 thru 34251. The amount of this margin or ''spread'' may only be known by the PBM, unless a State Medicaid program or managed care plan specifically requires the 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 managed care plans, and thus 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. 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.

We further noted in the preamble to the proposed rule that 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 are paid, are both necessary for efficient and proper operation of Medicaid programs. Moreover, this lack of transparency makes it more difficult for States and Medicaid-managed care plans to ensure that the plan's Medical Loss Ratio (MLR) calculation is limited to the true medical costs associated with the provision of CODs. We noted that MLR calculations are used as part of capitation rate development. Capitation rates are paid to Medicaid managed care plans; thus, their accuracy is critical in assuring that Medicaid payments are reasonable and appropriate. We further noted that 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, requirements related to accurate MLRs are key to ensuring that Medicaid managed care capitation rates are actuarially sound. In addition, Medicaid managed care plans may need to pay remittances to States should they not achieve a specific MLR target when a remittance is required by a State. Thus, the accuracy of MLR calculation is important to conserving Medicaid funds.

We also pointed out that CMS issued a Center for Medicaid & CHIP Services (CMCS) Informational Bulletin on May 15, 2019, for States and 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*), specifying MLR data collection requirements when a managed care plan uses subcontractors for plan activities. The 2019 CIB provided additional guidance, including an example regarding the MLR data collection requirements when third party vendors, such as PBMs, are involved. However, while the 2019 CIB uses PBM spread pricing as a specific example, there was nothing currently in Federal regulation that specifically detailed contract requirements that (non-claim) administrative costs, fees, or expenses of a managed care plan's subcontractor should not be counted as incurred claims for purposes of the managed care plan's MLR calculation.

In addition, the preamble to the proposed rule discussed that the Medicaid managed care regulation at § 438.230(c)(1) requires that certain agreements are to be included in subcontracts, including that subcontractors agree to perform the delegated activities and reporting responsibilities in compliance with the managed care plan's contract obligations, and that 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 explained how these regulatory obligations require 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 and that the requirements and definitions in § 438.8 for these categories of costs and expenditures must be applied to the required reporting.

For these reasons, we proposed to amend § 438.3(s) to require 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 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 patients 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. We noted that this proposal will 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.

We received public comments on these proposals. The following is a summary of the comments we received and our responses.

Comment: Many commenters supported the requirement that managed care plans separately report the amounts for incurred claims for CODs and not include administrative costs in the MLR numerator, and by doing so, this new requirement would provide transparency to help identify PBM spread pricing practices that potentially lead to pharmacies being underpaid for their services. Other commenters, while supporting the proposal, questioned why spread pricing is not entirely prohibited.

Response: We appreciate commenters' support regarding the regulation as proposed. We note that CMS does not have the authority under Federal Medicaid statute to prohibit a PBM's practice of spread pricing. However, we believe this regulation, once final, will provide greater transparency to State Medicaid agencies and managed care plans regarding how the PBMs are spending the payments that are made to them by the Medicaid managed care plan to administer the Medicaid prescription drug benefit. We believe this information will help to inform the State's decision-making relating to the administration of the prescription drug benefit. It will also help the Medicaid managed care plans have more accurate data to calculate their MLRs, as well as ensure that States can accurately develop capitation rates. Finally, it will help States and managed care plans ensure that PBMs are being appropriately compensated for their services by requiring that the subcontractors report separately incurred claims for CODs and administrative fees, costs, and expenses in sufficient detail and the level of detail must be no less than the reporting requirements in 42 CFR 438.8(k).

Comment: With respect to CMS' proposal to separate the amounts related to incurred claims (for example, COD reimbursement and dispensing fees) from a PBM's administrative fees, commenters urged CMS to also consider downstream impacts in the supply chain. The commenters indicated that to support robust pharmacy market competition and lower health care costs for beneficiaries, CMS must ensure that pharmacies and other health care providers' proprietary information, such as the pharmacy reimbursement (dollar amount) is not disclosed and cannot be traced back to an individual pharmacy. The commenters also indicated that they understand the difficulty in balancing both promoting market

competition and striving for greater transparency in the marketplace; however, these commenters noted this balance could be achieved with transparent accountability measures and comprehensive PBM reform.

Response: We continue to believe this requirement will not deter market competition because it does not require public disclosure of provider-specific proprietary information. Instead, § 438.3(s)(8) will require that the managed care plans contract with the subcontractor will require the subcontractor report separately incurred claims and administrative costs, fees and expenses of the subcontractor necessary for the managed care plan's reporting of the MLR consistent with the requirements at § 438.8(e)(2). The reporting must be in 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. As provided in the 2019 CIB, the level of detail must be no less than the reporting requirements in 42 CFR 438.8(k), but may need to be more if 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. We note that there is nothing in the regulation that prevents the subcontractor from negotiating terms limiting the identification of provider-specific expenditures in the contract with the managed care plan, as long as those terms are consistent with the requirements of this final rule and other Federal contract requirements in regulation at 42 CFR part 438.

Comment: Many commenters requested that CMS implement Federal requirements on PBMs' arrangements with pharmacies rather than just focus on contracting requirements between the managed care plans and PBMs. The commenters encouraged CMS to consider issuing rulemaking that would enhance pharmacy network adequacy, ensure reasonable reimbursement for pharmacies, require certain payment models for managed care plans that cover CODs, and promote payment parity between PBM affiliated and non-affiliated pharmacies in Medicaid managed care. Other commenters suggested including data quality controls, alignment with other payer models, and limitations of reimbursements to non-PBM affiliates. Specifically, commenters requested that CMS revise § 438.3(s)(8) to:

- Require managed care plans eliminate spread pricing, such as by requiring the plans to utilize certain payment models with their PBM subcontractors which dictate how much the PBM is paid for their administrative activities and require specific payment models of how much providers and pharmacies are paid. The commenter also pointed to its support of current proposed Federal legislation (S. 1038, Drug Price Transparency in Medicaid Act of 2023/HR 3561, the PATIENT Act) that includes similar proposals that would ban spread pricing in Medicaid.
- Require that managed care plans' contracts with their subcontracted PBMs require reimbursement for all in-network pharmacies in the managed care program based on a transparent benchmark of National Average Drug Acquisition Cost (NADAC), or WAC when there is not a NADAC price, for a Medicaid COD with a commensurate dispensing fee comparable to the State's Medicaid survey-based fee-for-service PDF as a final payment, absent written proof of fraud. The commenter also suggested that CMS should require that the managed care plan only include these claim cost payments paid by the PBM to the pharmacy for the managed care plan's reported MLR to a State Medicaid program.
- Prohibit managed care plans and their subcontracted PBMs from reimbursing non-PBM affiliated pharmacies less than PBM-owned or PBM-affiliated pharmacies.

The commenters expressed their belief that by adding these provisions to the proposed regulations, CMS would take important steps to eliminate the managed care PBM practices that the commenter indicates have led to nearly $1 billion in Medicaid fraud settlements by 17 States against managed care plans for overbilling Medicaid programs for managed care prescription benefits.

Response: We are aware of the settlements between PBMs and States, and the potential that such spread pricing arrangements will result in overbilling Medicaid. We believe that § 438.3(s)(8), which will require the subcontractor report to the managed care plan separately incurred claims (for example, covered outpatient drug reimbursement) from administrative costs, fees, and expenses for purposes of calculating the managed care plan's MLR, will likely impact the practice of PBM spread pricing. That is, greater transparency to the States of how prescription expenditures are being allocated by the PBMs contracted with the Medicaid managed care plans to provide pharmacy benefits may reduce the likelihood that the PBM will engage in spread pricing.

Furthermore, we are aware of actions taken by individual States at their option to end or limit impact of PBM spread pricing, including in Medicaid. However, as noted in the preamble, we do not believe we have Federal authority to prohibit spread pricing. Nonetheless, we believe that this final rule will provide greater transparency to State Medicaid agencies and Medicaid managed care plans to help inform the State's decision-making relating to the administration of the prescription drug benefit and improving accuracy of plans' MLR calculations.

With regards to pharmacy reimbursement, the adequacy of reimbursement by managed care plans or their subcontractors to their network or non-network pharmacies or providers is out of scope of this final rule. Furthermore, CMS does not have authority to impose on Medicaid managed care plans the State plan requirements at § 447.518, which require State Medicaid FFS payment methodologies for retail community pharmacies be in accordance with the definition of actual acquisition costs at § 447.502, including requiring the use of an Actual Acquisition Cost (AAC) benchmark in setting prescription drug reimbursement at the retail level. These regulations do not apply to Medicaid managed care plan payments to pharmacies or providers for CODs.

We note that if a State or CMS finds that a Medicaid managed care plan does not have a sufficient network of pharmacies or providers to ensure enrollee access to prescription drug benefits, the States and CMS can engage with the Medicaid managed care plans on whether the reimbursement to pharmacies and/or providers for prescription drugs is adequate to attract pharmacies/providers in their network and ensure Medicaid beneficiaries have access to the Medicaid prescription drug benefit. We remind States of their obligation to develop and enforce a quantitative network adequacy standard for pharmacies at § 438.68(b)(1)(vi).

Comment: One commenter suggested that CMS urge PBMs to disclose and document their profit usage and accounting for when profit is used to augment beneficiaries' drug access. This same commenter questioned CMS' position on PBMs charging insurers higher than what they pay pharmacies, and recommended CMS investigate the efficacy of using PBMs for negotiating reduced drug prices.

Response: We may consider the commenter's concerns in future policy development. Otherwise, the use of a PBM's profits and investigation of PBM practices are not a subject of this final rule.

Comment: Several commenters expressed their belief that increasing the level and detail of reporting by PBMs is a good first step in increasing transparency; however, they noted more could be done to protect the intent and the efficacy of the 340B Program and its eligible covered entities by not allowing PBMs to use discriminatory practices, such as PBM payment cuts, that harm hospitals and community health centers that are 340B covered entities and possibly jeopardize patient access to 340B covered entities and contract pharmacies. The commenters indicated that this would allow the savings generated through the 340B Program to be passed along to the PBM to increase their profits. The commenters supported provisions addressing the contracting between PBMs and managed care plans but do not support any policies that will impact a pharmacy's reimbursement.

Response: The efficacy of the 340B Program and any discriminatory practices of PBMs is out of scope of this final rule. Furthermore, as stated earlier, the adequacy of reimbursement by a plan (via its PBM) to a managed care plan's network or non-network pharmacy, which could be a covered entity, is also not a subject of this final rule, nor is the effect of PBM practices on 340B entities and use of 340B savings.

Comment: Several commenters supported the proposed changes, including the information subcontractors of managed care plans need to separately identify (separately identify incurred claims from administrative costs, fees, or expenses) and provide to managed care plans, but requested that CMS develop detailed guidance on the specific cost elements to be reported and a reporting template to ensure standardization and ease of adoption. They indicated that it would be helpful for CMS to indicate the specific parameters that would be included in this requirement to provide greater transparency into PBM and pharmacy services administrative organizations (PSAOs) and any other subcontractor that has incurred claims on behalf of the managed care plan associated with covered outpatient drug coverage.

Response: We appreciate the commenters' request for more detailed guidance. We will evaluate if additional guidance is needed as part of implementation efforts for this requirement and will take these suggestions into consideration as part of that evaluation.

Comment: One commenter indicated that its State currently requires its managed care plans to produce reports with claim level data on the payment made to the PBM by its managed care plans and the amount of payment the PBM has paid to the pharmacy. In addition to claim level data, the commenter indicated that this State requires its managed care plans to report on all payments, including administrative fees, to and from the PBM, managed care plan, and pharmacies at an aggregate level. The commenter believes additional Federal requirements would strengthen States' abilities to secure data around drug costs. Another commenter further pointed to the National Academy of State Health Policy (NASHP) website, in which NASHP analyzed PBM contracts in a subset of States and developed model contract language to address the lack of transparency and promote cost-saving incentives in typical PBM contracts.

Response: We appreciate the commenter's support for finalizing § 438.3(s)(8). We do not intend to further revise the Federal requirements in § 438.3(s)(8) at this time. We encourage States to assess if they wish to impose additional reporting requirements on plans or their subcontractors to facilitate State priorities such as those on transparency and payment, or develop model contract language for plans to utilize with their subcontractors.

Comment: One commenter suggested that CMS consider alignment with other payer models for drug cost data collection, such as the Prescription Drug Data Collection (RxDC) required by the Consolidated Appropriations Act of 2021. The commenter noted that alignment would facilitate the ability of managed care plans to provide cost transparency, minimize burden, and improve the ability of CMS to compare drug costs across delivery systems.

Response: We appreciate the commenter's suggestion that we align Medicaid data collection efforts from payers with other data collection programs, such as the RxDC, especially for purposes of transparency. However, the data collection required under this provision is distinct from the RxDC program and serves to ensure a Medicaid managed care plan has the data it needs from its subcontractors to accurately calculate and report its MLR.

Comment: A few commenters requested clarification regarding the applicability date for § 438.3(s)(8) and urged CMS to grant managed care plans and their subcontractors sufficient time, such as 6 months or more, to allow for necessary operational, system, and contracting changes.

Response: The applicability date for § 438.3(s)(8) as finalized is no later than the State's first rating period for contracts with MCOs, PIHPs, and PAHPs beginning on or after 1 year from the effective date of this final rule. As part of this final rule, we have added § 438.3(w) to finalize this applicability date.

Comment: One commenter requested that spread pricing information be made public where possible, stating it is vital to the public's interest to understand what the cost of PBMs are to Medicaid and enrollees.

Response: We assume that the commenter is requesting that CMS and/or States publicly publish the information collected by the managed care plans from PBMs that distinguish the PBM's payment for the drug and the administration fee and how much the managed care plan paid the PBM for such services. This final rule does not modify the elements States are required to include in their MLR summary reports to CMS under § 438.74; therefore, CMS will not have routine access to PBM payment information that is provided by PBMs to managed care plans and cannot release it to the public. States may consider additional steps, such as what level of data they wish to compile from plans and their subcontractors, in addition to those required for reporting in accordance with § 438.74 and associated transparency on the State's public website.

Comment: A few commenters acknowledged that, making PBMs break out their costs would give State Medicaid programs a better sense of whether spread pricing is occurring, but commenters suggested a more effective approach would be to prohibit spread pricing in Medicaid managed care. They noted that the Congress is currently considering numerous bills related to PBM practices and could include a prohibition of spread pricing in Medicaid managed care as part of those efforts.

Response: We appreciate the support for this final rule. As noted previously, we do not have the authority to completely prohibit these PBM practices.

Comment: One commenter requested clarification on the separate identification of a COD, if a COD is deemed to be eligible for a MDRP rebate. The commenter supported a requirement that if a Medicaid managed care plan contracts with any subcontractor for the delivery or administration of CODs, the managed care plan must require the subcontractor to separately identify CODs, even if the

CODs are reimbursed as a bundled payment.

Response: As specified in § 438.3(s)(8), we are finalizing a requirement for Medicaid MCOs, PIHPs, and PAHPs that provide coverage of CODs to require any subcontractor for the delivery or administration of the COD benefit to report separately the amounts related to the incurred claims described in § 438.8(e)(2), such as reimbursement for the CODs, from the administrative costs, fees, and expenses of the subcontractor. The separate reporting requirement for the delivery or administration of the covered outpatient drug benefit under § 438.3(s)(8) is not limited to those instances when the COD benefit is paid separately as a claim; the separate reporting requirement applies regardless of the COD benefit reimbursement methodology (for example, bundled payment for a specific service).

After consideration of public comments on this provision, we are finalizing § 438.3(s) with some changes to the proposed regulatory text. While we discussed in the preamble of the proposed rule that this would apply to MCOs, PIHPs, and PAHPs, we did not include the phrase ''MCO, PIHP, or PAHP'' in the regulatory text. Thus, we will modify § 438.3(s)(8) by adding at the beginning of the paragraph the phrase ''The MCO, PIHP, or PAHP'' to conform with the other paragraphs in § 438.3(s), inserting ''must'' to replace ''to'' for additional clarity, and inserting ''to the MCO, PIHP, or PAHP'' for clarity on the entity that the subcontractor reports the required information to. We also are adding § 438.3(w) to include an applicability date for the requirements of paragraphs (s)(7) and (s)(8), which will be the first rating period for contracts with MCOs, PIHPs, or PAHPs beginning on or after 1 year following November 19, 2024.

C. MDRP Administrative and Program Integrity Changes

1. Definitions (§ 447.502)

a. Modification to the Definition of Covered Outpatient Drug (§ 447.502)

In the proposed rule, we proposed to modify the definition of a COD. We noted as background that 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 other words, a product that would otherwise qualify as a COD, is excluded from the definition if it is administered in certain settings and not directly reimbursed.

We also noted that in the 2016 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) 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 anyone 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.

We noted in the proposed rule that, 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. Such situations would render the drug eligible for rebates under section 1927 of the Act as a COD, or in other words, the limiting definition exclusion would be inapplicable in certain circumstances. We had proposed that, if a drug and its cost can be separately identified on a bundled claim for payment, and the identified amount attributable to the drug is made solely for the drug (and no other services), it can be considered direct reimbursement for the drug. Therefore, we indicated that 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 is separately identified on the claim. The payment for the drug is not required to be a distinct, separate payment for such payment to be considered direct reimbursement.

Specifically, we proposed to amend the regulatory definition of the term covered outpatient drug at § 447.502 to add that direct reimbursement for the drug includes situations in which a claim for an all-inclusive payment identifies the drug plus the itemized cost of the drug.

Additionally, to support our proposal, we noted that 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 definition of the term covered outpatient drug in § 447.502 includes similar limiting language in a 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).'' We noted that there was no meaningful distinction between the statutory and regulatory parenthetical language for purposes of the MDRP, and thus, we proposed to make a technical change by modifying the regulatory language so that it more closely mirrors the statutory language. We proposed 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).''

We received public comments on these proposals. The following is a summary of the comments we received and our responses.

Comment: We received several comments supporting the proposed definition of direct reimbursement with respect to the COD's limiting definition. Some comments provided general support for the proposed definition. One commenter stated that the definition will help ensure that Medicaid beneficiaries with a rare disease continue to have access to affordable outpatient drugs. Another commenter stated that the change will help ensure that States receive the MDRP rebates to which they are entitled, allowing providers to make treatment decisions based on the individual clinical circumstances of a patient. One commenter supported the definition and noted that current claims processing standards support the ability of a claim to contain the required information so that rebates may be billed. One commenter supported the definition and stated they believe that the modification to the definition reflects our current policy, and they requested clarification to confirm that understanding.

Response: We appreciate the support for the modification of the definition of a direct reimbursement as it relates to the definition of a COD. The modification to the definition was not intended to be a departure from current practice or in conflict with the current regulation or statute. Rather, the modification was intended to address the fact that States are now using newer reimbursement methodologies where it is not entirely clear whether drugs

reimbursed through that new methodology are CODs. As discussed subsequently, we are also adding clarifying language to ensure that our intention is clear that the definition does not inadvertently include drugs that do in fact meet the statutory limiting definition of COD.

Comment: We received several comments that are outside the scope of this rule. One commenter stated that the modified definition of COD would affect the covered entities that participate under the HRSA 340B Program because they use our definition of COD to determine if a drug is subject to 340B pricing. One commenter stated that CMS fails to convey how medical research and development will be protected with the proposed revisions. A few commenters noted that the modified definition of COD would increase the number of CODs subject to rebates which may make it difficult for manufacturers to continue to offer their drugs in Medicaid.

Response: Because these 340B issues are outside the scope of this rule, we are not addressing them. We appreciate the commenters' concern regarding the modification of the definition of COD and the increased number of CODs subject to rebates. While we do not believe this clarification to the definition will result in a significant change in the number of CODs, it may increase the number of instances where a COD may qualify for rebates. With respect to impact on research and development, this proposal will clarify for States when a drug is a COD and thus subject to rebates in some instances, and thus may result in States collecting rebates in circumstances where they are not currently collecting any rebates. As a result, States may take these clarifications into account when determining coverage and reimbursement policies for particular drugs. The impact of these clarifications may result in States having a net reduction in cost for these drugs, which may increase access to these drugs, and in turn, support manufacturers' research and development efforts. CMS does not believe that the clarification of the definition of a COD in this rule indicates that scientific drug development is not valued or that the definition will disincentivize the scientific development. The United States pharmaceutical market is the largest in the world, with a strong record of fostering innovation, and Federal health care programs are large payers for medications in the United States, supporting incentives for manufacturers to continue to develop innovative medicines and make drugs available in the Medicaid program.

Comment: We received many comments stating that our proposed clarification of the term ''direct reimbursement'' conflicts with the language of the statute. Commenters also stated that the proposed revision would represent a significant and impermissible change to the meaning of the limiting language in the COD definition and stated that it would render language in the statute unnecessary. Commenters pointed to legislative history, assertions made by HHS in litigation that ''a drug is not a covered outpatient drug if it is provided, and paid for, as part of a bundled service,'' language in the 2016 COD final rule, and responses in an FAQ published under the 2016 COD final rule to support their position that CMS historically considered that a drug was not a COD unless the drug was separately reimbursed. One commenter cited the following language from the 2016 COD final rule to support their position: ''a drug which is billed as part of a bundled service with, and provided as part of or incident to and in the same setting as the services'' [will only qualify as] a COD if ''the State authorizes and provides a direct payment for the drug, consistent with the applicable State plan, separately from the service.''

Response: Upon review of these comments, we are clarifying for States the situations in which they will be able to bill for a rebate for a COD that is directly reimbursed as part of a bundled or inclusive payment. Specifically, we are clarifying the term ''direct reimbursement'' as we agree that the proposed regulatory definition may not have clearly identified those situations that will qualify as direct reimbursement. In this final rule, we are adding language to the regulatory definition to indicate that direct reimbursement includes reimbursement for a drug that is part of an inclusive payment when the inclusive payment includes an amount attributable to the drug, the number of units of the drug that were dispensed or administered to the patient, and the amount paid that is attributable to the drug is based on a reimbursement methodology that is included in the applicable section of the State plan.

Comment: Several commenters disagreed with CMS' assertion that the proposed modification to the definition of COD is a clarification of existing policy on the application of the limiting definition. They stated that rather than a clarification, they view the modification as a policy change with no presented rationale. Commenters also stated that CMS' proposal is a departure from the agency's longstanding policy that no Medicaid rebate liability attaches to units reimbursed via bundled payments. Commenters also stated that our definition marks a significant and unacknowledged departure from the agency's longstanding approach to manufacturer rebate liability. A commenter mentioned that a basic requirement of the Administrative Procedure Act is that an agency must acknowledge that ''it is in fact changing its position'' and provide good reasons for any change in policy. They stated that CMS failed even to acknowledge its changing position and was, therefore, acting in an arbitrary and capricious manner. A few other commenters referenced language in the preamble to the 2016 COD final rule, when CMS previously stated, ''if the drug is provided as part of a bundled service and not separately reimbursed, then the drug does not qualify as a [covered outpatient drug], in accordance with section 1927(k)(3) of the Act and is not subject to rebates.''

Response: Our intent in the proposed rule was to provide clarification regarding when a payment represents direct reimbursement for a drug. Essentially, we were clarifying that, as used in the quoted language, ''not separately reimbursed'' in the context of bundled rates means not separately identified or itemized, with an amount associated with payment for the drug. Based on the comments, we agree that our proposed modification to the definition could be further clarified. In the past we have stated that no rebate liability attaches to drugs that are paid for as part of bundled payments. As just noted, this was intended to address situations in which an amount paid for a COD is not identified or itemized. As noted in the preamble to the proposed rule, interested parties have requested that we define situations in which rebates can be billed for drugs that are part of inclusive payments if the quantity of drug dispensed or administered can be identified. As noted in the response to previous comments, we are modifying the definition of direct reimbursement in this final rule to make it clear that, for rebates to be billed, the inclusive payment must include an amount directly attributable to the drug, and the amount paid that is attributable to the drug is based on a reimbursement methodology that is included in the applicable section of the State plan.

Comment: We received some comments indicating that the proposed change to the definition of COD would

nullify the distinction between direct reimbursement and reimbursement made as part of a bundled payment. Commenters stated that ''direct reimbursement'' cannot be construed to mean ''separately identified'' without there being a distinct payment for the drug. Commenters also indicated that CMS failed to acknowledge that where a drug has been paid for as part of an indivisible payment for the drug and its associated services, Medicaid, by definition, has not directly reimbursed for the drug, and there is no ''direct'' throughline between the reimbursement amount and the payment associated with any one of the bundled items or services. Some commenters also stated that the proposed change ignores what they consider to be a reasonable interpretation of direct reimbursement.

Response: We agree that the proposed revision to the definition of COD regarding direct reimbursement did not adequately reflect that the amount of reimbursement for the drug should be tied to the State's approved reimbursement methodology for that drug. We have therefore added language to the definition in this final rule to indicate that in order for the payment for the drug to be treated as direct reimbursement, the payment methodology for the inclusive payment must identify an amount directly attributable to the drug, such that the amount paid is based on a reimbursement methodology that is included in the applicable section of the State plan.

Comment: We received a few comments that because our modified definition of COD provides that drugs administered in an inpatient setting could be included in the definition of ''covered outpatient drug,'' we give no meaning to the word ''outpatient'' contained within the term.

Response: The term ''covered outpatient drug'' is a statutory term of art. The limiting definition in section 1927(k)(3) states that the term COD does not include any drug provided as part of, or as incident to and in the same setting as ''inpatient hospital services,'' among others, and for which payment is not made as direct reimbursement for the drug. If the Congress had intended for the statutory term of ''COD'' to be limited to the outpatient setting only, the limiting definition would be superfluous as applied to being included in inpatient hospital services. Because statutory interpretation principles hold that an agency should not construe a statute in a manner that renders a provision to have no effect, we disagree that the term COD is limited to drugs dispensed or administered in an outpatient setting. Based on the plain text of 1927(k)(3), the term COD excludes a drug provided in the inpatient hospital setting only if the drug is provided as part of or as incident to and in the same setting as inpatient hospital services and for which payment is made as part of such services and not as direct reimbursement for the drug. We proposed to amend the regulatory definition of COD in a manner consistent with the statutory definition of this term of art to provide greater specificity as to when a drug provided in the inpatient setting is subject to the limiting definition and does not qualify as a COD.

Comment: A commenter noted that the statute focuses on the manner of payment, not the manner in which the provider's costs are reflected on the claim, and that our proposed definition was only focusing on how the claim was submitted.

Response: We agree that the definition should include language about the manner of payment, which we understand to mean how the claim is reimbursed, and not only based on the information submitted on the claim. We have therefore revised the proposed definition to include language about the manner of payment, including that the payment methodology for the inclusive payment must include an amount directly attributable to the drug, such that the amount paid is based on a reimbursement methodology that is included in the applicable section of the State plan.

Comment: Several commenters noted that when payments for new and innovative therapies (cell and gene therapies, for example) are reimbursed in a payment that is bundled with a service (for example, under the Diagnosis-Related Group (DRG) system), the reimbursement is often insufficient for the drug and potentially results in lack of patient access to these new therapies. The commenters noted that conversely, some States are reimbursing the hospital separately for their acquisition cost of certain new and innovative drugs from their inpatient services associated with administering the drug, and such methods of direct reimbursement are adequately reimbursing providers/hospitals and encouraging patient access.

