July 1, 2020

Proposed Rule Seeks to Promote Adoption of Value-Based Purchasing Arrangements

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On June 17, 2020, the Centers for Medicare & Medicaid Services (CMS) issued a proposed rule that, if finalized, would modify significantly the current Medicaid Drug Rebate Program (MDRP) regulations, generally (but not entirely) directions long-favored by drug makers. The proposed rule puts forth new regulatory policies, as well as providing clarification with regard to already established polices, intended to encourage drug manufacturers and states to participate in value-based purchasing arrangements (VBPs). Significantly, the proposed rule impacts best price (BP) reporting in VBPs, excludes pharmacy benefit managers (PBM) accumulator programs from BP and Average Manufacturer Price (AMP) determinations, and updates the definitions of several relevant terms to reflect recent statutory changes that came after the MDRP regulations in 2016. In an unusually short comment period, comments are due no later than 5p.m. on July 20, 2020.

This Alert summarizes key elements of the proposed rule and its implications. If you have any questions, please do not hesitate to contact one of the authors or your usual Ropes & Gray advisor.

Current State of Value-based Purchasing Arrangements under the MDRP

MDRP regulations have long been viewed as discouraging innovative contracting models between pharmaceutical firms and commercial insurers and Medicaid, particularly the Medicaid "best price" reporting requirements. Currently, in order to have a drug covered by Medicaid, pharmaceutical companies are generally required to sell their drugs to state Medicaid programs at the lowest price available to any wholesaler, retailer, or provider, referred to as the "best price." Accordingly, many have cited the BP requirement as an obstacle to outcome-based VBPs, which have the potential to significantly drop the BP if the drug is not effective in all cases. Pharmaceutical companies and trade groups have argued that there is ambiguity in how to capture innovative pricing methods in the current BP framework which can create uncertainty for innovators and payers, creating a barrier to entering into value-based contracts.

Changes to the Best Price Reporting Requirements to Support Value-based Purchasing Arrangements

In an attempt to encourage the adoption of VBPs, the proposed rule creates a definition for VBPs, and proposes two new mechanisms that manufacturers can use to calculate BP for arrangements that fall within the new VBP definition: (1) bundled sales; and (2) multiple BPs. These new options give manufacturers additional flexibility with regard to BP calculation and may facilitate the adoption of VBP arrangements, especially in the commercial market.

Value Based Purchasing Arrangement Definition

The proposed rule would define VBPs as "an arrangement or agreement intended to align pricing and/or payments to an observed or expected therapeutic or clinical value in a population (that is, outcomes relative to costs) and includes (but is not limited to):

- Evidence-based measures, which 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, which substantially link payment for the drug to that of the drug's actual performance in a patient or a population, or a reduction in other medical expenses."

In what is presumably a deliberate departure, this definition is narrower than the definitions of "value-based arrangement" set forth last Fall in proposed rules to protect such arrangements from liability under the Stark and Anti-kickback laws. In those proposed rules, OIG and CMS propose to define a "value-based arrangement" as an arrangement that (i) is between or among the value-based entity (VBE) and one or more of its VBE participants, or VBE participants in the same VBE, and (ii) provides for at least one value-based activity for a target patient population. Although a "value-based activity" must include an activity that is reasonably designed to achieve at least one value-based purpose of VBE, the requirement that a VBP arrangement "align" pricing with measurable outcomes seems to indicate a somewhat less sympathetic attitude towards the government's desire for good prices from pharma companies (notably, the protections proposed in the OIG/CMS rulemaking do not even apply to pharmaceutical manufacturers) than its willingness to tolerate pricing arrangements among health industry stakeholders outside the pharma industry.

Multiple BPs Could be Reported for VBPs

A frequently raised concern with the current MDRP is the ability to report only a single BP for a drug. The proposed rule would expand the definition of BP to permit reporting of multiple BPs, recognizing that "a single drug may be available at multiple price points, each of which may establish a 'best price' based on the relevant or applicable VBP and patient evidence-based or outcome-based measures."

