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Center for Medicaid and CHIP Services

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MEDICAID DRUG REBATE PROGRAM NOTICE **Release No. 189**

For Participating States

Technical Guidance - Value-Based Purchasing (VBP) Arrangements for Drug Therapies using Multiple Best Prices; State Reporting of VBP Supplemental Rebate Agreements

Section I – Value-Based Purchasing (VBP) Arrangements for Drug Therapies Using Multiple Best Prices

Beginning July 1, 2022, manufacturers will be able to report varying "best price" points (i.e., multiple best prices) for a covered outpatient drug to the Medicaid Drug Rebate Program (MDRP) if associated with a value-based purchasing (VBP) arrangement that meets the definition of such an arrangement at 42 CFR § 447.502, and that arrangement is offered to all states. Manufacturers will be reporting these VBP arrangements to the Centers for Medicare & Medicaid Services (CMS), and states will be notified of these VBP arrangement offerings, and will be able to decide whether or not to participate in the reported VBP arrangements. These arrangements will consist of additional rebates or price concessions that states may be able to earn based on the drug's clinical outcomes in Medicaid beneficiaries.

This new authority was finalized by CMS in a final rule published December 31, 2020, 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* (85 FR 87000) (hereinafter referred to as the final rule). The amendatory instruction 10.a. in the final rule regarding manufacturer reporting of multiple best prices connected to a VBP arrangement was delayed until July 1, 2022, in accordance with the final rule published November 19, 2021 entitled: *Medicaid Program: 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* (86 FR 64819).

The purpose of this release is to provide additional technical guidance and instructions to states. This guidance is divided into the following sections:

1. Overview of Interaction between Federal Section 1927 Rebates and VBP Arrangement Rebates;

2. Issues Relating to Multiple Best Price VBP Arrangement Implementation;

3. Oversight of Multiple Best Price Reporting Implementation;

4. Operational Implementation of Reporting Multiple Best Prices Using the Medicaid Drug Product (MDP) System; and,

5. State System Changes to Accommodate VBP Arrangements

1. Overview of Interaction between Federal Section 1927 Rebates and VBP Arrangement Rebates

The final rule permits manufacturers to report varying best price points for a drug's single dosage form and strength as the lowest price available as a result of a VBP arrangement in the MDP system if a manufacturer offers a VBP arrangement (as defined in regulation at 42 CFR § 447.502) to all states. See 42 CFR § 447.505(a) (definition of best price, effective July 1, 2022). Manufacturers that offer VBP arrangements to states will be able to provide descriptions of their VBP arrangements in the MDP system, including the applicable guaranteed net unit prices (GNUPs) available under the VBP arrangement for each outcome. The GNUPs represent the multiple best price points that states will realize under the VBP arrangement and is the agreed upon final price the state will pay for a covered outpatient drug after Federal rebates and any discounts/rebates owed by the manufacturer are paid to the state under the VBP arrangement. An example of the interactions of the Federal unit rebate amount (URA) and GNUP is further described below.

In general, states will have access to the manufacturer VBP arrangement information in the MDP system, including a description of the VBP arrangement, the GNUPs, and manufacturer contact information. States that want to take advantage of an arrangement will need to contact the manufacturer to enter into a state specific agreement for the VBP arrangement. Once the agreement is in place between the state and the manufacturer, the manufacturer will indicate the effective date of the state's agreement in the MDP system.

The MDP system will generate for the states the standard Federal URAs that the states will use to invoice manufacturers for the Federal rebate. The URA for single source and innovator multiple source drugs will be based upon the greater of: average manufacturer price (AMP) multiplied by applicable percentage (23.1% or 17.1% for exclusively pediatric drugs/clotting factors) or AMP - best price offered by the manufacturer *outside* of the VBP arrangement (i.e., the non-VBP best price) with possible additional rebates based upon inflation penalties. The MDP system will not be generating the additional discounts or rebates associated with the VBP arrangement. Instead, a state that enters into a VBP arrangement will invoice the manufacturer for any additional discounts or rebates, similar to the process used by states to bill manufacturers for supplemental rebates, to attain the GNUP under the VBP arrangement. For example, a drug with a cost (equal to AMP) of $100,000 with a GNUP of $50,000 as a result of a VBP arrangement, would result in a Federal URA of $23,100 (assuming the URA is based upon AMP multiplied by 23.1% (23.1% of $100,000)). An additional rebate of $26,900 would be paid to the state by the manufacturer to attain the GNUP (multiple best price point) of $50,000.

