CATALYST IMPLEMENTATION BRIEF

# Considerations for developers in applying the Multiple Best Price (MBP) rule to improve access to novel therapies

This brief highlights some key steps and considerations for biopharmaceutical developers of novel, high-value therapies seeking to successfully implement CMS's Multiple Best Price rule. The rule, which went into effect in 2022, addresses the challenge of establishing a Medicaid best price under a Value-Based Contract.

## WHAT IS MULTIPLE BEST PRICE?

One challenge for developers seeking to utilize Value-Based Contracts (VBCs) for new therapies has been a tension around the potential impact on Medicaid best price. State Medicaid agencies are entitled to rebates from developers, based on a percentage of the commercial sales price of the drug. Developers report Average Manufacturer Price (AMP) or the "best price," i.e. the lowest possible price to any purchaser for the therapy, to the Centers for Medicare & Medicaid Services (CMS). Under the historic rules, when VBCs are used, however, developers may risk a single failure in a rare disease leading to a very low best price for all recipients of the therapy, establishing high Medicaid rebate liability.

To address this challenge, CMS instituted the Multiple Best Price (MBP) rule for drug Value-Based Purchasing agreements, as the agency calls VBCs. It took effect in July 2022. The rule allows developers to report multiple best prices (instead of a single best price) for a single dosage form and strength of a covered drug, reducing the financial risk of offering VBCs to commercial payers. To benefit from this flexibility, the same value-based option must be available to all state Medicaid agencies, allowing state Medicaid organizations to access supplemental rebates based on the evidence-based or outcomes-measures achieved, thereby aiming to improve the efficiency, economy, and quality of care.

Despite the promise, new agreements utilizing the flexibilities afforded by the MBP rule have been limited so far, according to publicly available information. For developers interested in using the rule, CMS has provided some technical guidance regarding how to offer VBCs to states and how to report multiple best prices to the agency. But the MBP rule is complex for both developers and states to implement, leading to uncertainty and risk for developers interested in utilizing the rule.

Still, some developers are endeavoring to take on these challenges. We offer the following considerations for developers interested in evaluating, designing, and implementing a VBC using the MBP approach. The checklist of considerations is meant to be illustrative rather than exhaustive and should not be construed as legal counsel; determining whether a VBC qualifies under the MBP rule is nuanced and likely requires close counsel.

## IMPLEMENTATION

**Evaluation and design:**

- Consider whether a VBC would help increase patient access to a new product, manage and predict health spending, or improve patient health outcomes. If it would, identify what type of agreement terms would align with the product characteristics.
    - Consult with payers and other stakeholders (e.g., providers and patient advocacy groups) about contract terms and outcome measures. Ideally, these discussions should start while therapies are in clinical trials to allow significant time for VBC design. For more information on VBC design, including different precision financing tools, see the NEWDIGS FoCUS Paying for Cures Toolkit.
- Determine whether the draft contract would qualify as an MBP-eligible VBC based on the CMS requirements outlined below.
    - Consideration should be given to workability of the VBC for states, as outlined in CMS guidance.

**Incorporating MBP compliance:**

- Consult with CMS's guidance documents regarding MBP and discuss the MBP opportunity with legal counsel.
- To qualify as MBP-eligible VBC, contracts should be an arrangement or agreement intended to align pricing and/or payments to an observed or expected therapeutic or clinical value in a select population, as described in 42 CFR § 447.502. For example, arrangements that:
  - Use an evidence-based measure substantially linking the cost of the drug to documented existing evidence of effectiveness, *AND/OR*
  - Use outcome-based measures (e.g., hospitalization or remission) substantially linking the payment of the drug to the actual performance of the drug in a patient, a population of patients, or on medical expenses. The selection of evidence- or outcome-based measures does not need to be limited to those endpoints evaluated in clinical trials or included in the product label.
- Many arrangements (e.g., subscriptions, warranties, etc.) can be considered for VBC contracts applying the MBP rule. Pay-over-time contracts must also substantially link the scheduled payments to either evidence- or outcome-based measures.
- While CMS has not defined "substantially linked" or set a specific threshold percentage for payment, developers should make reasonable assumptions while considering a variety of relevant factors (e.g., disease, number of patients with a condition, health plan membership, etc.).
- In cases with less clarity about whether a VBC meets CMS requirements, consider consulting with CMS about the specific dynamics of the product and potential VBC.
- Document and retain records as outlined in 42 CFR § 417.410(f) supporting
  - the selection of evidence or outcome measures and
  - factors that justify a substantial link to payment.
- Develop and implement a record-keeping process for all agreements, invoices, outcomes, and supporting justification if the HHS Office of Inspector General or other federal agencies undertake an audit.
- CMS guidance specifies that, when using a specifically-structured warranty model, premiums paid by the developer to a third-party administrator are included in the price reporting (e.g., effectively lowering the best price). Payouts by the third-party administrator are not included when calculating best price.
- State Medicaid agencies that adopt a VBC arrangement may include Medicaid-managed care organizations. When these organizations negotiate price concessions outside the CMS-authorized rebate agreements, these price concessions may be included in best price reporting.
- Consider the potential impact of VBC arrangements on other reporting (e.g., AMP and Average Sales Price (ASP), the Medicare payment rate for Part B drugs). VBC discounts may be considered lagged price concessions. Careful modeling of the VBC contract is critical, as is careful price reporting, to avoid understating rebates and inadvertently being subject to legal liability.
- Consider the potential impact on accounting: Developers may not recognize revenue advantages from MBP if they offer refunds for adverse clinical outcomes without using insurer-like warranty structures. Warranty structures allow developers to transfer performance risk in lieu of premiums rather than carrying this risk.