Currently, if a VBP provides outcomes-based discounts, a single failed unit with the greatest discount could become the BP for all sales of the drug during a reporting period, and that BP alone would be reported. As a reminder, if only basic rebates are due, the rebate for a brand-name drug equals the greater of the drug's average manufacturer price (AMP) minus its BP, or 23.1% of its AMP.[1] So currently, if the VBP offers a full refund for a failed outcome, a single failed outcome would require a rebate of 100% of AMP for all Medicaid sales of the drug during the reporting period, obviously a potentially disastrous result for the drug maker.

Under the proposed rule, a manufacturer could report a distinct set of BPs based on "the range of evidence-based or outcomes measures for that drug that are possible under the VBP arrangement." The proposed rule states, as an example, that a manufacturer "could offer varying rebates based on a patient's response after the drug is administered". If participating in a VBP, the manufacturer could report multiple BPs, each corresponding to a different patient outcome. The manufacturer also would report a single BP for sales outside of the VBP arrangement in accordance with how BPs are currently calculated. The rebates manufacturers must pay to state Medicaid programs then would turn on whether each Medicaid beneficiary "participates" in the VBP. For a beneficiary whom the state treats as a "participant," the BP for purposes of calculating the rebate for that patient's sales will be the BP that is reported for the particular outcome achieved by the patient. A different Medicaid rebate would be calculated for each of the reported BPs for each outcome, meaning the rebate paid for a patient "would only represent the amount of rebate due to the state from the manufacturer for that patient, not all patients." If a state's Medicaid beneficiaries do not "participate," then the rebate for sales for all non-participants will be based on the single non-VBP BP that is calculated in accordance to current rules.

What this means for rebate calculation is not entirely clear, but at a minimum has the potential to be quite complicated. Take for example a hypothetical drug which if fully successful would lead to the elimination of 6 designated symptoms of a disease within 6 months, without recurrence within 2 years. The manufacturer offers the commercial purchaser a 100% discount (full refund) if no symptoms are eliminated in 6 months (Outcome 1), and again at 2 years, and a 50% discount (partial refund) if only 3 symptoms are eliminated (Outcome 2). Assume that 100 patients take the drug during a calendar quarter, and that 5 of them fail to reach Outcome 1 and another 5 patients fail to meet Outcome 2. Assume further that the effect of the 100% discount would set a BP at $0 (or a negative number) for the Outcome 1 group, and the 50% discount would set a BP at approximately 50% of AMP for the Outcome 2 group (assuming the drug was initially

[1] 42 U.S.C. § 1396r-8(k)(7)(A)(ii)(iv); 42 C.F.R. § 447.502. "Additional rebates" may be required if the AMP of the drug has increased faster than the rate of inflation. 42 C.F.R. § 447.509(a)(2).

bought at a price near AMP). Read literally, state Medicaid programs could "participate" in the VBP, in which case rebates for Medicaid beneficiaries will depend on each beneficiaries' outcomes. The rule would require the manufacturer to pay a rebate of 100% of AMP for any Medicaid beneficiaries who have no symptoms eliminated and would qualify for Outcome 1 (*i.e.*, the rebate is equal to AMP minus BP, or AMP minus $0, which is 100% AMP). For Medicaid beneficiaries who have 3 symptoms eliminated (Outcome 2), the manufacturer would pay a rebate of approximately 50% of AMP. The manufacturer also would report a single BP for sales outside of the VBP under current rules that would be used to calculate the MDRP rebate for any Medicaid beneficiaries who are not considered to "participate" in the VBP. But the manufacturer's offer also requires a check-in at two years, so the same exercise and a restatement would have to be performed at that time.

