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Medicaid Best Price 101: A Review of Medicaid Best Price Policy and New CMS Guidance on Medicaid Best Price Reporting for Value Based Purchasing Arrangements

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At the end of March 2022, the Centers for Medicare & Medicaid Services (CMS) released guidance to drug manufacturers and states on reporting Medicaid Best Price under value based purchasing (VBP) arrangements (Medicaid Best Price Guidance or Guidance). This Guidance follows CMS' final rule issued on December 31, 2020 (Final Rule) responding to criticism that Medicaid Best Price requirements are hindering the use of VBP arrangements. The Final Rule and Guidance will go into effect on July 1, 2022, allowing manufacturers to report multiple best prices for VBP arrangements so long as the manufacturer offers the VBP arrangement to state Medicaid programs. This blog post will begin with a "101" on the Medicaid Best Price Policy, and then delve into an overview of the Final Rule, including the surrounding criticism from stakeholders; summarize the Medicaid Best Price Guidance; and discuss the potential impact of this change on states and manufacturers.

What is the Medicaid Best Price Policy?

Medicaid Best Price rules are part of the Medicaid Drug Rebate Program (MDRP). At its core, the Medicaid Best Price policy requires manufacturers to provide state Medicaid programs the best price it offers any other purchaser (with certain exceptions). Under the MDRP, manufacturers must enter into a National Drug Rebate Agreement (NDRA) for their drugs to be covered by Medicare and Medicaid. The NDRA requires manufacturers to report certain drug pricing information to CMS and to pay rebates on their products to Medicaid.

A key piece of information reported under the MDRP is the manufacturer's "best price," which is defined as the:

> "[T]he lowest price available from the manufacturer during the rebate period to any wholesaler, retailer, provider, health maintenance organization, nonprofit entity, or governmental entity in the United States in any pricing structure (including capitated payments) in the same quarter for which the AMP is computed."

Key exceptions to this definition include discounts offered to Department of Veterans Affairs, the 340B drug discount program, Medicare Part D plans, including the Medicare Coverage Gap Discount Program, and Indian Health Services.

The best price is used to calculate the rebate amount owed to state Medicaid programs for brand name drugs. Specifically, for brand name drugs, the manufacturers must pay states a rebate equal to the greater of either:

1. 23.1% of Average Manufacturer Price (AMP) (or 17.1% of AMP for certain pediatric and clotting drugs), or
2. the difference between AMP and "best price."

The rebate calculation also includes an additional inflationary component to account for rising drug prices over time. States also have the option to negotiate supplemental rebates with manufacturers.

How has the Medicaid Best Price Policy Impacted VBP Arrangements?

Manufacturers and other stakeholders have argued that Medicaid best price requirements (pre-Final Rule) severely hindered the use of VBP arrangements in the commercial space. For example, if a manufacturer sought to offer a commercial plan an outcomes-based contract, where the manufacturer rebates a substantial cost of the drug to the payor in instances where the drug fails to produce a desired outcome, the manufacturer would have to offer that same substantial rebate to all states, regardless of whether the drug produces desired outcomes for Medicaid patients.

How does the Final Rule Change the Medicaid Best Price Policy's Impact on VBP Arrangements?

Under the Final Rule, CMS allows the manufacturer to report multiple best prices for VBP arrangements, so long as the manufacturer makes the VBP arrangement available to state Medicaid programs. CMS broadly defines "VBP arrangement" as follows:

> "Value-based purchasing (VBP) arrangement means an arrangement or agreement intended to align pricing and/or payments to an observed or expected therapeutic or clinical value in a select population and includes, but is not limited to:
>
> (1) Evidence-based measures, which substantially link the cost of a covered outpatient drug to existing evidence of effectiveness and potential value for specific uses of that product; and/or
>
> (2) Outcomes-based measures, which substantially link payment for the covered outpatient drug to that of the drug's actual performance in patient or a population, or a reduction in other medical expenses."

When a manufacturer enters into a VBP arrangement with a commercial payor, it must report (i) a non-VBP arrangement price, which is the best price offered absent a VBP arrangement; and (ii) the multiple prices tied to the various outcomes of the VBP arrangement. States then have the option to participate in that VBP arrangement. When states enter into the VBP arrangement, it would receive a best price rebate based on the patient's outcome. If a state elects not to enter into a VBP arrangement, the best price used in the Medicaid rebate formula would mirror the lowest price available absent a VBP arrangement.

