# CMS PROPOSED MEDICAID RULE:

# Best Price Impacts of Value-Based Purchasing, Co-Pay Assistance Programs, and More

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On June 17, 2020, the Centers for Medicare and Medicaid Services (CMS) published a proposed rule outlining nine specific changes to Medicaid regulations. Five of these directly affect manufacturers through changes in administration of the Medicaid Drug Rebate Program (MDRP); these five are described below.

## Proposed Rule

### VALUE-BASED PURCHASING AGREEMENTS (VBPS)

For many years, private payers have been looking for ways to get assurance of the efficacy of expensive therapies through paying for drugs based on "evidence-based" or "outcomes-based" measures. However, pharmaceutical manufacturers have been discouraged from pursuing alternative pricing structures due to the rigidity of the Medicaid Drug Rebate Program (MDRP) regulations, particularly Best Price (BP) and Average Manufacturer Price (AMP) reporting.

The proposed rule "recognized the importance of VBP especially when such arrangements benefit Medicaid patients' access to drug treatments." It further defines VBPs as "an arrangement or agreement intended to align pricing and/or payments to an observed or expected therapeutic or clinical value in a population (that is, outcomes relative to costs) and includes (but is not limited to):

1. Evidence-based measures, which substantially link the cost of a drug product to existing evidence of effectiveness and potential value for specific uses of that product;
2. Outcomes-based measures, which substantially link payment for the drug to that of the drug's actual performance in a patient or a population, or a reduction in other medical expenses."

VBPs cause two Best Price challenges for Government Pricing (GP) teams. The first is what the manufacturer should do if the time period for measured effectiveness (and thereby price) extends beyond the 12-quarter window allowed for BP restatements. The second is what the manufacturer should do if there are "product failures," as defined by the VBP, causing the net price for those therapies to become very low or zero. The proposed rule suggests two solutions:

1. Manufacturers may describe the arrangement as a Bundled Sale. The manufacturer may blend the net prices of the effective therapies with the low net prices applied to ineffective therapies for each VBP. As this methodology is already employed by manufacturers today, this could be an actionable solution going forward.
2. Various price points result in several Best Prices. The proposed rule does not fully describe how these multiple prices would be reported, how multiple Unit Rebate Amounts (URAs) would be attributed to individual Medicaid claims, or how those URAs would then be used to calculate derivative prices, like the 340B ceiling price. Therefore, this method has many hurdles to overcome before it could be a viable solution.

### LINE EXTENSIONS

The proposed rule changes treatment of new formulations as line extensions for the purpose of calculating the "alternative URA" for new drugs.

Neither the 2012 proposed rule nor the 2018 BBA adequately defined a line extension. In its definition, the proposed rule broadly increases the types of drugs that may be considered as line extensions. As a result, this introduces the possibility of greatly increasing URA and, therefore, PHS pricing for many new drugs. The new definition of a line extensions: "A new formulation of the drug contains at least one active ingredient in common with the initial brand name listed drug including combination drugs, extended release forms and new strengths."

Comments to this provision will likely point out that the definition is very broad and creates an inconsistent application of URA calculation over time. Older drugs with different dosage strengths, for example, would not be "new formulations" requiring an Alternative URA calculation, while newer drugs would. In addition, the proposed regulation stating that only the initial single-source drug or innovator multiple-source drug must be an oral solid-dosage form is quite far-reaching. Under this definition, virtually any formulation with the same active ingredient could be considered a line extension. This could even include combination drugs utilized in the treatment of a different disease class than the original product.

## PATIENT ASSISTANCE PROGRAMS

MDRP has historically excluded manufacturer Patient Assistance Programs (PAPs) from BP. This includes popular manufacturer patient co-pay coupons. The proposed rule adds a "requirement that manufacturers ensure that the benefits of their assistance programs … are provided entirely to the consumer and are proposing corresponding changes to the AMP regulations ..." Previously manufacturers could make the reasonable assumption that all of the benefit of the PAP or co-pay coupon was extended 100% to the patient or consumer.

