ROPES & GRAY

ALERT ▪ Health Care

December 23, 2020

Midnight Changes to the Medicaid Drug Rebate Program Regulations

Attorneys
Margaux J. Hall
Thomas N. Bulleit
Meredythe Ryan
Kelly Hamachi

On December 21, 2020, the Center for Medicare & Medicaid Services ("CMS") issued a Final Rule that makes significant modifications to the Medicaid Drug Rebate Program ("MDRP") regulations in several areas, including with respect to the treatment of value-based purchasing arrangements, the definition of key terms "line extension" and "new formulation," and the price reporting treatment of manufacturer-sponsored patient benefit programs. This Final Rule follows a proposed rule with 30-day-comment issued on June 17, 2020 ("Proposed Rule").

We summarize herein some of the most significant MDRP changes that impact price reporting functions of pharmaceutical manufacturers.[1]

- **New definition of value-based purchasing arrangement, new flexibility to report multiple Best Prices, and an upcoming overhaul of the Drug Data Reporting ("DDR") system.**

  In an effort to encourage the adoption of value-based purchasing ("VBP") arrangements in the commercial and Medicaid markets, the Final Rule implements changes to the MDRP price reporting requirements to address VBP arrangements and clarify how manufacturers should account for discounts, rebates, and pricing in calculating Average Manufacturers Price ("AMP") and Best Price ("BP") under such arrangements.

  New definition of value-based purchasing arrangement

  The Final Rule defines the term "value-based purchasing arrangements" as:

  > an arrangement or agreement intended to align pricing and/or payments to an observed or expected therapeutic or clinical value in select populations 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 a patient or a population, or a reduction in other medical expenses.

  This definition is largely similar to the one in the proposed rule, with a few notable changes. First, it adds the word "select" to emphasize that VBP arrangements apply only to specific populations using the drug therapy. Further, the Final Rule clarifies that either an evidence-based or an outcomes-based measure could cause an agreement to be considered a VBP arrangement, by inserting "and/or" into the definition. The Final Rule also confirms that VBPs apply to covered outpatient drugs.

  In issuing the Final Rule, CMS declined to define terms within this definition such as "effectiveness," "performance," or "substantially," noting that these terms will be fact-specific and defined as part of the VBP arrangement itself. The agency said that manufacturers may make reasonable assumptions and "should document how [the] arrangement substantially links the payment/cost of the drug to the outcome in the arrangement and therefore qualifies as a VBP arrangement under this final rule."

[1] The Final Rule also (i) makes conforming amendments to MDRP regulations based on statutory changes that have occurred since the current regulation was issued in 2016; (ii) implements certain provisions of the SUPPORT Act, including by adding minimum standards for state Medicaid Drug Utilization Review (DUR) programs, and (iii) implements regulatory changes related to Medicaid coordination of benefits and third-party liability. Those changes are not summarized herein.

The new definition of VBP will be effective 60 days after publication in the Federal Register. The agency said that "VBP arrangements offered on the commercial market before this regulation that do not meet the new regulatory definition of VBP arrangement … will have to be restructured to meet the new definition and requirements of this final regulation if a manufacturer wants to take advantage of the regulatory flexibilities included in this final rule."

Multiple BP reporting under VBPs.

The Final Rule also implements the "multiple BP model" contemplated under the Proposed Rule. Specifically, under the Final Rule, manufacturers may report varying BP points for a single dosage form and strength of a drug that reflect the terms of a VBP arrangement. States may opt not to participate in a multiple BP arrangement and, in that case, would receive rebates based on the manufacturer's non-VBP BP for the dosage form and strength of the relevant drug. Similarly, manufacturers may elect not to report multiple BPs, in which case they would follow the rules that otherwise apply with respect to price reporting. The changes that permit manufacturers to report multiple BPs will take effect on January 1, 2022.

CMS acknowledged that there may be unresolved issues regarding some aspects of these new VBP policies and said that it would address any such issues through operational guidance.

Clarification of bundled sale definition

The Final Rule clarifies that VBPs may qualify as a bundled sale.

Expanded AMP and BP restatement window for VBP arrangements

The agency finalized its proposal to allow manufacturers to restate AMP and BP outside the three-year window in a new circumstance – namely, when a change is a result of a VBP arrangement and the outcome must be evaluated outside the 12-quarter period. CMS will need to specifically authorize such restatements.

Upcoming overhaul of DDR

The agency also said that it is developing a new Medicaid Drug Program ("MDP") system that will replace both the current DDR and Medicaid Drug Reporting ("MDR") systems, with the new system expected to be fully functional in July 2021. The agency intends for this new MDP system to facilitate manufacturer reporting of multiple BPs.