The final rule also revised the definition of "bundled sale" to clarify that VBPs may qualify as a bundled sale, which permits manufacturers to spread out discounts resulting from a VBP arrangement over multiple units in the bundled sale, so that manufacturers may ultimately report a net discount that is a weighted average of the discounts provided based on individual patient outcomes.

What concerns arise out of the potential impact of the new VBP Arrangement Policy?

States and patient advocacy stakeholders expressed concern with the changes enacted by the Final Rule, stating that this policy change would increase costs to state Medicaid programs. Specifically, they argue that:

1. State Medicaid programs do not have the staff or resources to collect the required data or otherwise administer VBP arrangements, especially during COVID.
2. Manufacturers will move all large payors, whose arrangements currently establish the best price, to VBP arrangements.

Given financial and resource constraints, State Medicaid programs may be unable to take advantage of VBP arrangements, and associated discounted pricing. Even though the Final Rule

requires that manufacturers offer states a non-VBP best price if they do not participate in a VBP arrangement, they may still end up paying higher prices, especially if the manufacturers only offer their drugs through VBP arrangements.

What additional clarifications did CMS provide in its Medicaid Best Price Guidance on VBP Arrangements?

The Medicaid Best Price Guidance provides states and manufacturers additional clarity on key operational issues of reporting and implementing VBP arrangements and their impact on Medicaid Best Price. As part of this, CMS acknowledged and tried to address some of the stakeholder concerns discussed above.

Of particular note, CMS provided guidance on the following issues:

- Clarity on "Offering" VBP Arrangements to States: The Final Rule requires manufacturers offer VBP arrangements to all states. The Guidance clarifies that the manufacturer must include a description of the VBP arrangement, the guaranteed net unit prices (GNUPs) available under the VBP arrangement for each outcome, and the manufacturer contact information in the Medicaid Drug Product (MDP) System to meet the requirements for "offering" the VBP arrangement to States. States are then responsible for reaching out to the manufacturer to enter into a state specific agreement for the VBP arrangement.

- States are responsible for invoicing the manufacturer for additional rebates under VBP Arrangements. The Guidance clarifies that the MDP system will continue to generate the standard Federal rebate, based on the formula discussed above. States will have to invoice the manufacturer for additional rebates.

- Calculation of Non-VBP Best Price. The Guidance clarifies that manufacturers must provide a non-VBP arrangement best price if it is also reporting multiple best prices for a VBP arrangement. CMS recognizes that some manufacturers may not offer a product outside a VBP arrangement. In this case, the manufacturer may use "reasonable assumptions" to approximate the non-VBP best price by "estimating a lowest price available to the payer/provider if no additional discounts based upon outcomes are made under the VBP arrangement."

- State Flexibilities: The Guidance notes that state Medicaid programs operate under different constraints and do not have access to the same resources as commercial payors. Thus, it encourages manufacturers to permit states the flexibility to make minor adjustments to VBP arrangements to address the specific needs of the state Medicaid program and its beneficiaries. The Guidance provides the following examples:

- Offer the state the option of entering into a CMS-authorized supplemental rebate agreement, especially where the state is unable to enter into the manufacturer's VBP arrangement offered on the commercial market.
- Permit states to use existing and readily-available claims data to track outcomes for outcomes-based VBP arrangements and work with states to identify the most efficient way to track outcomes for a particular arrangement.
- Make the VBP arrangement available to all Medicaid patients regardless of their health status, and ensure the arrangement is not used to clinically test drugs or cause health disparities for any particular population.

What are the potential impacts of the Final Rule and Medicaid Best Price Guidance?

In issuing the Final Rule and Guidance, CMS eliminated a significant barrier for manufacturers seeking to enter into VBP arrangements with commercial payors, paving the way for a likely increase in the use of VBP arrangements. Although CMS indicates that it will not get involved in the approval or review of the specifics of any VBP arrangements, it will monitor the implementation of the policy and will make referrals to the Office of Inspector General in cases when they identify concerns with manufacturer price reporting under the MDRP. Manufacturers need to ensure that they maintain appropriate records, including records setting forth their non-VBP best price if no non-VBP best price exists, as CMS will certainly be closely monitoring manufacturers as they begin to implement this new policy.

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