Medicaid Program; Misclassification of Drugs, Program Administration and Program Integrity Updates Under the Medicaid Drug Rebate Program (CMS-2434-P) Summary of Proposed Rule

On May 26, 2023, the Centers for Medicare & Medicaid Services (CMS) published in the Federal Register (FR) a proposed rule entitled "Medicaid Program; Misclassification of Drugs, Program Administration and Program Integrity Updates Under the Medicaid Drug Rebate Program" (88 FR 34238-34296).

The rule proposes to implement policies in the Medicaid Drug Rebate Program (MDRP) related to legislative requirements addressing drug misclassification, as well as drug pricing and product data misreporting by manufacturers. Several other program integrity and program administration provisions are proposed for MDRP. The rule would also do the following: designate a time limit on manufacturers initiating audits with states; clarify and establish requirements for state fee-for-service (FFS) pharmacy reimbursement; codify conditions relating to states claiming federal Medicaid matching funds for physician-administered drugs (PADs); clarify the requirement of accumulating price concessions when determining best price; and designate drug price verification and transparency through data collection, including a new annual Medicaid Drug Price Verification Survey for verifying prices and publishing non-proprietary information about the prices for certain covered outpatient drugs (CODs). CMS also proposes two new contracting requirements between states and their Medicaid managed care plans. This rule includes a proposal, unrelated to MDRP, that makes revisions to the third-party liability (TPL) regulation due to legislative requirements. Consistent with a 2022 court order, the administration also proposes to rescind revisions made to regulations by a December 31, 2020 final rule regarding the determination of best price and average manufacturer price (AMP).

CMS' rollout package also included a press release, a fact sheet on the proposed rule, and a fact sheet specific to the provisions regarding the proposed annual survey and drug price transparency for arrangements between pharmacy benefit managers (PBMs) and Medicaid managed care plans.

The public comment period will end on July 25, 2023 (60-day comment period).

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I. Background

States have the option to provide coverage of prescription drugs in their Medicaid programs. If they do (and all do), federal financial participation (FFP)—that is, federal Medicaid matching funds—is available for state expenditures on CODs if the state complies with the requirements of section 1927 of the Social Security Act,[1] which governs the Medicaid Drug Rebate Program (MDRP). FFP for CODs is only available if manufacturers entered into a National Drug Rebate Agreement (NDRA), requiring them to pay certain rebates to states. The MDRP provides specific requirements for manufacturer rebate agreements, drug pricing submission and confidentiality requirements, the formulas for calculating rebate payments, drug utilization reviews (DUR), and requirements for states for CODs.

The required rebates are generally higher for brand-name drugs versus generic drugs (1927(c); §447.509). Brand-name drugs are a single source drug (S drug) or innovator multiple source drug (I drug). Other drugs, including noninnovator multiple source drugs (N drugs), are commonly referred to as generics. In the proposed rule, CMS reviews its requirements on manufacturers consistent with section 1927(b)(3)(A) for reporting product and pricing information, including for average manufacturer price (AMP) and best price, from which CMS calculates a unit rebate amount (URA) for each COD that states use to bill manufacturers for rebates. In addition, the rebate calculation for any COD may include an additional inflationary component, where the state collects a rebate for the amount by which the drug's current quarter AMP exceeds its base date AMP adjusted to the current period by the Consumer Price Index for All Urban Consumers (CPI-U).

Manufacturers' misreporting, misclassification, or failure to submit and certify timely monthly and quarterly pricing and drug product data may impede states' ability to invoice and collect appropriate rebate amounts. In the proposed rule, CMS reviews the history of regulatory and statutory changes to the definitions of a single source drug, innovator multiple source drug, and noninnovator multiple source drug. Notably, a COD final rule effective April 1, 2016, introduced a process by which manufacturers could submit a request for a narrow exception to have CMS recognize individual drugs approved under a new drug application (NDA) as noninnovator multiple source drugs prospectively from the effective date of the COD final rule, which would not affect their treatment prior to April 1, 2016. Nevertheless, CMS says that many

[1] Henceforth, unless noted otherwise, all statutory references will be to the Social Security Act and all regulatory section references will be to Title 42 of the Code of Federal Regulations (CFR).

manufacturers have disregarded its guidance and have continued to misreport drugs marketed under an NDA as noninnovator multiple source drugs for periods prior to April 1, 2016.

Section 6 of the Medicaid Services Investment and Accountability Act of 2019 (MSIAA, P.L. 116-16), titled "Preventing the Misclassification of Drugs Under the Medicaid Drug Rebate Program," amended federal Medicaid law to specify the definitions for multiple source drug, single source drug and innovator multiple source drug, and to provide the Secretary with additional authorities to ensure manufacturers' compliance with program requirements, including the appropriate classification of a drug. In general, a misclassification occurs when a manufacturer reports and certifies its covered outpatient drug in a drug category not supported by the statutory and regulatory definitions of S, I, or N. A misclassified drug is likely paying different rebates to states than those supported by statute and regulation.

CMS says that although much of the MSIAA is self-implementing, it is proposing a series of regulatory amendments at §§447.509 and 447.510 to codify the statutory changes in regulation. It proposes that a misclassification of a drug under the MDRP has occurred or is occurring when a manufacturer reports and certifies to the agency a drug category or drug product information relating to that COD that is not supported by the statutory and regulatory definitions of S, I or N. A misclassification would also include 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. Under the MSIAA, the reporting of false drug product information and data related to false drug product information is subject to possible civil monetary penalties (CMPs) by the Office of the Inspector General (OIG) of the Department of Health and Human Services (HHS). If a manufacturer fails to correct the misclassification of a drug in a timely manner after receiving notification from the agency, in addition to the manufacturer having to pay past unpaid rebates to the states (if applicable), the Secretary can take any or all of the following actions:

- Correct the misclassification;
- Suspend the misclassified drug and the drug's status as a COD under the manufacturer's rebate agreement, and exclude the misclassified drug from FFP; and
- Impose CMPs for each rebate period for which the drug is misclassified.

CMS says that codifying these statutory changes in regulation provides an opportunity to give additional clarity to and guidance on the new legal authorities for ensuring oversight of, compliance with, and enforcement of the provisions of the MDRP—and ultimately to ensure that federal and state programs are receiving appropriate rebates and that CMS continues to be a stringent steward of the Medicaid program.

The major provisions in the proposed rule include the following.

Modifying the Definition of Covered Outpatient Drug. The current, lengthy regulatory definition of a COD is a prescribed drug that meets any of several requirements. Excluded from that, however, are drugs provided as part of or incident to and made in the same setting as particular services, such as inpatient and hospice services. This regulatory exclusion includes a parenthetical that has generated confusion—that the exclusion from being a COD is available only if the payment for the drug is part of the service instead of as a direct reimbursement for the

drug. Questions have arisen as to whether separately identifying the cost of the drug on the same payment claim as the accompanying service qualifies as direct reimbursement for the drug, thus subjecting it to rebates. CMS seeks to clarify the issue in its amended definition—that direct reimbursement for a drug may include both reimbursement for a drug alone or for reimbursement for a drug plus the service in one inclusive payment if the drug and the itemized cost of the drug are separately identified on the claim.

Defining Internal Investigation for Pricing Metric Revisions. Under current regulations, manufacturers must report to CMS any revision to AMP, best price, customary prompt pay discounts or nominal prices (pricing data) not more than 12 quarters from the quarter when the data were due, unless one of a number of enumerated exceptions applies. One of the exemptions is if reporting is required "under an internal investigation," which was not defined and has led to different interpretations. The proposed definition of internal investigation would be a manufacturer's investigation of its AMP, best price, customary prompt pay discounts or nominal prices that have been previously certified and that results in a finding made by the manufacturer of fraud, abuse, or violation of law or regulation.

Modifying Definition of Manufacturer for National Drug Rebate Agreement (NDRA). Consistent with its interpretation of the statute, CMS proposes amending the definition of manufacturers subject to the NDRA to include all labelers associated or affiliated with the manufacturer. In addition, the regulatory definition would be modified to reflect the statutory requirement that a manufacturer must 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, as must all labelers (with their applicable codes) associated or affiliated with a manufacturer. Additional provisions address when manufacturers add or remove labelers.

