CAPITOL STREET

September 23, 2024

Mixed Bag: Medicaid Drug & Rebate Final Rules

Positively, AMP Cap, Accumulators & Best Price "Stacking" Removed

Relevant Companies

Our Take & Next Up

Largely neutral-positive for drug manufacturers and MCOs/PBMs that participate in the Medicaid program, as CMS punted on controversial policies. On September 20, 2024, the Centers for Medicare and Medicaid Services (CMS) released the final FY 2025 rules for Medicaid Drug Rebate Program (MDRP) (here). The final rules implement some new legislative requirements for Medicaid Drug Rebate Program and other program integrity and administration policies. Finalized changes also include the implementation of the AMP cap removal and rescinding the Accumulator Adjustment Rule. The AMP cap removal is likely detrimental for branded diabetes therapies (NVO, LLY) and asthma inhalers (GSK, AZN, Boehringer Ingelheim), which are likely to hit the rebate cap though manufacturers have adjusted in other ways (lowering prices etc.). Other policies include requiring state managed care organizations (MCOs) and their contracted PBMs to be transparent about spread pricing. This is intended to further pressure PBMs on transparency and will impact PBM business in states that already do not require administrative reporting. Final rules are effective on November 19, 2024. Most positively, the agency did not finalize best price stacking, where multiple price concessions would have been in play (see below for details); this policy was included as a proposal (May 2024) and therefore not new news.

Key Points

POSITIVE FOR DRUGMAKERS: Best price (BP) stacking is gone. One of the provisions in that proposed rule was for drug manufacturers to "stack" cumulative price concessions provided to different entities to determine a final best price realized by the manufacturer. The stacking provision would have amended existing BP regulations to require manufacturers to "stack" cumulative discounts, rebates, or other arrangements "provided to different [best price] eligible entities" for purposes of determining a final best price realized by the manufacturer, instead of identifying the best price available from the manufacturer. If finalized, the proposal would have signaled a stark reversal of CMS' prior guidance on the methodology for calculating best price and would likely be subject to legal challenges, in our view.

NEGATIVE FOR BRANDS: CMS implements AMP cap removal, which impacts brand drugs (saves $14 B / ten). CMS will remove the "AMP cap" on Medicaid drug rebates (which was capped at 100% of AMP) for rebate periods beginning January 1, 2024 (saves $14.2 B over 10). CMS planned to sunset the maximum rebate

amount for brand and generic drugs by December 31, 2023 to conform with the American Rescue Plan Act of 2021. The lifting of the rebate cap is expected to impact brand drugs, especially those drugs that have already hit the rebate cap or have price increases much faster than inflation over time. In response to the elimination of the rebate cap, some drug companies are lowering drug prices or discontinuing drugs in favor of lower priced alternatives to avoid paying additional Medicaid rebates.

- While some comments requested flexibility for drugs in shortage, CMS does not have statutory authority to reduce rebate amounts or "cap" rebates when a drug is in shortage.
- Other comments noted concerns with potentially negative ceiling prices under the 340B Program's "penny pricing policy," which requires that the 340B ceiling price will be $0.01 when the ceiling price calculation results in an amount less than $0.01.

POSITIVE FOR MANUFACTURERS: "Accumulator Adjustment Rule" is rescinded based on successful PhRMA litigation. In the 2020 final rule, CMS required manufacturers to "ensure[] the full value of the prescription assistance or benefit is passed on to the consumer or patient for any financial assistance to an insured patient not to count toward the best price." In May 2022, the district court for the District of Columbia ruled in favor of PhRMA and ordered that the applicable provisions of the 2020 final rule be vacated and set aside.

MIXED FOR MANUFACTURERS & NEG FOR PBMs & MCOs: Medicaid spread pricing transparency included in final rules. Final rules require state managed care (PBMs) to be transparent about spread pricing (saves $930 M over 10). Managed care plans will be required to negotiate and revise contracts to identify administrative fees separately from reimbursement for covered outpatient drugs, dispensing fee costs and other patient costs. CMS estimates that requirements would affect 282 managed care plans and their subcontractors (mainly PBMs) in 40 states. Spread pricing occurs when the PBM retains the difference between what is paid by the managed care plan and what the PBM pays a provider for the cost and dispensing of a drug.

LESS CONSEQUENTIAL FOR MANUFACTURERS: **Final rules implement additional CMS authorities on drug misclassification, drug pricing, and product data misreporting by manufacturers.** The final rule would address other situations in which manufacturers are paying less rebates to states than are supported by the pricing and product data that is reported to Medicaid. While CMS believes that most of the drugs are appropriately classified, CMS notes that regulatory impact is difficult to determine due to the lack of knowledge of the exact number of drugs that are misclassified.

- Defines situations in which CMS would consider a drug misclassified, as well as other situations in which a manufacturer is paying rebates to states that are different from the rebates that are supported by the drug data being reported to Medicaid.
- Describes a process and timeline that CMS will use to notify the manufacturer that the agency has determined that a misclassification of a covered outpatient drug (COD) has occurred and the process for correcting the misclassification.
- Codifies a manufacturer's obligation to pay unpaid rebate amounts to states due to the misclassification of CODs.
- Allows CMS to suspend the National Drug Rebate Agreement of a manufacturer for no fewer than 30 days for late reporting of drug product and pricing information as is required under the statute and the agreement.
- Implements CMS' options for enforcing program requirements when a manufacturer does not correct a misclassification after being notified.

CMS is also changing certain definitions for the Medicaid program along with some operational changes. These changes are focused on increasing transparency and ensuring clarity around reimbursement. Changes to the program include:

- Define “market date” of a drug for purposes of establishing the base date average manufacturer price (AMP) quarter, which is used to calculate the inflation rebates that manufacturers owe on their covered outpatient drugs (COD).
- Limit the period for manufacturers to initiate disputes concerning state-invoiced utilization data during a period not to exceed 12 quarters from the last day of the quarter from the state invoice postmark date.
- Specify that both ingredient cost reimbursement and professional dispensing fee reimbursement, under Medicaid Fee-for-Service, must be based on pharmacy-established cost data, and market-based research does not qualify as supporting data.
- Require states to collect national drug code (NDC) information on all physician-administered drugs and specify that states should be invoicing for rebates for all physician-administered drugs to receive federal matching funds and secure manufacturer rebates.
- Modify the definition of COD to define 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.
- Specify the conditions that constitute an “internal investigation” of pricing data to allow the manufacturer to make changes to already reported pricing data outside the 12-quarter window.
- Specify that for the purposes of manufacturer drug rebates, the drug category “N” represents all “other drugs,” regardless of whether they satisfy the definition of a generic drug.

Ipsita Smolinski
Managing Director I Capitol Street
ipsita@capitol-street.com

202.250.3741 I www.capitol-street.com

900 19th St NW 6th Fl
Washington, D.C. 20006

CAPITOL STREET
