

VIA ELECTRONIC SUBMISSION

The Honorable Chiquita Brooks-LaSure
Centers for Medicare and Medicaid Services Administrator
200 Independence Avenue, S.W.
Washington, D.C. 20201

RE: 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: Delay of Effective Date for Provision Relating to Manufacturer Reporting of Multiple Best Prices Connected to a Value Based Purchasing Arrangement; Delay of Inclusion of Territories in Definition of States and United States

Dear Administrator Brooks-LaSure:

On December 31, 2020, the Centers for Medicare and Medicaid Services (CMS) published a final rule entitled, “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” (Final Rule). The Final Rule made several important changes to the calculation of rebates under the Medicaid Drug Rebate program to allow manufacturers to enter into VBP arrangements with commercial insurers and Medicaid, including reporting multiple best prices (BPs) based on VBP arrangements that the manufacturer offers across payers. On May 28, 2021, CMS issued a proposed rule, proposing to delay for 6 months the January 1, 2022 effective date of the multiple BP policy specifically.

The Robert J. Margolis, MD Center for Health Policy at Duke University (the Duke-Margolis Center or the Center) generates and analyzes evidence across the spectrum of health policy and supports the triple aim of better care, better health, and lower costs. A core mission of the Center is to focus on increasing the value of biomedical innovation to patients. To do so, we study the design, implementation, and feasibility of VBP arrangements for medical technologies, which shift away from payments based on volume and promote payments based on the value of the provided treatment. We identify the shift towards payment accountable to outcomes for biomedical technologies as parallel and complementary to healthcare providers’ efforts to shift towards payment that is linked to decreasing total medical expenditures, which is another key area of policy research for the Center. The suggestions below are informed by the Center’s expertise in designing new medical technology payment models; analyzing the impact of the current legal and regulatory environment on their adoption;¹ and working with multiple stakeholders to address the operational challenges to their use. The suggestions are also informed by the collaborative work of the Center’s VBP for Medical Products Consortium.

¹ Daniel GW, Hamilton Lopez M, Barker T et al. Overcoming the Legal and Regulatory Hurdles to Value-Based Payment Arrangements for Medical Products. Duke-Margolis Center for Health Policy. December 2017. Available from: https://healthpolicy.duke.edu/sites/default/files/2019-11/overcoming_legal_and_regulatory_hurdles_to_value-based_payment_arrangements_for_medical_products.pdf

Duke-Margolis is broadly supportive of the Final Rule's goals to increase the adoption of new payment models for medical products that are accountable to making significant improvements in patient health and modernize legacy Fee-for-Service (FFS) price reporting policies to accommodate new types of VBP that are closely tied to evidence and better outcomes. As Duke-Margolis has described, legislative and regulatory barriers currently limit the development of VBP arrangements.² These barriers include concerns about establishing an artificially low BP³ when a drug does not perform well in a single patient, or violating the federal Anti-Kickback Statute (AKS).

We appreciate CMS's recognition of the challenges posed for VBP arrangements by the existing BP rules, and for finalizing specific solutions for addressing the determination of BP in the context of VBP. In addition to creating a path to lift the BP restatement ceiling (from the current 12 quarters) and amending the bundled sales definition to include VBP arrangements under certain conditions, CMS also finalized the multiple BPs policy. Under the multiple BPs policy, drug manufacturers would be allowed to report multiple BPs based on VBP arrangements that the manufacturer offers to commercial payers and to the Medicaid program, in contrast to the single BP that they must report now. To qualify under this approach, the manufacturer must offer the VBP from the commercial market to all State Medicaid programs. States are not required to participate in the VBP, and only States that accept the terms and conditions and can adhere to the data submission requirements of a specific VBP will be eligible to use the multiple BP policy. If a State chooses to participate in the VBP arrangement, then its rebates will be based on the drug's performance in the State's patient population. The Medicaid rebates paid for those patients would only be due for those particular patients. In other words, the rebate due to the State from the manufacturer for a given patient would be based on the drug's performance as to that particular patient and not be the same for the entire Medicaid market.

The multiple BPs policy presents a creative approach that could help facilitate more VBP arrangements in the marketplace by mitigating the existing BP barrier. However, there are various operational and policy challenges that still need to be fully identified and addressed to implement this policy successfully. We therefore support CMS's assertion in the May 2021 proposed rule that implementing the multiple BP policy would require more time for the agency to consult with State Medicaid agencies, provide operational guidance and implement complex system changes, leading it to delay the policy's effective date to July 1, 2022.