As CMS admits in the preamble, this dramatic change to how BPs are reported will create significant "operational challenges." Questions not answered in the proposed rule include how will CMS and states track the terms of VBPs with commercial payers, how will states indicate whether or not their Medicaid beneficiaries are participating in a manufacturer's VBP, and how will manufacturers and states track beneficiary outcomes to ensure the correct rebate amounts are calculated and paid. The rule's many uncertainties, coupled with the substantial operational hurdles that manufacturers and states likely will face, underscore the importance of the public comment process for this proposed rule.

VBPs Could Qualify as Bundled Sales

Another protection against VBPs setting a too-low BP may result if the VBP qualifies as a bundled sale under the proposed rule's modified definition. The existing rule defines a bundled sale 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 national drug code (NDC) level) or another product or some other performance requirement (for example, the achievement of market share, inclusion of tier placement on a formulary), 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." While some manufacturers already make reasonable assumptions in their reporting that VBPs can qualify as bundled sales, the current definition is perceived by many as ambiguous regarding its applicability to VBPs. The proposed rule seeks to resolve such ambiguity by explicitly allowing for this practice by adding to the current MDRP definition of bundled sale, "value-based purchasing (VBP) arrangements may qualify as a bundled sale, if the arrangement contains a performance requirement such as an outcome(s) measurement metric."

With a bundled sale, a discount resulting from a performance-based failure in a VBP is "allocated proportionally to the total dollar value of the units of all the drugs or products sold under the bundled arrangement." For example, a manufacturer sells 100 units of the same drug in a VBP arrangement where each drug is priced at $100 per unit, and the manufacturer promises to rebate $50 to the payer for any patient who takes the drug and does not meet a defined outcome. All 100 units are taken and one patient does not meet the outcome. As a result, the manufacturer was paid $100 for 99 units and $50 for one unit where the manufacturer had to rebate $50 back to the payer. The $50 price for that one patient could become the manufacturer's new BP, resulting in greater rebate obligations. Under the proposed rule, however, the manufacturer could "bundle" the 100 sales and proportionately allocate the discount from the one sale with a rebate across all 100 units. In that case, the total price paid to the manufacturer divided by the total number of units in the bundle (*i.e.*, $9,950 divided by 100 units) yields a new BP of $99.50.

Exclusion of Pharmacy Benefit Managers (PBM) Accumulator Programs from Best Price and Average Manufacturer Price Determination

Even apart from VBPs, the rule also proposes changing requirements for excluding certain manufacturer-sponsored patient benefit programs from determinations of BP and AMP. Plans and PBMs are increasingly using what are known

as "accumulator programs." The proposed rule offers as an example of such a program the situation when a PBM instructs health plans not to allow manufacturer copay assistance to be applied towards a patient's plan deductible for a brand-name drug not on a plan's formulary. Under such accumulator programs, the value of any copay assistance or discount that a patient receives from a manufacturer does not accrue towards a patient's deductible or out-of-pocket limit. Under the current MDRP rule, copay assistance subject to such programs may be excluded from BP and AMP if a manufacturer claims that it was unaware that these practices by the health plans were taking place, and believed that the full value of the discount was passed onto the consumer.

As discussed in the proposed rule, CMS is concerned that such programs prevent the full value of the benefit provided by the manufacturer from being passed on to the patient. Accordingly, the proposed rule would state explicitly that such patient benefit programs would only be excluded from pricing calculations "to the extent the manufacturer ensures the full value of the assistance or benefit is passed on to the consumer or patient." Manufacturers may no longer claim to have made a reasonable assumption, but must ensure that the full value is passed on to the consumer. It would seem then that manufacturers would be obligated to include the value of common patient benefit programs—like co-pay cards and coupons—in BP determinations if the card or coupon was utilized by a patient covered under a health plan with a PBM accumulator program, potentially resulting in lower BPs. CMS states that it "believes" manufacturers have the capacity to track whether a drug is purchased under such a patient benefit program, through establishing coverage criteria around their manufacture assistance programs. Whether this is true is likely to be debated by drug makers in comments on the rule. At a minimum, it would seem to add considerably to the infrastructure costs of price reporting. Accordingly, if the rule is finalized in its current form, manufacturers may decrease their use of such programs due to the financial impact of lowered BPs and the costs of administering the new requirements.