In recent years, Pharmacy Benefit Managers (PBMs) have been reluctant to accept co-pay cards, as they encourage prescribing of high cost drugs. While the co-pay card shields the patient from the high-cost, they actually cost the PBM more because the copayments paid by manufacturers use up patient deductibles faster, thus shifting the prescription cost to the plan. PBMs have implemented "Accumulator Programs" where the contribution of the manufacturer is not applied to the patient deductible. When the co-pay benefit maximum is reached, the patient receives a significantly higher bill. CMS' position is that "manufacturers have the ability to establish coverage criteria around their manufacturer assistance programs to ensure the benefit goes exclusively to the consumer or patient." Therefore, manufacturers will need to establish criteria in the co-pay coupons, such that 100% of the benefit goes to the patient or those coupons will not be BP excluded. The co-pay would be considered a price concession to the PBM and would then be AMP and BP eligible. This change would require significant modifications in GP reporting systems, as well as the ability for manufacturers to be able to identify and track Accumulator Programs for determination of GP calculation inclusions/exclusions.

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## MDRP DEFINITION CLARIFICATIONS

In recent years, CMS has stressed the importance of correct classification of drugs for appropriate calculation of URA. CMS has reiterated the risk of civil monetary penalties for manufacturers that continue with misclassified drugs. To that end, the proposed rule includes revised definitions of key product categories.

**Innovator multiple-source drug (I)** means a "multiple-source drug, including an authorized generic drug, that is marketed under a **new drug application (NDA)** approved by the FDA, unless the Secretary determines that a narrow exception applies (as described in this section or any successor regulation). It also includes a drug product marketed by any cross-licensed producers, labelers or distributors operating under the NDA and a covered outpatient drug approved under a biologics license application (BLA), product license application (PLA), establishment license application (ELA) or antibiotic drug application (ADA)."

**Single-source drug (S)** means a "covered outpatient drug, including a drug product approved for marketing as a non-prescription drug that is regarded as a covered outpatient drug under section 1927(k)(4) of the Act, which is produced or distributed under a **new drug application (NDA)** approved by the FDA, including a drug product marketed by any cross-licensed producers or distributors operating under the new drug application unless the Secretary determines that a narrow exception applies (as described in this section or any successor regulation), and includes a covered outpatient drug that is a biological product licensed, produced or distributed under a biologics license application approved by the FDA CMS-authorized Supplemental Rebate agreements."

**Non-innovator multiple-source drug (N),** by contrast, is unchanged: "(1) A multiple-source drug that is not an innovator multiple-source drug or a single-source drug, (2) a multiple-source drug that is marketed under an **abbreviated new drug application (ANDA)** or an abbreviated antibiotic drug application." In simple terms S & I drugs are **NDA**-approved drugs. N drugs are approved under an **ANDA**.

**Oral solid-dosage form** means an "orally administered dosage form that is not a liquid or gas at the time the drug enters the oral cavity." For the purpose of qualifying the initial drug in the definition of a line extension, the definition is broadened slightly from the narrower previous definition, which included only "capsules, tablets or similar drugs products intended for oral use." In the new definition of oral solid-dosage form, swallowing the drug with entry into the gastrointestinal tract would not be necessary. Therefore, powdered drugs administered by oral inhalation and sublingual films would also qualify as solid oral-dosage forms.

## AUTHORIZED GENERICS

The proposed rule reiterates and clarifies the new rule from the 2019 Health Extenders Act that states sales for Authorized Generic (AG) drugs should not be included in the AMP of the branded single-source "primary drug." In so doing, the rule also changes the definition of wholesalers to not include manufacturers. This change in AG AMP only affects those manufacturers that had been including sales for the AG into the AMP of the primary product.