Defining Market Date for Determining Base Date AMP. As previously mentioned, any additional inflation-based rebates rely on calculations from the drug's base date AMP, which manufacturers are required to report for each dosage form and strength of a COD for all of its CODs. Due to numerous inquiries and incorrect reporting of market dates by manufacturers, CMS proposes to define market date in regulation as the date on which the covered outpatient drug was first sold by any manufacturer.

Modifying Definition of Noninnovator Multiple Source Drug. Many provisions of the MSIAA were codified in regulation in the December 31, 2020, final rule, including the definitions of multiple source drug, innovator multiple source (I) drug, and single source drug. That rule should also have updated the regulatory definition of noninnovator multiple source (N) drug but neglected to do. This rule proposes that update to align with the MSIAA changes.

Defining Vaccine for the MDRP Only. For purposes of the MDRP, federal statute explicitly excludes vaccines from the definition of CODs, even though there is no such definition in Title XI, XVIII, XIX or XXI (applicable to Medicare, Medicaid and the State Children's Health Insurance Program (CHIP)) or in the authorizing statutes of any other HHS agency. CMS proposes a regulatory definition for the purpose of identifying products that do not satisfy the definition of COD and are therefore not subject to requirements under section 1927, including Medicaid drug rebates. Vaccine would be defined as 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.

Proposal to Accumulate Price Concessions and Discounts ("Stacking") when Determining Best Price. Federal Medicaid law defines best price of a single source drug or innovator multiple source drug as 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. CMS proposes to modify the regulatory definition by adding language to make clearer that the manufacturer must adjust the best price 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. That is, manufacturers would have to stack all applicable discounts that they offer on a single sale of a COD, including discounts or rebates provided to more than one best price eligible entity.

Establishing a 12-Quarter Time Limitation for Audits over Utilization Data with States. No time limit currently exists for a manufacturer to initiate an audit or to resolve previously disputed state utilization data with respect to rebates owed. CMS proposes to limit the time period for manufacturers to initiate disputes, hearing requests and audits of state-invoiced utilization data to 12 quarters from the last day of the quarter from the date of state invoice to the manufacturer.

Drug Price Verification and Transparency through Data Collection. Since the MDRP's founding in 1991, section 1927(b)(3)(B) has provided the Secretary with specific authority to survey wholesalers and manufacturers that directly distribute their CODs. The purpose of this authority is to verify manufacturer prices that are reported under section 1927(b)(3)(A), which can include average manufacturer price (AMP), best price, average sales price (ASP) and wholesale acquisition cost (WAC). This information is used not only for Medicaid, but also for Medicare Part B (e.g., ASP for physician-administered drugs). State Medicaid programs generally use ASP for physician-administered drugs, WAC for reimbursing providers for the drug cost component of providing a drug, and AMP for calculating federal upper limits (FULs) for multiple source drugs.

Since the enactment of the MDRP, substantial evolution has occurred in the types of drugs paid for by Medicaid, manufacturers' pricing structures for these drugs, and the methods used by manufacturers to distribute these drugs. New highly individualized gene and cell therapy drug treatments have resulted in high launch prices, impacting the manufacturers' prices reported to CMS. Manufacturers and health plans now own pharmacy benefit managers (PBMs), and manufacturers are more frequently limiting the distribution of drugs through specialty pharmacies, some of which are owned by the PBMs themselves. All of these factors impact how manufacturers set drug pricing and the payments that state Medicaid programs make for these drugs.

In this rule, CMS describes situations in which it is proposing to send surveys to manufacturers and wholesalers to verify prices and charges, and the information that would be requested.

Clarifying and Establishing Requirements for FFS Pharmacy Reimbursement. Since the implementation of the 2016 COD final rule, FFS pharmacy reimbursement is to be based on actual acquisition cost-based reimbursement, under which pharmacists are paid for the ingredient costs of the drug plus a professional dispensing fee (PDF) reflecting their dispensing costs. Although almost every state has made the appropriate transition, and the updated pharmacy reimbursement methodology is accurately reflected in approved Medicaid state plan amendments (SPAs), CMS proposes revising §447.518 to ensure that pharmacy providers are reimbursed adequately for both their pharmacy ingredient costs and professional dispensing services costs consistent with the applicable statutory and regulatory requirements.

Current regulations require states to provide adequate data to support any proposed changes to either component of the reimbursement methodology (ingredient cost or PDF), such as a survey of retail pharmacy providers or other reliable data. CMS proposes to clarify that adequate data must ensure that, consistent with 1902(a)(30)(A), payments are consistent with efficiency, economy, and quality of care and are sufficient to enlist enough providers so that care and services are available at least to the extent that such care and services are available to the general population in the geographic area. Specifically, the regulation would require that the research and data must be based on costs and be sufficient to establish the adequacy of the pharmacy reimbursement methodology under the Medicaid state plan.

FFP Conditions for Physician-Administered Drugs. CMS proposes to require states to collect National Drug Code (NDC) information on all covered outpatient single and multiple source physician-administered drugs and to specify that states should be invoicing for rebates for all covered outpatient physician-administered drugs in order to receive FFP and secure manufacturer rebates. This is added to ensure compliance with statutory requirements from 2006[2] and to provide additional specificity and clarity to the corresponding regulatory requirements added in 2007.[3]

Suspension of a Manufacturer's Drug Rebate Agreement. A new proposed regulatory provision would authorize suspending a manufacturer's rebate agreement if it has failed to report timely information to CMS of information in existing §447.510(a) (regarding quarterly reports of AMP, best price and other prices) and (d), regarding monthly AMP. CMS would communicate electronically and in writing to the manufacturer, imposing a 90-day deadline to report the information, before the manufacturer would have its rebate agreement suspended.

The suspension would last at least 30 days and would apply to all the manufacturer's labelers consistent with the proposed definition of "manufacturer." During the suspension, FFS would not be available to states for the manufacturer's CODs.[4]

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[2] Sections 1903(i)(10)(C) and 1927(a)(7) as added by the Deficit Reduction Act (DRA) of 2005 (P.L. 109-171, enacted February 8, 2006).
[3] §447.520 per the final rule "Medicaid Program; Prescription Drugs" (72 FR 39142, 39162), hereafter referred to as the July 17, 2007 final rule.
[4] This suspension would not affect manufacturer participation in Medicare Part B or the 340B Drug Pricing Program.

Managed Care Plan Standard Contract Requirements. Health plans, including Medicaid managed care plans,[5] use two codes on the patient's identification card to identify the prescription health insurance and benefits—the National Council for Prescription Drug Programs (NCPDP) Processing Bank Identification Number (BIN) and Processor Control Number (PCN). This information, along with a group number, can specify that a beneficiary is part of a specific patient insurance group, such as being a Medicaid managed care beneficiary. However, the card often does not make clear if the coverage is through the organization's Medicaid managed care plan or other insurance they offer, such as through employers or the individual market. This occurs because Medicaid-specific BIN, PCN, and group numbers are not always placed on Medicaid managed care plan identification cards. CMS proposes to require Medicaid managed care plans that provide coverage of CODs to assign and exclusively use unique Medicaid BIN, PCN, and group number identifiers for all Medicaid managed care beneficiary identification cards for pharmacy benefits. Medicaid-specific BIN/PCN/group numbers can also help ensure duplicate rebates are not obtained under both the MDRP and 340B.

Each Medicaid managed care plan must report its medical loss ratio (MLR) by distinguishing between expenses for covered benefits versus administrative expenses. This applies to plans' subcontractors, including PBMs and their benefit versus administrative expenses (for example, claims adjudication and processing prior authorization requests). CMS proposes to specify that managed care plans covering CODs must structure any contract with subcontractors to require the subcontractor to report the amounts related to the MLR's incurred claims (§438.8(e)(2)).

Per Court Order, Rescinding Revisions from December 31, 2020 Final Rule to Determinations of Best Price (§447.505) and AMP (§447.504). The December 31, 2020 final rule included provisions to permit funds for manufacturers' patient assistance program to *not* be reflected in AMP or best price, but only if manufacturers ensure the full value of the assistance is passed on to the consumer. On May 17, 2022, the D.C. District Count vacated these provisions regarding best price. For consistency, CMS proposes to withdraw the changes made by the 2020 rule to both AMP and best price.

