



July 20, 2020

Seema Verma
Administrator
The Centers for Medicare and Medicaid Services
7500 Security Boulevard
Baltimore, MD 21244

Dear Administrator Verma,

On behalf of the nation's Medicaid Directors, NAMD is offering comments in response to the Notice of Proposed Rulemaking (NPRM) "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" [CMS – 2482 – P].

We are concerned that the rule's proposals would greatly favor manufacturers over states in terms of financial benefit, have significant impacts on the Medicaid pharmacy benefit, undermine best price protections that ensure the sustainability of Medicaid pharmacy budgets, and place substantial strain on state administrative resources. We further call for additional consideration of these proposals when state staff capacity is not stressed by the ongoing COVID-19 pandemic. While we strive to provide as detailed comments here, a 30-day comment period for a rule of this import is not sufficient. This rule merits longer and more thoughtful deliberation.

VBP and the MDRP

Prescription drugs are an optional benefit under Medicaid statute, with each Medicaid program electing to include prescription drug coverage. To ensure the sustainability of the program, federal law established the Medicaid drug rebate program (MDRP). The MDRP is administered via the National Drug Rebate Agreement, signed between drug manufacturers and the Secretary of the U.S. Department of Health and Human Services. In exchange for coverage of a manufacturer's drug products approved by the Food and Drug Administration, Medicaid receives mandatory rebates off list price, as well as inflation rebates for products whose annual price increases outpace inflation. While coverage is required, states may employ prior authorization and other measures to ensure safety and clinically appropriate utilization.

Further, Medicaid is guaranteed the best price a manufacturer offers to a commercial payer. These rebates are shared with the federal government, and so the MDRP generates value for both the states and Medicaid's federal partners. States may negotiate further supplemental rebates on top of those required by the MDRP, often in exchange for more favorable prior authorization criteria or placement on the state's preferred drug list (PDL).

In recent years, manufacturers have brought increasingly specialized and expensive therapies to market, such as gene therapies targeting small patient populations with rare conditions. To address high upfront

costs, manufacturers have expressed interest in value-based purchasing (VBP) for their products, under which payment is conditioned on certain parameters being met over the lifetime of the treatment. Manufacturers consistently identify the MDRP's best price provision as a barrier to widespread adoption of VBP in commercial markets, since a VBP arrangement which provides a full refund for a failed course of treatment could set the Medicaid price for that product to zero dollars (or an otherwise substantially low price point).

This is the primary barrier CMS seeks to address in this rule, via reinterpreting best price statutory requirements such that manufacturers may report multiple best prices unique to specific VBP arrangements. Best prices could also be realized in a bundled sale VBP arrangement under the proposal. Lastly, CMS proposes allowing manufacturers to report changes in Average Manufacturer Price and best price outside of the normally applicable 12 quarter period to support VBP arrangements conditioned on long-term outcomes.

Multiple Best Prices Incentivize Manufacturers to Game the MDRP and Create Burdens for States

While the proposal for multiple best prices – one reported normally for any non-VBP arrangement, and others tied to payments made for specific courses of treatment within VBP arrangements – would address manufacturer concerns, this approach introduces numerous challenges for states.

While CMS states in the preamble that it considers this change helpful for state adoption of pharmacy VBP, it is not clear what new flexibilities this would create for states that are not currently available. States are already able to negotiate VBP arrangements within supplemental rebates. CMS clearly articulates that such arrangements do not impact best price. To date, CMS has approved nine such supplemental VBP arrangements. Rather, this change is of direct benefit to manufacturers and commercial payers interested in VBP and removes the risk of low or no charge for a product from becoming Medicaid's default price going forward.

Contrary to the positive impacts for manufacturers and commercial payers, multiple best prices conditioned on specific VBP parameters create significant risks for states. It is not clear from the rule as drafted if states would default to having the option to participate in a VBP arrangement offered to a commercial payer. It is not even certain that manufacturers would be able to share the details of a VBP arrangement, as such information is generally proprietary. Nor is it clear if states would need to be in identical VBP arrangements with the same targets, metrics, and outcomes to avail themselves of best prices realized between manufacturers and private entities.