Below we outline some of the critical considerations for implementing the multiple BP policy:

Expand states' ability to enter into VBP arrangements to use the multiple BPs policy

As CMS considers how best to implement the multiple BPs policy, there are some key considerations for the ability of States to operationalize it, such as having the capabilities to track the same outcomes tracked in commercial markets in order to benefit from a new BP associated with a VBP arrangement. To do so, States will require dedicated resources to track patient-level outcomes for specific populations receiving a therapy. Depending on the design of the VBP arrangement, they may require access to various data sources including medical claims data, electronic health record (EHR) data, lab reports, pharmacy claims, and/or other clinical data. States will also need the capabilities to link these disparate

² Daniel GW, Hamilton Lopez M, et al. Overcoming the Legal and Regulatory Hurdles to Value-Based Payment Arrangements for Medical Products.

³ Arad N, Barker T, Daniel GW et al. Clarifying Medicaid Best Price Regulations in the Context of Value-Based Payment Arrangements. Duke-Margolis Center for Health Policy. September 2019. Available from:

<https://healthpolicy.duke.edu/news/clarifying-medicaid-best-price-regulations-context-value-based-payment-arrangements>

data sources to longitudinally track outcomes or resource utilization per the terms of any VBP agreement.

There is inherent variance in how States administer their programs and their programs' data infrastructure and operational capabilities. There are also differences in contractual agreements that States have with managed care organizations to manage medical and/or pharmacy claims. These differences will further impact States' abilities to track individual patient outcomes across multiple data sources.

At this time, States are able to enter into VBP agreements following a CMS authorization of a State Plan Amendment (SPA). There have been nine SPAs related to medical technology spending that have been used to enter into VBP agreements to date. States that entered into these VBP agreements ensured they had the resources and capabilities to implement them before doing so. It is unclear, however, if all States have the dedicated resources to implement such agreements.

State Medicaid agencies will likely have similar capabilities as commercial payers to measure utilization rates indicated in claims data. However, not all States will have access to other data types, such as clinical measures or outcomes not captured in routine care. Some States will inevitably have better access and/or more sophisticated analytical capabilities to track measures at a patient level through various data sources based on their previous experiences in entering VBP arrangements.⁴ Accordingly, States may also have other systems that could be used to track outcomes, such as the Health Information Exchange. However, these systems may not necessarily be well-suited to tracking outcomes with enough precision that Medicaid agencies and manufacturers would be willing to commit to payment at risk based on its underlying quality.

To maximize States' ability to participate in VBP arrangements while ensuring patient access to emerging therapies, CMS should seek to minimize the creation of new prior authorization barriers, develop guidance to States on how they may collaborate on multi-state VBP strategies quickly, and enhance their existing quality measurement and price reporting systems to track implemented VBPs. To do so, we recommend that CMS take the following actions to ensure that States can participate in VBP arrangements for pharmaceutical products:

- 1. Ensure that States have the resources to prioritize investments in technological solutions that facilitate longitudinal, site-agnostic measurement of patient outcomes from clinical and administrative claims data sources.** There are near-term and long-term strategies that can ensure that all States are able to operationalize the multiple BPs policy. Due to the inherent variability in States' operating infrastructure and administration, it is likely that in the near term, States will adopt their own information technology (IT) solutions necessary to operationalize this policy. The existing policy for enhanced federal matching rates (90%) for "development and installation of mechanized claims processing and information retrieval systems" is one way through which CMS can resource States to operationalize this policy.⁵ In doing so, CMS can promote expanding access to and scale of VBP arrangements, as well as Medicaid IT

⁴ Fiore N, Alexander M, Pothan M et al., Novel Payment Models for Prescription Drugs: Early Implementation Successes and Challenges. Duke-Margolis Center for Health Policy. September 2019. Available from:

<https://healthpolicy.duke.edu/sites/default/files/2020-07/Novel%20State%20Payment%20Models%20Final%20Revised%20091219.pdf>

⁵ Center for Medicare and Medicaid Services. Medicaid Management Information System. Available from:

<https://www.medicare.gov/medicaid/data-systems/medicaid-management-information-system/index.html>

modernization. We recommend that CMS clarify and make an enhanced federal administrative matching rate of 90% for design and implementation of the necessary new capabilities, and a clear, consistent availability of 75% federal administrative match for all associated operating and upgrade costs. In the short term, CMS could also expedite reviews and offer greater flexibility for States to collaborate and enter into multi-State, State-led (non-proprietary) collaboratives sharing data, capabilities, results, expertise and training.