Implementing Statutory Removal of Manufacturer Rebate Cap (100 percent AMP). Section 9816 of the American Rescue Plan Act of 2021 (ARP, P.L. 117-2, enacted March 11, 2021) sunsets the limit on maximum rebate amounts for single source and innovator multiple source drugs by adding "and before January 1, 2024," after "December 31, 2009" in section 1927(c)(2)(D).[6] CMS states that other statutory provisions[7] result in this provision also applying to the limit on maximum rebate amounts for CODs other than single source or innovator multiple source drugs and proposes to update regulations accordingly.

RFI: Requiring a Diagnosis on Medicaid Prescriptions as a Condition for Claims Payment. While the statute limits the definition of a COD to "medically accepted indications," it is difficult

[5] Throughout this summary, the term managed care plans refers to Medicaid managed care organizations (MCOs), prepaid inpatient health plans (PIHPs), and prepaid ambulatory health plans (PAHPs).
[6] According to the Congressional Budget Office (CBO), this provision in ARP was estimated to save $14.5 billion in federal outlays from FY2024-2030. See row 207 of Table 9 of CBO's Detailed Tables of "Estimated Budgetary Effects of H.R. 1319, American Rescue Plan Act of 2021."
[7] Sections 1927(c)(3)(C)(i), (ii)(IV), and (ii)(V), which ARP did not amend.

to determine whether a drug is being used for a medically accepted indication—and if it therefore satisfies the definition of a COD and is rebate eligible— without a diagnosis on the prescription drug claims. CMS is soliciting comments on possibly proposing a requirement that a patient's diagnosis be included on a prescription as a condition of receiving Medicaid FFP for that prescription.

II. Provisions of the Proposed Regulations

A. Payment of Claims (§433.139)

In general, Medicaid is the "payer of last resort," meaning that Medicaid pays for only the portion of a covered service not paid for by other payers. Longstanding federal law, along with regulations from 1980, outline requirements for state Medicaid agencies to support coordination of benefits (COB) by identifying any third party liability (TPL). These TPL regulations are generally structured to avoid the costs of "pay and chase"—in this context, where the agency pays the entire amount and then must chase down TPL dollars. An exception to this is, for example, the Medicaid agency must pay its full amount for preventive pediatric services and obtain any TPL after the fact (§433.139(b)(3)(i)).

The Bipartisan Budget Act of 2018 (BBA 2018, P.L. 115-123, enacted Feb. 9, 2018) amended statutory TPL provisions, with requirements including that states do the following:

- Take all reasonable measures to ascertain the legal liability of third parties to pay for care and services available under the Medicaid state plan; and
- Provide for the collection of sufficient information to enable the state to pursue claims against third parties.

The 2020 final rule updated the regulation to reflect the statutory TPL changes, with one omission that CMS proposes to address. CMS proposes to add that a state must 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.

B. Standard Medicaid Managed Care Contract Requirements

1. <u>BIN/PCN on Medicaid Managed Care Cards (§438.3(s)(7))</u>

CMS proposes to require that states contracting with managed care plans providing coverage of CODs to in turn require those plans to assign and exclusively use unique Medicaid-specific Processing Bank Identification Number (BIN), and Processor Control Number (PCN), and group number identifiers for all Medicaid managed care beneficiary identification cards for pharmacy benefits. As proposed, this requirement would apply no later than the next rating period for Medicaid managed care contracts, following the effective date of the final rule adopting this new provision. CMS believes 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 plans with adequate time to prepare the necessary contract terms and to finish the necessary administrative processes for creating and issuing cards with these newly required Medicaid-specific BIN, PCN, and group number identifiers.

This change would make the Medicaid drug program run more efficiently, improve the level of pharmacy services provided to Medicaid beneficiaries, and improve pharmacies' ability to identify patients as Medicaid beneficiaries and better provide pharmacy services. Medicaid-specific BIN, PCN, and group numbers would make the beneficiary's Medicaid managed care status distinguishable from other lines of business offered by the same entity. It would also be helpful to all parties to ensure that Medicaid benefits are provided correctly, including the confirmation of accurate cost sharing amounts, and to reduce the incidence of 340B duplicate discounts, which are prohibited under section 340B(a)(5)(A) of the Public Health Service (PHS) Act as well as under section 1927.

Medicare Part D has had a similar requirement for years (§423.120(c)(4)). Additional reasons for the similar requirement under Medicare Part D included making the pharmacy aware that Medicare statute and rules may apply, such as not allowing certain manufacturer coupons, which plan benefits apply, appeals rights, etc.

CMS is soliciting comments on the implementation time frame and other possible operational issues of requiring unique Medicaid BIN, PCN, and group numbers to be on Medicaid managed care beneficiary identification cards.

2. Drug Cost Transparency in Medicaid Managed Care Contracts (§438.3(s)(8))

CMS proposes to specify that managed care plans covering CODs must structure any contract with subcontractors for the delivery or administration of CODs to ensure drug cost spending transparency by requiring the subcontractor to report separately certain expenses and costs. These subcontractors may include PBMs.

a. Background on PBM Payments

Most Medicaid beneficiaries are enrolled in a managed care plan, and because of the specialized nature of the COD benefit, many managed care plans contract with or have their own PBMs administer the COD benefit. CMS characterizes PBMs as the middlemen of the relationship between the managed care plans and the health care (medical and pharmacy) providers that provide CODs. That is, the PBMs have contracts both with the managed care plans and the health care providers administering or providing the drugs to the plans' enrollees. The PBMs' tasks may include developing a drug formulary, collecting manufacturer rebates on behalf of the plan, performing drug utilization review (DUR), negotiating rates to pay pharmacy providers, adjudicating claims, and contracting with retail community pharmacies and other health care providers to develop a network of pharmacy providers.

CMS describes a number of ways that PBMs may pay pharmacy providers under their contracts, which may differ from how the PBM charges the managed care plan. Under Medicare Part D, CMS requires that the price the PBM pays to the pharmacy is passed through to the plan, and any "spread" that the PBM keeps is an administrative cost that must be reported to the plan. Medicaid-contracted PBMs often reimburse health care providers using methods similar to those used in the commercial and Medicare Part D markets, which are heavily dependent on drug

pricing benchmarks provided by manufacturers and published by commercial publishers of drug pricing data—Average Wholesale Price (AWP) or Wholesale Acquisition Cost (WAC). PBMs may also use a Maximum Allowable Cost (MAC) benchmark for generic drugs, which is a PBM proprietary benchmark for generics.

PBMs' payment to contracted health care providers might be based on a discount off AWP, a markup on WAC, or the MAC for generics, plus any contractually defined professional dispensing fee (PDF), which determines the total reimbursement for each COD. However, the PBM might charge the plans for dispensing that same COD based on a different fixed percentage discount from AWP, for example, or a higher percentage of WAC. Thus, there is little to no transparency to the managed care plan as to how much the plan actually pays for the COD administered or dispensed to the patient, and how much is paid to the PBM for fees related to the administration of the COD benefit.

CMS describes the margin between the amount charged to a managed care plan for a COD and the amount paid by a PBM to a pharmacy provider as the "spread" or "spread pricing," which may only be known by the PBM, unless a state Medicaid program or managed care plan specifically requires disclosure. This information deficit results in a lack of accountability and transparency to the Medicaid program, which CMS believes is contrary to proper and efficient operation of the state Medicaid program and potentially creates conflicts of interest in connection with payment for CODs.

CMS says that greater transparency and accountability by Medicaid managed care plans (and their subcontractors) to states for how Medicaid benefits are paid—compared to how administrative fees or services are paid—are necessary for efficient and proper operation of Medicaid programs. Section 1902(a)(4)(A) requires that the Medicaid state plan comply with methods of administration that are found by the Secretary to be necessary for the proper and efficient operation of the state plan.