What this could mean in practice is manufacturers create multiple concurrent VBP arrangements, each with slightly different parameters, and not offer the same arrangements to states that are offered to private payers. This would in effect sidestep best price protections, reducing MDRP mandatory rebates and increasing costs for states. Manufacturers could potentially lock states out of VBP entirely by extending VBP opportunities exclusively to private payers, leaving states subject to only mandatory rebates on high list price products. Moreover, with financial incentives tilting heavily towards VBP, manufacturers may have less incentive to participate in supplemental rebate agreements to the degree they do so today, which would further increase state costs. These concerns also hold true between fee-for-service (FFS) Medicaid and Medicaid managed care programs, where manufacturers may choose to

offer VBPs to Medicaid plans but not to FFS Medicaid. Such scenarios will reduce states' supplemental rebate collections since many states do not collect supplemental rebates on Medicaid managed care claims.

Setting aside these potential increases on direct pharmacy spending, the administrative burdens and demands on state staff resources to implement multiple best prices is significant. States and rebate vendors would need to transition their systems and supplemental rebate agreements to support multiple unit rebate amounts (URAs) derived from multiple best prices. This is a significant departure from current system parameters, requiring new resources to develop and manage, as CMS itself acknowledges. States are not in a position to secure these resources in the midst of severe declines in state general revenues resulting from COVID-19.

As long-term VBP arrangements go into effect and best prices are modified beyond the currently applicable 12 quarter window, states and fiscal agents may see additional burdens over a period of years. This is due to potential large credits to manufacturers or large amounts of rebates owed to Medicaid, which for some states requires manual review to identify.

Further, the ability for manufacturers to use bundled sales in a VBP arrangement would potentially allow unrelated products with minimal impacts on outcomes also be exempt from ordinary best price rules. This could inhibit states' ability to effectively manage their PDLs.

Finally, multiple best prices could have impacts on the 340B drug discount program administered by the Health Resources and Services Administration (HRSA). It is unclear if multiple best prices in Medicaid would create multiple ceiling prices in 340B. If there were to be multiple ceiling prices, it is unclear which ceiling price would be used for which 340B patient. The interactions between the MDRP and the 340B program are already complex and administratively burdensome, and this rule could substantially increase these complexities.

CMS should address these issues in final rulemaking. Recommendations for CMS action include:

- Require manufacturers to share specific details of their extant commercial VBP arrangements with states and mandate that states may be allowed to participate in the arrangement. If there are concerns that this information is proprietary, CMS can develop a process for serving as an intermediary for purposes of sharing this information. Manufacturers should make these details available timely to minimize any gaps between an arrangement going into effect and a state beginning to participate in the arrangement.
- Limit the number of VBP arrangements a manufacturer may offer, for example allowing only two VBP arrangements per drug with no more than three tiers of prices within each arrangement.
- Require VBP arrangements to include minimum, maximum, and expected percentage rebates that will be offered.
- Consider "any pricing structure" in the definition of best price as inclusive of any and all pricing structures, such that no pricing structure would be excluded from the best price calculation.

- Include all payments related to VBP in the best price calculation.
- Remove the option to report multiple best prices in VBP arrangements, and instead use the bundled sale methodology to incorporate all VBP best prices into one URA, such that commercial VBP payments are not treated differently from any other rebate. Alternatively, CMS could define best price as the lower of the current best price methodology or the bundled sale methodology.
- Limit permissible VBP arrangements to drugs meeting certain characteristics, such as a floor for average annual cost, course of treatment cost, and/or genetic therapies and other similarly specialized drugs.

Challenges in Defining “Value”

CMS seeks comment on how much “value” must be present in a VBP arrangement for it to truly be considered VBP. CMS considers whether a threshold of evidence-based or outcomes-based metrics would satisfy this need, specifically using the term “substantially.”

While identifying common benchmark metrics applicable across VBP arrangements would be useful from an administrative perspective, the reality is that these agreements will almost always be unique to the specific payers, manufacturers, target populations, and conditions being treated. Significant flexibility and discretion is necessary to set these parameters appropriately.

That said, some guardrails would be useful to ensure states are protected from the scenarios described above which could result in the gaming of VBP arrangements. These include:

- Requiring the drug to meet or exceed product performance in clinical trials.
- Requiring VBP arrangements to be either cost-based or outcomes-based, rather than simply evidence-based, unless the state determines that an evidence-based arrangement is appropriate for its needs. In general, evidence-based metrics alone without cost-based or outcomes-based metrics are not sufficient to ensure value.
- Allow full recoupment of the drug’s cost if treatment fails to generate response in a patient.
- Requiring that the VBP arrangement be anticipated to generate savings larger than those available under the current MDRP framework, inclusive of administrative costs to operate the VBP arrangement and any ancillary products included in a bundled sale.
- Allowing the state to be the final arbiter of whether a VBP arrangement’s terms were upheld for any VBP arrangement the state is participating in, similar to the state’s ability to determine medical necessity in other dimensions of the Medicaid program.