- **Amendments to patient assistance program price reporting exceptions.**

  CMS finalized its proposal to revise the patient program exclusions to make clear that the exclusions apply only to the extent the manufacturer "ensures" that the full value of any manufacturer-sponsored patient assistance is passed onto the patient and that the pharmacy, agent or other entity does not receive any price concession. CMS "believe[s] manufacturers can implement a system to ensure the full benefit of its manufacturer-sponsored assistance passes on to the patient."

  In practice, this will raise challenges in light of the growing trend of pharmacy benefit manager ("PBM") accumulator programs, under which PBMs prohibit or discourage health plans from applying assistance towards a patient's health plan deductible. These programs have the effect of shifting drug costs back to the patient, and allowing the health plan to reap the financial benefits of the assistance.

  The changes to the patient assistance program exceptions are likely to place a heavy burden on manufacturers. CMS has delayed the effective date until January 1, 2023 in order to "give manufacturers time to implement a system that will ensure the full value of assistance under their manufacturer-sponsored assistance program is passed on to the patient."

- **"Line Extension" and "New Formulation" definitions.**

  In 2010, the Affordable Care Act amended the Medicaid statute to apply an "alternative rebate" formula to drugs that are line extensions of an original drug. The Final Rule defines "line extension" to mirror the Medicaid

statutory definition as "a new formulation of the drug, [which] does not include an abuse-deterrent formulation of the drug."

It also finalizes, for the most part, the proposed expansive definition of "new formulation" – the key term within the line extension definition. Under the Final Rule, "new formulation" is defined as "a change to the drug, including, but not limited to: an extended release formulation or other change in release mechanism, a change in dosage form, strength, route of administration, or ingredients."

This definition is largely similar to the definition in the Proposed Rule with a few exceptions. For instance, the agency did not finalize its proposal that a change in indication, accompanied by marketing as a separately identifiable drug, be included in the definition. Also, CMS removed changes in "pharmacodynamics or pharmacokinetics" from the definition of "new formulation" to reflect a narrower focus on changes in release mechanisms.

The agency also finalized its proposed interpretation of line extension such that *only* the initial single source drug or innovator multiple source drug must be an oral solid dosage form for purposes of determining whether a drug is a line extension. CMS finalized the proposed modification to the definition of "oral solid dosage form" such that the term means "an orally administered dosage form that is not a liquid or gas at the time the drug enters the oral cavity." These changes, too, will expand the universe of drugs that arguably qualify as line extensions.

CMS did not resolve questions regarding how to identify the original drug for purposes of conducting the line extension analysis. Instead, the agency suggests that manufacturers must consider all strengths of potential "initial drugs" on a quarterly basis – such that the original drug could vary across quarters and is not necessarily identified by virtue of its chronological date of approval or first marketing.

In finalizing these definitions and interpretations, the agency expressed its view that its proposed interpretation is not contrary to Congressional intent. CMS said that, in its view, if Congress had wanted a more limited definition of line extension, it would have included such a narrow definition in the statute. The agency also expressed its general view that "the statute does not require that in order for a drug to be a line extension, the change to a drug must be a slight alteration."

These definitions will become effective on January 1, 2022 and will apply to a company that manufactures both the original drug and the line extension, as well as a company that has a corporate relationship with the manufacturer of the original drug. For periods prior to January 1, 2022, manufacturers are instructed to continue to rely on the statutory definition and make reasonable assumptions to determine whether a drug qualifies as a line extension.

- **Authorized generic drugs and AMP blending.**

  CMS finalized the policy that manufacturers cannot blend the sales of the AMPs for the brand name drug sold under the New Drug Application ("NDA") and the sales of any other drug sold under the NDA, regardless of the relationships between the entities selling the drugs. The agency did not distinguish among business or corporate relationships between companies. However, it made a revision to the definition of secondary manufacturer to clarify that, regardless of the relationship that exists between the primary and secondary manufacturer, "sales of the authorized generic cannot be blended with the sales of the brand name drug."

- **CMS-authorized supplemental rebate agreement.**

  The agency finalized the proposed definition of CMS-authorized supplemental rebate agreement to mean an agreement that CMS approves through a state plan amendment, and which allows a state to enter into single and/or multi-state supplemental drug rebate arrangements that generate rebates that are at least as large as the rebates set forth in the national rebate agreement with drug manufacturers. The agency clarified that revenue from these supplemental rebates must be used by the state to offset a state's drug expenditures resulting in shared savings with the federal government.