Medicaid managed care regulations (§438.8) require states, through their contracts with managed care plans, to require each managed care plan to calculate and report an annual MLR starting on or after July 2017, consistent with the requirements of the regulation detailing the calculation, including which expenses are in the numerator and the denominator. In 2019, CMS also published an informational bulletin (2019 CIB) on calculating the MLR when a managed care plan uses subcontractors, using PBM spread pricing as a specific example.[8]

MLR calculations are used to develop capitation rates paid to Medicaid managed care plans, thus their accuracy is critical. Under existing regulations, in addition to other standards regarding MLR information and capitation rates, managed care capitation rates must be developed so that the plan would reasonably achieve an 85 percent MLR (§438.4(b)(9)). Medicaid managed care plans may need to pay remittances (that is, refund part of the capitation payments) to states if they do not achieve the specific MLR target.

[8] Center for Medicaid & CHIP Services (CMCS) Informational Bulletin (CIB) "Medicaid Loss Ratio (MLR) Requirements Related to Third Party Vendors," May 15, 2019.

CMS notes that although there is not currently a federal prohibition on using spread pricing in Medicaid, the agency issued the 2019 CIB regarding the impact of the lack of transparency between costs for administrative functions versus actual Medicaid services on the managed care plan's MLR calculation. The 2019 CIB is clear that when the PBM is performing administrative functions—for example, 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. Other regulatory provisions require subcontractors to perform reporting responsibilities and to provide underlying data associated with MLR calculation and reporting. As a result, as explained in the 2019 CIB, 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. CMS provides examples in the proposed rule (including Table 2, not reproduced here) for how the lack of transparency around the "spread" can obscure from Medicaid and the managed care plans the actual cost of the CODs dispensed to plan enrollees.

Although the dollar amounts of spread pricing on each prescription may seem small, the overall impact can be significant. For example, Ohio's auditor found $208.4 million in spread (31.4 percent) for PBM transactions on generics between April 1, 2017, and March 31, 2018.

Based on information on state PBM laws posted by the National Academy for State Health Policy (NASHP), CMS determined that 11 states have enacted legislation related to the practice of spread pricing. Four (Arkansas, Delaware, Michigan, and Oklahoma) have complete statewide prohibitions on the practice of spread pricing for any PBM operating within the state, regardless of the payer. Five (Kentucky, Louisiana, New York, Pennsylvania, and Virginia) prohibit the practice of spread pricing by PBMs or MCOs in Medicaid. One (Pennsylvania) further requires that all Medicaid MCOs include a spread pricing prohibition clause in all contracts with PBMs. Two of the 11 states with spread pricing laws (Alabama and Montana) merely require disclosure of certain spread pricing information—that is, annual report of aggregate rebate information and whether the PBM engages in spread pricing.

b. PBM Transparency Proposal

In §438.3(s)(8), CMS proposes to require that Medicaid managed care plans—MCOs, PIHPs or PAHPs—structure any contract with any subcontractor for the delivery or administration of CODs to require the subcontractor to report separately the amounts related to:

- **Included in MLR numerator.** The incurred claims described in §438.8(e)(2) such as reimbursement for the COD, payments for other patient services, and the fees paid to providers or pharmacies for dispensing or administering a COD; and
- **Excluded from MLR numerator.** Administrative costs, fees and expenses of the subcontractor.

Under this proposal, the managed care plan would have to separately identify prescription drug and dispensing or administration fee claim costs when calculating the MLR, in contrast to administrative costs. Thus, any payments for costs above the cost of the prescription and

dispensing fee would be separately identifiable by the managed care plan and cannot be used to inappropriately inflate the MLR, which may result in managed care plan capitation rates that are not actuarially sound, according to CMS.

The separate payment requirements would help states and plans better understand whether they are appropriately and efficiently paying for the delivery of CODs. Fully aligning the subcontractor's reports and billing (invoices) with how the MLR regulation categorizes and treats specific costs and expenditures would make clearer to plans how their payments to a subcontractor are used and allow those plans to incorporate the subcontractor's costs into the MLR reporting and calculation. However, CMS acknowledges that this might not be representative of how the industry works, might require systems changes and impose burden not taken into account, or might result in unintended consequences. **CMS solicits comment** on this and on other alternatives for how plans could require information from their subcontractors and how they should structure payment or billing arrangements to achieve the policy goals outlined.

This proposal does not change the applicability of the 2019 CIB to PBM subcontractors or to other subcontracting arrangements used by a Medicaid managed care plan. This proposal would create additional requirements for managed care plans that help ensure the objectives and responsibilities outlined in the 2019 CIB are met.

C. MDRP Administrative and Program Integrity Changes

CMS proposes to define certain key terms and to modify existing definitions of other key terms in the regulations. The goal of these proposals is to provide greater clarity on requirements of the MDRP and the agency's expectations of manufacturers with respect to those requirements.

1. Covered Outpatient Drug (§447.502)

Sections 1927(k)(2) and (3) of the Act define the term "covered outpatient drug" (COD). That definition excludes certain drugs, biological products, and insulin provided as part of, or as incident to and in the same setting as, certain services and settings. This exclusion is limited to when payment may be made as part of payment for the enumerated service or setting, and not as direct reimbursement for the drug.

Questions have been raised about when payment for a COD is considered to be a direct reimbursement for the drug and whether identifying a drug separately on a claim for payment may qualify as direct reimbursement for a drug, rendering the drug eligible for rebates under section 1927 as a COD. CMS has responded that if a drug and its cost can be separately identified on a claim for payment it can be considered subject to direct reimbursement.

CMS proposes to amend the definition of covered outpatient drug by adding that direct reimbursement for a drug may include both reimbursement for a drug alone, or reimbursement for a drug plus the service, in one inclusive payment, if the drug and the itemized cost of the drug are separately identified on the claim. A technical change to the regulatory definition is also proposed to mirror the statutory language more closely; specifically, the limiting language of the

exclusion would read as follows: "… (and for which payment may be made as part of payment for that service and not as direct reimbursement for the drug)."

2. Drug Product Information (§447.502)

The MSIAA added a requirement for manufacturers to report drug product information for each of the manufacturer's CODs. To implement this requirement, CMS proposes to add the following definition of the term drug product information:

> *Drug product information* includes National Drug Code (NDC), drug name, units per package size (UPPS), drug category ("S", "I", "N"), unit type (for example, TAB, CAP, ML, EA), drug product type (prescription, over-the-counter), base date AMP, therapeutic equivalent code (TEC), line extension indicator, 5i indicator and route of administration, if applicable, FDA approval date, FDA application number or OTC monograph citation as applicable, market date, COD status, and any other information deemed necessary by the agency to perform accurate unit rebate amount (URA) calculations.

CMS notes that the drug category for an NDC should be single source or innovator for the entire history of the NDC if it was always produced, distributed, or marketed under an NDA, unless a narrow exception applies, or single source if marketed under a BLA. If CMS granted a narrow exception, the drug category for that NDC should historically be reported as single source or innovator, and can be changed to noninnovator, effective April 1, 2016.

The agency reminds manufacturers that they should ensure each NDC is reported with an accurate market date; CMS also proposes to define the term market date (see below). Generally, corrections to drug product information must be done by requesting the agency to make the changes on behalf of the manufacturer, which would then be available for certification by the manufacturer. Changes in the CMS system would not be considered final until certified by the manufacturer. Changes that are not certified would mean that the drug is considered misclassified or misreported, which would be considered late reporting and which could lead to penalties including suspension or even termination of the rebate agreement.

3. Internal Investigation (§§447.502 and 447.510)

Generally, manufacturers must report any revision to AMP, best price, customary prompt pay discounts or nominal prices to CMS for a period not to exceed 12 quarters from the quarter in which the data were due (the "12-quarter rule") unless an exception applies. One of those exceptions is to address specific rebate adjustments to states by manufacturers, as required by CMS or court order, or under an internal investigation or an OIG or Department of Justice (DOJ) investigation. However, the regulations do not define the applicability of the exception to the 12-quarter rule for instances when manufacturers perform an internal investigation of the prices (AMP and best price) reported and certified in the Medicaid Drug Product systems by another manufacturer.