Response: We note that section 1902(a)(30)(A) of the Act requires States 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 under the plan at least to the extent that such care and services are available to the general population in the geographic area.'' The payment methodology for a COD must be identified in the State Plan and meet the foregoing standard. Some States already have approved methodologies outlined in their State plan that results in the ability for the State to collect rebates on some inpatient drugs. If a State plan does not address a distinct reimbursement methodology for a drug included in a bundled payment, then a SPA would need to be submitted and approved that includes such methodology in the appropriate section of the State plan.

Comment: One commenter stated that manufacturers have launched certain products assuming there would be limited MDRP rebates given the products are included in a bundled payment arrangement and altering this will lead to significant operational challenges, unsustainable pricing expectations, potential drug shortages, and compromised utilization within Medicaid.

Response: Again, we note that our intent for this clarification is to help manufacturers and States better understand how the term direct reimbursement for a drug will be applied with respect to the limiting language within the COD definition. Our review of comments alerted us to the fact that the proposed definition, as originally written, may be open to multiple interpretations. As a result, in response to such comments, we have modified the definition in this final rule to be clearer about when a payment is a direct reimbursement for a drug. Given the revisions, we do not believe that the challenges cited by the commenter will occur. We also note that there are States whose current Medicaid reimbursement policies account for carved out inpatient drugs for separate payment. These payment models have been intact for years and we do not have evidence that these payment models lead to significant operational challenges, unstable pricing expectations, drug shortages, or compromised Medicaid utilization. We also intend to provide additional guidance to States with respect to how the interpretation of direct reimbursement may be operationalized so that States can invoice for rebates for these CODs.

Comment: A few commenters expressed their concerns regarding drug manufacturers' lack of access to claims level data for purposes of validating rebate invoices if CODs are merely identified or itemized and not separately reimbursed. One commenter stated that neither CMS nor States nor manufacturers have visibility into all payer claims to be able to ascertain how

bundled drugs and associated items and services are itemized. Manufacturers would have to obtain the billing document to verify the validity of rebate invoices. Another commenter stated that it was unclear that States would have the mechanism to collect such claims data for bundled drugs and present to manufacturers if requested.

Response: Manufacturers are always able to work with States to verify a claim for a Medicaid rebate. States will need to determine how they instruct their providers and managed care plans to identify for rebate billing purposes those inclusive payment claims where direct reimbursement is being made for a COD. This will allow States to include the COD in the rebate billings, as well as identify for Medicaid managed care plans such claims that they will have to report to the States for rebate billings.

For States that choose to reimburse these drugs separately, the State will have the information submitted on the claim identifying the drug and the number of dispensed or administered units of the drug. For States that choose to use a bundled reimbursement model that separately identifies the drug and takes the cost of the drug into account in the reimbursement as outlined in the methodology in the State plan, those States will also have sufficient information to identify the drug and the number of dispensed or administered units of the drug. This claim information will allow the State to provide utilization information to the manufacturer in order for the manufacturer to verify that utilization. Collection of the data and how it may be presented to manufacturers may vary by State or manufacturer.

Comment: Several commenters stated that finalizing the COD definition as proposed would subject some drugs (for example, cell and gene therapies to new rebate requirements and would undermine efforts to offer value-based payment models and innovative payment arrangements.

Response: All CODs, including cell and gene therapy drugs that are CODs for which the manufacturer has a rebate agreement, are subject to basic minimum Medicaid rebate requirements, regardless of whether they are provided as part of a value-based purchasing arrangement. As noted previously, some States have already received approval for a State plan amendment to carve out drugs, such as cell and gene therapy drugs from inpatient hospital payment rates, and reimburse them separately, thus allowing them to collect rebates. Further, the Cell and Gene Therapy Access Model being tested by the CMS Innovation Center will require participating States to carve model cell & gene therapy drugs out of an inpatient payment bundle if the States want to participate in the Model so that the States may collect rebates on the drugs. With the clarification to the definition of direct reimbursement, as finalized in this rule, States may also bill for rebates for drugs that are provided as part of inclusive payments if they are itemized on the provider's bill, the number of units dispensed are identified, and the drug is paid according to the State's approved plan methodology for the drug. With these clarifications, we also believe that manufacturers and States may still pursue enhancements in patient access, equity, and health outcomes by executing VBP agreements and supplemental rebates for any COD per the State plan.

Comment: A few commenters stated that the cost of a drug has not necessarily been included in the development of a bundled payment rate for the underlying service. One commenter stated that a DRG-based payment for a hospital inpatient stay does not provide reimbursement for any one item or service involved in the bundle. Instead, the commenter stated that bundled payment rates are meant to reimburse generally for the collection of various items and services that may or may not be necessary to the delivery of care for a specific illness, procedure, or condition. The commenter noted that, typically, when DRG rates are used to reimburse providers, the payment is a predetermined amount that does not change based on the cost or amount of a specific drug that is administered or dispensed to the patient.

Response: We recognize that DRG is a commonly employed bundled payment methodology for an inpatient stay for a procedure or diagnosis. The modified definition of COD that we are finalizing will continue to exclude drugs from the definition of COD that are provided as part of, or as incident to and in the same setting, as defined in section1927(k)(3)(A) through (H) of the Act, for which payment for the drug is bundled and not distinguishable from other costs associated with that service. In addition, given that under a bundled payment, the units of a drug that were provided during the service are not identified on the bill, the State would not know how many units to bill for rebates. We modified the proposed regulatory definition in this final rule such that in order for the definition of direct reimbursement to be met, the number of units administered to the patient must be identified on the invoice for the inclusive payment and reflected in a payment methodology in the State plan.

Comment: Several commenters noted that some States are reimbursing the hospital for their acquisition cost of certain new and innovative therapies separately from their inpatient services associated with administering the drug. They believe this would qualify as direct reimbursement, and result in States adequately reimbursing providers/hospitals and encouraging patient access. One commenter suggested that accounting for the drug cost separately in the reimbursement calculation is a win-win situation.

Response: We agree that payment for drugs provided in this manner consistent with the State plan constitutes a direct reimbursement and the drug meet the definition of a covered outpatient drug.

Comment: A few commenters stated that the proposed definition could make drugs reimbursed under a DRG reimbursement methodology or other bundled payment subject to rebates when they historically were not. These commenters supported this result and noted that these drugs are currently carved out of DRGs to collect rebates. They noted that this clarification would ensure States have the authority to collect rebates regardless of the State's COD reimbursement methodology. These commenters stated this may be particularly important for new high-cost cell and gene therapies which are typically administered in medical facilities.

Response: We agree the proposed definition could have been interpreted to make drugs reimbursed under a DRG reimbursement methodology or similar bundled payment methodology subject to rebates regardless of the State's COD reimbursement methodology. As indicated in response to previous comments, we did not intend for the modification of the definition of COD to change current policy, but our review of comments alerted us to the fact that the proposed definition could be open to multiple interpretations. Based on such comments, we have modified the definition in this final rule to clarify that direct reimbursement does not occur unless the reimbursement for the drug is based on a reimbursement methodology that is included in the applicable section of the State plan, and that the inclusive payment includes an amount directly attributable to the drug. Thus, a drug that is reimbursed as part of a bundled payment under a DRG or similar bundled payment methodology is not subject to rebates. However, if that drug is carved out of the bundled payment and reimbursed directly, then

the drug is subject to rebates when applicable.

Comment: One commenter stated CMS should encourage State Medicaid programs to implement reimbursement methodologies for gene therapies that adequately cover both the direct gene therapy costs and the patient care costs for services incident to that therapy.

Response: We note that reimbursement for gene therapies, as with all CODs, are subject to section 1902(a)(30)(A) of the Act's requirements ensuring that States' ''payments are consistent with efficiency, economy, and quality of care and are sufficient to enlist enough providers so that care and services are available under the plan at least to the extent that such care and services are available to the general population in the geographic area.''

Comment: One commenter stated that separate payment creates greater equity in reimbursement rates across settings of care, such as inpatient hospital versus outpatient hospital reimbursement.

Response: Our definition of COD is not designed to address site of service concerns such as those raised by this commenter. Rather, it addresses when drugs are considered CODs, and thus the States can collect rebates, within various reimbursement methodologies.

Comment: One commenter stated that allowing States to seek rebates on inpatient-administered drugs merely by identifying the drug on the claim form and without some form of separate payment, would enable States to seek rebates on drugs without establishing the separate payment policies that make hospitals whole and help ensure patient access.

Response: We agree that this is a potential outcome of defining direct reimbursement without requiring a separate reimbursement policy to account for the cost of the drug via the applicable State plan, and that was not our intent. Our modified definition of direct reimbursement as finalized addresses this potential issue by requiring that the methodology for determining the reimbursement for a COD as part of a bundled payment be set forth in the State plan.

Comment: A few commenters stated CMS does not explain what the ''itemized cost'' represents and how it is to be determined and claimed it could essentially be a ''fictional amount.''

Response: This term is being revised in this final rule to ''the charge for the drug''. Providers should rely on the State's billing instructions to determine what to report to allow for appropriate reimbursement.

Comment: A commenter questioned whether the bundled service must be one in which the drug is always used.

Response: As noted in previous responses to comments, the definition, as finalized in this rule, makes it clear that in order for the drug to satisfy the COD definition, the drug used must be identified, the charge for the drug must be itemized on the claim form, and the payment must be consistent with the reimbursement methodology for CODs in an approved State plan. These requirements may apply to drugs that are always used in the bundled services and to drugs for which this is not the case.

Comment: Commenters stated that simple ''itemization'' on a claim form is not equivalent to ''direct reimbursement.''

Response: We agree, and therefore modified the definition in the rule to more clearly state that direct reimbursement includes a distinct methodology reflected in the State plan that accounts for the reimbursement of the drug and is used to determine the inclusive payment.

Comment: A few commenters stated that States would respond to this modified definition of COD by requiring providers to include NDCs and ingredient costs on all PAD claims in the future. One commenter recommended that CMS consider the impact that its new proposed definition has on providers' administrative burdens by requiring collection of NDCs and ingredient cost information, suggesting that including such information on Medicaid claims forms is both time-consuming and labor-intensive.

Response: We appreciate the comments regarding the potential burden to providers. Under their State plans, States have the discretion to choose which reimbursement methodology to use for health care services and what drugs, if any, they will carve out from that methodology and directly reimburse for them. As of January 1, 2007, CMS regulations at § 447.520 have obligated States to require that providers submit NDCs for physician-administered single source drugs and the 20 multiple source drugs identified by the Secretary. Additionally, we note that in section II. L. of this rule, States are required to provide for the collection of NDCs for all physician-administered single source drugs and multiple source drugs.

Comment: Some commenters stated that if a drug satisfies the definition of COD, all requirements of section 1927 of the Act apply (for example, all drugs of the manufacturer must be covered regardless of hospital formularies, and reimbursement methodology must be described in the State plan). Commenters acknowledged that States could impose prior authorization requirements and that coverage decisions should rest with the State and not the hospital. One commenter suggested that States not be allowed to skirt the coverage requirements of section 1927 of the Act by allowing hospitals to exclude from their inpatient formulary drugs of a manufacturer that has signed a NDRA. A few commenters expressed their concerns with their view that the proposed rule did not address how a bundled drug would be covered in the inpatient setting where restrictive formularies may apply.

Response: If a drug typically administered in the inpatient setting qualifies as a COD, then we agree, notwithstanding exclusions, that section 1927 of the Act applies to that drug. Our revised definition of COD does not change the State's ability to decide the reimbursement methodology for drugs so long as it is approved in their State plan.

Comment: One commenter stated that all reimbursement limitations that apply to CODs would need to apply to these bundled hospital inpatient drugs, specifically the Federal upper limit requirements found in §§ 447.512 and 447.514. The commenter noted that this issue is not addressed in the proposed rule by the lack of new language at § 447.516 ''Upper limits on drugs furnished as part of service''.

Response: We did not intend for the modification to the definition of COD to change current policy, including Federal upper limit regulations, but our review of comments alerted us to the fact that the proposed definition as originally written could be open to multiple interpretations. A ''bundled'' hospital inpatient drug that the commenter mentions, for which direct reimbursement is not made, does not qualify as a COD. Generally, the Federal upper limit requirements only apply to multiple source drugs dispensed by a retail community pharmacy. The regulatory language in § 447.516 applies Federal upper limits to payment for prescribed drugs furnished as part of a service when provided as part of a skilled nursing facility service, intermediate care facility service and under prepaid capitation arrangement. This change to the COD definition does not make any changes to the regulatory language in § 447.516.

After considering the issues raised by the commenters, we have decided to finalize this provision with modifications to our proposed

definition. In order for a payment to be considered direct reimbursement for a drug, the claim must include the charge for the drug, the number of units utilized, and the payment made to the provider must include an amount directly attributable to the drug and is based on a CMS approved reimbursement methodology.

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

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. Section 6(a)(1)(A)(iv) of MSIAA amended section 1927(b)(3) of the Act by adding section (b)(3)(A)(v), under which a manufacturer must 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. To support the implementation of this new statutory requirement to report drug product information, we proposed to define drug product information in regulation at § 447.502.

In the proposed rule, we noted that we currently require manufacturers to submit drug product information when the COD is entered into the Medicaid Drug Programs (MDP) system, but that there is no regulatory definition of drug product information. We, therefore, proposed 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 (single source drug (S), innovator multiple source drug (I), and noninnovator multiple source drug (N)), unit type (for example, tablet, capsule, milliliter, each, etc.), 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 discussed in the proposed rule, the drug category for an NDC should be single source drug or innovator multiple source drug 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 drug or innovator multiple source drug, and can be changed to noninnovator multiple source drug, effective April 1, 2016. We noted that we use the FDA ''applications.txt'' file to verify the type of application associated with an application number and that the file may be accessed using the link to the Drugs@FDA download file found on the FDA website at *https://www.fda.gov/drugs/drug-approvals-and-databases/drugsfda-data-files.*

We also noted in the proposed rule that the only situation in which a drug that is produced or marketed under an NDA may be reported as a noninnovator multiple source drug is if a narrow exception was granted by CMS in accordance with the process established in the 2016 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.

We indicated that manufacturers should evaluate all of their NDCs for compliance with drug product information reporting, and if they determine corrections are required, they should contact CMS for assistance. We also referenced Manufacturer Release No. 113, in which we addressed a manufacturer's responsibility to ensure that all of their CODs are correctly classified and reported in the Drug Data Reporting system (DDR) (currently known as the MDP system) 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*). We also noted that 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 the proposed rule, we proposed 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.

For most drug product information changes, we noted 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, we noted that in some situations where monthly 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. Additionally, we noted that regardless of whether we make a data change on behalf of a manufacturer or whether the manufacturer enters required data directly in the MDP system, manufacturers would be required to certify the information in accordance with § 447.510. Thus, we indicated that 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.

We also stated that 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 remain 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 noted that 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.

We received public comments on these proposals. The following is a summary of the comments we received and our responses.

Comment: We received several comments supporting our proposed definition of drug product information. Commenters indicated that the proposed definition removes ambiguity and closes potential loopholes.

Response: We appreciate the commenters' support for the proposed definition of drug product information.

Comment: A few commenters stated that the statute's scope is limited to drug product attributes found in the statute and the regulation, and that several data elements that we included in the definition are not found in statute or regulation.

Response: We disagree that drug product information must be limited to product attributes specifically mentioned in the statute. The statute provides direction for CMS to administer the MDRP, which includes how rebate amounts are calculated. Some data fields that are utilized in calculating the unit rebate amount are not specifically set forth in statute but are nonetheless required to perform the calculations that are detailed in the statute or to confirm the accuracy of

those calculations. For example, although ''unit type'' is not a data element mentioned in statute, it is an important data element that helps to identify what the reported AMP represents. If the unit type is reported incorrectly, it is possible that the AMP value may be misinterpreted. CMS has determined to set forth by regulation the data elements that must be reported as part of drug product information.

Comment: One commenter suggested CMS limit the items included in the definition of drug product information to those items related to drug category.

Response: We are not limiting the items included in the definition of drug product information to those items related to drug category because we do not believe that approach would be consistent with the statute. MSIAA inserted the words ''and drug product'' to the title of section (b)(3) of the Act, as well as other references to drug product information, when addressing the information required to be reported by manufacturers and the misclassification of drugs. Therefore, the definition must include not only elements that are related to drug category, but also other elements that are required to perform the calculations of the unit rebate amount and to be able to help confirm the accuracy of the calculations in accordance with the statute. CMS believes the elements chosen for inclusion in this definition are essential to ensure that unit rebate amount calculations are accurate, and that CMS has accurate data to be able to oversee the MDRP.

Comment: One commenter requested clarification on the inclusion of base date AMP as an element of drug product information and questioned if the current file format will be amended to include base date AMP.

Response: The current file format will not need to be amended for the reasons explained later in this section. In order to fully respond to this comment, we need to delineate between different base date AMP values. If a drug has a market date of September 30, 1990, because it was first available for sale on or before that date, then the base AMP for the drug is referred to as the OBRA '90 base date AMP. The OBRA '90 base date AMP value, as well as all of the different base date AMP values, are considered to be product data. A manufacturer reports the OBRA '90 base date AMP value into MDP as part of the product data when first reporting the drug to CMS. The OBRA '90 base date AMP value is a value on the product data file (Form CMS–367c), and no file format amendments are required.

In general, if a drug has a market date after September 30, 1990, which is the date it was first available for sale, the base date AMP values are derived from quarterly pricing information that is reported by the manufacturer for the base AMP quarter. For each base date AMP value other that the OBRA '90 base date AMP value, the MDP system automatically populates the base date AMP value in the product data using the quarterly pricing information submitted by the manufacturer as pricing data for the base AMP quarter. Although these other base date AMP values are derived from quarterly pricing information for the base AMP quarter, the base date AMP values are not considered to be pricing data. Those base date AMP values other than the OBRA '90 base date AMP values are not reported directly into MDP as product data and do not appear in the product data file.

Comment: A few commenters stated that the changes that the Congress made to the statute were to address misclassifications, not drug pricing issues, and therefore any drug pricing references should be removed from definition of drug product information.

Response: The changes to the statute made by MSIAA are not solely to address drug category, but also to address incorrect reporting of additional drug product information. The items included in the definition of drug product information are all considered to be product information. As an example, although the base date AMP value is a pricing value, it is considered product information. It generally does not change once established and is tied to the drug throughout the history of that drug in the MDP system. Pricing information is reported monthly and quarterly and may change from one reporting period to the next. Additionally, elements such as unit type or TEC code are not directly related to drug category, however they are included in the definition of drug product information.

Comment: A few commenters stated that the definition of drug product information must be prospective only and that CMS should clarify the effective dates of definition changes.

Response: The definition of drug product information becomes effective on the effective date of this final rule. With this definition of drug product information, we are not adding or changing any reporting requirements, we are only defining which reporting elements are included in the definition of drug product information.

Comment: A few commenters were concerned that the proposed rule would treat a clerical error that has no impact on the MDRP the same as a misreported data element that has direct impact on URA calculations, such as base date AMP.

Response: The proposed definition of drug product information lists the data elements that are considered to be drug product information. The definition itself does not indicate how misreporting of any element of drug product information will be evaluated for potential penalties; misclassification of drug product information is addressed in the misclassification section of the rule. In that section, we state that we believe misclassification includes any incorrect drug product information reported by the manufacturer. Also in that section, we proposed several penalty options in accordance with the penalty options contained in section 1927(c)(4)(B) of the Act and note that CMS may utilize one or more of them in each situation. One of those options is for CMS to correct the misclassification on behalf of the manufacturer using drug product information provided by the manufacturer. As discussed in the misclassification section, the enforcement provisions in section 1927(c)(4)(B)(ii) provide options for CMS to take action when a manufacturer fails to correct a misclassification. CMS' current process within the MDP system requires the manufacturer to certify any change made in the MDP system. However, CMS may certify changes on behalf of the manufacturer and would do so in this specific situation. Outside of this specific situation, as discussed in the preamble of the proposed rule, any change made in the MDP system by CMS must be certified by the manufacturer before it becomes effective.

Comment: We received several comments regarding the ''open-ended'' definition of drug product information. Commenters were concerned that although we listed specific data that would be included in the definition, we also specified that the definition was not limited to those data elements. Specifically, commenters disagreed with the inclusion of ''information that includes but is not limited to'' and ''and any other information deemed necessary by the Agency to perform accurate Unit Rebate Amount calculations.'' Commenters stated that we lack the authority to leave the definition open-ended, that issuing ''catch-all'' phrases in definitions bypasses the notice and comment requirements, and that we must define terms with precision. Other commenters were concerned that the broad, open-ended provision in the

definition gives CMS a vehicle for arbitrary enforcement and leaves open the opportunity for inconsistent application year to year. One commenter stated that we should either strike the open-ended definition or delete ''drug product information'' from § 447.509(d)(1).

Response: While we disagree that we lack the authority to adopt provisions such as the definition proposed, we agree with the commenters that it would be appropriate to remove the ''open-ended'' provisions in the proposed definition of drug product information. We are additionally making slight edits to the construction of the proposed definition to make it clear to which elements the term ''if applicable'' applies. Therefore, drug product information will now be defined as 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 type (prescription, over-the-counter), base date AMP, therapeutic equivalent code (TEC), line extension drug indicator, 5i indicator, 5i route of administration (if applicable), FDA approval date, FDA-approved application number or OTC monograph citation (if applicable), market date, and COD status.

Comment: A few commenters stated that the language proposes that manufacturers would have to report each element of drug product information repeatedly and that would be burdensome or unnecessary.

Response: Section 1927(b)(3)(A)(v) of the Act states that manufacturers must 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. Currently, we require that drug product information be reported not later than 30 days after the date of entering into a rebate agreement, or, for newly introduced drugs, not later than 30 days after the last day of the month during which the new drug is introduced. Such drug product information is not required to be reported on a monthly or quarterly basis at this time, and we therefore disagree with commenters' concerns that the definition requires unnecessary, repetitive, or overly burdensome reporting.

Based on the comments received, we are finalizing the definition as proposed with the previously described sentence structure changes and the following additional changes:

- Deleting ''. . . includes but is not limited to . . .'' and replacing it with ''means''
- Deleting ''. . . COD status, and any other information deemed necessary by the agency to perform accurate unit rebate amount (URA) calculations.'' and replacing it with ''and COD status.''

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

In the proposed rule, we included a provision that would define internal investigation related to manufacturer reporting of quarterly pricing metrics. As background, we noted in the preamble to the proposed rule, 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 for the purposes of the MDRP, or else they could incur penalties or be subject to other compliance and enforcement measures. We noted that 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 period for reporting revisions to AMP or best price information in final rule (Medicaid Program; Time Limitation on Price Recalculations and Recordkeeping Requirements Under the Drug Rebate Program) on August 29, 2003. However, we have continued to receive requests outside of the 12-quarter time period from manufacturers to revise pricing data. We stated that these types of manufacturer requests, which could span multiple years prior to the 12-quarter time period, could sometimes result in substantial recoupment of Medicaid rebates already paid to States and impede the economic and efficient operation of the Medicaid program.

We noted that in the 2016 COD final rule we offered exceptions to the 12-quarter time period (81 FR 5278, See § 447.510(b)(1)(i) through (vi)). Specifically, we discussed one exception at § 447.510(b)(1)(v) (which provides an exception to the 12-quarter time period price reporting rule if the change requested by the manufacturer 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) pertaining to adjustments pursuant to an internal investigation. We explained that our policy has been that internal investigation is intended to mean a manufacturer's internal investigation, and that if a manufacturer discovers any discrepancy with its reported product and pricing data to the MDRP that is outside of the applicable timeframes, the manufacturer should determine if the change satisfies one of the enumerated exceptions (81 FR 5280). However, we acknowledged that we have not further defined or given any greater explanation for the applicability of the exception to the 12-quarter time period rule up to that point, particularly in instances when manufacturers perform an internal investigation of the drug price information (AMP and best price) reported and certified in MDP by another manufacturer. Additionally, we noted that, 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 time period rule. Consequently, in the proposed rule, we proposed a definition to provide greater clarity in this area. Our requirement does not override or otherwise diminish a manufacturer's obligation to make sure that it has paid the statutorily required rebate amount. The discussion herein only applies to the paragraph of § 447.510(b)(1)(v) ''internal investigation'' and does not obviate or negate any requirement resulting from a CMS or court order, or an OIG or DOJ investigation.

In cases when a manufacturer requests an exception to the 12-quarter time period rule due to an internal investigation, we proposed to specify that the manufacturer must make a finding that indicates a violation of statute or regulation before we consider such a request. For example, a request by a manufacturer to restate or revise previously reported and certified pricing data outside of the 12-quarter time period based upon a mere disagreement with a 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 period. In this example, the manufacturer must make findings that include actual data from the prior manufacturer as evidence that the prior manufacturer violated statute or regulation.

We noted in the preamble to the proposed rule that manufacturers should not use the internal investigation exception to allow for application of 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. Therefore, to ensure clarity on when the internal investigation exception may be appropriately applied, we proposed 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. We further indicated that a manufacturer must make data available to CMS to support its finding. We also proposed to amend § 447.510(b)(1)(v) to reference the definition of internal investigation at § 447.502.

We received public comments on these proposals. The following is a summary of the comments we received and our responses.

Comment: A few commenters opposed the proposed definition of internal investigation, with some stating that this definition will lead manufacturers to avoid internal audits and fail to identify violations of fraud, abuse, or violations of law or regulation, such that it would reduce the accuracy and reliability of price reporting metrics. The commenters encouraged CMS to develop a proposal that maintains the viability of the internal investigation exception to the 12-quarter time period rule, instead of foreclosing price revision requests following an internal investigation.

Specifically, commenters indicated that manufacturers would have to admit legal fault in order to request a restatement outside the 12-quarter time period, which would have a chilling effect on appropriate restatements when there is no legal fault. For example, commenters indicated that manufacturers that are risk averse, or maintain a more conservative approach to price reporting than the previous owner, would likely not pursue price revision requests because of admission of fault. The commenters further indicated that there are many reasons why a manufacturer's reported AMP and best price may require correction, including resolution of price disputes for certain providers/customers that eventually impact best price and/or AMP or discovery of good-faith mathematical errors. They stated that CMS should withdraw its proposal of the definition of internal investigation and recognize manufacturer requests outside the 12-quarter time period for what they are: good faith attempts to comply with complex and consequential government reporting obligations.

Response: CMS believes that most manufacturers are making good faith attempts to comply with MDRP price reporting rules. CMS also maintains that manufacturers have sufficient time to address revisions in MDP to the manufacturer's AMP, best price, customary prompt pay discounts, or nominal prices within the 12-quarter time period (3-year time period) in accordance with the timeframe set in § 447.510. Through notice and comment rulemaking, CMS published the final rule (CMS–2175–FC) that set forth the 12-quarter (3-year) time period on August 29, 2003. In the 2003 final rule, CMS reiterated concerns expressed by States regarding pricing changes and recalculations that were occurring under the MDRP back to 1991, and the significant burden on States and manufacturers to maintain pricing data and supporting documentation for such an extended time period. Based on these considerations, a time limit was adopted (68 FR 51913). As there were no comments received regarding extending this period beyond 12-quarters in response to the 2003 proposed rule, CMS adopted the 12-quarter time period and communicated that we would not choose a longer period than 3 years because it would not sufficiently alleviate States' fiscal vulnerability with regard to retroactive pricing changes (68 FR 51916).