In the long term, we recommend that Congress and the Administration consider transformative investments in health information technology that facilitates a robust interoperable data exchange.⁶ VBP arrangements for medical products require tracking patients that receive a specific product over time with potentially different providers, insurers, types of data involved, and sites of care. While challenging in the current landscape, secure linkage, analysis, and reporting of data over time are problems that sophisticated, emerging technologies can assist in solving. To facilitate integration of the new reporting requirements under the Medicaid Drug Program (MDP) System, there will be a need for additional investments in Medicaid health information technology infrastructure.

- 2. Clarify federal Anti-kickback Statute (AKS) implications.** The multiple BPs policy, and its associated requirement to create a State-manufacturer VBP, do not address whether and to what degree these VBP arrangements might run afoul of the AKS in the event that the drug manufacturer provides ancillary services such as analytic support to assist in the tracking of relevant clinical outcome data relating to the drug. Depending on a particular arrangement's structure, such provision of services might be considered "remuneration" that could induce the provider to purchase the drug and violate a safe harbor's requirement that the receipt of the technology not be conditioned on doing business with the manufacturer.⁷ As discussed above, some States may be limited in their capabilities to track outcome measures at a patient level and these AKS safe harbor restrictions might limit manufacturers' ability to provide some of the necessary data collection and analytics capabilities that are needed for these arrangements.

Furthermore, while an AKS final rule from November 2020 created safe harbors for risk-sharing and care coordination efforts between participants in a VBP in an effort to remove regulatory barriers that have stymied value-based care, it generally excluded drug manufacturers from the group of entities that are eligible for protection. Former Health and Human Services (HHS) Secretary, Alex Azar, noted, however, that additional AKS clarity for pharmaceutical products in the context of VBP arrangements might be considered in future rulemaking.⁸

As a result of these potential AKS barriers, States may decline to participate in a VBP, forgoing the benefits of innovative risk-sharing opportunities with manufacturers and BP rebates they could be entitled to under the multiple BP approach. Instead, States would only be receiving BP rebates that are based on the traditional FFS formula absent any VBP, which are potentially lower than the rebates they could be entitled to under the multiple BPs policy dependent upon the outcomes achieved by their patient population.

⁶ Shrank W, De Parle N, Gottlieb S et al. Health Costs and Financing: Challenges and Strategies for a New Administration. *HEALTH AFFAIRS*. 40, NO. 2 (2021): 235–242. [doi: 10.1377/hlthaff.2020.01560](https://doi.org/10.1377/hlthaff.2020.01560).

⁷ Daniel GW, Hamilton Lopez M, et al. Overcoming the Legal and Regulatory Hurdles to Value-Based Payment Arrangements for Medical Products.

⁸ Azar: HHS Working On Protections For Value-Based Drug Contracts, Inside Health Policy, October 2019, <https://insidehealthpolicy.com/daily-news/azar-hhs-working-protections-value-based-drug-contracts>.

As States and manufacturers seek to implement VBP arrangements through the multiple BPs option and as these arrangements proliferate over time, CMS and the HHS Office of Inspector General (OIG) could provide targeted, future clarifications on AKS considerations involving drug manufacturers. We recommend that CMS work with the OIG to consider additional mechanisms to address AKS concerns, such as a safe harbor for VBP arrangements for pharmaceutical products.⁹

Facilitate the development of State price reporting systems

As stated in the rule, the new MDP system is intended to facilitate the exchange of information between manufacturers and States regarding VBP arrangements. Ideally, the updated MDP system can act as a catalogue of eligible VBP arrangements. The MDP system can be designed to allow States to access current VBP arrangements that are being offered without compromising confidentiality. Further, it will be helpful to both States and manufacturers if this system enables sharing of VBPs with all States, as opposed to individual States, each time a manufacturer has a different VBP offer. States could survey all available VBP arrangements, review terms and conditions, and contact the respective manufacturers to express interest in participation. This proposed model of a catalogue would preserve confidentiality of manufacturer VBPs, while ensuring a streamlined process for solicitation.