CMS indicates that some manufacturers have sought revisions to AMP and best price outside of the 12-quarter rule based upon an internal investigation related to newly acquired products or lines of business previously certified by the prior manufacturers without making findings that the prior manufacturer violated any law. CMS proposes to specify that the manufacturer must make a finding that indicates the prior manufacturer violated the statute or regulation before it would consider such a request. The term internal investigation would be defined 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 fraud, abuse or violation of law or regulation. The manufacturer would have to make data available to CMS to support its finding.

CMS estimates that only one percent of manufacturers would submit a request for a recalculation annually outside of the 12-quarters and estimates a total one-time cost of $5,693.

4. Manufacturer (§447.502)

CMS proposes to revise its definition of manufacturer for purposes of compliance with the manufacturer's National Drug Rebate Agreement (NDRA). The agency has in the past sought to prevent selective reporting of NDCs by requiring manufacturers to ensure that all their associated labeler codes with CODs enter into a rebate agreement to comply with the terms of the NDRA. This includes newly acquired labeler codes, newly formed subsidiaries, and labeler codes previously omitted from the original rebate agreement. Each associated labeler code must have effectuated a rebate agreement, and CMS treats each associated labeler code as part of the single manufacturer. If any of the labeler codes of a manufacturer do not have an NDRA in effect, no FFP is available for any of the CODs of the labeler codes of the manufacturer, and all of the labelers would be subject to potential termination from the MDRP.

Manufacturers that enter into a rebate agreement cannot exclude any COD from their listings; this applies to all CODs associated with any of the manufacturer's labeler codes that market CODs, including newly-purchased labeler codes and newly-formed subsidiaries. CMS reports that a few manufacturers have suggested that certain labeler codes are exempt from this requirement or not otherwise required to be included in the program under the rebate agreement.

CMS proposes to revise the definition of manufacturer to read as follows:

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

Additionally, under §447.510(h), manufacturers would be required to provide CMS with all labeler codes for all the manufacturer's applicable drugs. It would further specify that "if any manufacturer with a signed rebate agreement in effect, acquires or purchases another labeler,

acquires or purchases covered outpatient drugs from another labeler code, or forms a new subsidiary, they must ensure that a signed rebate agreement is in effect for these entities or covered outpatient drugs, consistent with the definition of manufacturer at §447.502, within the first 30 days of the next full calendar quarter beginning at least 60 days after the acquisition, purchase, asset transfer, or formation of the subsidiary." CMS also proposes to add a provision on termination. Each associated labeler code of a manufacturer would be considered part of the single manufacturer, and if any of the associated labeler codes do not have an NDRA in effect, or are terminated, then all of the labeler codes would be subject to termination.

CMS estimates that the burden associated with the proposed modification to the definition of manufacturer is a one-time cost of $43,884, estimating it would take 792 manufacturers 0.5 hours at $110.82 per hour, including fringe benefits and other indirect costs, for an operations manager to log onto the CMS system and review associated labeler codes. This provision would not impose substantial costs on states.

5. Market Date (§447.502)

Section 602 of the Bipartisan Budget Act (BBA) of 2015 requires that manufacturers pay additional rebates for certain covered outpatient drugs[9] when the average manufacturer prices of those covered outpatient drugs increase at a rate that exceeds the rate of inflation. To calculate the additional rebate, the AMP for the dosage form and strength of the drug for the current rebate quarter is compared to the AMP for the dosage form and strength of that drug for the base date AMP quarter. To make this calculation, the critical data point is the day on which the drug was first marketed (which CMS refers to as the market date) by any manufacturer or under any NDC.

CMS notes 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. This is because section 1927(c)(3)(C) of the Act requires an additional rebate amount based on the market date for each dosage form and strength of a covered outpatient drug. CMS notes that some manufacturers have sought to establish a new base date AMP for reasons other than for dosage form and strength.

For purposes of establishing the base date AMP quarter, CMS proposes to define the term market date to mean the earliest date on which the covered outpatient drug was first sold by any manufacturer. CMS would also clarify that "first sold" means any sale of the drug and that "sold" means the drug has been transferred (including in transit) to a purchasing entity. **CMS seeks comment** on determining what qualifies as sold for purposes of determining the market date of a drug.

The agency believes 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 data as opposed to relying on reasonable assumptions. As a result, the unit rebate amount (URA) would also be calculated more accurately because actual sales would be available for reporting.

[9] Single source drugs and innovator multiple source drugs of a manufacturer are excluded from this requirement.

CMS does not believe that this proposal would impose substantial costs on states.

6. Noninnovator Multiple Source Drug (§447.502)

The statute defines noninnovator multiple source drug as a drug that is not an innovator multiple source drug. The MSIAA amended the definition of innovator multiple source drug by striking the language "was originally marketed" and inserting in lieu thereof "is marketed," and the agency implemented those statutory changes to its regulatory definition of innovator multiple source drug in rulemaking. However, it did not make the same change to its regulatory definition of noninnovator multiple source drug in that rulemaking. CMS proposes to do so now.

7. Vaccine (§447.502)

Vaccines are specifically excluded from the statutory definition of covered outpatient drug, and the term vaccine is not defined in the MDRP statute or elsewhere in the Social Security Act. CMS posits that when the MDRP was first enacted in 1990, vaccines were excluded because of their unique characteristics among medical products marketed at the time of preventing disease by inducing an immune response (i.e., preventive vaccines); it does not believe that Congress thought the term included therapeutic vaccines. Because immunology has become more advanced, drugs and biological products are used for therapeutic purposes as opposed to solely for preventive purposes. CMS goes into some detail in the preamble describing this distinction, noting that the exclusion of what it refers to as therapeutic vaccines from the definition of COD means there are no manufacturer rebate requirements for such vaccines.

CMS proposes, for the specific purpose of the MDRP only, to define vaccine as follows:

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

The definition would not apply to any other provisions in title XIX, to separate CHIPs, or to the Vaccines for Children Program. **Comment is sought** on (i) whether the proposed definition appropriately distinguishes between preventive and therapeutic vaccines; (ii) whether there could be indirect consequences for other Medicaid benefits; and (iii) the consequences for Medicaid of ACIP recommending immunization with a product that would not qualify as a vaccine under this definition.

CMS cannot determine an estimate for this proposal at this time; however, it believes that the proposal would not impose substantial costs on states.

8. Regulatory Impact

CMS does not believe any of the proposals for new or revised definitions would require any effort or impose burden on any public or private entities.

D. Accounting for Stacking When Determining Best Price (§447.505)

CMS has previously expressed a position that a manufacturer must include all price concessions that adjust the price realized by the manufacturer for the drug in its determination of best price. Additionally, if a manufacturer offers multiple price concessions to two entities for the same drug transaction, all discounts related to that transaction which adjust the price available from the manufacturer should be considered in the final price of that drug when determining best price. An example of this would be rebates to a PBM where the rebates are designed to adjust prices at the retail or provider level in addition to discounts to a retail community pharmacy's final drug price. In response to comments to the COD final rule, CMS indicated if multiple price concessions are provided to two entities for the same drug transaction, all discounts related to that transaction which adjust the price available from the manufacturer should be considered when determining best price; this is referred to as stacking. However, this was not codified in the regulations.

For clarity and effective prospectively, CMS proposes to revise the rule at §447.505(d)(3) to require that (i) manufacturers adjust the best price for a drug for a rebate period if cumulative discounts, rebates, or other arrangements to best price eligible entities subsequently adjust the price available from the manufacturer; and (ii) cumulative discounts, rebates or other arrangements be stacked to generate a final price realized by the manufacturer for a covered outpatient drug, including discounts, rebates or other arrangements provided to different best price eligible entities.

CMS notes that it is unable to determine cost estimates for this proposal.

E. Rescinding Revisions from December 31, 2020 Rule Consistent with Court Order

In the December 31, 2020 final rule, CMS revised its regulations to address the effect of PBM accumulator assistance programs on best price calculations and AMP for the MDRP. As finalized, exclusions for manufacturers' financial assistance payments only applied to the extent the manufacturers ensure that the "full value" of the assistance or benefit is passed on to the consumer or patient. The effective date for these provisions was January 1, 2023. On May 17, 2022, the United States District Court for the District of Columbia ordered that these 2020 regulatory changes (which the Court referred to as the accumulator adjustment rule of 2020) be vacated and set aside. CMS proposes to carry out the District Court's order by striking the relevant provisions in §§447.504 and 447.505.