2. Issues Relating to Multiple Best Price VBP Arrangement Implementation

a. Calculation of Non-VBP Best Price: Before July 1, 2022 (the effective date of the amendatory instruction 10.a. of the November 21, 2021 final rule), a manufacturer was only permitted to report a single best price each quarter for each dosage form and strength of a drug. The final rule amended 42 CFR § 447.505(a) to add that if a manufacturer offers a VBP arrangement (as defined at § 447.502) to all states, the lowest price available from a manufacturer may include varying best price points for a single dosage form and strength of a drug as a result of that VBP arrangement. The final rule did not eliminate the requirement that the manufacturer also report a single best price in addition to these varying best price points (i.e., multiple best prices) (see 85 FR at 87031 - 87032). Therefore, CMS will require that a manufacturer report a non-VBP best price when a manufacturer is also reporting multiple best prices or GNUPs for the VBP arrangement being offered to states.

We recognize there may be instances when manufacturers do not offer to sell the covered outpatient drug commercially outside of a VBP arrangement. In those cases, manufacturers have indicated that there is no "lowest price available outside of the VBP arrangement" to set a non-VBP best price. To address this situation, manufacturers may use reasonable assumptions. For example, the manufacturer could approximate the non-VBP best price by estimating a lowest price available to the payer/provider if no additional discounts based upon outcomes are made under the VBP arrangement. Manufacturers must document reasonable assumptions in accordance with the recordkeeping requirements at 42 CFR § 447.510(f).

Manufacturers are reminded that if they do not offer a multiple best price VBP arrangement (as defined at 42 CFR § 447.502) to all states, they must include the lowest price available from the manufacturer under all sales arrangements in its single best price, including the prices realized under the VBP arrangement. That is, the best price would include the lowest price available for the single source drug or innovator multiple source drug, including the lowest price available under the VBP arrangement that is not offered to the states, even if that price is $0.

In the event the state does not choose to participate in a VBP arrangement, and there is no other non-VBP payment arrangement outside of the VBP arrangement, the state will receive a Federal URA that is at least equal to the greater of: AMP multiplied by the applicable percentage (23.1% or 17.1% for exclusively pediatric drugs/clotting factors) or AMP minus the non-VBP best price. We note that if states decide not to participate in a VBP arrangement offered by the manufacturer, manufacturers and states may still negotiate CMS-authorized supplemental VBP rebates (which are excluded from best price under 42 CFR § 447.505(c)(7)), and receive rebates pursuant to the Federal URA that they would realize for the drug under the normal course. States and manufacturers may also negotiate CMS-authorized supplemental rebates in addition to the rebates resulting from the VBP arrangement reported in MDP. We highly encourage manufacturers to work with states to enter into supplemental rebate agreements in cases when a state cannot take advantage of the multiple best price VBP arrangement.

b. Manufacturer Choosing Multiple Best Price Approach: Manufacturers may elect to report to CMS multiple best prices associated with its VBP arrangement in accordance with 42 CFR § 447.505(a) or allocate the price concessions provided under the VBP arrangement as provided in the definition of bundled sale at 42 CFR §447.502. This was addressed in a comment and response in the final rule (see 85 FR at 87024).

If the manufacturer chooses to report multiple best prices associated with the price concessions provided under its VBP arrangement as provided in a bundled sale, the manufacturer is not required to allocate discounts or rebates associated with the VBP arrangement as a bundled sale to a single payer when determining the best price.

c. Pay-over-time VBP Arrangements and Calculation of AMP: Manufacturers may receive payments in installments from payers/providers based upon the VBP arrangements. We received two comments regarding pay-over-time payments and the calculation of AMP during the rulemaking process, and provided responses in the preamble to the final rule of which we remind manufacturers as they are instructive in the context of this guidance.