While we have enacted exceptions to allow for restatements in certain circumstances beyond the 12-quarter time period, we continue to believe that we should minimize requests to restate outside of that time period to improve the administration and efficiency of the MDRP and to assist States and manufacturers that would otherwise be required to retain drug utilization pricing data records indefinitely (88 FR 34253). As a result, we are finalizing the definition of internal investigation, but we are amending the definition to add the term ''possible'' so that such restatements would not be construed as an admission of legal fault. Therefore, as finalized, we will 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 the MDRP that results in a finding made by the manufacturer of possible fraud, abuse, or violation of law or regulation. A manufacturer must make data available to CMS to support its finding. CMS notes that neither the general 12-quarter time period for restatements nor the exceptions allowing for restatements in certain circumstances beyond the 12-quarter time period, including pursuant to an internal investigation, alleviate the manufacturer of its obligation to accurately report product and pricing information for covered outpatient drugs to CMS consistent with section 1927 of the Act and applicable regulations and guidance.

Comment: A commenter indicated that a manufacturer may conclude after an internal investigation that it should change a unit type for a drug (for example, the unit type of a vial of lyophilized powder for reconstitution and injection from gram to each) based on CMS guidance. The commenter also indicated that although the use of the initial unit type is not a violation of law or regulation, let alone fraud or abuse, restatement beyond the 3-year window would be prohibited, and the prospective use of the preferable unit type would be precluded by the inability to correct the base date AMP. The commenter provided as another example a manufacturer that, as a result of an internal investigation, changes a reasonable assumption about a customer or its class of trade. The commenter noted that an internal investigation may uncover new information that a group purchasing organization (GPO) passes through administrative fees to its members, or that a pharmacy dispenses greater than 50 percent of its prescriptions through the mail, which the commenter indicated could lead to a different treatment of the customer in the AMP and best price calculations.

Response: Existing regulation at 447.510(b)(1)(v) provides that if ''[t]he change is to address specific rebate adjustments to States by manufacturers, as required by CMS . . .'' and a manufacturer requests a change to a drug's unit type in our system because CMS has directed the manufacturer to make the change, that reason may be considered by CMS as an exception to the 12-quarter time period rule. Revisions to a manufacturer's determination of AMP and best price because a manufacturer uncovers new information about the calculation it made 12 quarters in the past may meet the exception only if the change is to address rebate adjustments to States as directed under 447.510(b)(1)(v). That is, the change is required by CMS or court order, or under an internal investigation (as defined at 447.502) or an OIG or DOJ investigation.

Comment: Several commenters noted that they are concerned with CMS' assertion in the proposed rule that a manufacturer purchasing another manufacturer or another manufacturer's products, are not valid reasons to restate

pricing outside of the 12-quarter limit. A commenter stated that revisions made outside of the 12-quarter time period conflict with a basic operating premise of the MDRP, as codified in the NDRA. That is, acknowledging the complexity of the Medicaid rebate statute and price reporting requirements, the commenter stated that CMS has long encouraged manufacturers to make ''reasonable assumptions'' in calculating price reporting metrics. As a result, the commenter noted that a manufacturer may revise the previously reported pricing data of a prior manufacturer using a different, reasonable methodology to align a newly acquired product with the reasonable assumptions and price reporting practices of existing company products.

Commenters also indicated that the proposed definition would prevent a manufacturer from requesting to restate pricing metrics calculated using the manufacturer's preferred compliant method upon acquiring a new COD where the pricing metrics for the COD were initially reported with a different compliant method. They stated that this policy would discourage merging entities from harmonizing their reporting methods and could require a manufacturer to employ various methods of calculating pricing metrics to various different CODs, increasing the administrative burdens of complying with its reporting obligations and increasing the risk of reporting inaccuracies by introducing the potential for misapplication of the wrong calculation method for a given COD.

Response: CMS reiterates that we will not accept a change in pricing outside the 12-quarter time period because of a change in a manufacturer's reasonable assumptions or ownership. The manufacturer may prospectively, or within the 12-quarter time period, revise reasonable assumptions associated with the drug pricing, including correcting any customer or class of trade transactions associated with the revised reasonable assumptions. Manufacturers may also harmonize their preferred compliant methodology for pricing within the 12-quarter time period. Permitting manufacturers to revise prices retroactively that were previously verified by another manufacturer and in perpetuity because of changes to a transfer of ownership would be contrary to the established 12-quarter time period CMS adopted in rulemaking in 2003 under CMS–2175–FC. As previously noted, at that time, CMS decided not to extend the 12-quarter time period and communicated that we would not choose a longer recordkeeping than 3 years because it would not sufficiently alleviate States' fiscal vulnerability with regard to retroactive pricing changes (68 FR 51916). Therefore, while we have established exceptions to the 12-quarter time period rule at § 447.510(b), we believe we should minimize granting requests outside of the 12-quarter time period, including restatements of pricing reported for a product previously owned, reported, and certified by another manufacturer.

Also, as noted in a prior response to comments, CMS seeks to minimize requests to restate drug pricing information outside of the 3-year timeframe 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 (88 FR 34253). In this regard, we continue to believe the 12-quarter time period with the existing exceptions, as clarified in this final rule, allows manufacturers to revise pricing without disrupting the administration and efficiency of the MDRP. We note that if a manufacturer is concerned with liability associated with the prices or pricing metrics used by the selling manufacturer, CMS believes that such concerns regarding legal liability because of the incorrect reported price information should be addressed as part of contract negations between the selling and buying manufacturer.

Comment: One commenter supported CMS' request for data to support compliance with laws and regulations in 12-quarter time period rule exception requests. The commenter agreed that it sets a clearer and stricter standard for the exception of the 12-quarter time period by excluding subsequent internal reviews to revise in the manufacturer's favor pricing data that was compliant with laws and regulations.

Response: We agree with the commenter that the use of data to support revisions to prices outside of the 3-year timeframe to reinforce a manufacturer's finding of potential non-compliance with laws and regulations establishes a clear standard for when an exception may apply. We believe the definition of internal investigation, as finalized in this rule, will address this concern.

Comment: A commenter indicated that the inability to restate a base date AMP to harmonize different calculation methods could distort the Medicaid additional rebate calculation. Such rebates are calculated by reference to the difference between a COD's current AMP and its baseline AMP. The commenter stated that if a manufacturer is prevented from restating baseline AMP under its current AMP calculation method, then the additional rebate calculations for every future period will be distorted by the methodology difference.

Response: Manufacturers can restate base date AMP within 3 years of the initial price reported consistent with § 447.510(b). Furthermore, when CMS issues final regulations to reflect revisions made to the statute's calculation of AMP, CMS allows manufacturers to restate their base date AMP in accordance with those regulatory and statutory changes so that the baseline AMP is consistent with the reported AMP. For example, in the 2016 COD final rule, CMS permitted manufacturers to recalculate their base date AMP in accordance with the revisions made to the determination of AMP under the Affordable Care Act (see 81 FR 5281). In accordance with the § 447.502 definition of internal investigation, as finalized in this rule, CMS will not permit a manufacturer to revise the base date AMP outside of the 3-year timeframe unless the internal investigation results in a finding made by the manufacturer of possible fraud, abuse, or violation of law or regulation.

Comment: Several commenters pointed out that rebates under the Medicare Part D Drug Inflation Rebate Program for Part D rebateable drugs are calculated by reference to the amount by which the drug's ''annual manufacturer price'' (AnMP) exceeds the ''inflation-adjusted rebate amount.'' AnMP is calculated by using, in part, the AMP of a drug over 4 calendar quarters. The commenters indicated that any inflation rebate calculated for Medicare Part D purposes could also be distorted by CMS' proposal. They stated that if manufacturers are prevented from restating AMP under this proposal in MDRP rulemaking, then future Part D rebate calculations will be based on the same distorted comparison as the Medicaid rebates. They also noted that as AnMP and the benchmark period manufacturer price are calculated by using multiple quarterly AMPs, any adjustments to CMS' proposed redefinition intended to avoid these distortions should allow manufacturers to restate AMP for all quarters relevant to these calculations for the particular drug.

Response: As noted in the response to the previous comment, manufacturers can restate base date AMP within 3 years of the initial price reported consistent with § 447.510(b), and CMS will allow manufacturers to revise base date AMP to reflect revisions made to the statute's calculation of AMP.

However, in accordance with the § 447.502 definition of internal investigation as finalized in this rule, CMS will not permit a manufacturer to revise the base date AMP outside of the 3-year timeframe unless the manufacturer's investigation results in findings of possible fraud, abuse, or violation of law or regulation. As previously stated and in the proposed rule, the definition will clarify for manufacturers that they should not use the internal investigation exception to allow for the application of 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 previously. CMS has published revised guidance with respect to the operation of the Medicare Part D Drug Inflation Rebate Program, *Medicare Part D Drug Inflation Rebates Paid by Manufacturers: Revised Guidance, Implementation of Section 1860D–14B of the Social Security Act*,[8] and is engaged in rulemaking for this program.[9] CMS refers commenters to Medicare Part D Drug Inflation Rebate Program materials for information on how the Medicare Part D Drug Inflation Rebate Program will use AMP data for the purposes of calculating inflation rebates.

Comment: Several commenters believe that the proposed rule would discourage manufacturers from taking the required measures of correcting the calculations beyond the 12-quarter time period, which could result in calculations that are inconsistent with the manufacturer's methodology and may result in favor of the State. The commenters suggested that CMS allow manufacturers to submit policy changes prior to the 12-quarter time period and seek approval from CMS with documentation and the reason for the policy change, but not necessarily details pertaining to pricing impact either in States or manufacturer's favor. The commenters indicated that, if CMS does not approve the manufacturer's policy changes prior to the 12-quarter time period, then the manufacturer should not proceed with restating the price. The commenter also suggested that manufacturers be allowed to get approval from CMS to recalculate prices when the manufacturer has identified new or changed information in the underlying data which caused the earlier calculation to be incorrect.

Response: We believe the commenter is requesting that CMS approve a manufacturer's pricing methodology or change in information prior to the manufacturer submitting a restatement beyond the 12-quarter time period and not before the 12-quarter time period. Current CMS policy allows the manufacturer to change its pricing information prior to the 12-quarter time period without requesting CMS approval. CMS has a long-held policy that a manufacturer that needs to make future recalculations regarding AMP or best price methodology may do so without prior review and approval by CMS and that manufacturers must report to CMS these revisions to AMP and or best price for a period not to exceed 12 quarters from the quarter which the data were due.[10] This final rule does not impact this CMS policy. However, if the manufacturer provides findings to CMS that the manufacturer's pricing methodology may result in possible fraud, abuse, or violation of law or regulation, CMS may consider permitting the manufacturer to restate its pricing based on the revised methodology outside of the 12-quarter time period.

Therefore, as we noted in the response to the previous comment, we will finalize the definition of internal investigation but amend the definition to add the term ''possible'' so that a manufacturer's restatements would not be construed as an admission of legal fault. Instead, we will 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 the MDRP that results in a finding made by the manufacturer of possible fraud, abuse, or violation of law or regulation. A manufacturer must make data available to CMS to support its finding.

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

We proposed to further refine the definition of 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 also proposed to codify in regulation that all entities (with their applicable labeler 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.

CMS received a number of thoughtful comments on this topic, and we determined not to finalize the proposed policy at this time. We are continuing to review the input provided by commenters, which may inform future rulemaking on this topic.

e. Proposal To Define Market Date (§ 447.502)

In the proposed rule, we included a provision that would establish a definition for market date in regulation. This proposed definition would: (1) modify one aspect of previous agency guidance regarding the market date for a drug by requiring in regulation that the market date reflect the date of first sale of the drug, rather than the date the drug was first available for sale, by any manufacturer; and, (2) codify CMS' historical policy that the market date does not change if a drug is purchased or otherwise acquired from another manufacturer.

Prior instructions and guidance to assist manufacturers in determining the market date for a drug to report to MDP specified that the market date was the date the drug was first available for sale by any manufacturer. This prior guidance is available in various sources, including program notices, the MDP User Guide located within MDP, user manuals previously available in the older Drug Data Reporting for Medicaid (DDR) system, and in data definitions in CMS form 367c.

As background in the preamble to the proposed rule, we noted that section 1927 of the Act governs the MDRP and payment for CODs, which are defined in section 1927(k)(2) of the Act. Pursuant to section 1927(b)(1)(A) 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. Additionally, 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 owed by

[8] *https://www.cms.gov/files/document/medicare-part-d-inflation-rebate-program-revised-guidance.pdf.*

[9] *https://www.federalregister.gov/documents/2024/07/31/2024-14828/medicare-and-medicaid-programs-cy-2025-payment-policies-under-the-physician-fee-schedule-and-other.*

[10] Manufacturer Release #80: (*https://www.medicaid.gov/sites/default/files/medicaid-chip-program-information/by-topics/prescription-drugs/downloads/rx-releases/mfr-releases/mfr-rel-080.pdf*).

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).[11]

We also noted in the proposed rule that 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.[12] For S or I drugs, the 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.[13] (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), we noted that the 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, we noted that a critical data point is the day on which the drug was first marketed. We refer to 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.

We also noted that 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. As such, we noted that 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, we noted that 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.

We also stated that 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 statute requires an additional rebate amount based on the market date for each dosage form and strength of a COD.[14] Thus, if a drug is purchased or otherwise acquired from another manufacturer, we noted that the market date should not change, and should be the same as the market date of the drug first marketed under the FDA-approved application.

Because over the years, manufacturers have occasionally raised questions to CMS regarding the determination of a COD's market date, base date AMP quarter, and base date AMP under various fact-driven scenarios, we proposed to clarify the term market date as used in the MDRP and to resolve potential questions related to these issues. Specifically, to assist manufacturers in reporting a more accurately calculated AMP, for the purposes of determining the base date AMP quarter and the base date AMP, we proposed that the market date be based on the first sale of the drug by any manufacturer rather than the date the drug was first available for sale by any manufacturer. We indicated that 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 based on actual sales data. As a result, the Unit Rebate Amount (URA) would also be calculated more accurately because actual sales would be available for reporting the AMP and calculating the URA.

In other words, under our proposal, for purposes of determining the base date AMP quarter and thus the base date AMP, the market date is based upon the earliest date on which the drug was first sold, by any manufacturer. As noted previously in this section, our proposal also would codify the existing requirement that the market date for a COD is determined with respect to ''any manufacturer.''

We also stated that we understand that defining market date, for purposes of determining a COD's base date AMP, based on the date the COD was first sold, may not completely eliminate a manufacturer's need to make reasonable assumptions because the first sale(s) 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 proposed that sold means that the drug has been transferred (including in transit) to a purchasing entity. We requested 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.

We received public comments on the proposed definition of market date for the purposes of the MDRP. The following is a summary of the comments we received and our responses.

Comment: We received numerous comments expressing support for the proposed definition of market date and one comment that noted no concerns with the proposed definition.

Response: We appreciate the support of the proposed definition of market date.

Comment: We received a comment about how our proposed definition of market date might intersect with the way Medicare proposes to determine the market date for the purposes of certain provisions under the Inflation Reduction Act (IRA). Commenters suggested that applying the same

[11] 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).

[12] Base Date AMP is defined in the National Drug Rebate Agreement (NDRA) at I.(c) as follows: ''Base 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 are incorporated into rebate agreements without further action. See also Manufacturer Release 113—Misclassification of Drugs (*medicaid.gov*); *https://www.medicaid.gov/prescription-drugs/downloads/mfr-rel-113.pdf.*

[13] 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).

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

definition across CMS would provide consistency across the agency.

Response: CMS' interpretation of terms and the applicability of those terms for programs other than the MDRP are outside the scope of this final rule.

Comment: A few commenters suggested that we forgo setting forth a definition for market date and allow manufacturers to continue to make reasonable assumptions.

Response: We disagree that we should forgo finalizing a definition for market date, because we believe a regulatory definition will bring additional consistency to the MDRP and will assist manufacturers in identifying the accurate market date. However, to the extent the definition does not address a specific situation, manufacturers may still need to make reasonable assumptions. As an example, we discuss the potential need for reasonable assumptions further in our response to comments regarding the proposed definition of ''sold'' within the definition of market date.

Comment: One commenter questioned if the market date should be the same for all 11-digit NDCs within a 9-digit NDC family, even if an individual 11-digit NDC was introduced at a later time.

Response: The market date is the same for all 11-digit NDCs within a 9-digit NDC family. The 9-digit NDC identifies a drug, dosage form, and strength. The Package Size Intro Date (that is, the date of introduction of a particular package size, identified by the last segment of the 11-digit NDC), may or may not coincide with the market date of the drug, dosage form, and strength, and therefore the date of introduction of a package size is not a factor in determining the market date of the drug, dosage form, and strength for the purposes of determining AMP and URA. To reiterate, the market date for the 9-digit NDC applies to every 11-digit NDC in the family and is tied to the drug, dosage form, and strength marketed under an FDA-approved application; it is not tied to the Package Size Intro Date for a particular 11-digit NDC.

Comment: Several commenters discussed the effective date of the definition of market date. The commenters inquired whether the definition will be applied retroactively and suggested that retroactive application is not permitted and would be a burden on States and manufacturers.

Response: The definition of market date adopted under this final rule applies as of the effective date of this final rule. Specifically, if a manufacturer previously reported a market date based on earlier program instructions that the market date was the earliest date the drug was *available for sale* by any manufacturer, they will not be required to change the market date to reflect the earliest date the drug was *sold* by any manufacturer. However, after the effective date of this final rule, manufacturers must use the earliest date the drug was sold as the market date for new drug products.

The finalized definition of market date will change how manufacturers determine what date to use to determine the value to report; that is, manufacturers must use the date of first sale of the drug, rather than the date first available for sale, as of the effective date of this final rule. The finalized definition does not make any changes to the already existing requirement that the market date is linked to the drug, dosage form, and strength that was first marketed under an FDA-approved application. Consistent with the statute and prior CMS guidance, the market date of a specific drug, dosage form, and strength does not change, even if the specific drug, dosage form, and strength might be subsequently marketed under a different NDC or by a different manufacturer. Specifically, prior instructions and guidance given by CMS to assist manufacturers in determining the accurate market date to report to MDP specifies that the market date is the date the drug was first available for sale under the FDA-approved application number by any labeler. This was first included in Manufacturer Release #69 (May 13, 2005). It is also included in CMS' NDRA Reference Guide, the MDP User Guide located within MDP, user manuals previously available in the older Drug Data Reporting for Medicaid (DDR) system, and in data definitions in CMS form 367c.

The finalized definition thus modifies one aspect of the previous guidance regarding market date by requiring that the relevant date be the date of first sale, while codifying CMS' historical policy that the market date does not change if a drug is purchased or otherwise acquired from another manufacturer. We reiterate that this finalized definition does not change the requirement given in previous instructions to report the market date as the earliest date the drug was available for sale by any manufacturer. For example, if a manufacturer that acquires a drug instead reports the date that they first made the NDC available for sale, then that manufacturer would be expected to correct or request that the market date be corrected in the MDP system if they were not the earliest manufacturer to sell the drug. Manufacturer Release No. 113 (June 5, 2020), available at *https://www.medicaid.gov/sites/default/files/2020-06/mfr-rel-113_0.pdf* also addresses the historic policy. That release states:

''As manufacturers evaluate their NDCs for compliance, they should also ensure they are accurately reporting the drug's market date. As stated in section 4.15 of the Medicaid Drug Rebate Data Guide for Labelers June 2019 (available within [MDP]), the market date for S, I, and N drugs marketed under an FDA-approved application (for example, BLA, NDA, ANDA) is the earliest date the drug was first marketed under the application number by any labeler. If a drug was purchased or otherwise acquired from another labeler, the market date should equal the market date of the original product. However, if a market date entered into [MDP] falls on a date that is earlier than 9/30/1990, [MDP] automatically populates the market date field with a value of 9/30/1990 (because dates earlier than the start of the MDRP are not applicable).

In addition to being a required product data field under the MDRP, the market date is also used to determine the quarter that is used to establish each drug's Baseline Average Manufacturer Price (AMP). Because the Baseline AMP is used to calculate the additional rebate portion of the Unit Rebate Amount (URA) calculation, accurate market date reporting is imperative in order to ensure that correct Baseline AMP values are established. Prior to the implementation of the additional rebate for N drugs, manufacturers may have reported a market date that represented the date they began marketing the drug, rather than the earliest date that the drug was marketed under the application number by any labeler. If this is the case, a manufacturer must request a change from the incorrectly reported market date to the correct one to ensure that the correct Baseline AMP is accurately reflected in [MDP]. CMS addresses a manufacturer's responsibility with respect to correct reporting of baseline data for a drug that was purchased from another manufacturer in Manufacturer Release No. 90 and Manufacturer Release No. 101.''

In order to request corrections to the market date, manufacturers should follow the instructions at *https://www.medicaid.gov/medicaid/prescription-drugs/medicaid-drug-rebate-program/medicaid-drug-rebate-program-change-request/index.html.*

We also note that MSIAA added civil money penalties and provided enforcement authority if a manufacturer provides false information related to drug product information, which, as explained at section F of this final rule, includes the market date. Penalties that were added by MSIAA take effect as of the effective date of MSIAA. However, if correcting a misreported market date leads to changes in a drug's URA, manufacturers may be required to reconcile prior rebate payments with the States.

Comment: In response to a request for comments about how to determine what qualifies as sold for the purposes of determining the market date of a drug, we received several suggestions. Several commenters suggested CMS allow a manufacturer to use reasonable assumptions. Reasons provided for using reasonable assumptions included that manufacturers may identify their sale date based on commercial agreements, business practices, date of payment, date of invoice, and other determining factors. Other commenters suggested that a drug should be considered sold on the date it is transferred to a purchasing entity, or that it should be based on a customer invoice date.

Another commenter suggested that a sale only occurs if the purchaser is AMP-eligible.

Response: We agree that different manufacturers may record sale dates differently, based on their business practices. Therefore, although we proposed a definition for the term sold and requested comments regarding such a definition, we will not define sold as it applies to the definition of market date and will permit manufacturers to use reasonable assumptions as to the date a sale has occurred. However, this does not mean that a manufacturer should report a market date as the date they first sold the drug when another manufacturer first sold the drug, dosage form, and strength under the FDA-approved application number at an earlier date, as doing so would be inconsistent with our previous guidance and the requirements of section 1927 of the Act. Rather, the manufacturer needs to report the market date as the earliest date the drug was available for sale by any manufacturer.

We disagree that only sales to purchasers that are AMP-eligible should be considered when determining the date on which the drug was first sold. The first date of sale, and therefore the market date, does not depend on what entity is making the purchase.

After consideration of public comments on this provision, we are finalizing the definition of market date as proposed. In the proposed, rule we requested comments on what is meant by sold and what qualifies as being sold, and we incorporated the comments we received into our review of the definition of market date. We are not creating nor finalizing a definition of sold for the purposes of determining the market date of a drug.

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

As discussed previously in the proposed rule, section 6(c) of MSIAA included a number of amendments to statutory definitions in section 1927 of the Act. Generally, those statutory amendments were discussed in the 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 MSIAA. However, although we made conforming changes to the regulatory definition of an I drug in the 2020 final rule, because MSIAA did not expressly amend 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.

In the proposed rule, after further evaluation, we proposed to amend the regulatory definition of an N drug to conform it to the regulatory definition of an I drug. We noted that when we established a regulatory definition of an N drug in the 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, 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 approved NDA, and N drugs are marketed under an approved ANDA or are unapproved.

We noted that section 1927(k)(7)(A)(iii) of the Act, which was not expressly amended or clarified by MSIAA, defines a noninnovator multiple source (N) drug as a multiple source drug that is not an I drug. As noted, MSIAA amended the statutory definition of an I drug by removing ''was originally marketed'' and adding ''is marketed,'' and we therefore made conforming changes to the regulatory definition of an I drug in the 2020 final rule. However, as noted in the proposed 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. We noted that 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 and conform with the statute's clear distinction between an I drug and an N drug, we therefore proposed 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 I drug) based on the authority under which the drug is marketed, not how the drug was originally marketed.

Accordingly, we proposed to amend § 447.502 by revising paragraph (3) of the definition of an N drug to read, ''A covered outpatient drug 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.

We received public comments on this proposal. The following is a summary of the comments we received and our response.

Comment: One commenter stated that the group they represent did not report concerns with the proposed change in definition of noninnovator multiple source drug. Another commenter supported CMS' efforts to further clarify key program definitions, including the definition of noninnovator multiple source drug.

Response: We appreciate the support of the proposed definition of noninnovator multiple source drug.

After consideration of public comments, we are finalizing the definition of noninnovator multiple source drug as proposed.

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

In the proposed rule, we included a provision that would define vaccine for the purpose of operating the MDRP. As background, we noted that 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.

Section 1927(k)(2)(B) of the Act specifically excludes vaccines from the definition of COD for purposes of the MDRP, and this provision is codified in paragraph (1)(iv) of the regulatory definition of COD at § 447.502. We noted in the proposed rule that section 1927 of the Act does not define vaccine, nor is there a relevant 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.[15] Moreover, we noted that 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. Therefore, we proposed a regulatory definition of vaccine for the purposes of the MDRP to specify which products are considered vaccines and thus excluded from the definition of COD.[16]

Specifically, we proposed 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 MDRP rebate liability. We proposed that the definition would be applicable only to the MDRP and would not be applicable to any other agencies or agency program implementation, including FDA and CDC. We stated that the definition will only be applicable to the HRSA 340B Program to the extent the definition defines what drug products are CODs but otherwise will have no applicability. We also stated that the definition of vaccine would not apply under any title XIX statutory provisions other than section 1927(k)(2), or to separate CHIPs operating under § 457.70(a)(1) and (d), or for purposes of the VFC Program. However, we noted that the definition will apply to the MDRP for purposes of Medicaid expansion CHIPs, under § 457.70(c)(2). We stated that the proposed definition would also not apply with respect to any applicable Federal or State requirements to cover immunizations for Medicaid beneficiaries.

We proposed 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. To meet the definition of a vaccine for the purposes of the MDRP, we proposed that a product must be administered prophylactically—that is, to prevent a disease and not to treat a disease—because we do not interpret the statutory exclusion of vaccines from the definition of COD to exclude drugs or biologicals that treat a disease. We also proposed that a vaccine must be administered to induce active, antigen-specific immunity because that is a characteristic of preventive vaccines.

Finally, we proposed 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, and that also appear on a current or previous list of vaccines compiled by FDA. FDA publishes a list of vaccines licensed for use in the United States.[17] As FDA is the agency responsible for licensing vaccines, we stated our belief 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 sought 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 COD and would not be subject to the requirements of section 1927 of the Act), and therapeutic vaccines (which would not satisfy the definition of vaccine and therefore could satisfy the definition of a COD and thus be subject to the requirements of section 1927 of the Act). Additionally, while we proposed to limit this definition to the MDRP, we sought comment on whether this definition might result in indirect consequences for Medicaid benefits other than the prescribed drugs benefit. We also requested comment about the consequences for Medicaid of ACIP's recommending immunization with a product that would not qualify as a vaccine under this definition.