F. Drug Classification—Oversight and Enforcement of Manufacturer's Data Reporting Requirements; Calculation of Medicaid Drug Rebates; Requirements for Manufacturers

The MSIAA amended sections 1903 and 1927 of the Act to clarify the definitions for multiple source drug, single source drug and innovator multiple source drug; it also gave the Secretary additional authority to ensure compliance with program requirements for reporting of drug product and pricing information by manufacturers, which includes the appropriate classification of a drug. Generally, a misclassification in the MDRP occurs when a manufacturer reports and certifies its COD under a drug category, or uses drug product information, that is not supported

by the statutory and regulatory definitions of S, I, or N. CMS may identify and correct a manufacturer's misclassification of a drug and impose other penalties on manufacturers that fail to correct their misclassifications.

Though it believes the statute is largely self-executing, CMS nonetheless proposes to codify a process for the identification, notification, and correction of a manufacturer's drug category misclassifications and also for the imposition of other penalties. While the MSIAA clarified that reporting false drug product information and data related to false drug product information would also be subject to possible civil money penalties (CMPs) by the HHS Office of the Inspector General (OIG), this rulemaking does not address that OIG authority. The proposed rule would, however, include policies on notifying the OIG and other governmental agencies about possible MDRP violations.

1. Proposed Process for Identification and Notification to Manufacturers to Correct Misclassification (§447.509(d)(1) through (4))

CMS proposes to add a new paragraph (d) to §447.509 that would set forth the process by which the agency would identify when a misclassification of a drug has occurred in MDRP, subsequently notify a manufacturer that it determined that a drug is misclassified in MDRP, and indicate the penalties that may be imposed on the manufacturer and that the manufacturer may owe past due rebates.

Definition of Misclassification. A misclassification would occur when a manufacturer has reported and certified to CMS (i) drug category or drug product information related to its COD that is not supported by the statute and regulations or (ii) drug category or drug product information that is supported by the statute and regulations, but rebates paid were not at a level associated with that classification.

Notice to Manufacturer of Drug Misclassification. If a misclassification has occurred, CMS would notify the manufacturer (both in writing and electronically) of the misclassification; the notice could also indicate that past rebates are due. The manufacturer would have 30 calendar days from the date of notification to do the following:

- Provide CMS the requisite drug product and drug pricing information to correct the misclassification of the COD and calculate rebate obligations due; and
- Certify the price and drug product data that CMS entered into the system.

The pricing data submitted by the manufacturer to the agency would have to include the best price information for the drug, if applicable, for the rebate periods for which the manufacturer misclassified the COD.

Manufacturer Payment of Unpaid Rebates Due to Misclassification. If a manufacturer's misclassification of a COD results in rebates owed to the states and CMS provided notice to the manufacturer, the manufacturer must pay to each state an amount equal to the sum of the products of (A) the difference between the per unit rebate amount (URA) the manufacturer paid the state for the period of misclassification and the per URA that the manufacturer should have paid and (B) the total units of the drug paid for under the state plan in each period.

Manufacturers would have 60 calendar days upon receipt of notice from CMS to pay those owed rebate amounts to the states and to provide documentation to CMS that the manufacturer contacted the states and that the requisite payments were made within the 60-calendar-day period.

Agency Authority to Correct Misclassifications and Additional Penalties For Drug Misclassification. CMS would review the drug product and drug pricing information as well as the documentation submitted by the manufacturer on payment of unpaid rebates. Failure to comply with requirements to correct misclassifications, to pay rebates owed, or to provide CMS documentation of payment within the applicable period could result in the agency taking any or all of the following actions:

- Correct the misclassification of the drug in the system on behalf of the manufacturer, using any pricing and drug product information provided by 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;
- Impose a CMP for each rebate period during which the drug is misclassified; or
- Take other actions and impose other penalties available under section 1927 of the Act (or any other provision of law), including referral to the OIG and termination from the MDRP.

The amount of a CMP could not exceed an amount equal to the product of (i) the total number of units of each dosage form and strength of the misclassified drug paid for under any state plan during such a rebate period; and (ii) 23.1 percent of the AMP for the dosage form and strength of such misclassified drug for that period.

Transparency of Manufacturers' Drug Misclassifications. CMS would post on a public website an annual report on the covered outpatient drug(s) that were identified as misclassified during the previous year. The report would include 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. It would also disclose the expenditures associated with these efforts from the fund for oversight and enforcement of the MDRP.

Regulatory Impact. CMS believes this provision would not impose new costs on states. It would benefits states by assuring that manufacturers are accurately paying rebates. However, CMS cannot estimate the amount of rebates that would be recovered because of these new misclassification provisions.

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

CMS proposes to rename this section of the regulations as "Requirements and penalties for manufacturers" and to add a new paragraph (i) to codify a process by which a manufacturer's NDRA would be suspended when it fails to report timely information, including drug pricing and drug product information, and the reporting timeframes for such information.

Suspension of NDRA for Late Reporting of Drug Pricing and Drug Product Information. If a manufacturer fails to timely provide information required to be reported to the agency, CMS would provide written notice (including in electronic form) to the manufacturer of that failure. The manufacturer would have 90 calendar days to provide the necessary information; failure to do so would result in the suspension of the manufacturer's rebate agreement for all its CODs furnished after the end of that 90-day period.

Period of Suspension. The rebate agreement would remain suspended until the later of (i) 30 calendar days or (ii) the date the information is reported to the agency in full and certified, and the agency has reviewed it for completeness. Continued suspension of the rebate agreement could result in termination for cause. During the period of the suspension, the CODs of the manufacturer would not be eligible for FFP.

Impact of Suspension on other Programs. CMS notes that suspension of a manufacturer's rebate agreement under this section applies for Medicaid purposes only; it would not affect manufacturer obligations and responsibilities under the 340B Drug Pricing Program or reimbursement under Medicare Part B during the period of the suspension.

Notice to States. CMS would notify states 30 calendar days before the beginning of the suspension period for the manufacturer's rebate agreement and any applicable associated labeler rebate agreements. It acknowledges that suspension of a manufacturer's agreement and the loss of FFP likely means that the manufacturer's drugs would not be available to Medicaid beneficiaries during the suspension period, but it hopes that the process would incentivize manufacturers to ensure timely, accurate reporting of price and drug product information. CMS notes that it considers partial reporting of information to be late reporting.

Regulatory Impact. CMS believes this provision would impose minimal new costs on states because they would only be required to notify prescribers and patients that a drug is not available under the MDRP for the period of the suspension. CMS cannot estimate the costs because states may choose their own method for notification; **comment is sought** on how to develop a cost estimate.

G. Amendments Made by the American Rescue Act of 2021 - Removal of Manufacturer Rebate Cap (100 percent AMP)

Section 1927(c)(2)(D) of the Act provides for a maximum of 100 percent of AMP for the total rebate amount for each single source or innovator multiple source drug. Section 1927(c)(3)(C) of the Act applies the Medicaid additional rebate requirement, including the cap on the rebate amount under section 1927(c)(2)(D), to CODs other than single source or innovator multiple source drugs (other CODs). The limit of maximum rebate amounts for single source and innovator multiple source drugs as well as such limit as applied for other CODs is at §§447.509(a)(5) and 447.509(a)(9), respectively. Section 9816 of the American Rescue Plan Act of 2021 sunsets the limit on the maximum rebate amounts for single source and innovator multiple source drugs to rebate periods beginning before January 1, 2024. This sunset, by reason of the application provisions under subclauses (IV) and (V) of section 1927(c)(3)(C)(ii) of the Act, would also apply to the maximum rebate amounts for other CODs.

Therefore, CMS proposes to make conforming changes at §§447.509(a)(5) and 447.509(a)(9) to clarify that the limit on maximum rebate amounts would not apply to any rebate period beginning on or after January 1, 2024.

