



Summary: Medicaid Program; Establishing Minimum Standards in Medicaid State Drug Utilization Review (DUR) and Supporting Value-Based Purchasing (VBP) for Drugs Covered in Medicaid, Revising Medicaid Drug Rebate and Third Party Liability (TPL) Requirements

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On June 19, 2020, the Centers for Medicare & Medicaid Services (CMS) released [Medicaid Program; Establishing Minimum Standards in Medicaid State Drug Utilization Review \(DUR\) and Supporting Value Based Purchasing \(VBP\) for Drugs Covered in Medicaid, Revising Medicaid Drug Rebate and Third Party Liability \(TPL\) Requirements](#), outlining proposed changes to the calculation of best price under the Medicaid Drug Rebate Program (MDRP). In particular, the proposed rule details how manufacturers should account for value-based purchasing (VBP) programs and contracts in their reporting of best price. Additionally, the proposed rule clarifies how the use of copay accumulator programs should be accounted for in the reporting of best price.

Comments on this proposed rule must be submitted to CMS by July 20, 2020. You may provide feedback via email to advocacy@amcp.org on any provisions included in the proposed rule by July 13. AMCP's final comments will be available on the AMCP website and included in the Legislative-Regulatory Briefing Newsletter that is distributed to all AMCP members.

The following is a summary of key sections in the proposed rule that may be of interest to AMCP members:

A. Value-Based Purchasing and Medicaid Best Price

- a. CMS had previously released guidance (2016) for manufacturers describing how they could seek agency direction on VBP arrangements. The use and interest in the use of VBPs from manufacturers, states, and other payers has increased, leading CMS to propose these regulatory changes.
- b. Manufacturers have previously cited concerns about the impact of VBPs on the calculation of best price under the MDRP. For example, manufacturers are concerned about cases where the VBP requires a full refund to the payer if the drug fails to achieve the intended clinical outcome, which could result in the resetting of the best price to zero, even if only one such patient fails on the treatment.
- c. The MDRP defines best price as "with respect to a single source drug or innovator multiple source drug of a manufacturer the lowest price available from the manufacturer during the rebate period to any wholesaler, retailer, provider, health maintenance organization, non-profit entity, or governmental entity within the United States." Manufacturer rebates due to the states are based off of this lowest price calculation.

- d. CMS proposes three changes to the MDRP and best price to account for VBPs:
1. **Defining VBPs as “an arrangement or agreement intended to align pricing or payment to an observed or expected therapeutic or clinical value in a population and includes, but is not limited to, evidence-based and outcomes-based measures.”**
 - Evidence-based measures should substantially link the cost of a drug product to existing evidence of effectiveness and potential value for specific uses of that product.
 - Outcomes-based measures should substantially link payment for the drug to that of the drug’s actual performance in a patient or populations, or a reduction in other medical expenses.
 - CMS solicits input on other measures that should be considered under VBPs.
 2. **Redefining the regulatory definition of ‘bundled sale’ to prevent the abovementioned situation where the failure of one patient results in the resetting of the best price to zero for all sales of the drug in the MDRP.**
 - Bundled sales are defined as any arrangement regardless of physical packaging under which the rebate, discount, or other price concession is conditioned upon the purchase of the same drug, drugs of different types (that is, at the nine-digit NDC level) or another product or some other performance requirement, or where the resulting discounts or other price concessions are greater than those which would have been available had the bundled drugs been purchased separately or outside the bundled arrangement.
 - Manufacturers have used this bundled sale definition to account for VBPs for the purposes of best price by aggregating the value of all discounts in the VBP arrangement and proportionally allocating them across all of the drugs included in the arrangement.
 - CMS proposes to add language specifically including VBPs in the definition of bundled sales to codify this practice.
 3. **Modifying the regulation to allow a single drug to have multiple price points.**
 - This is a major departure from CMS’s historical interpretation of the calculation of best price, which was based on a single price. This is again an attempt to mitigate situations in which a single patient failure results in a reset of the best price for all drug sales.
 - CMS’s new interpretation of the statutory phrase “lowest price available” to permit the availability of a set of prices in a pricing structure that is part of a VBP arrangement.

B. Accounting for Copay Accumulator Programs in Medicaid Best Price

- a. Under these programs, plans and payers do not count the value of manufacturer assistance programs, such as copay coupons or discount cards, toward a patient’s out-of-pocket maximum or deductible. CMS, in this proposed rule, defines a copay or PBM accumulator program as a program where manufacturer assistance for certain drugs does not accrue towards a patient’s deductible under their health plan.

- b. While manufacturer cost sharing assistance programs are not available to Medicaid beneficiaries, CMS notes their applicability to the best price calculations under the MDRP since the administration of copay accumulator programs by payers and PBMs in the commercial market can affect the rebates that Medicaid receives from manufacturers. The current MDRP excludes certain manufacturer assistance programs from the definition of best price if the full value of the coupon or discount is passed on to the patient or similar qualifications to ensure that only assistance to patients is excluded from best price. Manufacturers, however, contest that they do not know when a payer or PBM imposes a copay accumulator program.
- c. **CMS proposes to revise the MDRP regulation “to provide expressly that the exclusions [from best price] apply only to the extent the manufacturer ensures the full value of the assistance or benefit is passed on to the consumer or patient.”**
 - 1. CMS does not provide any further guidance on how manufacturers can determine if a payer or PBM is imposing a copay accumulator program for specific drugs, nor does it provide any clarity on what recourse a manufacturer has if a payer or PBM does apply an accumulator program and to prevent that from being counted toward best price.
- d. The language of the proposed rule seems to imply that the use of copay accumulator programs is problematic, a differing approach from CMS to the recently finalized ACA Notice of Benefit and Payment Parameters rule which makes it substantially easier for plans and PBMs to utilize copay accumulators. The agency also does not elaborate on how requiring manufacturers to count cost sharing assistance toward best price when used with a copay accumulator will dissuade plans and PBMs from utilizing these programs.