Administrative Costs for States Participating in VBP

Outcomes-based VBP is not a trivial undertaking from a data collection and analysis perspective. States would need to collect different types of data (such as claims, health outcomes, non-claim costs, activities of daily living status, and other data), aggregate multiple data sources, design meaningful outcomes measures, analyze the data, develop mechanisms to track individual outcomes even as individuals cycle off of Medicaid coverage or switch between managed care plans, or even track only a

subset of indications for a given drug. These issues are further exacerbated by difficulties in accurately calculating savings across multiple potential payers and navigating health information privacy laws for individuals switching coverage over the lifetime of the VBP arrangement. There will also be challenges in negotiating consensus with manufacturers on the performance of a drug if the state and manufacturer disagree on how to interpret outcomes measures.

Developing this infrastructure will be costly, and states are differently positioned to undertake these steps. Depending on the scale of VBP arrangements on offer, states may be excluded from participation purely due to administrative costs outweighing potential savings. This challenge adds another nuance in favor of manufacturers and private payer VBP, with the risks for states discussed above.

Potential mechanisms for addressing these administrative challenges for the states could be:

- CMS utilizing a single federal contractor to monitor VBP arrangements available in the market and support data collection and analysis
- Allowing multi-state VBP contracts to support pooling of state administrative resources and a larger pool of covered lives for VBP negotiations.

CMS proposes annual VBP reporting for states participating in VBP arrangements as well. Generally, these requirements are straightforward and feasible, though there is always an element of administrative expense in meeting such requirements. However, two elements require additional clarification:

- How states should calculate savings associated with a VBP arrangement. It is unclear if the baseline for such a calculation should be expenses for a drug absent the VBP arrangement or some other metric.
- How states should calculate the expense of administering the VBP arrangement. As discussed above, several activities may be necessary to administer an arrangement. CMS should clearly articulate which activities it considers necessary for inclusion in this calculation.

Lastly, CMS should clarify in final rulemaking specifically how it intends to utilize these annual state reports to evaluate VBP arrangements.

Modification of the Definition of Line Extension

CMS proposes to implement the Affordable Care Act's statutory changes to the definition of line extension drugs, which are subject to an alternative rebate calculation that provides a greater share of rebates to the federal government than those ordinarily collected under the MDRP. These definitional changes would be retroactive to 2011.

The proposed line extension definition is quite broad and may have unintended consequences for state rebates because of this breadth. With the proposed definition, a substantial number of drugs would be considered line extension products. In addition to the alternative rebate calculation being more favorable to the federal government than the states, states may also have significant supplemental rebates in place for products that would be considered line extensions under this rule. As the base

rebate amount increases, the supplemental rebate amount would decrease, with potentially serious fiscal ramifications for states. Many of NAMD's members are concerned with the scope of this change.

To mitigate these concerns, CMS should narrow its definition of line definition and should consider applying it only prospectively.

Changes to the SDUD Reporting Process

CMS proposes changes to how states report state drug utilization data (SDUD) on the CMS – R – 144 form. While these changes should be relatively straightforward to implement, some states may encounter difficulties with adding a certifying statement to a raw data file. Further, it is unclear what CMS aims to achieve in requiring the Medicaid Director or an individual with delegated authority certify SDUD submissions. Current transmittal procedures should suffice for meeting CMS expectations for this data.

We recommend CMS remove the certification requirement, or at minimum allow the Medicaid Director to designate a contractor for this function in states using data vendors for SDUD submissions.

Third Party Liability

CMS proposes to implement several statutory changes to Medicaid third party liability that Congress passed in recent years. In reviewing these proposals, we offer one suggestion on the requirement for payment of pediatric preventive services without regard to third party liability unless the state has made a determination related to cost-effectiveness and access to care that warrants cost avoidance for 90 days.

Rather than requiring states make a burdensome determination of cost-effectiveness and access to care, CMS should allow states to attest that the Medicaid program is in compliance with EPSDT requirements, has an "exception, grievance, fair hearing" process, and does not have a known access to care issue for individuals seeking these type of services.

Thank you for the opportunity to provide comment on this important rule. NAMD and our members remain ready to engage with CMS and other stakeholders to collectively solve challenges in the pharmacy space going forward.

Sincerely,



Matt Salo
Executive Director