We appreciate the thoughtful comments we received on this issue. At this time, we are not finalizing the proposed regulatory definition. We are continuing to review the input provided by commenters on the proposed definition, which may inform future rulemaking on this topic.

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

In the proposed rule, we proposed revisions to the regulations for the determination of best price at § 447.505(d)(3) 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.

We described that 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. Consistent with this provision, in 2007, CMS promulgated § 447.505(e)(3) (currently § 447.505(d)(3)) to make clear that in order to reflect market transactions, the best price for a rebate period should be adjusted by the manufacturer if cumulative discounts or other arrangements subsequently adjust the prices actually realized.[18]

In the 2016 COD final rule, in response to a comment, CMS further

[15] 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.

[16] Beginning October 1, 2023, under section 11405 of the Inflation Reduction Act of 2022, States were required to cover approved adult vaccines recommended by the ACIP, and their administration, for many adults enrolled in Medicaid and all adults enrolled in CHIP, without cost sharing. States are required to cover COVID–19 vaccines and COVID–19 vaccine administration through September 30, 2024, for all CHIP beneficiaries and nearly all Medicaid beneficiaries. For more information on Medicaid and CHIP vaccination coverage, including on what types of CDC/ACIP recommendations are relevant to that coverage, see *https://www.medicaid.gov/sites/default/files/2023-06/sho23003.pdf.*

[17] *https://www.fda.gov/vaccines-blood-biologics/vaccines/vaccines-licensed-use-united-states.*

[18] *https://www.govinfo.gov/content/pkg/FR-2023-05-26/pdf/2023-10934.pdf.*

clarified 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. CMS' response provided a specific example in which two best price eligible entities each receive a rebate or discounts for the same drug transaction as it moves through the supply chain, such as a rebate paid by a manufacturer to a PBM where such rebate is designed to adjust prices at the retail or provider level, and a discount to a retail community pharmacy. Each transaction adjusts the final price realized by the manufacturer for the sale of that drug. That is, all discounts, rebates, and price concessions related to that transaction, which adjust the ultimate price realized by the manufacturer, should be considered in the manufacturer's final price of that drug when determining the best price to be reported.[19]

We indicated that we have considered stacking, as stated in the preamble to the 2016 COD final rule, as consistent with current § 447.505(d)(3), which requires that if cumulative discounts subsequently adjust the price available from the manufacturer, they should be included in the best price calculation. We indicated that the proposed revisions to the regulatory text at § 447.505(d)(3) would make clearer that manufacturers must stack all applicable price concessions 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.

We received comments both supporting and opposing the proposed revisions to § 447.505(d)(3). Based on these comments, we are not finalizing the proposal at this time. Instead, we are going to pursue the collection of additional information from manufacturers related to best price stacking methodologies to inform future rulemaking. We will continue to consider the comments regarding stacking during this time.

While we believe that some manufacturers are already using some type of stacking methodology in determining their best price, we believe it important to further understand the various ways that manufacturers are, in fact, determining their best price and the extent they are using a stacking methodology in doing so. We understand from a 2019 OIG report (Reasonable Assumptions in Manufacturer Reporting of AMPs and Best Prices) [20] that about half of the manufacturers responding to the survey indicated that they did stack their price concessions in determining best price, but several indicated that they wanted additional guidance from CMS.

We intend to undertake a separate collection of information from manufacturers to help us better understand the areas in which additional guidance might be useful related to stacking methodologies. The information collection would be intended to ascertain whether a manufacturer implements any form of stacking and, if so, how that stacking is performed.

We acknowledge that we may not have all the information necessary to assess how stacking impacts manufacturers' reporting of best prices. Collecting this additional information will assist the agency in its consideration of the stacking issue and the comments submitted and may inform future rulemaking.

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

In the proposed rule, we included a provision that would withdraw changes to our regulations found at §§ 447.504 and 447.505, based on a court order. As background, on June 19, 2020, CMS proposed regulations to address the effect of PBM accumulator adjustment programs on best price and AMP calculations (85 FR 37286) in relation to purported manufacturer financial assistance payments (that is, financial assistance payments in the form of copay coupons to patients for purposes of paying the patient cost obligation of certain drugs) by instructing manufacturers on how to consider the impact of such programs when determining best price and AMP for purposes of the MDRP. CMS proposed that the exclusions for manufacturers' 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). The 2020 final rule finalized this proposed change and 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'' (85 FR 87053).

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

In response to this court order, we proposed in this rule to withdraw the applicable changes made to the best price regulation and to also withdraw the corresponding changes to the AMP regulation to apply consistent rules for determining best price and AMP. Thus, in making this proposal, we suggested the removal of 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 proposed the removal of the phrase ''the manufacturer ensures'' from these provisions. As a result, these regulations would revert back to the language that has been in place since 2016.

We received public comments on this proposal. The following is a summary of the comments we received and our responses.

Comment: A few commenters expressed support for the proposal to rescind the revisions made by the 2020 final rule because they were supportive of patient assistance programs and were concerned that the requirement that AMP and best price include such price concessions would have been detrimental to patient assistance programs (for example, manufacturer coupons) if adopted. Many commenters also suggested CMS search for alternative regulatory mechanisms to reduce impacts caused by the transfer of the value of patient assistance programs to payers through accumulator programs and consider ways to correctly account for such programs in Medicaid AMP and best price reporting for MDRP. They also emphasized that CMS should continue to explore ways to minimize the harmful impact of manufacturer coupons on beneficiaries and health care costs, specifically researching the effects of induced demand, unnecessary spending, and the role they play in the price manufacturers set for their drugs.

Response: We thank the commenters for sharing their views. Per the court decision, CMS is rescinding the applicable revisions made by the 2020 final rule. We will continue to explore other ways to protect consumers from accumulator programs that leave

[19] *https://www.govinfo.gov/content/pkg/FR-2016-02-01/pdf/2016-01274.pdf.*

[20] *https://oig.hhs.gov/documents/evaluation/3188/OEI-12-17-00130-Complete%20Report.pdf.*

vulnerable patient populations with a significant cost-sharing burden once a patient exhausts a manufacturer patient benefit program.

Comment: A commenter requested that CMS rescind the portion of the 2021 Notice of Benefit and Payment Parameters (NBPP) final rule that enables plans to not count manufacturer cost-sharing assistance toward patients' annual cost-sharing limits, thereby effectively enabling the use of PBM accumulator programs, which are harmful to patients.

Response: We thank the commenter but note that this request is outside of the scope of this final rule.

Given the direction by the court's ruling to vacate and set aside the changes made by the 2020 final rule, we are finalizing as proposed 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).

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)

In the proposed rule, we included a new process to identify, notify and correct a manufacturer's drug category misclassifications. As background, we noted that section 6 of 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 regarding the 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 (S), innovator multiple source (I), or noninnovator multiple source drug (N)—for the purposes of determining the correct rebates that a manufacturer owes the States. We noted that 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.

We noted that 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. 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.

Although much of this law is self-implementing, we proposed a series of regulatory amendments at §§ 447.509 and 447.510 to implement and codify the statutory changes in regulation. In § 447.509, we proposed 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 MSIAA, which amended sections 1903 and 1927 of the Act.

MSIAA also 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 civil monetary penalties (CMPs) by the HHS Office of the Inspector General (OIG), and to provide specific new authority to the Secretary to issue CMPs related to knowing misclassifications by drug manufacturers of drug product or misreported information. We clarified in the proposed rule that these new OIG authorities were not a subject of this rulemaking.

We also noted that, under 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.

a. Summary of Misclassification and General Comments Relating to Proposed Regulation (§ 447.509(d)(1) Through (4))

We proposed 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, notify a manufacturer that we have determined that a drug is misclassified in MDRP, clarify the manufacturer's responsibility to pay past rebates due to the misclassification, and indicate the penalties that may be imposed on the manufacturer.

We received several general public comments on these proposals. The following is a summary of the general comments we received and our responses.

Comment: Some commenters provided overall support of the misclassification sections of the proposed rule in § 447.509(d), as they believe it would lead to more accurate and consistent manufacturer reporting and transparency, allow CMS to be able to correct drug misclassifications, and penalize manufacturers in effective ways if they continue to misclassify their drugs and not correct their misclassifications. Other commenters expressed some level of support but raised concerns about using suspension of the drug from the MDRP as the tool for compliance with the new misclassification requirements, or about the feasibility of the timelines.

Response: We thank the commenters for their support and address the specific concerns in more detail later in this section.

Comment: Many commenters opposed various components of the proposed enforcement options under MSIAA for those manufacturers that have misclassified their drugs and continue to misclassify their drugs. The commenters stated that these proposed enforcement regulations are overly broad, and CMS lacks statutory authority to propose them.

Response: We appreciate the comments and address the specific concerns in more detail with the other comments. However, we note that the proposed regulations align with the requirements in the applicable statutes, which gives CMS statutory authority to implement these regulations.

Comment: A few commenters urged CMS to explicitly state in the final rule that manufacturers who fail to provide 340B discounts during the suspension of the drug due to the misclassification of the COD will face civil monetary penalties. The commenters also seek clear guidance on coverage and payment for 340B-eligible products in relation to Medicaid during such suspensions of the drug due to misclassification.

Response: CMPs for not providing 340B pricing are outside the scope of the rule and will not be addressed. However, regarding coverage and payment for 340B-eligible products during the period of the suspension of the COD for misclassification, manufacturers must still provide drugs through the 340B Program pursuant to 42 U.S.C. 256b, and 340B covered entities may dispense those medications to eligible patients. To the extent the patients who receive these drugs acquired under the 340B Program are Medicaid beneficiaries, FFP would not be available for the claims for these drugs as Medicaid FFP is not available for the misclassified drug or drugs of this manufacturer during the period of the suspension. States could opt to cover those claims through State-only funds.

Comment: A few commenters suggested that MSIAA can only be applied prospectively and any efforts to deem a product as misclassified or impose any penalties retrospectively cannot be done. Specifically, several commenters suggested that no misclassification can apply prior to April 18, 2019, the effective date of MSIAA.

Response: The provisions of 42 CFR 447.509(d) become effective on the effective date of this final rule. However, there is no provision in the statute which would exempt manufacturers from their responsibility of correcting their misclassification from before 2019. Manufacturers have always been responsible for accurate reporting of the classification of their drug and must certify to the completeness and accuracy of that reporting when submitting data to CMS to comply with statute and regulation, as well as the terms of the NDRA. MSIAA provided new authorities to CMS to enforce this requirement with respect to drug misclassification, including the ability to identify and correct a manufacturer's misclassification as well as impose other penalties on manufacturers that fail to correct their misclassifications. CMS already provided guidance to manufacturers regarding MSIAA in Manufacturer Release #113 on June 5, 2020. This rule provides additional regulatory support to that guidance.

Comment: A commenter expressed concern that the proposed rule inappropriately attempts to end-run a 6-year statute of limitations. The commenter stated that CMS is attempting to apply penalties to manufacturers for drug category misclassifications that occurred for periods prior to 2Q2016. As such, the commenter stated that such claims would likely be time-barred today. The commenter also stated that what the commenter alleged to be CMS' failure to act on narrow exception request appeals in a timely manner should not result in the application of the civil monetary penalty process to drugs that may have been misclassified during such time periods.

The commenter suggested that CMS consider drug classification assumptions made by manufacturers in periods prior to 2Q2016 to have been made on their merits (to the extent not already time-barred), without summarily rejecting them because they were made prior to the establishment of the ''narrow exception'' process. In particular, the commenter suggested that products granted narrow exception status should be assumed to be ''N'' drugs prior to 2Q2016, consistent with reasonable assumptions made contemporaneously by the manufacturer.

Response: The development of a narrow exception process in the 2016 COD final rule, 81 FR 5170 (February 1, 2016) did not change the MDRP manufacturer drug classification requirements prior to the development of that process. In addition, CMS provided guidance to manufacturers regarding MSIAA in Manufacturer Release #113 on June 5, 2020.

Comment: A couple of commenters requested that CMS clarify that no manufacturer will be penalized if the manufacturer has an active and pending narrow exception request and/or appeal. Some suggested CMS should revise the definition of misclassification to make clear that the definition does not include a COD for which a manufacturer has submitted a narrow exception request but has not received a written response from CMS regarding the disposition of that narrow exception request.

Response: We agree that no penalty would apply until CMS completes the narrow exception process. We do not believe this needs to be addressed in the regulation, and no change to the definition of misclassification is needed.

b. Definition of Misclassification—§ 447.509(d)(1)

We proposed to define what constitutes a misclassification in paragraph (d)(1). As proposed at § 447.509(d)(1)(i), a 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.

We also proposed 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 as 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.

We received public comments on these proposals. The following is a summary of the comments we received and our responses.

Comment: Several commenters stated that the definition of misclassification should only apply to the drug product's classification under the MDRP and that MSIAA does not authorize CMS to include any other misreported or inaccurate drug product information that may have been reported by the manufacturer in the definition of misclassification.

These commenters also expressed concern about the phrase ''any other information CMS deems necessary'' in the drug product information definition. They stated that what they called this ''open-ended'' phrase may result in the inclusion of drug product information in the definition of misclassification to exceed the authority granted in MSIAA. They suggested ''drug product information'' should be deleted from 447.509(d), but if not, the ''open-ended'' language in the definition of drug product information should be removed.

Response: We believe that drug product information can be included in the definition of misclassification. The statute does not define drug misclassification, and we believe the Congress intended the term misclassification to include any incorrect drug product information reported by the manufacturer, including but not limited to inaccurate drug category. Section 1927(c)(4)(B)(ii)(I) of

the Act provides the Secretary with the authority to use drug product information reported by a manufacturer to correct a drug misclassification. Moreover, section 1927(b)(3)(C)(iii) of the Act subjects a manufacturer to CMPs if it misclassifies a COD, such as by knowingly submitting incorrect drug product information, or if the manufacturer pays rebates at a level other than that associated with the drug's classification. This provision clarifies that incorrect drug product information constitutes a misclassification under section 1927(b)(3) of the Act. Through statutory construction, it implies that incorrect drug product information in section 1927(c)(4) of the Act is considered a misclassification as well. Thus, we are including drug product information in the definition of misclassification.

As addressed in the drug product information section, we agree that the phrase ''any other information CMS deems necessary'' should be removed from the drug product information definition. Therefore, we have removed this phrase in this final rule.

Comment: One commenter noted that the proposed definition omits any mention of the extent to which the manufacturer had to have knowledge of incorrect drug product information reporting that is necessary to give rise to the sanctions contemplated by the statute. They suggested that the regulation should clearly require that the manufacturer knowingly misclassified the drug.

Response: Section 1927(d)(4) of the Act expressly states that a drug misclassification can occur without regard to whether the manufacturer knowingly made the misclassification or should have known that the misclassification would be made. It is the legal responsibility of the manufacturer to report and certify the correct classification of its covered outpatient drugs as well as the drug product information associated with those covered outpatient drugs.

c. Manufacturer Notification by the Agency of Drug Misclassification—§ 447.509(d)(2)

We proposed at § 447.509(d)(2) that if the agency makes a determination of a misclassification, the agency would send a written and electronic notice to the manufacturer, which may include a notification that past rebates are due. The manufacturer would have 30 calendar days from date of the notice to submit the corrected drug product information as well as any additional drug product and pricing information necessary to calculate its rebate obligations to the States. For example, if a manufacturer misclassified a drug as an N when it should have been an S or I, then the manufacturer must submit the correct drug category as well as the drug's ''best price'' data for the period or periods during which it was misclassified because that data is required to calculate rebate obligations applicable to S or I drugs, but not N drugs. Once the information is changed in the MDP system, the manufacturer must certify the data.

Upon notification by CMS that the manufacturer's information was updated in the system, we proposed that the manufacturer certify the applicable price and drug product data. We proposed that the manufacturer must correct the misclassification and respond to the agency's request to certify the information in the system within that same timeline of 30 calendar days from the date of the original notification to the manufacturer of the misclassification.

We received public comments on these proposals. The following is a summary of the comments we received and our responses.

Comment: Several commenters raised concerns that the proposal regarding the 30-day period for manufacturers to correct misclassification is unreasonable and exposes manufacturers to enforcement action with potential severe consequences and request that CMS allow manufacturers more than 30 days post notification to provide and certify data. One commenter suggested that CMS should liberally provide for reasonable extensions to accommodate complex reclassification and payment obligations.

Response: We believe that the 30-day period is sufficient in most circumstances for manufacturers to correct and certify a data field. Misclassification can affect the amount of rebates owed by manufacturers to States, so it is important that it be addressed in a timely manner. In other circumstances, manufacturers can informally request extensions. Accordingly, if there are extenuating circumstances that result in the manufacturer not being able to make the change within 30 days, they may request an informal extension of this deadline as well.

Comment: Some commenters urged CMS to adopt into the regulation a dispute resolution process because they believe it is unfair that CMS can solely determine if a misclassification occurred. Other commenters suggested a collaborative process or a process by which manufacturers are afforded the opportunity to investigate and validate suspected misclassifications with the Agency before the start of the corrective action. They recommend that the 30-day correction period start once the manufacturer has validated with the Agency that a correction is needed.

Response: This misclassification process that was established in MSIAA does not provide for a specific dispute resolution process for misclassified drugs. CMS is implementing what the Congress set forth, which did not propose a dispute resolution process. However, we will take this suggestion into consideration for future rulemaking.

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

Once a determination that a misclassification has occurred in § 447.509(d)(1) and the manufacturer has been notified of the misclassification in accordance with the proposed process steps at § 447.509(d)(2), we proposed 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 proposed that a manufacturer must pay to each State an amount equal to the sum of the products of the difference between: the per unit rebate amount (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 proposed in § 447.509(d)(3)(i) a requirement for manufacturers to pay these unpaid rebate amounts and proposed to codify at § 447.509(d)(3) the timeframe by which the manufacturer must pay the 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. Specifically, we proposed that 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 also proposed

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.

We received public comments on these proposals. The following is a summary of the comments we received and our responses.

Comment: Several commenters supported the idea that manufacturers must pay unpaid rebates that result from the correction to misclassifications. One commenter recommended CMS clarify that this is not limited to the previous 12 quarters.

Response: We appreciate the support and agree that past due rebates from manufacturers to States for misclassified drugs are not limited to just the previous 12 quarters. Manufacturers are responsible for providing accurate information to CMS for their CODs for the entire amount of time that the COD is reported in the system, and if the inaccuracy of the reported drug product information goes back more than 12 quarters, manufacturers should address it back to the beginning of the reporting of the incorrect drug product information.

Comment: A couple of commenters suggested that the payment of unpaid rebates cannot go back further than 10 years since the manufacturer record retention requirement is 10 years. They noted that it might be difficult to meet this requirement in circumstances where the drug was determined to be misclassified more than 10 years ago.

Response: There is no time limit in section 1927 of the Act regarding manufacturers paying unpaid rebates back to States, whether for misclassification of the drug or for other reasons. In other words, there may be several reasons why a manufacturer may owe States past due rebates, and that is not necessarily limited to drug misclassifications. We note that 42 CFR 447.510(f) does include a 10-year record keeping requirement for manufacturers with respect to their price reporting. However, there are also provisions in that section that require record keeping beyond the 10-year period in certain circumstances, including situations in which the records are subject to a government investigation or audit relating to pricing data of which the manufacturer is aware (so long as that investigation or audit began within the 10-year time period).

Comment: A few commenters expressed concerns about a manufacturer's ability to meet the 60-day requirement to pay owed rebates for misclassified drugs due to the volume of rebate invoices they already receive from States under the MDRP and would further receive under this provision. Commenters also stated that 60 days is an insufficient amount of time to confirm a drug has been misclassified, collect and submit the information to CMS, calculate any owed rebates to the States, make the payment to the States, and provide documentation to CMS that it is completed.

The commenters suggested the payment of any rebates due to misclassification should be facilitated through the same mechanism currently used for Medicaid rebates so they would be processed as prior quarter adjustments. Another suggested that 180-day periods be allowed to pay rebates due to misclassification (with reasonable extensions to accommodate complex reclassification and payment obligations) since that timeframe would be more reasonable. Another commenter requested CMS provide manufacturers with the opportunity to start the 60-day timeframe when the URA is updated in the MDP system.

Response: We disagree with the commenters' contentions and believe that the assessment of a misclassification of a COD, and any resulting rebate payments, can be made by the manufacturers within the 60-day limit. Manufacturers must process revised rebates, which includes calculating any updated pricing statistics, such as best price and AMP, report those to CMS and certify them, and then use those revised data to calculate new URAs for the misclassified drug. Manufacturers must then use those data to adjust the rebates that they have already paid to the State for the misclassified drug and pay those adjustments to the State. We believe that a process separate from the normal quarterly rebate cycle would help States ensure that the payments were made for these misclassified drugs and could be tracked by States.

A separate process can ensure there is a collection for rebates due for past quarters resulting from the misclassification. We also believe that processing these requests for rebates for misclassified drugs as the misclassification occurs rather than waiting for a quarterly rebate invoice process ensures that the misclassification is handled timely and appropriately. Accordingly, we believe a manufacturer can address a misclassification and any subsequent rebate payment within the 60-day timeframe.

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

We proposed § 447.509(d)(4), consistent with section 1927(c)(4)(B) of the Act, which would allow 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 proposed 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 and to certify applicable pricing and drug product information within 30 calendar days after the agency notifies the manufacturer of the misclassification, 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 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.

We also proposed at § 447.509(d)(4)(iv) to indicate that, in addition to the actions described previously in the 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. We noted that 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 proposed that a manufacturer may be subject to termination from the program if it fails to meet the agency's specifications for participation in the MDRP program as proposed when it is in violation of section 1927(b)(4)(B)(i) or (c)(4)(D) of the Act. This 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 noted 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.

We also clarified that suspension of a drug under this section as a COD due to a misclassification would not affect its status as a reimbursable drug under Medicare Part B or a drug covered under the 340B Program.

We received public comments on these proposals. The following is a summary of the comments we received and our responses.

Comment: Some commenters expressed support for CMS to be able to reclassify a misclassified drug. Other commenters raised concerns about CMS being able to do this and suggested having a collaborative process or a dispute resolution process if the manufacturer disagrees.

Response: We acknowledge the commenter's concern but note that manufactures can collaborate with CMS under the process set forth in the proposed rule. As stated previously, under § 447.509(d)(2), when a manufacturer is notified of a misclassification, it must provide the information necessary to correct the misclassification. Upon receipt, CMS will make the corrections, and then the manufacturer must certify the applicable price and/or drug product information entered by CMS. This process allows for manufacturers to work with CMS to ensure the information in the system is accurate.

It is only when the manufacturer takes no action to correct the misclassification that section 1927(C)(4)(B)(i) of the Act now gives CMS authority to correct misclassifications on behalf of the manufacturer. Thus, the regulation gives the manufacturer time to correct the misclassification and work with CMS to ensure the information is accurate, but if they do not, in accordance with the statute, CMS can use pricing and drug product information provided by the manufacturer to make the correction. This is one of several actions CMS may take if the manufacturer has not corrected the misclassification in a timely manner.

In the Medicaid Drug Rebate Program Data Guide (July 2023), we clarified that any change made in the MDP system, including any change made by CMS, must be certified by the manufacturer in order for the changes to be effective in the MDP system. This applies to any changes made pursuant to CMS' authority in § 447.509(d)(4). Given the comments and concerns raised, we are amending the regulatory text in § 447.509(d)(4)(i) in this final rule to be consistent with this guidance and to clarify that any changes made by CMS must be certified by the manufacturer. Manufacturers will be given 30 days to certify those changes; if they do not, then CMS may take other authorized actions against the manufacturer.

Finally, we note that the process to address misclassifications was established in MSIAA, and no dispute process was included in the statute. That said, we will consider such a process for future rulemaking.

Comment: Some commenters mentioned that if CMS and the manufacturer are in a disagreement regarding a misclassification, CMS should not revise the pricing data points. They suggest this should be part of future rulemaking.

Response: Pursuant to the statute, CMS has authority to correct a misclassification using the drug product information provided by the manufacturer on behalf of the manufacturer. The enforcement provisions in section 1927(c)(4)(B)(ii) of the Act provide options for CMS to take action when a manufacturer fails to correct a misclassification. CMS' current process within the MDP system requires the manufacturer to certify any change made in the MDP system. However, CMS may certify changes on behalf of the manufacturer and would do so in this specific situation. We do not believe any additional regulatory changes are necessary based on these comments.

Comment: Some commenters expressed support of CMS being able to impose the enumerated penalties in § 447.509(d)(4). Several raised concerns specifically about the use of the suspension penalty. Some provided suggestions for other enforcement actions, such as keeping the drug available to Medicaid beneficiaries and taking other actions such as the manufacturer covering the entire cost of the drug during the suspension period, increasing the maximum civil monetary penalty that may be imposed, or only imposing the suspension after repeated failure by the manufacturer to correct the misclassification. One commenter suggested the suspension should only be imposed if the misclassification has a material impact on rebates.

Response: We appreciate the suggestions regarding enforcement actions and the concerns that are raised about suspensions specifically. The statute sets forth several alternative penalties, including CMS making the correction on behalf of the manufacturer, civil money penalties, and suspension of the misclassified drug. CMS has incorporated these options into § 447.509(d)(4) and provides for flexibility for which penalties will be imposed on the manufacturer. As noted previously, misclassifications of CODs that occurred prior to 2019 must be corrected and must be done so in accordance with the provisions in § 447.509(d). There is no provision in the statute which would exempt CODs from these provisions if they were misclassified before 2019. If the manufacturer does not take such actions to correct misclassifications of their CODs, the penalties contained in § 447.509(d)(4) will apply.

Comment: A commenter supported the proposed enforcement actions and penalties as long as those are limited to data within the 10-year retention period.

Response: As noted in other responses to comments, the reporting requirements under section 1927 of the Act are not limited to 10 years and, as such, changes may be necessary to correct misclassifications that were reported more than 10 years ago. In the absence of guidance and adequate documentation to the contrary, manufacturers may make reasonable assumptions that are consistent with the requirements and intent of section 1927 of the Act and Federal regulations for reporting data for time periods prior to

10 years if they did not retain documents. However, if manufacturers do not take the actions set forth in § 447.509(d)(2) and/or (3), the penalties in § 447.509(d)(4) may be applied.

f. Transparency of Manufacturers' Drug Misclassification—§ 447.509(d)(5)

We proposed § 447.509(d)(5) 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.

We received public comments on these proposals. The following is a summary of the comments we received and our responses.

Comment: Several commenters supported CMS' proposal that to meet the requirements of section 1927(c)(4)(C)(ii) of the Act, CMS will provide public notice of misclassification of drugs through annual reporting on a public website. One commenter questioned whether the report will include drug pricing information.

