



# Clarifying Medicaid Best Price Regulations In the Context of Value-Based Payment Arrangements

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### Key Themes

- Medicaid Best Price plays a critical role in achieving relatively low fee-for-service (FFS) drug prices in Medicaid, yet has become a barrier to innovative payment models such as value-based payment arrangements involving pharmaceuticals.
- Using its existing authority, CMS could issue regulatory clarifications for applying Medicaid Best Price to value-based payment arrangements, including two clarifications to the bundled sales provision and the free goods exception to Best Price.
- These clarifications would help encourage the development of innovative value-based payment arrangements without creating an exemption from Best Price reporting, allowing states to continue to benefit from the lowest available marketplace prices.

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## Introduction

The Medicaid Best Price (MBP) policy requiring drug manufacturers to give Medicaid programs the lowest price among purchasers (with a few exceptions) plays a critical role in achieving relatively low fee-for-service (FFS) drug prices in Medicaid. However, its current interpretation has been widely cited as a substantial barrier to the adoption of alternative payment models for drugs that shift away from FFS reimbursement. For example, if a Value-Based Payment (VBP) arrangement ties payments to outcomes,<sup>1</sup> a very low payment for a particular patient in which a treatment does not work could become a new MBP for all patients – even if it only applies to a non-representative subset of patients in the drug payment contract.

In this paper, developed by the Duke-Margolis Center for Health Policy, with guidance from its Value-based Payment for Medical Products Consortium, we describe how the Centers for Medicare and Medicaid Services (CMS) could use its existing statutory authority to provide clarifications for applying MBP to VBP models, without compromising the key goal of MBP. Specifically, we focus on CMS' interpretation of the bundled sales provision, which requires that discounts on all drugs in the bundle are allocated proportionately across the undiscounted value of the products for MBP reporting, in the context of VBP arrangements. We argue that a low price paid for a patient with a poor outcome as an element of an outcome-based contract for a covered population does not accurately reflect the “unit price” for the drug in that population. Rather, that particular drug price should be “bundled” with other prices for the population – including the mix of higher payments when the drug achieves its performance goal. This approach is consistent with past examples of how MBP should be calculated in the context of bundled drug pricing contracts and, importantly, does not create an exemption of VBP arrangements from MBP reporting; indeed, if the resulting average price of the drug for patients in the VBP arrangement is lower than in other contracts, then that lower price will be the MBP. Rather, this clarification of existing regulations is intended to update the concept of bundled sales to accommodate VBP arrangements, and to increase legal certainty for payers and manufacturers who seek to enter VBP arrangements, without restricting the statutory intent of MBP to enable a population of Medicaid recipients to get the best price that is offered in the marketplace. Additionally, we consider the role of the limited free goods exception in interpreting the MBP requirements.

Below, we outline the basis for CMS' statutory authority to revise its interpretations regarding the bundled sales provision and free goods flexibilities to MBP. These potential revisions would reduce uncertainty about the implications of VBP arrangements for manufacturers and payers, while still preserving the role of MBP to achieve the lowest net drug prices for Medicaid populations.

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<sup>1</sup> Another example for a model that has significant MBP implications, depending on the payer involved, is the drug subscription model, where a payer pays a flat amount for unlimited access to the therapy over a pre-defined period of time.

## The Bundled Sales Provision

### Background

As part of their reporting obligations under the Medicaid Drug Rebate Program (MDRP), manufacturers must report their Average Manufacturer Price (AMP) for each covered outpatient drug (COD) on a quarterly basis by National Drug Codes (NDCs). Existing regulations already require calculation of a weighted-average price for certain “bundled sales”. For drugs purchased in contracts that meet the bundled sale definition, manufacturers must determine the total value of all the discounts on all drugs in the bundle and allocate those discounts proportionately across the undiscounted value of the products that were part of the bundled sale. The results of this “unbundling” calculation are then included in AMP and MBP.

The bundled sales definition (hereinafter “bundled sales provision”) is a regulatory construct and not explicitly mentioned in section 1927 of the Social Security Act, which governs the MDRP with MBP and AMP reporting. Rather, the bundled sales provision reflects a regulatory understanding that AMP and MBP must reflect market conditions and corresponding contractual arrangements when multiple drug prices are grouped in a single bundle.<sup>2</sup>

In particular, CMS defines a “bundled sale” in regulations to mean:

[A]ny 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 or 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.<sup>3</sup>

Thus, a bundled sales arrangement *does not* exist if:

- 1) A discount or price concession is established independently for each product within the contract;
- 2) The purchase price under the contract is not contingent upon any other product in the contract or upon some other performance requirement (such as the achievement of market share or inclusion or tier placement on a formulary); and
- 3) The discount provided for any product under the contract is no greater than if the product was purchased outside of the contract.<sup>4</sup>

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<sup>2</sup> 72 Fed. Reg. 39141, 39159 (July 17, 2007) (“It has always been our policy that AMP and best price must be adjusted to reflect discounts offered in bundled sale arrangements to those entities included in the determination of AMP and best price.”)