Other Notable Changes

In addition to the above changes, the proposed rule seeks to update regulatory definitions and language to reflect recent statutory changes made by the Medicaid Services Investment and Accountability Act of 2019, Bipartisan Budget Act (BBA) of 2018 and Affordable Care Act (ACA):

Innovator Multiple Source Drug

The Medicaid Services Investment and Accountability Act of 2019 clarified the definition of innovator multiple source drug as a "multiple source drug that is marketed under a new drug application approved by the Food and Drug Administration (FDA), unless the Secretary determines that a narrow exception applies." The agency proposes to align the regulatory definition with the statute's definition.

Line Extension and New Formulation

The Medicaid Services Investment and Accountability Act of 2019 defines line extension to mean a new formulation of a drug that does not include an abuse-deterrent formulation of the drug. The proposed rule attempts to provide further guidance on interpreting the statute by defining "line extension" and "new formulation." The agency proposes to define line extension to mirror the statute, and further define new formulation as "any change to the drug, provided that the new formulation contains at least one active ingredient in common with the initial brand-name listed drug."

Oral Solid Dosage Form

The proposed rule notes that in determining whether a drug is a line extension, the initial single source drug or innovator multiple source drug must be an oral solid dosage form. The agency then explains that currently manufacturers may not be interpreting the term oral solid dosage form consistently, and proposes to modify the definition as "a dosage form that is neither a gas nor a liquid" in order to mitigate any confusion.

CMS-Authorized Supplemental Rebate Agreements

Under the MDRP, rebates paid by manufacturers in supplemental rebate agreements approved by CMS are excluded from AMP and BP. After the ACA made sales to Medicaid managed care organizations (MCO) rebatable, some states required MCOs to share supplemental rebates under the CMS-authorized supplemental rebate agreement, while other states allowed MCOs to negotiate their own rebates with manufacturers which allowed the MCOs to keep the savings from the supplemental rebates. CMS states that it is concerned with manufacturers' assumptions that all supplemental rebates paid by manufacturers for prescriptions dispensed to Medicaid MCO enrollees should be excluded from AMP and BP since rebates that are paid directly to Medicaid MCOs are not shared with the state or eventually used to offset state drug expenditures prior to claiming Federal financial participation. To clarify that such rebates paid by manufacturers are not part of a state's CMS-authorized supplemental rebate agreement, the proposed rule creates a new definition of the term "CMS-authorized supplemental rebate agreement," so that the AMP and BP exclusion applies only if supplemental rebates are paid directly to the state and used to offset a state's drug expenditures resulting in shared savings with the Federal government.

Finally, the proposed rule also seeks to implement provisions of the Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment (SUPPORT) for Patients and Communities Act. Specifically, the agency proposes to implement the opioid-related drug utilization review standards required under the SUPPORT Act. Currently, each state's Drug Utilization Review program assesses drug use against predetermined standards. The proposed rule would set a universal minimum standard that must be followed by all states.

Potential Implications of the Proposed Rule

The proposed rule appears to give manufacturers more flexibility in how to report and calculate BP, which could significantly change incentives for manufacturers to participate in VBP arrangements. However, some of the rule's regulatory language is vague and it remains unclear how the new BP reporting will work in practice. Further guidance from CMS may be necessary to resolve ambiguities and lack of clarity in the new proposals. Another possible outcome of the proposed rule, if adopted, is a decrease in patient assistance programs like copay cards and coupons, though it is worth noting that the proposed rules' purpose is to encourage the adoption of VBP, not to lower consumer drug prices. Stakeholders should be aware of the short comment period and consider these implications in carefully reviewing the proposed rule.