Response: We appreciate the support of CMS' proposal. For the question about including drug pricing information, we will not include such information. The report will only include items that were used in making the determination that the drug was misclassified, which will not include any proprietary or confidential pricing information. Instead, as included in the proposed rule, the report will include the CODs that were identified as misclassified, any steps taken by CMS to reclassify the drugs and ensure payment of unpaid rebate amounts, and a disclosure of the expenditures of the funds created under section 1927(b)(3)(C)(iv) of the Act.

After consideration of public comments on this provision, we are finalizing § 447.509(d) as proposed with the exception of making a modification to proposed § 447.509(d)(4)(i), which will be amended to add the following language at the end of that section: ''In such case, the manufacturer must certify the applicable correction within 30 calendar days.''

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

Section 447.510(h) describes the process by which a manufacturer's NDRA would be suspended after a manufacturer fails to report information, which includes drug pricing and drug product information, as described in section 1927(b)(3)(A) of the Act, within a specified timeframe. This drug product and pricing information includes 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(h)(1) (originally § 447.510(i) in the proposed rule), proposed that if a manufacturer fails to provide the information required to be reported to the agency under § 447.510(a) and (d), the agency will provide written notice to the manufacturer of the failure to provide timely information and provide a deadline by which such information must be reported. If the manufacturer does not report the information within 90 calendar days after that deadline, the manufacturer's rebate agreement will be suspended for all CODs furnished after the end of the 90-calendar-day period. Further, the rebate agreement will remain suspended for Medicaid until such information is reported in full and certified, but not for a period of less than 30 calendar days. This section also proposed that continued suspension of the rebate agreement could result in termination for cause.

As noted in the proposed rule, 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 Program.

Under proposed § 447.510(i)(2), we indicated that the agency would notify the States 30 calendar days before the effective date of the manufacturer's suspension. In the preamble to the proposed rule, we noted that the suspension of a manufacturer's agreement, and loss of the availability of FFP for a period of time, would likely mean that these manufacturer's drugs would not be available to Medicaid beneficiaries during the period of the suspension. We indicated that the 30-day notice would give States time 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 also stated our belief that the intermediate step of suspension rather than termination should be sufficient incentive for 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 also stated that we believe the proposed process provided clear 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.

We received public comments on these proposals. The following is a summary of the comments we received and our responses.

Comment: Some commenters provided overall support of the proposed rule in § 447.510(i).

Response: We thank the commenters for their support.

Comment: Several commenters expressed opposition to the proposed suspension regulations in general or to specific provisions within the proposed regulations.

Response: We appreciate the comments and note that the proposed regulations align with the requirements in the applicable statutes.

Comment: Several commenters urged CMS to explicitly state in the final rule that manufacturers who fail to provide 340B discounts during the suspension of the NDRA will face civil monetary penalties. Commenters also seek clear guidance on coverage and payment for 340B-eligible products in relation to Medicaid during such suspensions.

Response: CMPs on manufacturers for not providing 340B pricing is outside the scope of the rule and will not be addressed. However, regarding coverage and payment for 340B-eligible products during the period of the suspension of the COD for misclassification, manufacturers must still provide drugs through the 340B Program pursuant to 42 U.S.C. 256b, and 340B covered entities may dispense those medications. To the extent the patients who receive these drugs acquired under

the 340B Program are Medicaid beneficiaries, there would be no FFP available for the claims for these drugs as Medicaid FFP is not available for the misclassified drugs of this manufacturer during the period of the suspension. States could opt to cover those claims through State-only funds.

Comment: A commenter suggested that while CMS' ability to suspend NDRAs might prompt quicker pricing data disclosures, it does not guarantee their accuracy; thus, CMS should audit suspicious claims.

Response: We appreciate the concern. Under section 1927(b)(3)(A) of the Act, manufacturers have always been required to accurately report their data to CMS, and in a timely manner as prescribed by statute. Upon submitting their data, manufacturers certify their completeness and accuracy. If a manufacturer subsequently needs to adjust their pricing or product data, it may do so within specified periods of time and under certain conditions, and may also adjust rebates paid to States, if applicable. If CMS suspects that the manufacturer's data is not complete or inaccurate, CMS will contact the manufacturer to inquire about the data's completeness or accuracy, or if there are still questions about the completeness or accuracy of the data, the manufacturer can be referred to the OIG.

Comment: Some commenters suggested CMS provide a weekly file or use another system to provide the updated suspended manufacturer information on a more timely basis.

Response: For terminations of manufacturers from the program, States are given a 30-day notice through a notification system, and such terminations are noted at *https://www.medicaid.gov/medicaid/prescription-drugs/medicaid-drug-rebate-program/newreinstated-terminated-labeler-information/index.html.* CMS will use the same type of process to notify affected parties of suspensions of manufacturer rebate agreements, and the status of such suspensions.

Comment: Many commenters suggested that providing a 30-day notice to States regarding an upcoming suspension is too short. They expressed concern about the impact on patient care. Others noted that it is unclear how long the suspension will last, which impacts a State's decision on coverage of a suspended manufacturer's covered outpatient drugs.

Response: We provide a 30-day notice for terminations and believe that it makes sense for this to be consistent for suspensions. After the minimum 30-day suspension, the suspension can end as soon as the late information is reported to CMS, CMS has reviewed for completeness, and the manufacturer certifies the data. We also note that the length of the suspension depends on how soon the manufacturer reports the data.

Comment: Some commenters expressed concerns over CMS' proposed 90-day window for manufacturers to provide information that was not received by the statutory deadline prior to suspension. They expressed a need for flexibility and requested additional time for data review and validation.

Response: The statute does not allow for flexibility in the timeline, and we believe the timeline is reasonable. The statute states that if the information is not reported within 90 days of the imposed deadline, the manufacturer's rebate agreement shall be suspended. Manufacturers are expected to report on a timely basis; this proposal provides an additional 90 days after missing a deadline to report prior to suspension.

Comment: Several commenters expressed concern regarding the requirement that CMS suspend a manufacturer's NDRA for a minimum of 30 days. Commenters also advocated for alternative compliance measures such as fines or extended deadlines.

Response: We appreciate the comments but note that a suspension is required by the statute. The statute requires the suspension for no less than 30 days. We proposed that the manufacturer is suspended until the date the information is reported to the agency and the agency reviews for completeness but not for a period of fewer than 30 days.

The Secretary is authorized to impose penalties for late reporting. CMS notes that the statute authorizes penalties for each day in which the information has not been provided, and if such information is not reported within 90 days of the imposed deadline, the agreement shall be suspended. Penalties are assessed by the OIG and are outside the scope of this rule; our rule addresses the situation once the suspension phase is reached.

Comment: Several commenters noted that the loss of FFP could result in an increased cost to the State if the products are covered with State-only funds, which may result in States not covering the products and effectively end coverage of these products. Some suggested that the claims should not lose eligibility for Federal funding or should be eligible for an additional 60 days after notice of suspension.

Response: As noted in our preamble in the proposed rule, during the period of a suspension, the claims for the suspended drug are not eligible for FFP. States may cover the product using State-only funds if they choose or may choose to not cover the products while the product is suspended. This is consistent with other coverage decisions of products for which there is no FFP. Our hope is that manufacturers will choose to report their required information in a timely manner and not be subject to this suspension.

Comment: One commenter requested CMS clarify if FFP would be available for crossover Part B claims for these drugs.

Response: FFP would not be available for Part B crossover claims for dual eligibles. As we noted in the proposed rule, reimbursement availability under Medicare Part B would not change. Thus, our rule does not impact Medicare coverage or reimbursement. However, for crossover purposes, the claim would not be eligible for FFP if the Medicaid program made any payment on the claim. In addition, the claim would not be eligible for manufacturer rebates.

After consideration of public comments on this provision, we are finalizing this provision as proposed.

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

In the proposed rule, we added provisions that would make conforming changes to our regulations based on section 9816 of the American Rescue Plan Act (ARP) of 2021, which sunsetted the limit on maximum rebate amounts for single source and innovator multiple source drugs by amending section 1927(c)(2)(D) of the 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 the 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.

We noted that section 2501(e) of the Affordable Care Act had 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 dosage form and strength of a single source or innovator multiple source drug at 100 percent of AMP, effective January 1, 2010. This limit or ''rebate cap'' 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 each dosage form and strength of such drugs if the AMPs of such drugs increase at a rate that exceeds the rate of inflation. This provision of BBA 2015 was effective beginning with the quarter starting on January 1, 2017, and the limit on maximum rebates for drugs other than single source or innovator multiple source drugs was added at § 447.509(a)(9).

To align § 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 proposed 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 proposed to amend § 447.509(a)(5) and (9) to state that the limit on maximum rebate amounts applies to certain timeframes, 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.

We received public comments on these proposals. The following is a summary of the comments we received and our responses.

Comment: Commenters commended CMS' proactive steps in aligning the regulations with the ARP provision to remove the manufacturer rebate cap by January 1, 2024. One commenter indicated that while they support the proposed change to regulation on the manufacturer rebate cap, they also believe the Secretary should be given flexibility to reduce Medicaid inflation rebate amounts owed under the MDRP for drugs in shortage, consistent with a separate policy enacted under the Inflation Reduction Act for rebate amounts owed under the Medicare Prescription Drug Inflation Rebate Programs.

Response: We appreciate the support for the revisions made to the regulation to remove the manufacturer rebate cap. As for the comment regarding drug shortages, there is no statutory authority for the Secretary to reduce rebate amounts or ''cap'' rebates with respect to the MDRP in cases when a drug is in shortage.

Comment: A commenter raised concerns that the proposed rule prompts questions about the 340B Program's ''penny pricing policy,'' potentially leading to negative ceiling prices, and how that aligns with the intention to penalize manufacturers for rapid price hikes. Specifically, the commenter requested that CMS work with HRSA to clarify the impact of this provision on HRSA's ''penny pricing policy,'' which requires that when the ceiling price calculation at 42 CFR 10.10(b) results in an amount less than $0.01, the 340B ceiling price will be $0.01. The commenter stated that the current policy needs to be addressed given that, beginning January 1, 2024, the ceiling price calculation for the 340B Program could be a negative number substantially lower than $0.01.

Response: This comment is outside of the scope of this rule. HRSA administers the 340B Program and developed the policy referred to as ''penny pricing'' when the ceiling price (the maximum price a manufacturer may charge a 340B covered entity) is zero. We note that while CMS does not administer the 340B Program, HRSA and CMS often work together when statutory changes to the MDRP may affect the 340B Program. These comments have been shared with HRSA.

Comment: A commenter requested that CMS adopt what the commenter considers to be a ''standard'' definition of ''rebate,'' that would ensure that rebates under the MDRP do not surpass the State Medicaid program's payment for a drug, eliminating potential constitutional concerns and ambiguities. The commenter indicated that the meaning of ''rebate'' is compelled not only by the plain language of the statute, but also by constitutional doctrines. The commenter stated that the Takings Clause of the Fifth Amendment to the United States Constitution (Takings Clause) supports this meaning because, otherwise, manufacturers could be deprived of the economic value of their drugs and, in some cases, even forced to pay States to dispense or administer their drugs to Medicaid recipients. Furthermore, the commenter indicated that Federal courts have consistently recognized that ''completely depriv[ing] an owner of 'all economically beneficial us[e]' of her property,'' or ''reduc[ing] to zero'' the economic value of something, such as a drug product, would constitute a taking, which presupposes, a fortiori, that making each sale cost the company more than it earns would also affect a taking. The commenter noted that the interpretation of the statute to which the commenter objects would take drug manufacturers' property based on actions (such as price increases) that took place long before the law was enacted, raising significant retroactivity concerns that also implicate the Takings Clause.

The commenter indicated that these retroactivity concerns also implicate the Due Process Clause, which ''protects the interests in fair notice and repose that may be compromised by retroactive legislation.'' The commenter noted that drug manufacturers made business decisions years ago based on their understanding that they would supply drugs at a discount under the MDRP, not pay States to dispense or administer their products to Medicaid recipients. The commenter stated that if the agency were to stray from the ordinary meaning of ''rebate,'' that would effectively impose a potential penalty without providing manufacturers with the requisite ''fair warning of the conduct [the] regulation prohibits or requires.'' The commenter recommended CMS codify in § 447.509 that, irrespective of the sunset of the statutory AMP rebate cap, there is a separate and distinct natural limit on MDRP rebates stemming from the ordinary meaning of the term ''rebate'' that does not permit such rebates to exceed State purchase prices. The commenter recommended CMS address this directly and adopt this ordinary meaning of the term ''rebate'' by regulation so that there is no ambiguity on this point among the State Medicaid programs.

Response: The ARP did not define rebate for purposes of the MDRP, and CMS is not defining the term rebate as part of this final rule. Furthermore, the amount of the rebate that is paid by the manufacturer is not solely driven by the statute's removal of the cap, but also by how much a manufacturer increases its drug prices, as reflected by changes in the AMP, compared to the rate of inflation.

After consideration of public comments on this provision, we are finalizing as proposed.

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

In the proposed rule, we included a provision that would replace each appearance of the term ''noninnovator multiple source drug(s)'' in § 447.509 with ''drug(s) other than a single source drug or an innovator multiple source drug.'' As background, we noted that section 1927(c) of the Act describes how the unit rebate amount (URA) is determined for a COD. We also noted that there is a defined calculation of the applicable basic rebate and additional rebate for a COD 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 COD that is a drug other than a single source drug or an innovator multiple source drug at section 1927(c)(3) of the Act.

We provided background in the proposed rule explaining that 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 CODs other than single source drugs and innovator multiple source drugs. We noted that section 1927(c)(3)(C) of the Act describes the additional rebate calculation for CODs other than single source drugs or innovator multiple source drugs, explaining that the statute makes it clear that rebates are applicable to all CODs, whether they are single source drugs, innovator multiple source drugs, or drugs other than such drugs.

We also noted that manufacturers are required to report all of their CODs in the 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 COD other than a single source drug or an innovator multiple source drug in our system for operational purposes. Choosing N in the MDRP 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. We noted that because manufacturers are to report all of their CODs and identify the applicable drug category, all CODs other than a single source drug or an innovator multiple source drug should be identified with the drug category of N, regardless of whether they satisfy the definition of noninnovator multiple source drug.

We noted that in the 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). We stated that over the years, interested parties 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. We therefore noted that we believe that the regulatory definition of noninnovator multiple source drug may not fully align with the statutory definition because the regulatory definition does not capture every COD that is something other than a single source drug or an innovator multiple source drug; that is, not every ''other drug'' is a multiple source drug. Practically, though, we noted that while the terms ''other drugs'' and ''noninnovator multiple source drugs'' are not synonymous, they are treated so for purposes of reporting the COD in the MDRP system, because ''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 CODs, regardless of whether 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 proposed 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.''

We proposed 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 was proposed to be made in § 447.509(a)(6), (7), (8), and (9) and (c)(4).

We received a public comment on this proposal. The following is a summary of the comment we received and our response.

Comment: One commenter stated that CMS should clarify that the replacement of ''noninnovator multiple source drug'' with ''drug other than a single source drug or innovator multiple source drug'' is not intended to have any effect on the narrow exceptions process.

Response: The replacement of the term ''noninnovator multiple source drug(s)'' in § 447.509 with ''drug(s) other than a single source drug or an innovator multiple source drug'' was proposed to align the regulatory language with the statute, which requires rebates for CODs other than single source drugs and innovator multiple source drugs regardless of whether they are multiple source drugs. The proposed change was also intended to clarify our longstanding policy and practices of identifying ''other drugs'' as N drugs for the purposes of the MDRP. The proposed changes in § 447.509 are not intended to change the narrow exception process.

After consideration of public comments, we are finalizing the clarifications to the language in § 447.509 as proposed. This clarification should not affect the drug category code reported in the MDRP reporting system for drugs other than single source drugs or innovator multiple source drugs. 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 the proposed rule, we included provisions to provide a 12-quarter time limit for processes related to the initiation of rebate audits by manufacturers. As background, we noted that 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. For the purposes of the regulation, we noted that audit authority is intended to refer to any process a manufacturer is using to seek an adjustment to State drug utilization data under section 1927(b)(2)(B) of the Act.

We also noted that section V. of the NDRA describes how the agency operationalizes the manufacturer audit authority; that is, it describes the procedures for manufacturer dispute resolutions 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.[21] The audit/

[21] See section V, Dispute Resolution, ''Medicaid Program: Announcement of Medicaid Drug Rebate

Continued

dispute resolution processes are further discussed in a number of manufacturer releases.[22] We explained that 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.[23] 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.'' Finally, consistent with section 1927(b)(2)(B) of the Act, we noted that all disputes must be resolved on a unit basis only, and not on any other factor (for example, monetary amounts, percentages, etc.).[24] 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's utilization invoice is sent.

We also pointed out that while section V. of the NDRA, along with several CMS-issued program releases, addresses 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.[25] Thus, we indicated that 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 data and is not an efficient use of resources. We, therefore, proposed to use our authority under sections 1102 and 1902(a)(4) of the Act, which authorizes the Secretary to specify methods of administration found to be necessary for proper and efficient administration of the Medicaid program, 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. Consistent with this authority, we proposed 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 proposed a time limitation to help ensure that discrepancies are identified and resolved, thereby promoting the efficient operation of the MDRP.

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; while we believe 38 days is optimal, we stated in the proposed rule that 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. We reminded manufacturers it also mirrors the timeline for reporting revisions to monthly AMP at § 447.510(d)(3). We also noted that there are 2-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, we proposed 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. This is consistent with our authority at section 1902(a)(4) of the Act.[26]

Accordingly, we proposed at § 447.510(i) 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 SDUD reported under section 1927(b)(2)(A) of the Act on the State rebate invoices.

We received public comments on this proposal. The following is a summary of the comments received and our responses.

Comment: We received numerous comments supporting CMS' proposal to impose a 12-quarter limit on manufacturers initiating disputes on State drug utilization data, as it will streamline administrative processes, reduce burdens on States and providers, and ensure that disputes are based on recent, validated data. Additionally, commenters noted that imposing time limits on the initiation of disputes and audits streamlines the States' management of the drug rebate program.

Response: We appreciate commenters' support. We are focused on increasing efficiency and economy of overall MDRP resources to better facilitate the needs of Medicaid beneficiaries. We believe the time limitation on rebate disputes by manufacturers will help ensure that discrepancies are timely identified and efficiently resolved, thereby providing increased financial certainty to manufacturers and States, while promoting the efficient operation of the MDRP.

Comment: Multiple commenters opposed CMS' proposal for a 12-quarter audit limit, citing a lack of statutory authority, and questioned CMS' authority to implement such a requirement.

Response: We believe that a limitation on the timeline of when a manufacturer may audit comports with our policy goals and is supported by CMS' general rulemaking authority in section 1102, as well as 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 have the responsibility of administering the MDRP and ensuring the proper and efficient operation of the Medicaid program, and establishing a timeframe limitation for manufacturer audits is consistent with this goal. Additionally, having this timeline limitation provides more financial certainty for States and Manufacturers for rebate purposes because invoices, transactions, and payments can be settled, therefore increasing stability in program operations.

Comment: Some commenters suggested that if CMS imposes a 12-quarter limit on manufacturers' ability to dispute rebates, they should ensure the timeframe starts when manufacturers receive the State invoice. Specifically, commenters stated that the timeframe should begin when manufacturers receive the State invoice that includes the disputed utilization or when manufacturers receive detailed claims data.

Response: We continue to encourage States to respond to reasonable requests from manufacturers for claims level data, as the willingness to share data, methodologies, and resolution strategies generally leads to resolutions. However, as these requests are on an as-needed

Program National Rebate Agreement,'' Final Notice, 83 FR 12770 (Mar. 23, 2018).

[22] State Release 177, State Release 181, State Release 56, Manufacturer Release 115, Manufacturer Release 105, Manufacturer Release 95, and Manufacturer Release 20.

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

[24] Please see State Release 181, *https://www.hhs.gov/guidance/sites/default/files/hhs-guidance-documents/state-rel-181_42.pdf.*

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

[26] We had also referenced section 1102 of the Act for our authority to implement this provision. Section 1102 of the Act grants the Secretary authority to promulgate regulations but not the authority to impose specific requirements and thus does not need to be cited as authority to implement this provision.

basis, we do not believe the date for which claims level details are received by the manufacturer is an appropriate date to start the dispute initiation timeline limitation.

Upon further consideration, we believe the invoice postmark date will offer the same clarity for the interested parties involved in the dispute process and will better align with established Medicaid policy. In accordance with section 1927(b)(1)(A) of the Act and the terms of the NDRA, manufacturers are required to pay a rebate to each State for all CODs of the manufacturer that were paid for in a quarterly rebate period. This section of the Act also states that such rebate payments are to be paid within 30 days of the manufacturer's receipt of the State invoice. For purposes of calculating interest on late rebate payments, previously issued guidance has noted that manufacturers have 37 calendar days as evidenced by the postmark by the U.S. Postal Service on the envelope to pay rebates before interest begins to accrue.[27] That is, upon receipt of a quarterly invoice, manufacturers have 37 calendar days' time from the invoice postmark date to pay rebates before interest begins to accrue on the 38th day. Therefore, to maintain consistency, we are amending the proposed language in this final rule to specify that upon receipt of a quarterly invoice, the period for manufacturers to initiate audits or disputes concerning State drug utilization data begins on the last day of the quarter from the State invoice's postmark date.

As an example, if the invoice postmark date is in the fourth quarter of 2024, then the time period to initiate a dispute ends 12 quarters after the last day of the fourth quarter of 2024, which would be the last day of the fourth quarter of 2027. If States use electronic invoicing via email, we expect States to include the invoice itself within the body of the email to a manufacturer or, at minimum, information on the number of units paid by NDC. In this case, we view the postmark date as the date on which the email is sent. Similarly, if a State sends an email with the invoice attached, then the date when the initiation time period ends is 12 quarters from the last day of the quarter in which the email was sent. For example, if the email was sent in the fourth quarter of 2024, then the time period to initiate a dispute ends 12 quarters after the last day of the fourth quarter of 2024, which would be the last day of 4Q2027.[28]

Comment: Some commenters expressed concerns regarding fairness and parity between manufacturers and States. While advocating for equitable treatment between manufacturers and States, some suggested either adjustments to the proposal or that CMS set forth similar time limits for similar types of requests by States or manufacturers. Some stated that because similar limitations were not placed on States, the provision is biased against manufacturers, possibly compromising accuracy and fairness in the MDRP. Additionally, a few commenters stated that manufacturers have reported receiving State rebate invoices related to decades-old utilization, and that States should have time limitations on disputes and submitting invoices to manufacturers, including limitations on the initiation of corrections or resubmissions of invoice data. These commenters stated that if manufacturers are to be time-limited in their ability to audit invoices, State Medicaid programs need to be held to a comparably limited period in which to submit rebate utilization.

Response: Section 1927(b)(2)(B) of the Act provides that a manufacturer may audit the rebate billing information provided by the State under section 1927(b)(2)(A) of the Act. This includes 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. Adjustments to rebates are based on unit utilization and are authorized to the extent that the information provided by States indicates that utilization was greater or less than the amount previously specified.

States have similar equitable timelines with which to comply when invoicing for rebates. States are required to invoice manufacturers based on the State's utilization of the manufacturer's CODs each quarter and must provide invoices no later than 60 days after the end of each quarter. Additionally, States have a 2-year timely claim filing deadline under section 1132(A) of the Act. This incentivizes States to manage and resolve disputes within this timeframe.

Disputes handled beyond this 2-year deadline create recordkeeping and fiscal issues for the States, hindering them in claiming FFP from the Federal government because the dispute exceeds the timely filing window. Resolving disputes requires the claim to be reversed and resubmitted, with States not receiving Federal match on these resubmitted claims if the dates of service fall outside the timely filing window. Therefore, we believe this timely filing deadline provides necessary incentives for States to resolve rebate disputes swiftly, as they must absorb the full cost of a rebate correction, including the portion that would otherwise be paid for through FFP.

Furthermore, the 12-quarter timeframe provided to manufacturers significantly extends the timeframe that was specified in previous guidance. State Release Number 45 and Manufacturer Release Number 11 outline the Dispute Resolution Process for manufacturers and States in rebate disputes. In these releases, we specified that manufacturers should notify a State of disputed data no later than 38 days after the State utilization data is sent. We continue to believe that manufacturers and States need to communicate as soon as possible on suspected drug unit issues to prevent and resolve disputes, preferably even before rebates are due. Establishing the 12-quarter time limitation for manufacturers to initiate disputes also aligns with the timelines permitted for manufacturers to report changes to data elements relevant to the calculation of MDRP rebate amounts. For these reasons, we continue to believe this is a balanced solution that is equitable for both manufacturers and States, providing sufficient time for dispute initiation.

Comment: One commenter expressed concern that States do not always engage effectively with manufacturers and their representatives when disputes arise. They stated that CMS should require States to respond to manufacturer-initiated disputes in a timely and effective manner and provide guidance when such disputes reach an impasse.

[27] Please reference Manufacturer Release 89 *https://www.medicaid.gov/sites/default/files/medicaid-chip-program-information/by-topics/prescription-drugs/downloads/rx-releases/mfr-releases/mfr-rel-089.pdf,* Manufacturer Release 7 *https://www.medicaid.gov/sites/default/files/medicaid-chip-program-information/by-topics/prescription-drugs/downloads/rx-releases/mfr-releases/mfr-rel-007.pdf,* and State Release 29 *https://www.medicaid.gov/sites/default/files/medicaid-chip-program-information/by-topics/prescription-drugs/downloads/rx-releases/mfr-releases/mfr-rel-029.pdf,* for our policy on postmark dates.

[28] Please see State Release 166 *https://www.medicaid.gov/sites/default/files/medicaid-chip-program-information/by-topics/prescription-drugs/downloads/rx-releases/state-releases/state-rel-166.pdf,* State Release 154 *https://www.medicaid.gov/sites/default/files/medicaid-chip-program-information/by-topics/prescription-drugs/downloads/rx-releases/state-releases/state-rel-154.pdf,* and Manufacturer Release 80 *https://www.medicaid.gov/sites/default/files/medicaid-chip-program-information/by-topics/prescription-drugs/downloads/rx-releases/mfr-releases/mfr-rel-080.pdf* for our policy and guidance related to postmark dates.

Response: As stated in the NDRA, both the State and the manufacturer are expected to use their best efforts to resolve a dispute within a reasonable timeframe after the State's receipt of the manufacturer's Reconciliation of State Invoice (ROSI) or Prior Quarter Adjustment Statement (PQAS). CMS expects manufacturers and States to work in partnership to resolve outstanding units in dispute. CMS has issued guidance on dispute resolutions and we encourage commenters to reference *https://www.medicaid.gov/sites/default/files/medicaid-chip-program-information/by-topics/prescription-drugs/downloads/rx-releases/mfr-releases/mfr-rel-105.pdf, https://www.medicaid.gov/sites/default/files/medicaid-chip-program-information/by-topics/prescription-drugs/downloads/rx-releases/mfr-releases/mfr-rel-095.pdf* and *https://www.medicaid.gov/sites/default/files/medicaid-chip-program-information/by-topics/prescription-drugs/downloads/rx-releases/state-releases/state-rel-181.pdf* for dispute related issues. In addition, as noted previously, we believe the prompt notice of disputes will encourage States to resolve these issues in a timely manner.