First, several commenters recommended that manufacturers be permitted to report AMP as the full price of the drug in the quarter in which the drug is administered, even if installment payments would extend to subsequent quarters. A few commenters recommended CMS clarify that any installment that is forgiven under a VBP arrangement will be treated as a lagged price concession for purposes of the AMP smoothing methodology. In response to that comment (85 FR at 87019) we indicated –

> *Manufacturers must include the full price of the drug in the quarter in which the drug is sold in the determination of AMP in accordance with the definition of AMP at section 1927(k)(1) of the Act regardless of the payment arrangements negotiated with payers. Both the statutory and regulatory definition of AMP at § 447.504(a) require that AMP reflect ''the average price paid'' to the manufacturer for the drug in the United States by wholesalers for drugs distributed to retail community pharmacies and retail community pharmacies that purchase drugs directly from the manufacturer. Installment payments do not represent the price of the drug, but rather a partial payment of the drug's price. We also believe it is appropriate that an installment payment not made because of a VBP arrangement outcome which would result in a significant discount, be treated as a lagged price concession (as defined at § 447.502) for purposes of the determination of AMP in accordance with § 447.504(f)(3) and best price in accordance with § 447.505(d)(3).*

Another comment and response in the final rule addressed cases when the payer/provider pays installments to an intermediary and the intermediary pays the manufacturer in full (85 FR at 87063).

> *We note that some manufacturers that are using a ''pay-over-time'' model that does not involve a VBP component may contract with an intermediary to receive full payment for the drug and thus report it in the manufacturer's AMP when reporting their pricing metrics. That is, the payer makes ''pay-over-time'' payments to the intermediary, and the intermediary makes full payment to the manufacturer so the manufacturer can report the full sale in the quarter in which the drug was administered or dispensed so as not to affect their AMP reporting. The ''best price'' for the quarter would also be reported. However, to the extent that future rebates or discounts adjust the AMP or ''best price'', adjustments would have to be reported as they would under a non pay-over-time model.*

We further stated in response to the same comment that we will need to remain flexible as additional VBP design structures come to market and will consider issuing further guidance to assist manufacturers in the reporting of AMP and best price to the extent there is no guidance specific to a manufacturer's VBP arrangement.

Manufacturers may continue to make reasonable assumptions consistent with statute and regulation regarding the determination of AMP and best price.

d. State and Manufacturer Negotiation: When a manufacturer offers a VBP arrangement on the commercial market, the final rule requires that the manufacturer offer that arrangement to all states (see 42 CFR § 447.505(a) best price defined) in order to opt to report multiple best prices associated with the VBP arrangement. While the manufacturer is only obligated to offer to states the arrangement as it is structured in order to opt to report multiple best prices, we are strongly encouraging manufacturers to work with the states to make any minor adjustments to the arrangement to address the specific needs of the Medicaid program and the beneficiaries it serves. Manufacturers should be mindful during negotiations that states do not necessarily operate like commercial payers. That being the case, we are encouraging manufacturers to:

- Make the VBP arrangement available to all Medicaid patients regardless of their health status, not be used as a way to further clinically test drugs in certain populations, and not result in health disparities for any select population.

- Consider that resource-intensive data tracking options for outcomes-based arrangements may not be achievable for some states because they may not have resources to accomplish the tracking and auditing of outcomes. States have indicated that they would rather rely on readily-available claims data, and not rely on requiring provider/patient reported data beyond data already reported to Medicaid. Each state, however, may be different in their abilities to use various data sets beyond prescription claims data.

- Discuss with states how to use claims data in the most efficient manner to track outcomes for the specific arrangement and whether the drug and population is small enough such that a state will be able to handle manual tracking.

