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Medicaid High Drug Price Wall of Shame

MCOs, PBMs & States Must Disclose Prices Paid for Drugs

Relevant Companies

CMS released proposed rules to increase drug spending oversight in Medicaid and to address potential loopholes being used by manufacturers, including misclassification of drugs to reduce Medicaid rebates. Link to proposals here. Transparency is a theme we are seeing from CMS and Congress – think hospitals, health insurers, Medicare drug prices and now Medicaid drug prices. See Our Take below, as some of these new policies are impactful, as policymakers strive to decipher the supply chain, and require brand new reporting from PBMs and Medicaid MCOs.

Our Take & Next Up

CMS seeks new reporting and disclosures from drug makers, PBMs, states and MCOs, along with the eventual implementation of a Medicaid Rx wall of shame. The rule aims to make pricing and distribution (PBM) of Medicaid's most expensive drugs more transparent. This is a proposal (comments due July 25), with final rules before implementation in 2024+. If finalized, CMS will advertise 3-10 drugs with abnormally high prices in Medicaid or obnoxious price increases. CMS cannot force manufacturers to lower prices: this is a naming and shaming policy. The PBM reporting requirement for Medicaid managed care (CNC, MOH, UNH, ELV, CVS, others) marks the first time PBMs would be required to disclose actual drug prices under federal law. The regulation also would make specialty drugs administered in hospitals eligible for rebates.

Key Points

CMS survey data (see details below) will not be used to assess clinical or cost effectiveness and therefore may not impact payment but will "name-and-shame" companies who may be bad actors. Manufacturers may have to report AMP, best price, Average Sales Price (ASP), and in certain cases, Wholesale Acquisition Cost (WAC) for a drug. A reminder, CMS can survey wholesalers and manufacturers that directly distribute covered outpatient drugs, when necessary, to verify manufacturer prices, but there has not been a centralized collection of specific data before from manufacturers.

CMS would verify drug prices through an annual Medicaid Drug Price Verification Survey. With a Medicaid Drug Price Verification survey, CMS would compile a list of single-source covered outpatient drugs (3-10) that have high Medicaid spend, a high launch price, or the highest 1-year price increase. Specifically, included drugs would fall within any criteria below.

- Highest Medicaid drug spending per claim, falling within the top 5% of Medicaid spending per claim (>$35k/claim)
- Highest total Medicaid drug spending with annual spending greater than 0.5% of total annual Medicaid drug spending, net of federal Medicaid drug rebates (~$80M/drug);
- Highest 1-year price increase among single source CODs, (~20 NDCs); or,
- Highest launch price estimated to be in the top 5% of Medicaid spending per claim, or a launch price that is estimated to result in a total annual treatment price that is greater than $500,000 ($35k/claim or ~$500k/year)

Drugs would be excluded from the survey if they are being negotiated by CMS or if their supplemental rebates are higher in at least 50% of states. If there are more than 10 drugs remaining that qualify after CMS exclusions, CMS would further exclude drugs based on input from state Medicaid programs.

***(Not new*) Elimination of the Average Manufacturer Price (AMP) cap (Medicaid rebates) starts 1/1/24 and impacts top spend Medicaid drugs with a high yearly growth rate in spending and high average spending per dosage.** In 2021, drugs with top Medicaid spend and an increasingly high average spending per dosage included **Biktarvy** (GILD), **Invega Sustenna** (JNJ), **Trulicity** (LLY), **Stelara** (JNJ), and **Enbrel** (AMGN). Historically, Medicaid rebate amounts required from a drug manufacturer were capped at 100% of the AMP so that manufacturers would never have to pay a rebate higher than the statutory average purchase price. The *American Rescue Plan Act* eliminated the 100% AMP rebate cap and as a result, manufacturers may be required to pay amount greater than what the state Medicaid programs pay. Drug manufacturers might effectively have to pay states for the use of certain drugs in their Medicaid programs.

The agency wants any contract between MCOs, PBMs and States to include a new requirement for transparent reporting of drug payments. Medicaid managed care plans that subcontract with PBM will be required to provide details on pharmacy benefit costs to improve accuracy of Medicaid managed care medical loss ratios (MLR). Medicaid contracted PBMs will be required to report the cost of the covered outpatient drug and dispensing separately from any other fees charged to the plan by the PBMs.

We expect a spread pricing ban at some point, though few states appear to have Medicaid PBM contracts structured in this manner. A House bill, *Drug Price Transparency in Medicaid Act,* bans spread pricing in Medicaid and is advancing in the House. Previous CBO analysis found a pass-through model PBM requirement would generate $929 M in savings over 10 years, a less than 1% decline in federal Medicaid drug spending. This may negatively impact the capitation rates that managed care plans would receive as managed care plans with spread pricing models would have a lower MLR to cover their cost of care.

States would be allowed to recoup any past rebates that were denied due to misclassification of drugs by manufacturers. Proposal also addresses rebating issues that come from a minority of drugs that are inaccurately listed as non-innovator multiple-source drug when the drug should be listed as a single-source drug or an innovator multiple source drug. The difference in listing impacts the rebates that states can collect, and CMS has found some manufacturers choose to list their drug as a non-innovator multiple source drug inaccurately to reduce the rebate amount that they provide to states.

Other proposals include rescinding the "accumulator adjustment rule," along with best price, N-classifications and NDC data reporting. Recall in December 2020, CMS attempted to address accumulator programs by requiring manufacturers to make sure health plans and their PBMs count patient copay assistance toward the patients meeting their deductibles or maximum out-of-pocket expenses. The proposal was overturned by the DC District Court from a resulting lawsuit and the proposal never went into effect. Other proposals are focused on improving Medicaid program operations and includes:

- Revising Medicaid "best price" to specify for manufacturers that cumulative discounts, rebates, or other arrangements must be "stacked" (aggregated) to generate a final price, including discounts, rebates or other arrangements provided to different best price eligible entities.
- Defining "vaccine" to specify what can be excluded from Medicaid rebates.
- Limiting the period for manufacturers to initiate disputes concerning state utilization unit rebate data to 12 quarters from the last day of the quarter from the date of the state invoice.
- Specifying that both ingredient cost reimbursement and professional dispensing fee reimbursement under Medicaid fee for service must be based on pharmacy-established cost data.

- Specifying 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.
- Requiring 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 in order to receive FFP and secure manufacturer rebates.

Congressional bills moving through the Congress echo some PBM rules here, so more is coming. The *Drug Price Transparency in Medicaid Act* (here) would require pass-through pricing models in Medicaid, bans spread pricing, and limit PBM reimbursement for administrative services. The bill passed the House E&C subcommittee on Health last week and await a full committee markup. We expect the Medicaid Drug Price Verification survey to impact a handful of manufacturers as data <10 drugs will dictate a list, but will not impact Medicaid payments or coverage. The elimination of the AMP cap is expected to have the highest material impact on manufacturers, particularly manufacturers (LLY, GILD, JNJ, among others) with high-cost drugs that treat conditions common in Medicaid populations e.g., mental health.

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