Comment: Several commenters emphasized that 340B Program-related audits may require more time than the proposed 12 quarters and suggest CMS should clarify and potentially adjust the rule's applicability to ensure fairness in dispute processes. Multiple commenters opposed the proposed time limit, especially concerning 340B duplicate discounts, which take longer to identify and resolve and suggest exemptions or adjustments to the rule. Certain commenters also suggested that a manufacturer be allowed to toll the time to request necessary data from the State and during certain 340B disputes.

Response: We believe that manufacturers should, within 12 quarters from the invoice postmark date, initiate a dispute with or audit of a State for any disputes they may have with regard to 340B duplicate discounts. We understand that covered entities and their contract pharmacies work with their own third-party administrators (TPAs) that help to identify prescription claims as 340B within a few days, or at most a few weeks, well within the 12-quarter timeline that was proposed. Thus, the 12-quarter timeframe should be sufficient for identification of 340B claims and any disputes that may arise. CMS issued guidance to States and other interested parties in January 2020 on Best Practices for Avoiding 340B Duplicate Discounts in Medicaid. We have previously outlined a number of best practices that States are encouraged to consider to avoid duplicate discounts.[29] Additionally, our 12-quarter time audit initiation limitation aligns with HRSA's limitation of actions provision in 85 FR 80632, which specifies that a covered entity or manufacturer must file a written claim for administrative dispute resolution with HRSA within 3 years of the date of the alleged violation. Furthermore, other proposals in this regulation will help with that process, such as the proposal to include BIN/PCN numbers on Medicaid managed care enrollee identification cards for pharmacy benefits. Finally, we are finalizing that all audits must be initiated within the 12-quarter time period, not that all disputes are resolved within this timeline. We, therefore, do not believe a tolling provision is necessary.

Comment: A few commenters recommended that if CMS' proposed 12-quarter rule is finalized, it should only apply to future claims, ensuring manufacturers have time to address audits and disputes on past claims without hindrance and that State invoices received prior to the finalization of the rule would not be subject to the 12-quarter time limitation. Several commenters requested that if this policy is finalized, CMS should provide technical assistance on how to address outstanding disputes that were previously submitted but are beyond the proposed 12-quarter limit.

Response: The 12-quarter timeframe was proposed, in part, to 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. Unlike manufacturers that can make reasonable assumptions regarding data and reporting that occur beyond their record keeping requirements, States must be able to provide specific drug unit data related to utilization. Ideally, as we have stated, disputes should be raised and resolved promptly before the invoice is paid by the manufacturers. However, manufacturers can, and do, raise disputes after payment is made, sometimes even years later. The current lack of a clear time limit means previously settled invoices, transactions, and payments might not be settled in actuality given potential new or additional disputes. Having an unlimited period to initiate disputes is inconsistent with the proper and efficient operation of the rebate program.

In addition, when a dispute concerning a possible provider billing error arises, the passage of time makes investigation and correction by the State more difficult. Claims data may not be available after a number of years; States have reported they have trouble retrieving older claims data because system upgrades have made accessing old data and paper claims difficult or impossible. The provider may not have records for the claim anymore because the record keeping requirements do not require them to continue to retain the records, making resolving disputes unnecessarily complicated. Thus, establishing a time limit for manufacturers to initiate disputes will increase the efficiency of dispute resolutions as well as the administration of MDRP. For this reason, this provision should apply to all newly initiated rebate disputes, regardless of when the claim was processed; any claim currently in the dispute resolution process would not be affected. Rather, under the 12-quarter time limit, 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 postmark date of the State invoice.

Comment: Commenters stated that CMS' 12-quarter time limit proposal lacks operational feasibility and raised concerns the proposal may limit the ability of manufacturers to ensure accuracy of drug unit utilization data received from the States.

Response: Currently, the lack of time limit on rebate dispute initiation by manufacturers is creating operational challenges for both States and manufacturers. We believe this creates long-term operational feasibility challenges for States, and burdens resources that would be better used towards patient care. During the dispute resolution process, claims-level detail is normally required from the States to assist in resolving a dispute; however, States often do not have such data available to provide to manufacturers beyond a limited timeframe. States need this source data when manufacturers request further proof to resolve disputes. Such claim data may not still be available after a fixed number of years, and the lack of a definitive timeline for initiation of disputes on drug utilization data unreasonably burdens programs.

After considering the issues raised by the commenters, we are finalizing this provision as proposed except that we are amending the language to clarify

[29] For best practices for avoiding 340B duplicate discounts in Medicaid, please see our January 8, 2020 Informational Bulletin *https://www.medicaid.gov/federal-policy-guidance/downloads/cib010820.pdf.*

that the 12 quarters begin based on the postmark date: 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 postmark date of the State invoice. As noted in our previous responses, we understand that in certain instances the resolution of a dispute may extend beyond this time period, and we clarify that we are not requiring that disputes are resolved within this time period.

J. Proposal Regarding Drug Price Verification Through Data Collection (§ 447.510)

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'' the prices that manufacturers are reporting under section 1927(b)(3)(A) of the Act, and in accordance with § 447.510. Under this authority, we proposed rules to describe those situations when it would be considered necessary for such surveys to be sent to manufacturers and wholesalers, and the information that would be requested that we would use in order to verify the reported prices at issue. We stated our intent that the proposed surveys would help assure that Medicaid payments and applicable rebate payments for CODs are accurate.

As we noted in the preamble to the proposed rule, currently, there is no centralized process to collect specific data from manufacturers (or wholesalers) to verify prices manufacturers report to us under section 1927(b)(3)(A) of the Act. We proposed to interpret the language in section 1927(b)(3)(B) of the Act 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 stated that we believe this provision 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 to purchasers.

We noted in the proposed rule that participating manufacturers are required to report and certify to CMS certain product and pricing data for each of their CODs on a monthly and quarterly basis. 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 Program uses the AMP and the Unit Rebate Amount (which is the amount calculated to determine the quarterly 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, plus specified professional dispensing fees for CODs dispensed by 340B entities. Additionally, many State Medicaid programs use the ASP (as defined in section 1847A(c) of the Act) and the Wholesale Acquisition Cost (as defined in section 1847A(c)(6)(B) of the Act) for Medicaid payment for physician administered drugs, such as those administered in hospital outpatient departments and physician offices. Thus, we noted that it is important, particularly in the case of high cost drugs, that CMS have the ability to verify, in certain situations, the manufacturer's submitted pricing data to ensure its accuracy, given the foregoing ramifications.

We also proposed to publish non-proprietary information that we receive from the manufacturer through the drug price verification survey. We noted our belief that our proposed drug price verification survey process and the publication of non-proprietary information, along with the NADAC that we publish for retail community pharmacy costs, should provide the public with an understanding of how CMS is implementing its authority to understand how a manufacturer determines and verifies its reported pricing for its CODs. We also noted that our proposal would also provide information on the methods manufacturers use to produce accurate price information. We indicated that Medicaid managed care plans may be able to use such public information about the accuracy of prices or charges that are collected under this process in providing drug benefits if covered under their contracts.

For the foregoing reasons, we proposed to use the statutory authority in section 1927(b)(3)(B) of the Act to collect additional information about charges and prices from manufacturers and wholesalers to verify the prices reported to us for CODs. We stated our belief that this verification is extremely important, particularly in the case of the significant number of new high-cost drugs and biologics, including cell and gene therapy drugs, entering the market, as well as the costs and prices associated with new and different pharmaceutical preparation methods and distribution channels. We indicated that it is critical to ensure that pricing information associated with these products is accurate so that State Medicaid programs receive the full rebate amounts to which they are entitled. Assuring States obtain accurate rebates can make these products more affordable and thus more accessible to patients. In addition, we noted that the increasingly complex pharmaceutical distribution supply chain has made it more challenging for manufacturers to calculate, and for CMS and States to monitor the accuracy of, pricing information reported under section 1927 of the Act. Thus, we stated that the verification survey is needed to help ensure that such calculations are being done correctly, given the significant implications for MDRP rebate amounts and Medicaid payments.

In the preamble to the proposed rule, we underscored that 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. We noted that we would not be using the survey data to 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.

Therefore, we proposed 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 appreciate the thoughtful comments we received on this issue, and we determined not to finalize the proposed policy at this time. We are continuing to review the input provided by commenters, which may inform future rulemaking on this topic.

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

In the proposed rule, we included provisions 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 under Medicaid FFS. As background, we noted in the preamble to the proposed rule that section 1902(a)(30)(A) of the Act requires that States include in their State plans, 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. We also reminded States that, 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 that 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); [30] and, (2) a professional dispensing fee (PDF) for the drug based on the pharmacy's cost of dispensing.

As additional background to support our proposal, we pointed to existing policy requirements that the 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. We noted that, in SPA submissions, States must provide adequate data, such as a State or national survey of retail pharmacy providers or other reliable data (other than a survey) to support any proposed changes to either or both of the components of the reimbursement methodology. We also noted that while States are afforded the flexibility to adjust their reimbursement methodology 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.

With this background, we explained in the proposed rule that recently we have seen States submit proposed changes to either or both of the components of the reimbursement methodology without adequate supporting data that reflect current drug acquisition cost prices or actual costs to dispense, which is inconsistent with applicable law and regulations. We also affirmed that the PDF 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. We stated that 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. We noted that States must submit adequate cost data to CMS as part of its SPA process to justify its professional dispensing fee amounts and that the data submitted cannot 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, we affirmed in the preamble to the proposed rule that States must support determinations or proposed changes for ingredient cost reimbursement with adequate cost-based data. We cited previous rules and guidance, which provide ways States could establish pharmacy reimbursement methodologies, noting that the pricing benchmark that CMS makes available to States, for example the weekly NADAC files, reflect current prices. We also noted that freezing NADAC or AAC rates, and establishing a static provider reimbursement, would not be consistent with applicable laws and regulations and that reduced beneficiary access to medically necessary drugs could result if pharmacy providers are unable to purchase drugs at a rate reflective of current market conditions.

For these reasons, we proposed 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. Specifically, a State must submit adequate *cost-based* data to support any proposed changes to either or both of the components of the reimbursement methodology and a State cannot rely on the amounts that pharmacies are accepting from other third-party payers as a means of determining professional dispensing costs. Rather, the data that are acceptable could be a State's own survey, a neighboring States' survey, or other credible survey data that reflect the current cost of dispensing a prescription in the State (81 FR 5311). Additionally, to pay based on costs, we clarified that States need to periodically assess whether current rates being paid to pharmacies reflect current costs, noting that there is no specific requirement as to how often and when States must review their current fees. We therefore proposed to update the heading of § 447.518(d) heading to be ''Data requirements'' and to revise paragraph (d)(1) to specify these requirements in the regulatory text.

We received public comments on these proposals. The following is a summary of the comments we received and our responses.

Comment: Several commenters provided general support statements for the proposed updates to the data reporting requirements in § 447.518 regarding State plan requirements, findings, and assurances, which will ensure patient access and appropriate pharmacy reimbursements.

Response: We appreciate receiving the comments in support of this proposal.

Comment: One commenter agreed with the proposed rule and stated that if pharmacies are unable to successfully acquire drugs at a rate reflective of the current market, there would be a ripple effect, such as limited beneficiary access due to pharmacy closures, and a negative impact on health equity for these vulnerable populations.

Response: We agree with the commenter. To ensure beneficiaries can access pharmacy services, CMS reviews each State's SPA to ensure that the reimbursement methodologies are established in accordance with applicable Federal provisions so 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.

Comment: Several commenters recommended that CMS consider outlining how often States should assess if the pharmacy reimbursement rates accurately reflect current costs or other mechanisms to collect reliable data to ensure rates are current and adequate for pharmacies. Another commenter stated that an annual assessment is not realistic or feasible, and recommended that CMS consider requiring that States conduct a periodic assessment at least

[30] 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.

every 2–3 years to reflect current costs, but not less than 2 years.

Response: We appreciate the commenters' suggestions. CMS is not requiring that a State conduct a cost of dispensing study on an annual basis or any defined period of time. If the State proposes a change to the ingredient cost reimbursement methodology, the State must also review the adequacy of their current professional dispensing fees. While this final rule is not designed to mandate the frequency at which States should update their current professional dispensing fees, we encourage States to undertake a periodic assessment of whether pharmacy dispensing costs have changed, especially if there is a change to the ingredient cost such that the State should consider conducting a cost of dispensing study to comply with Federal regulations.

Comment: A commenter recommended enhanced professional dispensing fees for 340B prescriptions to ensure adequate reimbursement. The commenter specifically requested that CMS encourage States to consider enhanced professional dispensing fees for 340B prescriptions to ensure the adequacy of pharmacy reimbursement for 340B covered entities and contract pharmacies.

Response: We appreciate the recommendation regarding enhanced professional dispensing fees for 340B drugs. States continue to have the ability to propose different professional dispensing fees for CODs, such as for specialty drugs, hemophilia drugs, generics, brand drugs, 340B drugs, etc. CMS will review the proposed rates through the SPA process to ensure that each State's proposed reimbursement methodology 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.

Comment: Two commenters disagreed with the proposal to require professional dispensing fees to be based on cost data, as opposed to market-based research, and claimed that these proposals are unnecessary and redundant. One commenter was concerned that CMS' proposed requirements divert the States' limited resources away from other more pressing State Medicaid priorities and that CMS' prohibition on the use of market-based reviews of professional dispensing fees is not accompanied by findings that the States' approach is contributing to unsustainable dispensing fee reimbursement. Another commenter stated that imposing stricter standards for cost information in this case means that dispensing fees are treated differently than traditional Medicaid services. Conducting surveys or other research on cost-based data will be an added burden on States, and it may be difficult to obtain this information from providers as opposed to market-based research.

Response: We understand the concerns raised by commenters; however, CMS has no reason to believe that the provisions provided in this final rule will divert the States' limited resources away from other more pressing State Medicaid priorities. States are not required to complete their own cost of dispensing study. States can propose their professional dispensing fees based on a neighboring State's survey or other credible survey data, as long as it is adequate and reflects the current pharmacy costs of dispensing a prescription in their State.

CMS is requiring that the professional dispensing fee be based on pharmacy cost data, and not be based on a market-based review. We believe that market-based research is insufficient because it does not reflect actual costs to pharmacies to dispense prescriptions.

Comment: Several commenters provided support for data used to determine professional dispensing fees and ingredient costs and offered suggestions on ways to better understand these costs and accommodate individual States' needs. One commenter agreed that to the extent that a State is conducting a cost of dispensing study, it should be a transparent, comprehensive, and well-designed tool that addresses a pharmacy provider's cost to dispense the drug product to a Medicaid beneficiary. Several commenters expressed support for States to periodically assess if pharmacy reimbursement rates accurately reflect current costs, with suggestions for this assessment to occur every 2 to 3 years.

Response: We agree that a State's cost of dispensing survey should be transparent, comprehensive, and reflective of the pharmacy's actual cost of dispensing. As stated earlier, we are currently not requiring that a State conduct a cost of dispensing survey based on any timeframe, but States must review their current professional dispensing fee whenever they propose to change their reimbursement methodologies to ensure 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.

After consideration of public comments on this provision, we are finalizing as proposed.

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

In the proposed rule, we included a provision that would clarify when States are required to invoice for rebates for PADs that are CODs. As background, we noted that, generally, PADs may satisfy the definition of a COD set forth under section 1927(k)(2) of the Act, subject to the limiting definition at section 1927(k)(3) of the Act, and that manufacturer rebates should be collected on these PADs. We noted that in the past, many PADs were classified by Healthcare Common Procedure Coding System (HCPCS) [31] codes (commonly referred to as J-codes), which group together different manufacturers of the same drug that have different NDC codes within the same J-code, making it impossible to know which manufacturer supplied the drug in question. We noted that these broad J-codes cannot be used to bill for rebates, as they do not identify the specific PADs NDC. Many providers were submitting only these HCPCS codes to the States, rather than the NDC of the specific PAD, making it difficult if not impossible for the State to bill for rebates.[32]

To help address this situation, and to improve a State's ability to identify PADs that may be subject to rebates being invoiced, the Congress enacted section 6002 of the Deficit Reduction Act of 2005 (DRA) adding sections 1927(a)(7) and 1903(i)(10)(C) to the Act to require States to collect and submit certain utilization data on certain PADs as a condition for FFP to be available in payments for these drugs, and to facilitate State collection of manufacturer rebates. More specifically, the DRA provisions required that for payment to be available under section

[31] 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.

[32] In its report titled ''Medicaid Rebates for Physician Administered Drugs'' (April 2004, OEI–03–02–00660), the Office of Inspector General (OIG) reported that of the 17 States that collected drug manufacturer rebates for physician-administered drugs in 2001, 3 collected rebates on all physician-administered drugs. These three States used NDC codes for billing and the remaining 14 States used HCPC codes. These 14 States cross walked HCPC codes to NDC codes for single-source drugs and collected rebates on these drugs only.

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 NDCs) for all single source PADs (after January 1, 2006) and multiple source drugs (after January 1, 2008) that are a top 20 high dollar volume PAD that appears on a published list (based on highest dollar volume dispensed under Medicaid identified by the Secretary, after January 1, 2007) in order for FFP to be available under section 1903 of the Act in the case of these drugs, and to assist the States in securing applicable Medicaid rebates for these drugs.

We noted that the 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.) Also, the statute required that only NDCs be used after January 1, 2007 for billing for all PADs that are single source CODs or the 20 multiple source CODs on the list published by the Secretary, unless the Secretary specified that another alternative coding system be used, or the State obtains a ''hardship waiver'' under section 1927(a)(7)(D) of the Act. Further, if States are not collecting NDCs and submitting the appropriate utilization data for these drugs consistent with the foregoing requirements, FFP is not available in payments for the CODs at issue. In addition, States would be forgoing available manufacturer rebates for these drugs.

We also noted that the 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 complied with the foregoing requirements pertaining to submission of codes from its providers that allow it to appropriately bill manufacturers for rebates for PADs. For single source PADs, we noted that the requirement to submit appropriate coding went into effect as of January 1, 2006, and specified 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. We also noted that § 447.520(a)(2) further specified that as of January 1, 2008, a State must require providers to submit claims for single source and the top 20 multiple source PADs identified by the Secretary, using NDCs. As such, under current § 447.520(b), as of January 1, 2007, 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 noted that we retained this regulatory language without modification in the 2016 COD final rule. See 81 FR 5322.

In the proposed rule, we included a provision to update the regulatory language at § 447.520 to more specifically and accurately conform with the statutory requirements captured at section 1927(a)(7) of the Act. Specifically, in proposed § 447.520(a)(1) and (2), we outline the conditions under which FFP would be available for States, as related to the NDCs States must require providers to use in order for the State to secure rebates for PADs that are CODs. The proposed language clarified that rebates are only due for PADs that are CODs and specified that data must be submitted by providers in the State in order for States to receive FFP as stated under sections 1927(a)(7)(A) and 1927(a)(7)(B)(i) of the Act and secure applicable rebates. In proposed § 447.520(a)(2), we also proposed that States be required to collect rebates on all multiple source PADs in the manner required under section 1927(a)(7) of the Act, for those 20 identified under section 1927(b)(i) of the Act. We also similarly proposed at § 447.520(b) that after January 1, 2007, a State would have to require providers to submit claims for all COD single source and all multisource PADs using NDC numbers to collect FFP and secure rebates.

We also noted that States need to ensure that their Medicaid 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.[33] Additionally, we proposed at § 447.520(c) to continue to publish the top 20 list of multiple source PADs on an annual basis, as statutorily required, but also stated our expectation that States would invoice rebates for all multiple source PADs that are CODs, not just those identified on this list. In summary, the proposed regulation would require States to require providers to submit NDCs for all multiple source PADs that are CODs, which would then be subject to manufacturer rebate invoicing, and not limit such rebate invoicing to those on the top 20 high dollar multiple source drug list subject to the statutory requirements in section 1927(a)(7) of the Act. As technology and systems are currently in place, we noted that this proposed regulation would reduce the administrative burden of monitoring any revisions to the top 20 multiple source PADs and allow States to invoice rebates for these PADs that are CODs.

Since publication of the proposed rule, we have determined that we need to rely upon different statutory authority other than section 1927(d)(7) of the Act for our proposed requirements for multiple source drugs that are not among the 20 identified by CMS under section 1927(a)(7)(b)(i) of the Act and § 447.520(c). This is because the statutory language in section 1927(a)(7)(b)(ii) of the Act conditioning FFP on meeting its requirements, and the NDC code requirements in section 1927(c) of the Act, only apply to the 20 multiple source drugs identified under section 1927(a)(7)(b)(i) of the Act, and not to multiple source drugs not on that list. We accordingly are relying on our authority under section 1902(a)(4) of the Act to specify ''methods of administration'' that ''are found by the Secretary to be necessary for the proper and efficient operation'' of the State's Medicaid State plan as authority for our proposal to extend the multiple source PAD requirements under section 1927(a)(7)(B)(ii) and (C) of the Act that only apply to multiple source PADs identified under section 1927(b)(i) of the Act and § 447.520(c) to other multiple source PADs not so identified. Because requirements under section 1902(a)(4) of the Act are enforced under section 1904 of the Act and regulations at § 430.435, we have revised the regulation text to provide that compliance with requirements in § 447.520 applicable to multiple source PADs not on the list of 20 identified under section 1927(b)(i) of the Act and § 447.520(c) will be enforced under section 1904 of the Act and § 430.435. Finally, because the new requirements that apply to multiple source drugs not identified under section 1927(b)(i) of the Act and § 447.520(c) are not effective until the effective date of this final rule, we have distinguished in the regulation text between these new requirements and those that took effect for the 20 identified multiple source drugs in 2006, 2007 or 2008.

We received several public comments on this proposal. The following is a summary of the comments we received and our responses.

[33] 86 FR 27498, May 6, 2016 (*https://www.govinfo.gov/content/pkg/FR-2016-05-06/pdf/2016-09581.pdf*).

Comment: Several commenters support the revisions to the existing regulatory language regarding the use of NDCs to identify PADs and expanding rebate invoicing beyond the top 20 high-dollar volume list for multiple source drugs. Commenters agree this would increase transparency and allow States to obtain both manufacturer rebates and receive FFP for these CODs. One commenter stated that Medicaid managed care plans are in a position to require physicians to submit NDCs with medical claims for drugs administered in the provider office or an outpatient facility, which is consistent with Medicaid claims submission for medical benefit drugs.

Response: We agree with the commenters that the policies we are adopting in this final rule will allow States to obtain both manufacturer rebates and FFP for reporting and invoicing NDC numbers for all single source and multisource PADs that are CODs administered under both the Medicaid FFS and Medicaid managed care programs. Additionally, since most State Medicaid programs currently require their providers to submit NDC numbers on PAD claims for all CODs that are single source or multiple source drugs, we anticipate the administrative burden to be minimal. We expect that Medicaid managed care plans will continue to review and implement policies that will ensure that prescribers are required to include NDC numbers on all PAD claims.

Comment: One commenter noted that CMS and the Office of the National Coordinator for Health Information Technology (ONC) are moving in opposing directions when it comes to which drug codes to utilize when submitting claims. This commenter stated that the ONC HTI–1 proposed rule discusses the possibility of what they refer to as deprecating support for NDC codes in its certification programs in favor of always requiring the use of RxNorm for medications. Additionally, a commenter stated that if NDCs are required for any drug, they need to be supported by a certified health IT system.

Response: We appreciate the comments about ONC's HTI–1 proposed rule and use of RxNorm for exchanging information on clinical drugs to ensure there is no ambiguity when it comes to identical medications that have different names. We note that NDCs provide package-level information about drugs and are used by healthcare organizations when submitting claims for CODs and the vehicle used for State utilization reporting for rebate purposes. RxNorm does not separately capture drug manufacturer information and will not meet the needs of the MDRP involving direct manufacturer attribution of CODs, as NDCs are required for rebate purposes. The ONC Health IT Certification program establishes certification criteria for health IT products, which are generally used by health care providers in the provision of care. In the HTI–1 final rule, published on January 9, 2024, ONC finalized adoption of NDCs in 45 CFR 170.207(d)(4) through a cross reference to 45 CFR 162.1002(b)(2) as referenced in 45 CFR 162.1002(c)(1) for the period on and after October 1, 2015 (89 FR 1226). ONC also finalized adoption of the United States Core Data for Interoperability version 3 (USCDI v3), a standardized set of health data classes and constituent data elements, in 45 CFR 170.213 (89 FR 1210). In addition to requiring the use of RxNorm for medications, USCDI v3 added optional support for NDCs. As finalized in the HTI–1 final rule, USCDI version 3 will be the only version of USCDI referenced in certification criteria for health IT under the ONC Health IT Certification Program beginning on January 1, 2026 (89 FR 1211), however, health IT developers may update their products to conform to USCDI version 3 in advance of this compliance date. These actions will support the availability of NDCs within certified health IT products in alignment with finalized policies.

Comment: Several commenters opposed this proposed regulation as it mandates submission of NDCs for all CODs, stating it will considerably intensify the administrative tasks for Medicaid providers. It was stated that this requirement that expands the claims for which NDCs must be reported could strain the already limited resources of 340B covered entities. Another commenter suggested requiring NDCs only for medications that cost above a certain dollar threshold to reduce administrative burden.

Response: We appreciate the concerns stated by the commenters referencing the potential administrative burden to Medicaid providers to submit NDCs for all multiple source PADs that are CODs. However, since most State Medicaid programs currently require their providers to submit NDC numbers on their PAD claims for all CODs that are single source or multiple source drugs, we anticipate the administrative burden caused by this rule to be minimal.

After consideration of public comments on this provision, we are finalizing with the revisions set forth previously in this section.

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

In the proposed rule, we noted that Medicaid COD prescription claims do not currently require a diagnosis as a condition for payment. When reviewing claims without a diagnosis, we noted that it is difficult for the pharmacist or the State 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. We also noted that requiring a diagnosis on a prescription may provide more information to the dispensing pharmacist to enable counseling with a focus on drug-disease interaction, which may improve the beneficiary's overall health.

The proposed rule also noted a 2011 OIG Medicare audit that discovered that without a diagnosis code, it is difficult for Part D sponsors to determine whether a drug claim is medically appropriate.[34] OIG stated that without access to diagnosis information, CMS 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 the then Principal Deputy Inspector General (and now current Inspector General) and Chief Medical Officer from OIG advocated for a new mandate that physicians include a diagnosis code with prescriptions.[35] 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.

We also noted in the proposed rule that since many prescriptions are being electronically prescribed, it may make it easier for prescribers to include a diagnosis. Further, we noted several instances in which we believed a diagnosis on a prescription could help States, including implementation of certain Medicaid programs and benefits in which they are eligible for enhanced

[34] *https://oig.hhs.gov/reports/all/2011/medicare-atypical-antipsychotic-drug-claims-for-elderly-nursing-home-residents/.*

[35] 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*) *https://www.statnews.com/2021/03/01/why-drug-prescriptions-should-include-diagnoses/* March,1 2021.

Federal matching funds, assistance to pharmacists to identify safety issues and ensuring prescriptions are appropriate, medically necessary, and not likely to result in adverse medical results, and assurance that Medicaid reimbursement is limited to drugs with medically accepted indications.