- Consider offering to the state the option of entering into a CMS-authorized supplemental rebate agreement, especially if a state lacks resources to enter into the VBP arrangement offered by the manufacturer on the commercial market.

e. Timing of Acceptance of Terms of Contract: As discussed in response to comments in the preamble to the final rule regarding VBP arrangements, CMS will not be involved in the approval or review of the specifics of any VBP arrangements offered by manufacturers to commercial payers. Nor will we be engaged in the negotiation of terms between manufacturers and payers or states (see 85 FR at 87030). Therefore, CMS will not impose timelines for when a state should respond to a manufacturer about its VBP arrangements that are reported in the MDP system. Instead, a manufacturer should negotiate with the state a deadline date for a state to respond to a VBP arrangement. Once a state accepts the terms of the agreement, the manufacturer will identify in the MDP system the state's participation in the VBP arrangement and any additional rebates as a result of terms of the VBP arrangement will be paid to the state in addition to the Federal URA

f. Discretion to Discontinue VBP Participation: If a state enters into an agreement with a manufacturer, the timing and terms of discontinuation of such an agreement shall be based upon the terms of the agreement between a state and manufacturer. A manufacturer may only terminate a state from its VBP arrangement based upon the terms of the agreement.

If a manufacturer decides to discontinue to offer a VBP arrangement to states, yet has states participating in the program, the termination must be on a prospective basis. In these circumstances, the manufacturer must continue to report VBP multiple best prices until such time all participating state agreements have expired.

g. Impact of Multiple Best Prices on Medicare Part B ASP and 340B Ceiling Pricing: As stated above, the final rule still requires that the manufacturer report a single non-VBP best price each quarter aside from the varying best price points (i.e., multiple best prices). Because manufacturers will continue to report a non-VBP best price when reporting multiple best prices generated from a VBP arrangement, that non-VBP best price will be used to calculate the 340B ceiling price. This being the case, as indicated in a response to comment (85 FR at 87031), this policy will not have a significant impact on impact on 340B pricing.

As for the impact of a VBP arrangement that permits multiple best price reporting on a drug's average sales price (ASP), which is part of the computation for reimbursing provider-administered drugs, ASP is computed using a drug's sales prices, net of price concessions to U.S. purchasers, excluding sales that are exempt from inclusion in the determination of the Medicaid best price (42 CFR § 414.804). Price concessions that must be included in the calculation of ASP are volume discounts, prompt pay discounts, cash discounts, free goods, charge backs, rebates, and any other price reductions, including those discounts under VBP. Our final rule does not change the Medicare requirements for calculating and reporting ASP, and did not specifically address the impact of price concessions made under a VBP arrangement on the calculation of ASP.

3. Oversight of Multiple Best Price Reporting Implementation

The new multiple best price reporting flexibility provides greater opportunities for states to work with manufacturers to increase Medicaid beneficiary access to necessary medications. CMS will be working with states and other stakeholders in monitoring how this new policy is implemented to assure that it is meeting this goal. It is CMS' expectation that the new policy will encourage manufacturers to offer to states those VBP arrangements that are being offered in the commercial market as they are designed or with slight modifications, and that manufacturers will report these arrangements to CMS for state consideration.

It is our expectation that manufacturers will also continue to work with states on designing and implementing VBP arrangements under supplemental rebate agreements, particularly in states that may not want to participate in the commercial VBP arrangement offered by the manufacturer as provided in the MDP system. We will be monitoring the non-VBP best prices being reported by manufacturers that also report multiple best prices to ensure the minimum Federal URA reflects these non-VBP best prices when applicable.

We want to better understand whether manufacturers are using this new regulatory flexibility to report multiple best prices points and are willing to offer the VBP arrangements to states. In adopting this policy, it is our expectation that it will assist states to better serve the health care needs of Medicaid patients.

We will monitor the implementation of this new policy to ensure compliance with the new regulation and will consider making referrals to the Office of Inspector General (OIG) in cases when we believe there are concerns with manufacturer price reporting under the MDRP.

4. Operational Implementation of Reporting Multiple Best Prices Using the MDP System

This section provides an overview of the role of the MDP system for manufacturers and states with respect to reporting multiple best prices associated with VBP arrangements. Once the VBP module is fully developed in the MDP system, we will provide additional guidance about data input requirements.