<sup>3</sup> 42 C.F.R. § 447.502.

<sup>4</sup> 81 Fed. Reg. 5169, 5182 (Apr. 01, 2016).

In a 2007 rulemaking, CMS provided the following illustrative example of how to allocate pricing in a bundled sale involving multiple products. The example illustrates how to distribute a jointly-determined rebate across drug products sold under a single bundled contract:

“Products A and B are sold under a bundled arrangement and have a combined bundled discount equal to \$200,000 on total undiscounted sales of \$1 million. If Product A has undiscounted sales of \$600,000 and product B has undiscounted sales of \$400,000, the manufacturer would allocate 60 percent of the combined bundled discount to Product A when calculating AMP. Forty percent of the combined bundled discount would be allocated to Drug B. The effective unit price of each product would be calculated by subtracting the discount allocated to each drug product ( $\$600,000 - \$120,000 = \$480,000$  for Product A;  $\$400,000 - \$80,000 = \$320,000$  for Product B) and dividing the result by the number of units for each drug product in the bundled sale.”<sup>5</sup>

CMS has clarified that it would treat as a bundled sale a contingent discount involving a situation where a manufacturer must achieve a certain market share (i.e., performance requirement) of the product in one quarter for the purchaser to receive a discount in the second quarter.<sup>6</sup> That is, a single drug contract extending over two time periods also requires constructing a weighted average for the unit drug price. While CMS has not yet issued a clarifying example for value-based contracts, a logical extension of these bundled sales examples to the VBP contract setting would suggest an equivalent weighted-average calculation of the rebate for MBP reporting – *only* when the different drug prices are bundled together in a single contract for a covered population.

### *Proposed Clarification*

VBP contracts require the bundling of a higher net price when a drug works, with a lower net price when it does not. Manufacturers and commercial payers are concerned that the unit price would effectively be “un-bundled” for MBP reporting in such contracts. If the outcome-based contract is a substantial shift away from FFS payment, the very low “unbundled” net price for the patient who experienced the worst outcome could be interpreted as a new low MBP, even though it only occurs as one component of the outcome-based contract. That would diverge from the intent of the bundled sales provision.

Instead, we propose that the MBP should be calculated as a weighted average across the different drug prices included in the single bundled contract. That is, in the context of VBP contracting, the bundled sales provision would allocate the price for a product across sales and across different reporting periods for a population under the same contract (e.g., the outcome-based prices across multiple quarters if an outcome is tracked quarterly).

While manufacturers have occasionally approached CMS to ensure that their VBP arrangements meet the bundled sales provision, clarification from the agency is needed to increase the contracting parties’

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<sup>5</sup> 72 Fed. Reg. 39142, 39158 (July 17, 2007).

<sup>6</sup> *Id.*

confidence in applying it to these arrangements. Such a clarification from CMS on this issue would not require a change in the regulations. It could be achieved by the issuance of sub-regulatory guidance such as a manufacturer release, setting forth the parameters of a bundled sales approach to price reporting under VBP contracts.

This CMS clarification would need to address two components of its existing bundled sales policy:

#### Clarifying “Performance”

The first involves clarifying that the term “performance requirement” may include the performance of the product itself in the form of an outcome, as opposed to simply the performance of the contracting parties. Currently, the examples that CMS identifies as “performance requirements” tend to describe performance obligations between the parties themselves. For instance, when the manufacturer conditions a discount on the placement of its product on a formulary—it is the “performance” of placing the drug on the formulary that triggers the discount. Similarly, when a manufacturer conditions a discount on the purchaser achieving a certain market share for a given product—it is the “performance” of the purchaser achieving the specified market share (through any variety of means) that triggers the discount.

Rather than describing “performance” as something the contracting parties “perform,” CMS could clarify that the performance of the *product* can also characterize a “bundled sale”, thereby allocating the MBP across the population that may experience different outcomes and thus prices. For instance, as part of a VBP contract, the manufacturer may agree to offer a 50% discount on Product A if Product A fails to achieve X clinical outcome over the course of Y period. The “performance” in this case would be whether or not Product A itself fails to achieve X clinical outcome over Y period. But rather than applying the full 50% discount to a single sale for the purposes of price reporting (and increasing mandatory rebates while triggering MBP), the manufacturer would be able to average out the number of sales that trigger the 50% discount across all of its aggregate sales of Product A under the contract.