Given the various perspectives, we assumed there would be many interested parties that would have views on a potential requirement to include a diagnosis on a prescription, including but not limited to patients, prescribers, pharmacists, States, and drug manufacturers. Thus, we specifically solicited comments on this topic, its impact on beneficiaries, providers, States, and Medicaid, and any operational implications. We were particularly interested in understanding the benefits and burdens of such a proposal and sought comments on how to mitigate the impact on beneficiaries and providers, and steps which would be needed by States to successfully implement a Medicaid requirement for diagnoses on prescriptions as a condition of FFP. We also requested comments regarding the potential impact of a policy to require Medicaid diagnoses on prescriptions on payment, health care quality, access to care, and program integrity. In addition, we requested comments on the potential impact of such a policy on beneficiary access to commonly used, medically accepted, compendia supported, off-label uses of CODs.

We received many public comments on this request for information on requiring a diagnosis on Medicaid COD prescription claims. The following is a summary of the comments we received and our response.

Comment: A few commenters provided general support for the requirement of diagnoses on prescriptions; however, the majority of commenters stated their strong opposition to requiring diagnoses on prescriptions. These arguments focused mostly on administrative burden, potential information technology (IT) issues with delays in care, significant system alterations, stigma, and other complications. Several commenters stated that because of the technical and operational challenges of including a diagnosis on a prescription, it could also lead to manufacturers initiating unnecessary disputes. Furthermore, many commenters opposed the requirement of diagnoses on prescriptions due to possible impact on equitable access to care, including delays and denials in care, added burden to patients, exacerbation of already existing barriers to care, and overall reduction in care access.

Response: We appreciate the comments received in response to the request for information on requiring a diagnosis on Medicaid prescriptions. After careful review and consideration of the public comments received, and due to the overwhelming number of comments that were opposed to this requirement, we are not pursuing this requirement in rulemaking at this time. We will continue to review the feedback we receive from interested parties and may address this issue in future rulemaking if appropriate.

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.

Our May 26, 2023 (88 FR 34238) proposed rule (CMS–2434–P; RIN 0938–AU28) solicited public comment on each of the aforementioned issues for the following sections of the rule that contained collection of information requirements. Comments were received and are summarized and responded to later under sections III.B.1. (Identification and Notification to Manufacturer to Correct Drug Misclassification), III.B.2. (Definitions), III.B.3. (State Plan Requirements, Findings, and Assurances), III.B.4. (Federal Financial Participation (FFP): Conditions Relating to Physician-Administered Drugs), and III.B.6. (Standard Medicaid Managed Care Contract Requirements) of this final rule.

A. Wage Estimates

To derive average costs, we used data from the U.S. Bureau of Labor Statistics' (BLS') May 2023 National Occupational Employment and Wage Estimates for all salary estimates (*https://www.bls.gov/oes/current/oes_nat.htm#23-0000*). In this regard, Table 2 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 2—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	45.96	45.96	91.92

As indicated, we adjusted 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. Information Collection Requirements (ICRs)

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

We added new paragraphs (d)(1) through (4) to § 447.509 to 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. A manufacturer's effort to address the misclassification of its CODs is currently approved by OMB under control number 0938–0578 (CMS–367). The active collection considers 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 may vary by manufacturer based on the extent to which they misclassify drugs and subsequently need to correct those misclassifications. The extent of the burden may also be impacted based on when the misclassification originally occurred. Since the manufacturer requirements and burden do not require any changes as a result of this rule, we are not making any changes under the aforementioned OMB control number. The manufacturer burden is subject to a regulatory impact analysis which can be found in the Regulatory Impact Analysis section in section IV. of this final rule.

We received numerous public comments on these proposals, but very few, if any, addressed this burden. The following is a summary of the comments we received and our response.

Comment: We received three comments that stated that requiring a manufacturer to correct misclassifications of CODs that occurred more than 10 years ago will be more difficult to address due to the 10-year record retention requirement.

Response: Section 1927 of the Act specifies that rebates can be collected back to the effective date of that section of the Act. Thus, manufacturers must correct misclassifications back to the date of the misclassification so that correct rebates may be paid by the manufacturers on these misclassified drugs. As we note in other sections of this final regulation, manufacturers can make reasonable assumptions regarding their data for any period that extends beyond the 10-year record retention if such records are not available.

After consideration of the public comments, we are finalizing § 447.509(d)(1) through (4) as proposed, with the exception of making a modification to § 447.509(d)(4)(i), to add the following language at the end of that section: ''In such case, the manufacturer must certify the applicable correction within 30 calendar days.''

2. ICRs Regarding Definitions (§ 447.502)

To further consider commenters' concerns, we are not finalizing at this time our proposal to add a new paragraph (5) to the definition of manufacturer or § 447.510(h) or our proposal to add a new paragraph to § 447.502 to define vaccine for purposes of the MDRP only.

Consistent with our proposed rule, we do not believe that any of the following new terms or definition modifications and clarifications that are being finalized 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), and (5) proposal to clarify § 447.509(a)(6) through (9) and (c)(4) with respect to ''other drugs''. Consequently, none of the definition changes are subject to the requirements of the PRA.

We received extensive public comments on these proposals; however, only a few address estimates of effort and burden. The following is a summary of the comments we received and our responses.

Comment: Regarding the modification to the definition of COD, several commenters expressed their concerns regarding the lack of visibility that CMS, manufacturers, and States have into payer claims data to understand how drugs and associated services are itemized. One commenter suggested manufacturers would have to hire personnel to procure and assess claims data in order to verify rebate invoices from the State. A few commenters questioned the States' ability to capture necessary data for bundled drugs on payer claims. One commenter noted the proposed definition of COD will serve to generate even more good faith disputes, given the greater challenge posed by generating and providing such claims-level detail in relation to bundled payments, which will result in increases in disputed rebate claims and delayed payments to the States due to this longer validation time.

Response: Manufacturers and States should have current procedures and practices in place regarding how they validate invoices for the purpose of paying claims, and thus billing manufacturers for rebates. We acknowledge that as a result of the clarification to the definition of COD in this rule, States may have to consider how they instruct providers to bill for certain drugs that are paid for under an all-inclusive rate, such that the State or the Medicaid managed care plan can identify CODs that would be eligible for rebates under inclusive payment models.

Comment: One commenter stated that the proposed changes to § 447.502 would result in a significant burden on the manufacturer and thus are subject to the requirements of the PRA.

Response: The commenter did not describe the nature of the burden in any detail, so we are unable to provide a substantive response.

Comment: Regarding the modification to the definition of COD, one commenter stated collecting NDCs and ingredient cost information and applying such information on Medicaid claims forms is both time-consuming and labor-intensive. CMS should, therefore, refrain from imposing more administrative burdens on providers.

Response: We appreciate the comments regarding the potential burden to providers. Pursuant to their State plans, States have the discretion to choose which reimbursement methodology to employ and what drugs, if any, they will carve out from that methodology and directly reimburse for them. States also dictate the terms of what information is necessary from the provider in order for direct reimbursement to be executed. As of January 1, 2007, § 447.520 has obligated States to require that providers submit NDCs for physician-administered single source drugs and the 20 multiple source drugs identified by the Secretary. Additionally, we note that in section II.L of this rule, it is required that States provide for the collection of NDCs for all physician-administered single source drugs and multiple source drugs. However, since most State Medicaid programs currently require their providers to submit NDC numbers on their PAD claims for all CODs that are single source or multiple source drugs, we anticipate the administrative burden caused by this rule to be minimal.[36]

[36] Physician-Administered Drug, Paperwork Reduction Act (PRA)—*Identifying Medicaid Payment for Physician Administered Drugs (CMS–10215) OMB CONTROL NUMBER: 0938–1026.* At the time the original PRA (November 5, 2007) was approved, collecting and submitting PAD data was a greater burden. At that time, patient records were retained primarily in paper, and claim submissions were made utilizing paper forms. Initial estimates were all made based on the standard of practice in 2007. Since that time, subsequent PRA extensions have been approved; however, these versions did not address improved medical standards of practice with respect to record retention and billing, rule-making requirements relating to including the NDC on the claim so States could bill for rebates (that

Continued

Comment: We received a few comments suggesting that the proposed requirement to report drug product information monthly would place an unnecessary burden on both manufacturers and the Agency.

Response: Section 1927(b)(3)(A)(v) of the Act states that manufacturers must 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 CODs. Currently, approved by OMB under control number 0938–0578 (CMS–367), we require that certain drug product information be reported not later than 30 days after the date of entering into a rebate agreement, or, for newly introduced drugs, not later than 30 days after the last day of month during which the new drug is introduced. Such drug product information is not required on a monthly or quarterly basis at this time. Unless future changes are made to the MDRP that require monthly or quarterly reporting of certain drug product information, we will not require repeated reporting.

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

The burden for submissions relating to § 447.518 is currently approved by OMB under control number 0938–0193 (CMS–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 § 447.518 of this rule clarifies the data requirements that States must submit to establish the adequacy of both the current ingredient cost and the professional dispensing fee reimbursement, this will not add any new or revised requirements or burden, we are not making any changes under that control number.

The proposed rule had inadvertently identified the package as ''CMS–10398 #179''. The correct CMS identification number is ''CMS–179'' as indicated previously in this section. The control number is correct in both instances.

We received public comments on these proposals. The following is a summary of the comments we received and our responses.

Comment: Several commenters expressed support for the use of pharmacy cost data to determine professional dispensing fees and ingredient costs and offered suggestions on ways to better understand these costs and accommodate individual States' needs. One commenter agreed that to the extent that a State is conducting a cost of dispensing study, it should be a transparent, comprehensive, and well-designed tool that addresses a pharmacy provider's cost to dispense the drug product to a Medicaid beneficiary. Several commenters expressed support for States to periodically assess if pharmacy reimbursement rates accurately reflect current costs, with suggestions for this assessment to occur every 2 to 3 years.

Response: We appreciate the commenters' support. We agree that a State's cost of dispensing survey should be transparent and comprehensive, and the results should reflect the pharmacy's actual cost of dispensing a prescription and the ingredient cost of the drug. The survey must be based on actual pharmacy cost of dispensing data, not market-based data. As stated earlier, we are currently not requiring that a State conduct a cost of dispensing survey based on any timeframe, but States must review their current professional dispensing fee whenever they propose to change their reimbursement methodologies to ensure 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.

After consideration of the public comments, we are finalizing the proposed provisions without change.

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

We are updating § 447.520 to make it consistent with section 1927(a)(7) of the Act, and codifying the requirement that States must collect NDC information on all single and multiple source PADs that are CODs for the purposes of invoicing manufacturers for rebates, and ensuring that FFP is available, as appropriate. We are requiring that States must invoice for rebates for all PADs that are CODs. We will continue to publish the top 20 high dollar volume list of multiple source PADs, 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 thus not invoicing for rebates on these drugs. This will be applicable to all States; however, we believe this would cause minimal administrative burden because most 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 PADs and invoicing manufacturers for rebates as applicable under OMB control number 0938–1026 (CMS–10215). Since the provisions will not add any new or revised requirements or burden, we are not making any changes under that control number.

We received public comments on these proposals. The following is a summary of the comments we received and our response.

Comment: Several commenters opposed this proposed regulation as it mandates submission of NDCs for all CODs, and they stated it considerably intensifies the administrative tasks for Medicaid providers. It was stated that this requirement, previously limited to single source PADs and the top 20 multiple source PADs, could strain the already limited resources of 340B covered entities. Another commenter suggested requiring NDC numbers only for medications that cost above a certain dollar threshold to reduce administrative burden to States.

Response: We appreciate the concerns expressed by the commenters referencing potential administrative burden to State providers to submit NDCs for all single source and multiple source covered outpatient PADs. However, since most State Medicaid programs currently require their providers to submit utilization data through use of NDC numbers for all CODs that are single source or multiple source drugs, including PADs, we anticipate the administrative burden to be minimal.

After consideration of the public comments, we are finalizing the proposed provisions without change.

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

We proposed at § 447.510(k) a process to survey 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 would have been submitted to OMB for review if the proposed rule was finalized and the corresponding survey instruments (one for requesting information from States as proposed under § 447.510(k)(3)(ii) and (iii)(A), and another for surveying manufacturers).

Through the proposed rule, we solicited comments to help us develop the manufacturer survey and the State survey and received some suggestions. However, we determined not to finalize

is, CMS–2345–F, Medicaid Program; Covered Outpatient Drugs).

the proposed policy at this time. We are continuing to review the input provided by commenters, which may inform future rulemaking on this topic. The estimates included in the proposed rule regarding these survey instruments have been removed from the final rule.

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

The following changes regarding drug cost transparency in Medicaid managed care contracts will be submitted to OMB for approval under control number 0938–1445 (CMS–10855).

We are amending § 438.3(s) to require MCOs, PIHPs, and PAHPs that provide coverage of covered outpatient drugs to assign and exclusively use a unique Medicaid-specific BIN and PCN combination, and group number identifiers on all issued Medicaid managed care enrollee identification cards for pharmacy benefits. It is a standard business practice for the MCOs, PIHPs, and PAHPs to routinely issue enrollee identification cards for pharmacy benefits, even though there is no Federal requirement to issue such cards. The MCOs, PIHPs, and PAHPs 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 standard 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 plans 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 the Regulatory Impact Analysis section in section IV. of this final rule.

Comment: A few commenters noted the administrative burden of creating potentially thousands of unique BIN, PCN, and group number identifiers instead of the requirement using a BIN and PCN combination. Commenters also expressed concern regarding the administrative burden for assigning each enrollee with a unique BIN, PCN, and group number.

Response: CMS is finalizing the rule to include this recommendation to require a BIN and PCN combination, along with a group number identifier, rather than unique numbers for each component. We agree that it would be administratively burdensome to require unique BINs and unique PCNs, along with a group identifier. The combination approach will achieve the intended result, while minimizing any potential administrative issues.

Comment: One commenter stated that there would be a cost associated with reprinting pharmacy identification cards to meet with new requirement. Another commenter expressed concern regarding the potential operational burden for needing to reissue member ID cards to beneficiaries regarding the new BIN/PCN requirement.

Response: This final rule does not mandate reprinting or re-issuance of enrollee identification cards solely based on when a unique BIN and PCN combination and group number identifier is assigned, but rather re-issuance of cards shall bear the unique identifiers upon routine card issuance. Plans are expected to fulfill these requirements within their standard business practices.

The applicability date for the BIN and PCN combination, and group number identifier provision will be the first rating period for State contracts with MCOs, PIHPs, and PAHPs beginning on or after 1 year following the effective date of the final rule.

Comment: One commenter stated that pharmacies submitting a 340B identifier on claims involves high administrative burden and financial risk and should be considered a last resort.

Response: Inclusion of accurate submission clarification codes is a standard NCPDP guided practice for pharmacies to include additional information to the processor when submitting a claim. We do not believe the submission of accurate submission clarification codes is a burden outside of the normal current business practices. However, the inclusion of 340B identifiers on claims is outside the scope of this final rule.

Additionally, the provision outlined in § 438.3(s)(8) requires that MCOs, PIHPs, and PAHPs that provide coverage of covered outpatient drugs that contract with any subcontractor for the delivery or administration of the covered outpatient drug benefit must 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 reporting requirements would affect 282 managed care plans and 40 States. We further estimate that it would take an Operations Research Analyst at the State level, 25 hours at $91.92/hr to revise 282 managed care contracts to require those plans to comply with § 438.3(s)(8). In aggregate, we estimated a one-time burden of 1,000 hours (40 State responses × 25 hr/response) at a cost of $91,920 (1,000 hr × $91.92/hr).

For the same contract changes between the managed care plans and the subcontractors (mainly PBMs), we also estimated a one-time private sector burden of 7,050 hours (282 managed care plans × 25 hr/response) at a cost of $648,036 (7,050 hr × $91.92/hr).

With respect to the reporting burden, we estimate that for 282 PBMs of those 282 managed care plans to separately report incurred claims e×penses described in § 438.8(e)(2) from fees paid for administrative activities will take appro×imately 2 hours annually 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 $51,842.88 (564 hr × $91.92/hr).

We did not receive any comments regarding the proposed provisions and burden estimates. We are finalizing them in this rule without change.

C. Summary of Burden Estimates

In Table 3, we present a summary of this rule's collection of information requirements and associated burden estimates.

TABLE 3—SUMMARY OF BURDEN ESTIMATES

Regulatory section(s) under Title 42 of the CFR	OMB Control No. (CMS ID No.)	Number respondents	Total number of responses	Time per response (hr)	Total time (hr)	Labor cost ($/hr)	Total cost ($)
§ 438.3(s)(8)	0938–1445 (CMS–10855)	40 States	40	25	1,000	91.92	91,920
§ 438.3(s)(8)	0938–1445 (CMS–10855)	282 managed care plans	282	25	7,050	91.92	648,036
§ 438.8(s)(8)	0938–1445 (CMS–10855)	Subcontractor PBMs of the 282 managed care plans.	282	2	564	91.92	51,842.88

TABLE 3—SUMMARY OF BURDEN ESTIMATES—Continued

Regulatory section(s) under Title 42 of the CFR	OMB Control No. (CMS ID No.)	Number respondents	Total number of responses	Time per response (hr)	Total time (hr)	Labor cost ($/hr)	Total cost ($)
Total	322 (40 States + 282 managed care plans).	.....	604	Varies	8,614	91.92	791,798.88

IV. Regulatory Impact Analysis

A. Statement of Need

The intent of this final 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 MSIAA was signed into law on April 18, 2019. Section 6 of 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. The final rule includes policies to implement these new statutory authorities, as required.

The 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 finalizing several important MDRP program administration and integrity policies such as: implementing a time limitation on manufacturer disputes and audits with States regarding rebates. The final rule also specifies a number of existing policies including: 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.

The final rule includes two new requirements for the contracts between States and their Medicaid managed care plans, specifically MCOs, PIHPs, and PAHPs. That is, States would be required to include in their contracts with MCOs, PIHPs, and PAHPs a requirement that each Medicaid enrollee's identification card used for pharmacy benefits would include a unique Medicaid-specific BIN and PCN combination, along with a group number. The applicability date of these unique Medicaid-specific BIN and PCN combinations on the enrollee identification cards will be the first rating period for contracts with MCOs, PIHPs, and PAHPs beginning on or after 1 year following the effective date of the final rule. This requirement would assist providers in identifying patients as Medicaid beneficiaries.

In addition, we are finalizing that Medicaid MCO, PIHP, or PAHP (managed care plans) that contract with any subcontractor for the delivery or administration of the covered outpatient drug benefit must require the subcontractor to report separately to the MCO, PIHP, or PAHP incurred claims and administrative costs, fees, and expenses of the subcontractor.

Moreover, we are also finalizing 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, and market data; and modifying the definition of COD. Included was also a provision not directly related to MDRP, that is, a proposed revision to third-party liability regulation resulting from statutory changes in the BBA 2018.

On May 17, 2022, the United States District Court for the District of Columbia vacated and set aside the accumulator provisions within the 2020 final rule. The 2020 final rule required 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, before excluding such amounts from the determination of best price or AMP. In response to the district court's order, we are withdrawing the changes made to these sections by the 2020 final rule.

We received public comments on these provisions. The following is a summary of the comments we received and our responses.

Comment: One commenter stated the regulatory burden of the rule will stifle innovation.

Response: We do not believe the regulatory burden of the rule will stifle innovation. Rather, we believe our policies as contained in this final rule (including BIN/PCN on cards, drug cost transparency in Medicaid managed care contracts, etc.) will help promote transparency, flexibility, and innovation in the operation of the Medicaid Drug Rebate Program.

B. Overall Impact

We have examined the impacts of this rule as required by Executive Order 12866 on Regulatory Planning and Review (September 30, 1993), Executive Order 13563 on Improving Regulation and Regulatory Review (January 18, 2011), Executive Order 14094 entitled ''Modernizing Regulatory Review'' (April 6, 2023), the Regulatory Flexibility Act (RFA) (September 19, 1980, Pub. L. 96–354), section 1102(b) of the Social Security Act, section 202 of the Unfunded Mandates Reform Act of 1995 (March 22, 1995; Pub. L. 104–4), Executive Order 13132 on Federalism (August 4, 1999), and the Congressional Review Act (5 U.S.C. 804(2)).

Executive 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). The Executive Order 14094 entitled ''Modernizing Regulatory Review'' (hereinafter, the Modernizing E.O.) amends section 3(f)(1) of Executive Order 12866 (Regulatory Planning and Review). The amended 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 (adjusted every 3 years by the Administrator of OIRA for changes in gross domestic product), or adversely affect in a material way the economy, a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or State, local, territorial, 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) raise legal or policy issues for which centralized review would meaningfully further the President's

priorities or the principles set forth in this Executive order, as specifically authorized in a timely manner by the Administrator of OIRA in each case.

A regulatory impact analysis (RIA) must be prepared for major rules with significant regulatory action/s and/or with significant effects as per section 3(f)(1) ($200 million or more in any 1 year).

Based on our estimates, OMB's Office of Information and Regulatory Affairs has determined this rulemaking is significant under section 3(f)(1). The Office of Information and Regulatory Affairs has also determined that this final rule meets the criteria set forth in 5 U.S.C. 804(2) (Subtitle E of the Small Business Regulatory Enforcement Fairness Act of 1996, also known as the Congressional Review Act).

C. Detailed Economic Analysis

There is a need for greater clarity regarding some of the administrative policies of the MDRP, and this final rule aims to establish regulations to provide guidance to States, manufacturers, and other related parties. This final 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 final rule is mindful of the impact of changes in regulations on affected interested parties, and the degree of compliance issued 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 provisions in the final rule are not implemented, there would be no specific policies in place in the MDRP related to the new legislative requirements in MSIAA, and no clear policies to address drug misclassification and drug product information misreporting by manufacturers. Accordingly, the final 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, could not be conducted.

Additionally, if the provisions are not implemented, there would be no regulatory policies for addressing the provision in 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 drugs other than single source and innovator 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; market date; and noninnovator multiple source drug. Moreover, currently 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; and specify conditions relating to payment for PADs. The reasons and rationales for these provisions were detailed in the preamble section of the proposed rule. The economic impacts of these provisions are detailed later in this section of the final rule.

We solicited 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 final rule.

1. Benefits

The provision requiring that subcontractors of Medicaid managed care plans, such as PBMs or pharmacy benefit administrators (PBAs), report specific categories of drug expenditures to their contracted managed care plan will benefit States and Medicaid managed care plans, as it assures a more accurate calculation of plans' MLRs and aids States in development of managed care plan capitation rates, resulting in more accurate Medicaid spending. As indicated in the proposed rule, the shift in policy to eliminate spread pricing in Medicaid managed care pharmacy programs has begun in many States. Therefore, the benefit associated with this final regulation, as we noted in the proposed rule, cannot be quantified at the national level. We do not have data on which States have done this already, that is, eliminated spread pricing, versus States that would need to implement this because of this final rule.

However, we believe that the majority of States do not require their Medicaid managed care plans to include such PBM transparency language in their managed care contracts. For that reason, we do expect that implementation of this provision will result in savings to the Medicaid program, as States will have a better understanding of their pharmacy program spending and can make any adjustments accordingly. While this provision does not eliminate spread pricing in Medicaid, a March 2020 Congressional Budget Office (CBO) estimate of the Federal proposal [37] 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 decrease in Federal Medicaid prescription drug spending.

In regard to Medicaid Drug Rebates (MDR) and penalties for manufacturer misclassification of drugs, these provisions will implement MSIAA provisions related to misclassification. Finalization of the rule could result in monetary and non-monetary penalties against manufacturers, which are not quantifiable at this time. It could also benefit States if they receive any past rebates that are due to them as a result of a manufacturer's misclassification of drugs.

The majority of drugs are appropriately classified in the Medicaid Drug Programs (MDP) system 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 correct their misclassification and will also allow us to impose penalties on manufacturers that do not pay the unpaid rebates owed to the States as a result of the misclassification.

Modifying the definition of covered outpatient drug will benefit the manufacturers, States, and CMS. The provision will 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 and payment for the drug is made as direct reimbursement. This will make these therapies more affordable to States and increase beneficiary access to these medications. It will 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 benefit is currently not quantifiable because we

[37] *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.*

do not know how many drugs this provision will affect.

Finalizing the definition of internal investigation at § 447.502 for purposes of manufacturers making pricing metric revisions, as amended from the proposed definition, will benefit States and manufacturers. It will benefit manufacturers because it will 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 will benefit States because it will deter manufacturers from submitting to CMS a request for a 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. The benefit of defining internal investigation as part of this final rule is not quantifiable as it is not known how many manufacturers will be deterred from submitting the request to restate outside of the 12-quarter timeframe. However, as noted in the proposed rule, we do not get these requests frequently. We did not receive any comments regarding the impact of the definition of internal investigation at § 447.502.

We proposed to update the definition of manufacturer at § 447.502 and to add a new paragraph (h) in § 447.510 to further specify the responsibilities of a manufacturer. After consideration of public comments, we have opted not to proceed with finalizing the proposed definition of manufacturer at § 447.502 and related changes in § 447.510(h) to further consider commenters' concerns.

The provision to define market date using the date of first sale, rather than the date first available for sale, will benefit some manufacturers, CMS, and States. Manufacturers will not be required to report AMP information until they have actual pricing data based on sales data to report. As a result, there will be decreased reliance by manufacturers to use reasonable assumptions to calculate and report AMP. CMS and States will also benefit because we will 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 the market date of their drug as 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, which is not the case.

States are likely to benefit from the provision to establish a 12-quarter rebate manufacturer dispute, hearing, and audit time limitation in § 447.510(i). 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. With this provision, States will no longer have to look back and research paper claims dating back to as early as 1991, which is the beginning of the MDRP. We estimate the provision will reduce the amount of time it will 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 will no longer be considered.

Regarding the regulatory revisions regarding FFP for conditions relating to physician-administered drugs, these provisions will benefit States and the Federal Government. By revising the regulations to be consistent with the statute, States will gain a better understanding of the requirement that they must invoice for all covered outpatient single and multiple source physician-administered drugs. This final rule will help ensure that States will receive FFP for these PADs by requiring the collection of NDC numbers 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 provision for inclusion of a BIN/PCN combination, along with a group number identifier, on Medicaid managed care enrollee identification cards will benefit States, the Federal Government, providers, and manufacturers. With the inclusion of Medicaid-specific BIN/PCN combinations and group number identifiers on the pharmacy identification cards issued to the enrollees of MCOs, PIHPs, and PAHPs, pharmacies will be able to identify patients as Medicaid beneficiaries. This will be helpful to all parties to ensure that Medicaid benefits are applied appropriately. This will also help avoid duplicate discounts between Medicaid and the 340B Program, which occurs when a State bills for a Medicaid rebate on a discounted 340B drug, because it will provide 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.

The provision for drug cost transparency in Medicaid managed care contracts will benefit States and the Federal Government. It will 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, managed care plans that provide coverage of CODs must 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 will be able to calculate and report its MLR more accurately.

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 and appropriate. Managed care capitation rates must (1) be developed such that the plan will 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 to States should they not achieve the specific MLR target when a remittance is required by a State. Thus, the accuracy of MLR calculation is important to conserving Medicaid funds.