**Rolling out the VBC, based on CMS guidance:**

- Engage in discussions with private and public payers regarding agreements.
- Identify a developer point of contact for interested state Medicaid organizations to contact with questions or to initiate an agreement.
- Upload the VBC and the applicable guaranteed net unit prices (GNUP) in CMS's Medicaid Drug Product (MDP) system used to communicate VBCs available to all states.
- Consider if state-specific minor modifications will be needed. While developers must offer states the same VBC available in the commercial market, minor modifications are anticipated. Examples of minor modifications might include:
  - Broadening the VBC inclusion criteria to include patients regardless of health status and ensure health equity for all Medicaid patients.
  - Permitting differences in data tracking capabilities and preferences by state organization.
  - Adapting outcomes tracking to promote efficiency or providing guidance about how to optimally track outcomes if the anticipated use and population are small.
  - Offering a state organization the ability to enter into a CMS-approved Supplemental Rebate Agreement (SRA) if the state does not have the infrastructure or resources to implement the VBC.
- Identify a deadline for states to respond to the VBC offer.
- Once a state enters into a VBC, the developer updates the effective date in the MDP system. Non-participating states continue to receive rebates based on the manufacturer's non-VBC best price.
- Establish minimum data reporting requirements and timing (e.g., quarterly, semi-annually, annually) for states invoicing developers for rebates.
- State Medicaid Organization will report to CMS quarterly: the drugs covered in VBCs, costs to administer the VBCs, and savings from the programs.
- States participating in VBC programs invoice the developer for additional rebates based on the VBC GNUP for each outcome tier (e.g., hospitalization or readmission).
- Ensure that if VBC reporting requirements include Protected Health Information (PHI), all covered entities that may engage with VBC-generated PHI have a signed business associate agreement as required by the HIPAA Privacy Rule.
- Collect invoices from states for VBC rebates and reconcile the differences between the Federal Unit Rebate Amount (URA) for non-VBP agreements.
  - Reconciliation should also consider timing differences due

to rebates based on time lags due to outcomes reporting and the reconciliation of those payments in MBP price reporting and internal financial systems.
    - Unlike commercial contracts that typically offer a percent discount from a list price, the state contracts will be based on the GNUP. For example, each GNUP is based on a specific outcome tier (e.g., hospitalization in year one vs. hospitalization in year three), thus if a list price increases after a state enters a contract, the effective rebate may higher.
- Developer will report separate MBPs for the duration of all MBP-executed contracts.

## LESSONS LEARNED & FUTURE DEVELOPMENTS

VBC offerings addressing product clinical performance uncertainties can improve access to new therapies and provide fair reimbursement. Developers pioneering the MBP rule and states engaging in these agreements can offer insights to CMS as the agency enhances the MBP technical guidance. In addition, these learnings can aid other organizations seeking to implement VBCs with MBP safeguards.

We urge developers to share their lessons to illustrate how the journey toward successful implementation can progress. Ongoing stakeholder dialogue and dissemination of learnings from VBCs with MBP implementation will yield mutual benefits. MBP allows collaboration among developers, payers, and stakeholders to enhance patient access to innovative therapies.

## REFERENCES


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