We realize that there are a significant number of VBP arrangement types available in the commercial market, and similarly, there may also be multiple VBP related options for a drug for a state to review and choose from. For that reason, the MDP system will be structured to be flexible enough to capture information regarding a variety of manufacturer VBP arrangement types, as well as to share information about the VBP arrangement with states. The MDP system will electronically notify states of new manufacturer VBP arrangement offers, provide information on arrangements, and include manufacturer contact information in case a state is interested in receiving additional details on the arrangement.

a. Uploading a VBP Arrangement: Manufacturers will submit their VBP arrangements via the VBP module in the MDP system. They will have the option to either enter VBP arrangement data in an online form or upload it using a supplied template. When submitting a VBP arrangement, the following minimum information is required:

- Labeler Code: First segment of the National Drug Code (NDC) that identifies the labeler
- Product Code: Second segment of the NDC
- FDA Drug Name: Drug name as it appears on FDA Structed Product Labeling (SPL) listing
- Arrangement Identifier: Two-digit number assigned to each VBP arrangement offered for an NDC tier: Three-digit number assigned to each outcome-based tier within a given arrangement
- VBP GNUP: Value-Based Purchasing Guaranteed Net Unit Price associated with each outcome tier. This is the VBP best price available to the state if they enter into a VBP arrangement with a labeler. The VBP GNUP can vary depending on the terms of the arrangement.
- Arrangement Summary: Summary of the VBP arrangement, limited to 1,000 words and including a manufacturer contact, an explanation of the tiers, and the associated VBP GNUP associated with each tier.

  For example:
  Manufacturer A is offering a VBP arrangement that provides for discounts over a period of 3 years. Full price of drug before any discounts/rebates is $2000.

  - *If a beneficiary is hospitalized in year 1 (Tier 1) related to the disease state and is undergoing treatment, the VBP GNUP will only be $500.*
  - *If a beneficiary is hospitalized in year 2 (Tier 2) related to the disease state and is undergoing treatment, the VBP GNUP will only be $750.*

- *If a beneficiary is hospitalized in year 3 (Tier 3) related to the disease state and is undergoing treatment, the VBP GNUP will only be $1000.*

If appropriate, manufacturers may also upload a document not to exceed 25 pages containing specifics regarding the VBP arrangement.

b. Reviewing VBP Arrangements: As soon as a VBP arrangement is uploaded, it is available for states to review. States will have the ability to search all available VBP arrangements in the MDP system and will have the capability to view arrangement summaries and detailed VBP arrangements. The MDP system will also provide the manufacturer's contact information in case a state has questions or would like to proceed with a specific VBP agreement.

c. Selecting a VBP Arrangement: When the state and manufacturer agreement is finalized, the manufacturer will identify the state as a participant in the VBP arrangement by specifying the effective date of the agreement within the MDP system. Once identified, the MDP system will send an automated email to CMS, the state, and the manufacturer confirming the state's participation.

d. Invoicing and Reconciling Additional Rebates Under the VBP Arrangement: States and manufacturers will need to determine the specific information that will be required on the invoice in order to report and reconcile the clinical outcomes, and for the state to obtain the various GNUPs under the arrangement, should they be earned based on patient outcomes. If the decided-upon information contains Protected Health Information (PHI), HIPAA Privacy Rule requires all Covered Entities to have a signed Business Associate Agreement (BAA) with any Business Associate (BA) they hire that may come in contact with PHI.

CMS cannot recommend a reporting standard in this regard because each VBP arrangement will be different. We encourage manufacturers and states to establish a set of minimum data requirements necessary from states for invoicing.

The state will track the information necessary to invoice the manufacturer according to the tier structure outlined in the agreement. The state will also invoice the manufacturer following the agreed-upon arrangement details. VBP arrangements may require reviews on a specific timeline (e.g., quarterly, semi-annually or annually). The frequency for the invoicing and payment cycle should be specifically addressed in the agreement between the state and manufacturer.

e. Generating rebate amounts for invoicing: The MDP system will continue to generate the standard Federal URAs (and unit rebate offset amounts or UROAs) for all drugs that are active in the MDRP. However, the MDP system will not generate VBP rebate amounts as those will be handled at the state and manufacturer level. The reporting to the states of the standard Federal URA (and UROA) will follow the current process. States will use both the CMS-calculated Federal URA and specific manufacturer GNUPs to determine the outstanding balances due for each drug when the state has an active VBP agreement for that product.

f. Invoicing: The invoices sent by states to manufacturers for VBP rebates will not be developed by CMS. Furthermore, states may not use the Reconciliation of State Invoice (CMS-304) or Prior Quarter Adjustment Statement (CMS-304a) forms to invoice for drugs under a VBP agreement. VBP invoice formats will be determined by the state and manufacturer taking into account the specifics of the VBP arrangement such as outcomes measures and evaluation period for such measures. States may also consider using their existing supplemental rebate invoice if it is suitable.