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

Paragraphs (1) and (2) of section 1927(c) of the Act provide for basic rebates and additional rebates for single source and innovator multiple source CODs and describe how the unit rebate amount (URA) is calculated for these CODs. Section 1927(c)(3) of the Act provides for such rebates and a different URA calculation for all other CODs. Combined, the statute provides for rebates for all CODs. Manufacturers must report all of their CODs in the CMS MDRP reporting system and in doing so must select the appropriate drug category for each COD (S, I, or N). "N" has been used generally to indicate any COD other than a single source or innovator multiple source COD ("other drugs"), regardless of whether the drug satisfies the statutory definition of noninnovator multiple source drug. Section 1927(k)(7)(iii) of the Act defines a noninnovator multiple source drug as a multiple source drug that is not an innovator multiple source drug. Not every "other drug" is a multiple source drug. However, even though "other drugs" and noninnovator multiple source drugs are not synonymous, CMS has treated them as so for purposes of reporting the CODs in the MDRP system.

To align longstanding CMS policy of identifying "other drugs" as "N" drugs for purposes of the MDRP, CMS proposes to modify language in §447.509 by striking each occurrence of "noninnovator multiple source drug(s)" and instead inserting "drug(s) other than a single source drug or an innovator multiple source drug". This category of drugs would still be indicated as "N" in the MDRP system.

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

Under sections 1927(b)(1) and 1927(c) of the Act, manufacturers of CODs are required to pay quarterly rebates to states for their CODs dispensed and paid for under the Medicaid state plan for a rebate period. Section 1927(b)(2)(A) of the Act requires states to provide manufacturers rebate billing information 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. Section 1927(b)(2)(B) of the Act provides manufacturers with authority to audit such information provided by the state and requires adjustments to be made to rebates to the extent that information (from the audit) indicates that utilization was other than the amount previously specified by the state. The adjustments can result in manufacturers owing amounts to states or states owing amounts to the manufacturers.

There is no statutory or regulatory deadline by which a manufacturer must initiate a dispute[10] regarding utilization after receiving the utilization data from the state. CMS believes the

[10] In State Release 56 and Manufacturer Release 20, CMS 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" and that all disputes must be resolved on a unit basis only, and not on any other factor (such as dollar amount).

unlimited timeframe to initiate such disputes on rebates can result in manufacturer, state, and federal resources being spent to adjudicate extremely old disputes and is not an efficient use of resources.

Therefore, CMS proposes a 12-quarter time limit for manufacturers to initiate a dispute, request a hearing, or seek an audit with a state for any discrepancy with state drug utilization data reported under section 1927(b)(2)(A) of the Act. This time limit would be measured as 12 quarters from the last day of the quarter from the state invoice date.

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

Section 1927(b)(3)(A) of the Act requires manufacturers of CODs to report to CMS prices of the CODs. Section 1927(b)(3)(B) of the Act authorizes CMS to survey wholesalers and manufacturers that directly distribute their CODs, when necessary, to verify such manufacturer prices reported to CMS. There is currently no centralized collection of data from manufacturers used by CMS to verify such prices reported by manufacturers. CMS is interpreting the section 1927(b)(3)(B) authority as allowing it to verify prices reported both when a manufacturer sells CODs to wholesalers and when a manufacturer distributes CODs directly on their own to pharmacies and providers.

CMS provides a number of justifications for having a drug price verification survey process, including a need for more effective management of COD purchasing and reimbursement to non-retail health care providers and for more transparency for states to know how manufacturers determine the prices they charge wholesalers or direct distributers. CMS specifically notes concerns around the current lack of information relating to the production methods for novel drug products and how costs associated with novel methods are included in reported prices. CMS also notes the lack of transparent information relating to manufacturers increasing their WACs at a faster rate than their AMPs, which, when states use WAC to pay providers for reimbursement for drugs (such as high-cost specialty drugs), may result in states overspending and manufacturers underpaying in rebates because of the much lower reported AMP for the drug.

CMS believes that making non-proprietary information public would provide a number of benefits, including allowing Medicaid managed care plans to use such information to determine the appropriateness of payments to PBMs, states and managed care plans to determine the appropriateness of the drug spending component of the overall Medicaid managed care capitation rate attributable to pharmacy services, and states to have another tool to negotiate payment for Medicaid CODs.

Therefore, CMS proposes to provide for a drug price verification survey of manufacturers and wholesalers that directly distribute their CODs and to make certain non-proprietary manufacturer information from such surveys publicly available. The prices or charges that would be subject to verification would include those reported by a manufacturer under section 1927(b)(3)(A) of the Act, including the manufacturer's AMP, best price, ASP, and WAC for the COD. CMS clarifies that it would not use the survey data to further assess either the clinical or cost effectiveness of the COD.

Specifically, CMS proposes a 3-step verification process:

Step 1: At §447.510(k)(2) CMS would use measures related to Medicaid spending to annually (each April) compile a list of single source CODs that would be subject to a survey. The list that results from this step would not be made public. The CODs included on the list would be identified as follows:

(i) CODs with the highest drug spending per claim, determined using Medicaid drug spending data as reported from states to CMS in accordance with state drug utilization data (SDUD) reporting.[11] This per claim data would not be reduced by federal rebates since those rebates are not reported at the claim level.

(ii) CODs with the highest total Medicaid drug spending, also determined using Medicaid drug spending data as reported from states to CMS in accordance with the SDUD reporting. However, this would be reviewed net of federal rebates.

(iii) CODs with the highest 1-year price increase, determined using published WACs to determine when a COD's price increase falls in the top 1 percent of CODs with the highest median WAC increase over a 12-month period.

(iv) CODs with the highest launch price, determined by estimating whether or not the COD's cost would be in the top 5th percentile of Medicaid spending by comparing a manufacturer's published launch price to Medicaid per claim spending, or by whether treatment costs are greater than $500,000 (indexed for inflation using the CPI-U).

Step 2: CMS would then refine the initial survey list of CODs by considering additional criteria such as a manufacturer's willingness to negotiate further rebates through a CMS-authorized supplemental rebate or a manufacturer's participation in a CMS drug pricing program. CMS would publicly post a list of CMS drug pricing programs and initiatives for purposes of this exclusion. Under this step, CMS would specifically exclude:

(i) The COD of a manufacturer that participates in a CMS pricing program or initiative under which participating manufacturers negotiate the COD's price directly with CMS, such as the Medicare Drug Price Negotiation Program or certain CMI models developed pursuant to Executive Order 14087.[12]

(ii) The COD of a manufacturer that has negotiated CMS-authorized supplemental rebates with at least 50 percent of the states that, when combined with the federal rebate, results in:

a. A ratio of total (state and federal) rebates for the drug to total Medicaid expenditures (state and federal) for the drug, that is greater than

b. The ratio of total (state and federal) Medicaid rebates to total Medicaid drug expenditures for states that cover CODs only through fee-for-service.[13]

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[11] (https://www.medicaid.gov/medicaid/prescription-drugs/state-drug-utilization-data/index.html).

[12] See HHS' response to Executive Order 14087 at https://innovation.cms.gov/data-and-reports/2023/eo-rx-drug-cost-response-report.

[13] CMS proposes to use the federal fiscal year Medicaid Financial Management Report (FMR), determine total computable prescribed drug expenditures for the states that cover CODs only through fee-for-service, and analyze the rebates for those states. CMS proposes to consider only states that cover CODs entirely through fee-for-service because the prescribed drugs expenditures in the FMR do not include COD expenditures made by managed care entities, while the rebate lines do include the managed care rebate offset. Because of this, if managed care COD expenditures and rebates were included, the denominator in the comparison of rebates to total expenditures would be understated (resulting in a higher percentage).

Step 3: If more than 10 CODs remain, CMS would solicit state-specific Medicaid program information as to the manufacturer's level of effort to lower drug prices for Medicaid, such as a manufacturer offering other programs to lower the cost of the drug to the state such as subscription models, VBP arrangements under the multiple best price approach, or other special arrangements.