Continuing this example, suppose Product A costs \$100. The manufacturer treats 100 patients with Product A, for a total of \$10,000 with a contingent discount of 50% for each product that fails to satisfy X clinical outcome during Y period. Under the proposed clarification, if the treatment of 30 patients who receive Product A fails to satisfy X clinical outcome during Y period, then the manufacturer provides a discount of 50% for the products used by those patients. But for the purposes of price reporting, the manufacturer averages this 50% discount across all of its Product A sales under the contract, which results in a weighted average price of \$85 for Product A  $\{([100 \times 70] + [50 \times 30]) / 100\}$ . The “discount” reported to CMS for Product A as part of the bundled sale is 15%  $(100 - 85 / 100)$ . Importantly, the 15% discount does not reset MBP in a manner that is out of line with the discount received by the population of patients covered by the contract, in which most in the covered population did achieve the outcome. This weighted average reflects the net price per unit that the purchaser actually paid, not the \$50 price for the subset of patients who did not achieve the contracted outcome.

As this example shows, the weighted average approach, as is used in the case of other government price reporting calculations (e.g., Average Manufacturer Price) reflects the reality of how VBP arrangements are executed.

In some cases, such as for a gene therapy for a very rare condition, a single contract may not cover enough patients to mitigate the potential for large variations to occur in average net price and thus in the bundled MBP. If the number of patients covered by an individual contract is so low as to make the average price unreliable, MBP could potentially be calculated over a set of contracts with similar or identical discount/outcome provisions to determine MBP more reliably.

#### Clarifying number of products for a “bundle”

The second clarification effectively enables the scenario above and explains that a bundled sale does *not* require more than one product as long as the sale contains a performance requirement, which as described above, could include the performance of the product itself in achieving specified outcomes. Currently, the examples that CMS has identified for illustrating the performance requirement element of a bundled sale arrangement seem to involve, in one form or another, the sale of two different products. Yet in other descriptions, CMS suggests that bundled sales could involve only a single type of drug.<sup>7</sup> Restricting bundled sales to two or more product types unnecessarily limits the type of bundled sales arrangements that might leverage an outcome-based performance requirement, particularly if the manufacturer only has a single product on the market or coupling the sale of two distinct products is simply not feasible or appropriate.

#### Summary: Bundled Sales Clarification for Value-Based Payment Contracts

In summary, the two clarifications described above with respect to the bundled sales provision more accurately reflect net prices paid under VBP contracts, will improve certainty, and will encourage the development and adoption of VBP contracts for drugs and biologicals that feature more substantial links to outcomes, while still retaining intended MBP protections for Medicaid programs. Below we propose revisions in red to the current regulatory definition § 447.502 for “Bundled sale”:

*“Bundled sale means 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 or tier placement on a formulary, or the product’s achievement of pre-specified clinical or cost outcomes), 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.*

(1) The discounts in a bundled sale, including those discounts resulting from a contingent arrangement, are allocated proportionally to the total

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<sup>7</sup> 72 Fed. Reg. at 39158 (“A contingent arrangement involving drugs with different NDC-9s constitutes a bundled arrangement. A contingent arrangement involving drugs that share the same NDC-9 may constitute a bundled sale or volume discount. For these types of arrangements, the aggregate value of all the discounts must be allocated proportionately to all drugs within the bundled or volume discount arrangement.”).

dollar value of the units of all drugs or products sold under the bundled arrangement.

(2) For bundled sales where a single drug is discounted based on an outcome-based (clinical or cost) performance requirement, the average discount across all sales for the product under a given contract represents the reportable discount for that product.

(3) For bundled sales where multiple drugs are discounted, the aggregate value of all the discounts in the bundled arrangement must be proportionally allocated across all the drugs or products in the bundle.”

Finally, an extension of this regulatory clarification may be needed to allow manufacturers to accurately calculate MBP in long-term VBP contracts when the “actual” price of the drug will not be known until after the 3-year restatement window in which manufacturers may correct their initial MBP reporting. In VBP contracts, initial MBP reporting could be based on a best estimate of the rate of meeting the outcome-based goal, and MBP corrections could be made under the current MBP reporting rules for up to the existing regulatory MBP restatement window of 3 years (12 quarters) after the initial drug sale. In many cases, it is likely that evidence accumulated in those first three years will help improve the reported net price. However, some outcome contracts may extend for longer periods. As CMS currently allows manufacturers, under certain circumstances, to request to restate their MBP after the 12-quarter deadline outlined in regulations,<sup>8</sup> it could add to this list of circumstances situations where the price adjustment is a consequence of an outcome-based contract. Alternatively, it could adopt a best estimate of the longer-term net price based on an independent actuarial determination using the available evidence on the product’s performance.