CMS will not be involved in disputes between manufacturers and states regarding invoicing or VBP outcome evaluations, and corresponding data associated with the evaluation process.

g. Reporting VBP Rebate Amounts to CMS: CMS intends to add a line to the CMS-64 so that States will be required to report their VBP rebate amounts quarterly. States should work with their vendors to assure appropriate reporting of these rebates on the CMS-64 form whenever the State enters into a VBP arrangement. Additionally, CMS recognizes that there may only be annual reporting based on the reconciliation process.

5. State System Changes to Accommodate VBP Arrangements

States interested in drawing down enhanced system funding (i.e., 90/10) to support the collection of VBP arrangement rebates should perform an assessment of their current systems and/or interfaces to determine that such enhancements are solely for Medicaid. That is, the system changes will be made to state drug rebate systems to support the collection of VBP arrangement rebates used to offset Medicaid drug expenditures. States cannot use enhanced system funding to finance a manufacturer's system updates associated with VBP arrangements. Once a state performs the assessment and determines it needs systems funding to make systems changes, the state should reach out to their Data and Systems Group (DSG) State officer and submit the system funding request through their Advance Planning Document (APD) process for CMS review and approval.

Section II – State Reporting of VBP Supplemental Rebate Agreements

In the same final rule adopting the regulatory provision discussed above about permitting manufacturers to report multiple best prices under certain circumstances, CMS finalized a policy regarding data collection from states associated with CMS-authorized supplemental rebate agreements (SRAs) using VBP arrangements. Specifically, the final rule added 42 CFR § 447.518(d)(2), which requires a state participating in a manufacturer's VBP arrangement(s) under a CMS-authorized SRA to report to us the data described in the § 447.518(d)(3) within 60 days of the end of each calendar year. Specifically, 42 CFR § 447.518(d)(3) requires that the State must submit all of the following data, including cumulative data to date:

(i) State
(ii) National drug code(s) (for drugs covered under the CMS-authorized VBP SRA)
(iii) Product's FDA list name
(iv) Number of prescriptions
(v) Cost to the State to administer the CMS-authorized VBP SRA (for example, systems changes, tracking outcomes, etc.)

(vi) Total savings generated by the supplemental rebate due to the CMS-authorized VBP SRA

CMS sets forth the format states will use to report the required data as part of the Paperwork Reduction Act (PRA) package CMS-10722 and the Office of Management and Budget (OMB) approved the new collection on July 20, 2021. States may access the downloadable workbook that includes the PRA Disclosure statement, data reporting format and data definitions at https://omb.report/icr/202106-0938-006/doc/112336601. A state that is participating in a VBP arrangement via a CMS-authorized SRA in CY 2022 will be required to report annually the data associated with these arrangements beginning January 1, 2023 including those states that have already entered into such agreements. States should e-mail their reports to our drug policy mailbox (RxDrugPolicy@cms.hhs.gov) with the subject line "Annual Report on VBP SRA". Note that this reporting only applies to states that enter into VBP arrangements with manufacturers under CMS-authorized SRAs.

Conclusion

We anticipate that the MDP system updates and this guidance will generate additional questions regarding the implementation of the VBP multiple best price reporting regulations. CMS intends to send out additional guidance in the future as necessary, as well as provide manufacturers and states opportunities to participate in technical assistance meetings with regards to the MDP system. If you have additional questions around implementation of the new VBP arrangement multiple best price reporting regulations, or state reporting of VBP arrangements under CMS-authorized SRAs, please send your questions to Christine Hinds at Christine.hinds@cms.hhs.gov.