CMS would send a survey request to manufacturers of CODs on the resulting compiled list and would publicly post each request sent to manufacturers with the name of the COD to be surveyed. The survey would collect from the manufacturer:

(i) Information on the pricing, charges, distribution, and utilization for the COD.
(ii) Product and clinical information for the COD to understand the clinical benefits and risks to verify that the price reported fairly represents the benefits and/or risks of the COD.
(iii) Information on costs of production, research, and marketing to understand how the costs are accounted for in the prices and charges reported.
(iv) Other information determined by the Secretary specific to the particular COD.

CMS proposes to post on its website non-proprietary information provided through the surveys.

CMS further proposes that if a manufacturer or wholesaler refuses to provide information in response to the survey request within 90 days of CMS' request, or knowingly provides false information, the manufacturer or wholesaler would be referred to the Inspector General for possible imposition of civil monetary penalties under section 1927(b)(3)(B).

CMS invites comment on whether CODs that are identified under the proposed criteria at §447.510(k)(2)(i) through (iv) and that are also granted accelerated approval by FDA should be surveyed when a manufacturer has failed to demonstrate the clinical benefits of the drug through further confirmatory trials required by the FDA. CMS notes that surveying these drugs may be warranted by the high costs of some of these therapies and by some manufacturers' noncompliance with FDA's requirement for further confirmatory trials after accelerated approval of these drugs to verify and describe the predicted clinical benefit.

CMS also requests comment on the proposal to refine the list of CODs to be surveyed based on the manufacturer's level of effort at reducing the price for the drugs.

With respect to the portion of the proposal involving state surveys, CMS estimates an annual burden of 13 hours at a cost of $1,198. With respect to the portion of the proposal involving manufacturer surveys, CMS estimates an annual burden of 50 hours at a cost of $4,607.

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

Regulations at §§447.502, 447.512, and 447.518 provide that payments to pharmacies for CODs under the state plan that are dispensed by the pharmacies are to be based on a two-part formula which consists of:

1. The ingredient cost of the drug that is dispensed based on the actual acquisition cost (AAC); and
2. A professional dispensing fee (PDF) for the drug based on the cost of the pharmacist's professional services.

The AAC is defined as the pharmacy's actual prices paid to acquire the drugs marketed or sold by specific manufacturers. The ingredient cost must represent the actual, current ingredient cost of the drug and be calculated based on the amounts that pharmacies pay for the drug.

The PDF is incurred at the point of sale or service and pays for pharmacy costs in excess of the ingredient cost of a COD each time a COD is dispensed. The PDF includes (i) reasonable costs associated with delivery, special packaging and overhead associated with maintaining the facility and equipment necessary to operate the pharmacy; and (ii) costs for a pharmacist's time spent checking the computer for information about an individual's coverage, performing drug utilization review and preferred drug list review activities, measuring or mixing, filling the prescription, counseling a beneficiary, and physically providing the completed prescription to the beneficiary.

The state reimbursement formulas and any proposals to change either component of the reimbursement formula are subject to CMS review and approval through the state plan amendment (SPA) process. Under that process, a state must provide adequate cost data to support its professional dispensing fee amounts and ingredient cost reimbursement. The data must show that the state's proposed reimbursement methodology, with any proposed changes, would meet federal requirements,[14] including that it 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 PDF.

CMS describes that a state's assessment of other third-party payers' reimbursements to pharmacies for dispensing CODs would not satisfy these definitions or data submission requirements since such an assessment does not reflect the actual costs to pharmacies.

Therefore, CMS proposes to clarify that the ingredient cost of a drug and PDF must be based on pharmacy cost data and to specify that the data required to be submitted by states to justify the PDF cannot solely rely on the amounts that pharmacies are accepting from other private third-party payers. Also, to satisfy the requirement that the PDF must reflect the pharmacy's actual acquisition cost and cost of dispensing, states must periodically assess whether rates being paid reflect current costs.

[14] Section 1902(a)(30)(A) and 1927 of the Act and implementing rules at §§447.502, 447.512, and 447.518.

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

The National Drug Code (NDC) is necessary for states to bill manufacturers for drug rebates. It identifies the specific manufacturer, product, and package size. Physician-administered drugs (PADs) were previously classified and billed by Healthcare Common Procedure Coding System (HCPCS) codes. Since HCPCS codes group together different manufacturers of the same drug in the same code they cannot be used to bill for rebates.

Sections 1927(a)(7) and 1903(i)(10)(C) of the Act require that as a condition of payment under section 1903(a) of the Act for a COD that is a PAD, and in order for states to be able to bill for rebates for such COD, states must collect and submit utilization data and coding (such as J-codes and NDC numbers) as the Secretary specifies as necessary to identify the manufacturer in order to secure rebates. This is required for a PAD that is a single source drug or a multiple source drug that is a top 20 high dollar volume PAD on a list published by the Secretary. Under section 1927(b)(7)(C) of the Act, states are required to submit such information using NDCs.

CMS proposes to update the regulatory language at §447.520 to more accurately conform with the statutory requirements under section 1927(a)(7) of the Act. The language would specify no FFP would be available for a PAD that is a COD 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. CMS would continue to publish the top 20 list of multiple source PADs on an annual basis, as statutorily required. States would continue to be required to submit claims for single source CODs that are PADs and multiple source CODs that are PADs on the top 20 list using NDCs in order to receive FFP and secure rebates. CMS would also make clear the requirement that states invoice for rebates for all multiple source PADs that are CODs. The regulatory language would also clarify that states must require providers to submit claims for any COD that is a PAD using NDCs.

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

A COD is defined as a prescribed drug approved under section 505(c) or 505(j) of the Federal Food, Drug, and Cosmetic Act (FFDCA) or section 351 of the Public Health Service (PHS) Act when used for a medically accepted indication. Yet, Medicaid COD claims do not currently require a diagnosis code as a condition for payment, and there is no mechanism to cross-reference the use of a prescription drug with a Medicaid patient's medical diagnoses to ensure a drug is being used for a medically accepted indication.

CMS solicits comments on a possible requirement to include diagnosis on a prescription, the impact of such a requirement, and any operational implications. CMS specifically seeks comment on:

- The burden with such a proposal and its potential impact on payment, program integrity, and health care quality, stigma and access to care.
- How to address any negative foreseeable impact on beneficiaries and providers.
- Steps that would be needed by states to successfully implement a Medicaid requirement for diagnosis on prescriptions as a condition of FFP.

- Steps CMS should take with such a policy to protect beneficiary access to commonly used, medically accepted, compendia supported, off-label prescriptions.

III. Collection of Information Requirements

Under the Paperwork Reduction Act of 1995 (PRA), CMS is required to provide 60-day notice in the Federal Register and to solicit public comment before a collection of information requirement is submitted to the Office of Management and Budget (OMB) for review and approval. Table 4 of the proposed rule shows CMS' estimates of its potential information collection requirements (ICRs) related to this rule, if finalized.

The combined burden estimate for all of the provisions of this proposed rule is $799,499. Almost all of this burden is for the PBM-related MLR reporting requirements ($793,694), with most of this burden placed on 282 plans ($649,587 in total, or $2,303.50 per plan as a one-time cost). For the 40 states newly implementing this requirement at $2,303.50 per state as a one-time cost, the total is $92,140. Subcontractor PBMs' costs would be much lower per PBM ($184), totaling $51,967 across 282 subcontractor PBMs.

IV. Regulatory Impact Analysis

The federal government has a number of standards and sources defining a significant regulatory action. This proposed rule has an annual effect on the economy of $200 million or more in any 1 year and thus qualifies as a significant regulatory action, which requires the federal government to produce a Regulatory Impact Analysis, summarized here.

In terms of the one-time costs and benefits shown in Table 5 of the rule, CMS estimates total savings of $5 billion. There are estimated to be $6 billion in savings from establishing the 12-quarter rebate audit time limitation, which is offset by some one-time costs, the largest of which ($852 million) is for manufacturers, states, and trade associations to review this proposed rule.

In terms of the annual costs and benefits shown in Table 6 of the rule, CMS estimates a 10-year total of $15.1 billion. The savings are estimated at $14.2 billion for the removal of the manufacturer rebate cap (100% of AMP) and the PBM transparency provisions ($0.9 billion).