## The Free Goods Provision

### *Background*

CMS codified the statutory free goods provision as follows: “Best price excludes ...free goods, not contingent upon any purchase requirement.”<sup>9</sup> CMS has not discussed the “free goods” exception to MBP in much detail. In the 2016 Covered Outpatient Drug Final Rule, CMS mentioned the free goods MBP exception only in passing in the context of discussing free goods provided by manufacturers to

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<sup>8</sup> 42 C.F.R. § 447.510(b)(1).

<sup>9</sup> 42 C.F.R. § 447.505(c)(13).



patients.<sup>10</sup> In addition, CMS stated that they would issue further guidance, but this has not yet been released by the agency.<sup>11</sup>

### *Proposed Clarification*

The free goods exception to MBP can be a further resource for manufacturers and commercial payers that enter into VBP arrangements in which they effectively provide a 100 percent refund because of a product's failure to meet pre-specified clinical or cost outcomes. However, CMS' current lack of clear guidance on the free goods exception in the context of VBP arrangements contributes to a general reluctance by the contracting parties to interpret the free goods exception as a basis for providing 100 percent refund guarantees.

CMS could explicitly clarify that the free goods exception to MBP applies in situations where the manufacturer provides a 100 percent rebate to the purchaser because the product fails to meet pre-specified outcomes (e.g., clinical, total costs of care over an episode of care). Arguably, such an arrangement constitutes a "free good" because it is not "contingent upon any purchase requirement". In order to receive Product A for free, the purchaser is not required to make any other purchase from the manufacturer. It is the success or failure of Product A itself that determines whether the product is free, not the purchase of a product. Since the actual outcome may not be observed for some time, the manufacturer could be prohibited from collecting payment from the purchaser until the clinical or cost outcomes have been measured, so there is no purchase at all for the drug that fails to meet the target.

One potential counterargument to this proposed clarification is that such a payment arrangement does not involve "free goods" because the purchaser only receives Product A for free if they agree to "contingently purchase" Product A in the event the product is successful in meeting the pre-specified outcomes. Instead, we argue that receiving Product A for free and purchasing Product A are mutually exclusive outcomes. The purchaser cannot be assured that it will receive Product A for free if it agrees to "purchase" Product A. Arguably, the free goods exception is designed to apply to "contingent purchase" scenarios where the purchaser *invariably* receives Product A so long as they purchase X quantity of Product A, or if they purchase X quantity of some other product within the manufacturer's portfolio.

In summary, to lend certainty to the regulatory environment around applying the free goods exception for VBP contracts, CMS could clarify that the free goods exception to MBP applies when a manufacturer provides a product for free if pre-specified outcomes are not met. In such contracts, manufacturers must not condition the purchase of the product on any other purchase requirement, such as the

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<sup>10</sup> 81 Fed. Reg. at 5254. ("Furthermore, we are finalizing § 447.505(c)(13) to provide that free goods, not contingent upon any purchase requirement, are excluded from best price. Additionally, manufacturers must include the value of the discount, coupon, rebate, or voucher in the determination of best price if the program generates a price concession to a best price-eligible entity.").

<sup>11</sup> "We intend to issue guidance to provide consistency among manufacturers treatment of the 'any purchase requirement' of the free goods provision." 81 Fed. Reg. at 5235. CMS has never issued such guidance.

purchase of a certain quantity of the product or any other product, and the manufacturer must not invoice the purchaser until the clinical outcomes are observed.

## Conclusion

Lack of clarity about MBP reporting is not the only obstacle to the implementation of VBP arrangements. There are administrative obstacles such as reliable collection of performance measures and business obstacles such as manufacturers taking on more accountability for the performance of their products. Despite these obstacles, contracts that are linked to product performance are becoming more common, especially for medical products that are intended to have substantial impacts on health outcomes and potentially other medical costs over time. Consequently, reasonable clarifications about how prices should be reported for MBP in the contexts outlined above will improve certainty about the regulatory implications of such contracts. This will keep the MBP regulation up-to-date with marketplace developments - and enable the adoption of more advanced VBP arrangements with the potential for improving outcomes and avoiding unnecessary medical costs, while continuing to support states' ability to obtain the best available prices in the marketplace.