The payment of claims provision will benefit States, the Federal Government, providers, and beneficiaries. This provision will 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 will also benefit beneficiaries and providers as

they permit 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 clarify our longstanding policy to account for manufacturer stacking of discounts when determining best price is not being finalized at this time. Therefore, we will not be responding to any comments submitted on the impact of this specific proposal.

2. Costs

a. Manufacturer Misclassification of a Covered Outpatient Drug and Recovery of Unpaid Rebate Amounts Due to the Misclassification and Other Penalties

In regard to the costs associated with this provision, if CMS identifies that a drug has been misclassified, the manufacturer will be responsible for paying any unpaid rebates to the States as a result of the misclassification. This will mean that the manufacturers will have to determine which prices to use to calculate the past due rebates and for which unit rebates are owed, and then pay the States the calculated rebate amount. They will also have to report to CMS that such rebates have been paid. In this situation, the States will not incur any new costs; rather it will help ensure that manufacturers are accurately paying rebates to States, thus benefitting the States. 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. In this situation, the States would incur costs as they reimburse the manufacturer for the overpayment. CMS may be required to share in repayment of some of these rebates.

The amount of rebates owed or collected by the manufacturers under these new regulatory misclassification provisions cannot be estimated. We cannot predict how many, if any, drugs are or will be misclassified and require payment of unpaid rebates.

We did not receive public comments on this Regulatory Impact Analysis provision, and therefore, we are finalizing as proposed.

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

This provision will implement existing statute and is being implemented to encourage manufacturer adherence with program reporting requirements and enhance administrative efficiency. Manufacturers that are not reporting their pricing or product information in a timely manner per statutory and regulatory requirements will have their rebate agreement (and those of their associated labelers) suspended for purposes of Medicaid and the MDRP. This means that States will not have to cover or pay for the drugs of the manufacturer during the period of the suspension unless they are paid through their own State funds. 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 will serve as an incentive for manufacturers to report their product and pricing information timely so that drugs of the manufacturer will continue to be covered under Medicaid and the MDRP.

This provision will have minimal cost to the States as their only responsibility will 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 required 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 solicited comments on how to develop a cost estimate.

We did not receive public comments on this Regulatory Impact Analysis provision, and therefore, we are finalizing as proposed.

c. Modified the Definition of Covered Outpatient Drug

This provision may increase manufacturers' rebate liability to the States because it will 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 a 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 will involve minimal burden, as States could inform their providers as part of their regular communications.

We received public comments on these Regulatory Impact Analysis provisions. The following is a summary of the comments we received and our responses.

Comment: One commenter stated that CMS should undertake a formal regulatory impact analysis regarding the modification to the definition of covered outpatient drug to properly assess positive and negative effects.

Response: As we stated in the proposed rule, we are unable to quantify what impact the modification to the definition of covered outpatient drug will have. However, this will clarify for States and manufacturers the application of the ''direct reimbursement'' part of the definition of COD and may assist in identifying utilization that qualifies for rebates in situations where States have not previously collected rebates. We accounted for the administrative costs of reviewing and interpreting this definition in the Regulatory Review section later in this rule.

Comment: One commenter pointed out implementation challenges, including substantial changes to billing and claims systems to capture information about the specific services that are included in a bundled payment. They stated it would be extremely difficult to understand all of the scenarios where the payment for a code was inclusive of the drug reimbursement.

Response: We intend for the modification to the definition to provide clarification regarding when a payment represents direct reimbursement for a drug. Based on the comments, though, it is evident that our proposed modification to the definition did not make this clear. In the past we have stated that no rebate liability attaches to drugs that are paid for as part of bundled payments. However, we have received questions from interested parties to define situations in which rebates can be billed for drugs that are part of inclusive payments in which the quantity of drug dispensed or administered can be identified. We are therefore modifying the proposed definition of direct reimbursement to make it clear that, for such rebates to be billed, the inclusive payment includes an amount directly attributable to the drug, where such amount is based on a reimbursement methodology that is included in the applicable section of the State plan. We believe that the modification to the proposed definition resolves the implementation concerns.

After consideration of public comments, we are finalizing the provision with the amended language as set out at the end of this document.

d. Defined Internal Investigation for Purposes of Pricing Metric Revisions

The cost of the final definition will be the amount of time that needs to be taken by manufacturer personnel to determine how to apply the definition of internal investigation when considering submitting a request to CMS for a recalculation. This legal analysis will not apply to every manufacturer or to every drug of the manufacturer. It will 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. As stated in the proposed rule, we have received only a minimal number of such requests from manufacturers. We assumed the time to perform legal analysis is 5 hours. Using the May 2023 mean (average) wage information from the BLS for lawyers (Code 23–1011), we estimated that the cost of reviewing this provision is $169.68 per hour, including fringe benefits and other indirect costs (*https://www.bls.gov/oes/current/oes231011.htm)* with a total cost of ($169.68 × 5), is $848.40 for each manufacturer. We estimated that only one percent of manufacturers will 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 $6,787.20 (8 × $848.40). We estimated one percent because currently only one manufacturer has submitted such a request. This provision will not impose substantial costs on the State.

We received no public comments on these estimates associated with the definition of internal investigation. We are adopting a definition of internal investigation at § 447.502, as amended and discussed in section II.C.1.c. of this final rule.

e. Revised Definition of Manufacturer for NDRA Compliance

Several analyses and reviews were performed to better assess current manufacturer compliance with the requirement that a manufacturer have a rebate agreement in effect that includes all associated labeler codes. While this policy has already been specified in guidance and preambles, we are opting not to finalize the proposed definition of manufacturer and conforming changes in § 447.510 at this time to further consider commenters' concerns.

f. Define Market Date

In regard 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. That is because they may have assumed that the market date of the COD is the date that they purchased it, rather than the date the COD was sold by any manufacturer and may not have access to relevant pricing records before the date they purchased the drug. 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.

We did not receive public comments on this Regulatory Impact Analysis provision, and therefore, we are finalizing as proposed.

g. Modify the Definition of Noninnovator Multiple Source Drug

This provision proposed 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.

We did not receive public comments on this Regulatory Impact Analysis provision, and therefore, we are finalizing as proposed.

h. Define Vaccine for Purposes of the MDRP Only

We are opting not to finalize the proposed definition of vaccine at this time. We are continuing to review the input provided by commenters on the proposed definition, which may be used in future rule making on this topic.

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

We estimated a decrease in burden associated with this proposal. After contacting several States, we estimated 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 and 4 months to resolve, depending on the complexity of the dispute and how long ago the claim was paid. That means at any given time, the States, many of which have limited staff resources in the pharmacy program, are dealing with hundreds of manufacturer disputes for rebate claims that are more than 3 years old. For our best estimate of the quantifiable impact, with all 50 States, the District of Columbia, and Puerto Rico being affected, we estimated it would take 52 Operations Research Analysts, 15–2031 (1 for each State) 7 hours to resolve a dispute at $91.92/hr (*https://www.bls.gov/oes/current/oes152031.htm*) $643.44 ($91.92 × 7) (for 45 outstanding disputes [(10 disputes + 80 disputes)/2] per State for claims greater than 3 years old. We, therefore, estimated a one-time decreased burden reduction of $6,022,598.40 (45 disputes × $643.44 hr/dispute × 52 States × 4 quarters (1 year)). Manufacturers will only have the ability to initiate a dispute on claims for up to 12 quarters, from the last day of the quarter from the date of State invoice postmark.

We did not receive public comments relating to regulatory impact on this provision, and we are finalizing as proposed.

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

The 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 and services at least equivalent to the care and service available to the general population. Pharmacists must be accurately reimbursed by the State for drug ingredient costs and professional dispensing services under § 447.518.

We have not included time and cost burdens for individual State dispensing fee surveys in this final 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 the proposed rule, we specified that the type of data that States must submit to justify their professional dispensing fees must be based on actual costs of dispensing.

We received public comments on this Regulatory Impact Analysis provision. The following is a summary of the comments we received and our responses.

Comment: Two commenters disagreed with the proposal to require professional dispensing fees to be based on cost data, as opposed to market-based research, and claimed that these proposals are unnecessary and redundant. One commenter was concerned that CMS' proposed requirements divert the States' limited resources away from other more

pressing State Medicaid priorities and that CMS' prohibition on the use of market-based reviews of PDFs is not accompanied by findings that the States' approach is contributing to unsustainable dispensing fee reimbursement. Another commenter stated that imposing stricter standards for cost information in this case means that dispensing fees are treated differently than traditional Medicaid services. Conducting surveys or other research on cost-based data will be an added burden on States, and it may be difficult to obtain this information from providers as opposed to market-based research.

Response: We understand the concerns; however, CMS has no reason to believe that the provisions provided in this final rule will divert the States' limited resources away from other more pressing State Medicaid priorities. States are not required to complete their own cost of dispensing study. States can propose their professional dispensing fees based on a neighboring State's survey, or other credible survey data, as long as it is adequate and reflects the current pharmacy costs of dispensing a prescription in their State.

CMS is also requiring that the professional dispensing fee be based on pharmacy cost data, and not be based on a market-based review, since we believe that market-based research is insufficient because it does not reflect actual costs to pharmacies to dispense prescriptions.

After consideration of public comments on this provision, we are finalizing as proposed.

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 PADs.

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 under regulatory language in § 447.520.

These provisions clarify the existing statute to ensure FFP and rebate collection for all covered outpatient single and multiple source physician-administered drugs.

We received public comments on this Regulatory Impact Analysis provision. The following is a summary of the comments we received and our responses.

Comment: Several commenters opposed this proposed regulation which mandates submission of NDCs for all covered outpatient drugs, as it considerably intensifies the administrative tasks for Medicaid providers. It was stated that this requirement, previously limited to single source PADs and the top 20 multiple source PADs, could strain the already limited resources of 340B covered entities. Another commenter suggested requiring NDC numbers only for medications that cost above a certain dollar threshold to reduce administrative burden.

Response: We appreciate the concerns expressed by the commenters referencing potential administrative burden to State providers to submit NDC numbers for all single source and multiple source drugs. However, since most State Medicaid programs currently require their providers to submit utilization data through use of NDC numbers for all CODs that are single source or multiple source drugs, we anticipate administrative burden to be minimal. Additionally, 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.

After consideration of public comments on this Regulatory Impact Analysis provision, we are finalizing as proposed.

l. BIN/PCN on Medicaid Managed Care Cards

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

We did not receive public comments on this Regulatory Impact Analysis provision regarding the programming time it would take for managed care plans to assign the newly required BIN and PCN combination, and group number identifiers onto the enrollee identification cards, and therefore, we are finalizing as proposed.

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 the proposed rule, we estimated that these requirements would affect 282 managed care plans and their subcontractors (mainly PBMs) in the country and 40 States. We estimated it would take an Operations Research Analyst (Code 15–2031) 25 hours at $91.92 per hour, including fringe benefits and other indirect costs, to renegotiate and revise 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, estimated that the burden associated with this provision will be a one-time cost for each managed care plan of $2,298 or $648,036 for all managed care plans. There are 40 States with Medicaid managed care plans; therefore, we estimated the State's Operations Research Analyst (Code 15–2031) 25 hours at $91.92 per hour, including fringe benefits and other indirect costs to revise State contracts for a one-time cost per State of $2,298 or $91,920 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.[38] 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 currently no 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

[38] *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.*

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. By requiring managed care plans to 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 as well as the base data utilized when developing capitation rates 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.

We received the following comment regarding this Regulatory Impact Analysis provision.

Comment: A commenter specified that the proposed rule aiming to enhance transparency in PBM reporting may unintentionally raise costs for the Medicaid program due to PBMs acting as middlemen. Moreover, shifting away from spread pricing contracts, often without added fees, could lead to higher-cost fee-based contracts despite their increased transparency, ultimately imposing a higher cost on payers.

Response: We do not agree that the provision in § 438.3(s)(8) that requires the managed care plan to specify in its contract with subcontractors that the subcontractor is required to report separately the amounts related to incurred claims and administrative costs, fees and expenses of the subcontractor will unintentionally raise costs for the Medicaid program. We believe this information will help to inform the State's decision-making relating to the administration of the prescription drug benefit. It will also help the Medicaid managed care plans have more accurate data to calculate their MLRs, as well as ensure that States can accurately develop capitation rates. Finally, it will help States and managed care plans ensure that PBMs specifically are being appropriately compensated for their services by requiring that the subcontractors report separately incurred claims for CODs and administrative fees, costs, and expenses in sufficient detail and the level of detail must be no less than the reporting requirements in § 438.8(k).

After consideration of public comments on this provision, we are finalizing § 438.3(s) with some changes to the proposed regulatory text. We will modify § 438.3(s)(8) by: adding at the beginning of paragraph (8) the phrase ''The MCO, PIHP, or PAHP'' to conform with the other paragraphs in § 438.3(s), inserting ''must'' to replace ''to'' for additional clarity, and inserting ''to the MCO, PIHP, or PAHP'' for clarity on the entity that the subcontractor reports the required information to. We also are adding § 438.3(w) to include an applicability date for the requirements of paragraphs (s)(7) and (s)(8), which will be the first rating period for contracts with MCOs, PIHPs, or PAHPs beginning on or after 1 year following November 19, 2024.

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.[39] 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 5 includes the savings which are CBO estimates from when the 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 in the 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.

We did not receive public comments on the estimates related to this Regulatory Impact Analysis provision and are finalizing as proposed.

o. Payment of Claims

At this time, there is no need to determine cost estimates for this item. The 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 the 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.

We received 2 public comments on these proposals. The following is a summary of the comments we received and our responses.

Comment: A couple of commenters stated they were in support of our proposal to correct omissions in regulatory language to align with statutory language, ensuring Medicaid remains the payer of last resort while also permitting States to pay claims sooner than the specified waiting periods when doing so is cost-effective and necessary to ensure access to care.

Response: We appreciate the support for this proposal.

After consideration of public comments, we are finalizing this provision as proposed.

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

This provision was a request for information only. We sought 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.

We received many public comments on these proposals. The following is a summary of the comments we received and our response.

Comment: A few commenters provided general support for the requirement of diagnoses on prescriptions; however, the majority of commenters stated their opposition to requiring diagnoses on prescriptions. These arguments focused mostly on administrative burden, potential

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

information technology (IT) issues with delays in care, significant system alterations, stigma, and other complications. Several commenters stated that because of the technical and operational challenges of including a diagnosis on a prescription, it could also lead to manufacturers initiating unnecessary disputes. Furthermore, many commenters opposed the requirement of diagnoses on prescriptions due to possible impact on equitable access to care, including delays and denials in care, added burden to patients, exacerbation of existing barriers to care, and overall reduction in care access.

Response: We appreciate all the comments received for the request for information on requiring a diagnosis on Medicaid prescriptions.

After careful review and consideration of the public comments received, and due to the overwhelming number of comments that were opposed to this requirement, we are not going to pursue this requirement in rulemaking at this time. We will continue to review the feedback we receive from interested parties and may address this provision in future rulemaking if appropriate.

q. Proposal To Account for Stacking When Determining Best Price

We are opting not to finalize the proposed provision related to stacking when determining the best price at this time to further consider comments received and pursue collection of information through a separate Paperwork Reduction Act (PRA) request to collect additional information related to manufacturers' stacking methodologies.

r. Proposal Regarding Drug Price Verification Through Data Collection

We are opting not to finalize the proposed provision related to the drug price verification survey at this time.

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 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, and the pharmacy, agent, or other AMP or best price eligible entity does not receive any part of the manufacturer patient assistance in the form of additional price concessions.

As part of the 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 is being eroded by PBM copay accumulator programs because the patient assistance is accumulating to the economic benefit of health plans, not to patients, given that the health plans' spending on drugs for patients decreases as a result of such programs. We also believed that, 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 make 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 requesting that the court vacate these amendments to § 447.505(c)(8) through (11) (85 FR 87102 and 87103), as set forth in the 2020 final rule. On May 17, 2022, the United States District Court for the District of Columbia ruled in favor of the plaintiff and ordered that the applicable provisions of the 2020 final rule be vacated and set aside.

In response to the order issued by the United States District Court for the District of Columbia to vacate the applicable provisions of the 2020 final rule, we proposed to withdraw the applicable changes made to § 447.505, and, for consistency, withdraw the corresponding revisions to regulations addressing AMP made by the 2020 final rule. At the time of the 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.

3. Regulatory Review Cost Estimation

If regulations impose administrative costs on private entities, such as the time needed to read and interpret the 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 the proposed rule, we assume that the total number of unique commenters is based on the current 792 manufacturers participating in the MDRP. Nevertheless, we estimated that the current 792 manufacturers would need to review the proposed rule.

Furthermore, we anticipated 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 the proposed rule. Additionally, we estimated that 19 trade organizations may review the proposed rule. The 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 the proposed rule in detail, and it is also possible that some reviewers will choose not to comment on the proposed rule. In addition, we assumed 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 assumed that approximately 863 (792 manufacturers + 52 States + 19 trade associations) entities may review the proposed rule. For these reasons, we believed that the number of commenters would be a fair estimate of the number of reviewers who are directly impacted by the proposed rule. We solicited comments on this assumption.

We also recognized that different types of entities are in many cases affected by mutually exclusive sections of the proposed rule. However, for the purposes of our estimate, we assumed that each reviewer reads 100 percent of the proposed rule.

Using the May 2023 mean (average) wage information from the BLS for medical and health service managers (Code 11–9111), we estimated that the cost of reviewing the proposed rule is $129.28 per hour, including fringe benefits and other indirect costs (*https://www.bls.gov/oes/current/oes119111.htm*). Assuming an average reading speed of 250 words per minute, we estimated that it would take approximately 288 minutes (4.8 hours) for the staff to read the rule, which is approximately 72,000 words. For each medical and health service manager (Code 11–9111) that reviews the proposed rule, the estimated cost is (4.8 × $129.28) or $620.54. In part, we estimated that the cost of reviewing this final rule by medical and health service managers is $535,526.02 ($620.54 × 863

reviewers). Additionally, there is also a lawyer who will review the final rule. Using the May 2023 mean (average) wage information from the BLS for lawyers (Code 23–1011), we estimated that the cost of reviewing the final rule is $169.68 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 estimated that it would take approximately 288 minutes (4.8 hours) for the staff to review the final rule, which is approximately 72,000 words. For each lawyer (Code 23–1011) that reviews the proposed rule, the estimated cost is (4.8 × $169.68) or $814.46. In part, we estimated that the cost of reviewing the rule by lawyers is $702,878.98 ($814.46 × 863 lawyers). In total, we estimated the one-time cost of reviewing the rule is $1,238,405.00 ($535,526.02 + $702,878.98).

We acknowledged that these assumptions may understate or overstate the costs of reviewing the rule.

We did not receive public comments on this Regulatory Impact Analysis provision, and therefore, we are finalizing as proposed.

TABLE 4—SUMMARY OF THE ONE-TIME QUANTITATIVE COSTS AND BENEFITS

Line item	Cost	Entity	Timeframe
Regulatory review	$1,238,405.00	Manufacturers, States, Trade Association.	One-time cost.
Define manufacturer internal investigation	6,787.20	Manufacturers	One-time cost.
Establish a 12-Quarter Rebate Audit Time Limitation	(6,022,598.40)	States and Federal Government	One-time cost savings.
Drug Cost Transparency in Medicaid Managed Care Contracts	648,036.00	Managed care plans and their subcontractors.	One-time cost.
Drug Cost Transparency in Medicaid Managed Care Contracts	91,920	States	One-time cost.
Total	(4,037,450.20)		

TABLE 5—SUMMARY OF THE ANNUAL QUANTITATIVE COSTS AND BENEFIT

Line item	Cost	Entity	Timeframe
Drug cost transparency in Medicaid managed care contracts	($929,000,000.00)	Federal Government	Over 10 years.
Removal of manufacturer rebate cap (100% of AMP)	(14,211,000,000.00)	Federal and State Governments	Over 10 years.
Total	(15,140,000,000.00)		

D. Alternatives Considered

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

We proposed 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. However, based on public comment, we are not finalizing this proposal at this time.

We proposed to define vaccine to endeavor to prevent disputes with manufacturers about what products are and are not vaccines for purposes of the MDRP, given that there may be products coming to market for which this definition might help provide clarity. However, we are not finalizing this proposal at this time. We are continuing to review the input provided by commenters on the proposed definition, which may be used in future rule making on this topic.

We proposed 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 from States 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, this alternative would have allowed disputes to be initiated on claims for any 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. Additionally, we believe the more recent the claim corresponding with the dispute, the easier it will be to resolve disputes, and this provision will improve the accuracy and speed of dispute resolutions.

We did not receive public comment on this proposal, which relates to our regulatory impact analysis, and we are finalizing this provision.

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 6 showing the classification of the impact associated with the provisions of this final rule.

TABLE 6—ACCOUNTING STATEMENT: CLASSIFICATION OF ESTIMATED COSTS/SAVINGS

Category	Estimates	Units		
		Year dollar	Discount rate (%)	Period covered
Costs/Savings:				
Annualized Monetized ($million/year)	($0.54)	2021	7	2024–2034
	(0.46)	2021	3	2024–2034

TABLE 6—ACCOUNTING STATEMENT: CLASSIFICATION OF ESTIMATED COSTS/SAVINGS—Continued

Category	Estimates	Units		
		Year dollar	Discount rate (%)	Period covered
Costs/Savings:				
Annualized Monetized ($million/year)	(1,328.96)	2021	7	2024–2034
	(1,433.53)	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 estimated 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 that the SBA does not provide any revenue data at this time to measure the size of these industries.

According to the SBA's website at *https://www.sba.gov/document/support-table-size-standards,* the drug manufacturers referred to in the 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 that have less than 1,250 employees annually for pharmaceutical preparation manufacturing and biologic product (except diagnostic) manufacturing industries. Table 7 presents the total number of small businesses in each of the two industries mentioned.

TABLE 7—NAICS 32541 PHARMACEUTICAL AND MEDICINE MANUFACTURING SIZE STANDARDS

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

Source: 2019 Economic Census.

TABLE 8—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 9—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
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 8 and 9, the economic impacts are disproportionate for small firms. Tables 8 and 9 show the employees for each of the size categories and the employee impact per small entity. For example, in Table 8, 390 of the smallest firms employ only 0.68 percent of the employees in its industry; while, in Table 9, 71 of the smallest firms employ only 0.65 percent of the employees in its industry.

Therefore, as can be seen in Tables 8 and 9, almost all Pharmaceutical and Medicine Manufactures are small entities as that term is used in the RFA. Additionally, Tables 8 and 9 show the disproportionate impacts among firms, and between small and large firms. In Tables 8 and 9, 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 1,250 total employees in any 1 year.

At this time, revenue data are not currently available. However, 2012 revenue data from the U.S. Economic Census were 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 final rule will not have a significant impact (that is, a 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 the proposed rule. Therefore, the Secretary has certified that the 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 604 of the RFA. For purposes of section 1102(b) of the Act, we define a small rural hospital as a hospital that is located outside of a metropolitan statistical area and has fewer than 100 beds. This final rule will not have a significant impact on small rural hospitals. We did not prepare an analysis for section 1102(b) of the Act because we have determined, and the Secretary has certified, that the final 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 2024, that threshold is approximately $183 million.

This final rule imposes mandates that will result in anticipated costs to State, local, and Tribal governments or the private sector, but the transfer costs will be less than the threshold. States will receive additional monetary rebates

from manufacturers brought into compliance with drug misclassification. This final rule will 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 final rule will 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 $183 million in any 1 year.

H. Federalism

Executive Order 13132 establishes certain requirements that an agency must meet when it issues a proposed rule (and subsequent final rule) that imposes substantial direct requirement costs on State and local governments, preempts State law, or otherwise has Federalism implications. This final rule 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.

This final regulation is subject to the Congressional Review Act provisions of the Small Business Regulatory Enforcement Fairness Act of 1996 (5 U.S.C. 801 *et seq.*) and has been transmitted to the Congress and the Comptroller General for review.

Chiquita Brooks-LaSure, Administrator of the Centers for Medicare & Medicaid Services, approved this document on September 9, 2024.

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 amends 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) and (w) to read as follows:

§ 438.3 Standard contract requirements.

* * * * *

(s) * * *

(7) The MCO, PIHP, or PAHP must assign and exclusively use unique Medicaid-specific Bank Identification Number (BIN) and Processor Control Number (PCN) combination, and group number identifiers for all Medicaid managed care enrollee identification cards for pharmacy benefits.

(8) The MCO, PIHP, or PAHP that contracts with any subcontractor for the delivery or administration of the covered outpatient drug benefit must require the subcontractor to report separately to the MCO, PIHP, or PAHP 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.

* * * * *

(w) *Applicability date.* Paragraphs (s)(7) and (8) of this section apply to the first rating period for contracts with MCOs, PIHPs, and PAHPs beginning on or after 1 year following November 19, 2024.

* * * * *

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;

■ iii. Adding paragraph (4);

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

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

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, as described in paragraph (4) of this definition).

* * * * *

(4) Direct reimbursement for a drug may include both:

(i) Reimbursement for a drug alone, or

(ii) Reimbursement for a drug plus the service, in a single inclusive payment if:

(A) The drug, charge for the drug, and number of units of the drug are separately identified on the claim, and;

(B) The inclusive payment includes an amount directly attributable to the drug, and,

(C) The amount paid that is attributable to the drug is based on a reimbursement methodology that is included in the applicable section of the State plan.

* * * * *

Drug product information means 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 type (prescription, over-the-counter), base date AMP, therapeutic equivalent code (TEC), line extension indicator, 5i indicator, 5i route of administration (if applicable), FDA approval date, FDA application number or OTC monograph citation (if applicable), market date, and COD status.

* * * * *

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 possible fraud, abuse, or violation of law or regulation. A manufacturer must make data available to CMS to support its finding.

* * * * *

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;

* * * * *

■ 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) 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.

* * * * *

■ 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. In such case, the manufacturer must certify the applicable correction within 30 calendar days.

(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) and (i).

The revisions and additions 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) *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 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.

(i) *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 State invoice postmark date.

■ 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.

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■ 12. Section 447.520 is revised 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 single source drugs or the multiple source drugs identified under paragraph (c) of this section 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 in a manner consistent with the requirements of this section. In the case of multiple source drugs not identified under paragraph (c), a failure to comply with the requirements of this section may result in FFP being withheld as provided under 42 CFR 430.35.[40]

(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 © 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.

(3) States are required to invoice for rebates consistent with this section for multiple source physician-administered drugs that are CODs and that are not on the top 20 multiple source physician-administered drug list published under paragraph (c) of this section, or may be subject to a withhold of FFP as provided under 42 CFR 430.35.[41]

(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 that is a physician-administered drug using NDC numbers. As of November 19, 2024, a State must also comply with this requirement for a covered outpatient drug that is a physician-administered drug described in paragraph (a)(3) of this section.

(c) *Top 20 multiple source physician-administered drug list.* The top 20 multiple source physician-administered drug list, identified by the Secretary as

[40] *https://www.ecfr.gov/current/title-42/chapter-IV/subchapter-C/part-430.*

[41] Ibid.

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.

Xavier Becerra,

Secretary, Department of Health and Human Services.

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