We illustrate an example catalogue entry below for two medical products:

Product	Total Payment at Risk	Outcome Measures	Payment reconciliation	Contract length
<i>Product A</i>	25% of the negotiated net price	Reduction in hospitalizations	Every quarter.	2 years
<i>Product A</i>	35% of the negotiated net price	Reduction in agreed upon definition of total cost of care	Every 6 months.	3 years
<i>Product B</i>	25% of the negotiated price	Prescription adherence	Every quarter	3 years

This table illustrates how States can evaluate information to compare VBP arrangements for a given product. These specifications are the minimum information States will be able to discern whether they have the resources to implement and monitor a VBP arrangement that includes stated levels of financial risk, certain frequencies of reporting, and data capabilities to track specific measures. Content in the catalogue should be structured to align the obligations of the State with the obligations of the commercial insurer.

In the event that a manufacturer offers more than one VBP per given drug in the commercial market, State Medicaid agencies should be able to track the different arrangements to determine which one

⁹ Daniel GW, Hamilton Lopez M, et al. Overcoming the Legal and Regulatory Hurdles to Value-Based Payment Arrangements for Medical Products.

might work best for their patient population and is the most feasible from an implementation standpoint.

CMS should clarify the elements of a VBP arrangement that need to be communicated by manufacturers to the State in those cases. As illustrated in the table above, our suggestion is to include:

- The **outcome measure** that the commercial payer and manufacturer agreed on.
- The **time horizon** for that outcome, and
- The **structure of the rebates** tied to patient outcomes that the manufacturer provides to the payer.

The manufacturer should also report any other criteria on which the commercial VBP arrangement is contingent, including specific coverage requirements.

The manufacturer will report all of the above VBP components per arrangement to all State agencies when offering them entrance into VBP agreements using the multiple BPs approach, unless the VBPs are identical in the outcome measure(s) and time horizon and only differ in the rebate structure. In that case, the manufacturer may report only the VBP associated with the higher rebates, to provide States with the greatest benefit.

Conclusion

The implementation of the multiple best prices policy represents one of the more significant changes in federal policy to enable payment for medical technologies linked to evidence generation or improved patient outcomes. Value-based payment for medical technologies is in no way a panacea to address all policy priorities, such as patient affordability or how or whether to cover potentially promising new technologies. However, it can be a powerful tool in streamlining coverage decisions by aligning financial risk of a treatment's performance with its actual performance and serve as a mechanism to coordinate the collection of post-approval evidence to improve the technology's use in practice. Advancing the role of value-based payment for medical technologies is also essential for making progress on other efforts to transform payment in the health care system, such as improving population-level outcomes and cost in specialty care models and ensuring the equitable diffusion of new technologies to all patients, especially those from historically marginalized communities.

We think that the implementation of the multiple best prices policy with supporting data infrastructure that connects states and manufacturers, as outlined in this document, can clarify existing stakeholder uncertainty regarding the process and necessary reporting elements for a multiple best prices policy. Our recommendations also address forward looking areas for consideration in future agency guidance relating to the implementation of a multiple best prices policy.

Delaying the rule in order to update the MDP with the capabilities to serve as a platform to help non-proprietary contract information flow between states and manufacturers can help provide an implementation glidepath for States and manufacturers interested in implementing new payment models; defined contract reporting standards may also assist in establishing best practices for the implementation of VBP arrangements for medical technologies in the broader health care marketplace. The delay of the rule also provides an opportunity for States and manufacturers to engage with one another in early feasibility conversations about what functionality the MDP will support and what

additional systems changes may be needed for VBP implementation. We think the timeline and steps outlined in CMS' comments are appropriate for making the needed systems changes while allowing stakeholders time to be prepared to successfully transition to new value-based payment models when the multiple best prices policy becomes effective.

As novel technologies with potential promise along with risk of limited real-world effectiveness continue to be approved, VBP for medical technology can be an important tool that aligns the development of evidence and outcomes collection with product payment. Providing time for stakeholders to prepare for implementation of VBP arrangements at greater scale will ultimately promote the benefits of these new payment models and CMS' multiple best prices policy.

The Duke-Margolis Center appreciates CMS's consideration of our comments, and the Administration's support for advancing high-value, affordable healthcare. We and our colleagues would be pleased to provide more information on these issues if that would be helpful.

Sincerely,

Mark McClellan – Director, Duke-Margolis Center
Nitzan Arad – Research Associate, Duke-Margolis Center
Beena Bhuiyan Khan – Research Associate, Duke-Margolis Center
Nicholas Fiore – Policy Analyst, Duke-Margolis Center
Marianne Hamilton Lopez – Research Director, Value-Based Payment Reform, Duke-Margolis Center
(marianne.hamilton.lopez@duke.edu)