# Next Steps

### Considerations

These potential MDRP changes are part of a Proposed Rule, which can be introduced by the Administration without legislative action. As proposed rules, they are enforceable only after being accepted by the Administration, at which time they would be published as a Final Rule. Most often, Proposed Rules do not make it through to become Final Rules, typically through two primary circumstances. The first is that the Administration recognizes, through the public comment period, that the rule is not beneficial in its current form as originally envisioned. The second is that the intent of the Proposed Rule has already been achieved, simply through the threat of regulation.

There are numerous examples of this playing out. For example, the Proposed Rule to eliminate the safe harbor in the federal anti-kickback law for rebates negotiated by PBMs never proceeded to Final Ruling. The objective of this rule was to make rebates transparent and have them realized directly by the patient, such that beneficiaries would fully benefit. Due to the Congressional Budget Office (CBO) determining that this could increase costs to the Medicare program and possibly the beneficiaries, this proposal was not furthered.

Additionally, this Proposed Rule faces another obstacle in that rules are confirmed by Administration, which could potentially change in the near future. Considering these factors, the current CMS Proposed Rule, while improbable to proceed to a Final Rule as is, will still impact how payers and manufacturers operate. The result will likely be an increase in value-based arrangements that provide their own safeguards against dropping below current Best Prices.

### Recommendations

Even if the proposed rule is not adopted in its current form, there is a chance that parts of it will be pushed forward, passed into legislation or otherwise adopted by the marketplace. Manufacturers, therefore, are advised to conduct a review of their strategy and operations to ensure readiness for any potential changes.

#### *Strategy*

For many manufacturers, the "bundled sales" methodology proposed for VBPs is already in practice in current value-based arrangements. Its inclusion in the proposed rule demonstrates that CMS is open to this approach, which is encouraging to manufacturers currently using it and to those that desire to pursue further value-based agreements. For drug-makers not currently engaged in value-based purchasing, this presents an opportunity to review potential deal structures under the lens of this methodology and determine applicability to their customer base, product portfolio and business model.

Additionally, manufacturers should consult with their legal counsel and government pricing teams to determine whether any of their existing or upcoming products can be considered line extensions under this proposed definition of "new formulations." If finalized, manufacturers can then proceed to make appropriate changes in their applications to operationalize the new rule. Likewise, the classification of existing branded products in MDRP should be reviewed to determine whether they fit into the revised definitions of S and

I drugs. In addition to civil monetary penalties, non-compliance can mean a recalculation of rebates from affected time periods. Finally, a review should be conducted of all PAPs, especially co-pay coupons, to determine whether these discounts would be excluded or included from AMP and BP calculations under the new rule.

More broadly, drug makers should evaluate their contract and pricing strategies around line extension products, as their profitability may well be impacted for companies with high levels of Medicaid utilization compared to other channels. Other derivative prices will have to be examined as well. For example, the 340B ceiling price, used to set discounts for institutions covered under the 340B drug pricing program, is calculated as the current quarter Medicaid URA subtracted from the current quarter AMP. Consequently, 340B prices for line extension products will decrease as Medicaid URAs become higher.

***Operations***

To ensure compliance with the regulations around government price calculation and reporting, most pharmaceutical manufacturers use a Revenue Management System designed to operate within a given methodology. Drug makers, particularly those with value-based contracts and line extension products, will need to determine how their software may have to be modified to account for any new methodologies. For some platforms, these alterations may constitute simple formula modifications, while others may require more intensive reconfiguration. Value-based contracts, for example, may be able to use a Bundled Sales methodology with existing discount reallocation functionality, while multiple Best Prices may be much more difficult to implement. The new stipulations around PAPs also present similar multi-faceted system considerations. Transaction classifications may have to be modified to allow for PAPs to be considered as alternatively included or excluded in government pricing calculations based on the allocation of pricing discounts. New data sets may be required to determine which coupon transactions are included/excluded as well. While this may be easier to implement, the associated change to AMP and MP methodology would likely be more complex.

Manufacturers will also want to review their forecasting models, accrual workbooks and price reporting, as these will likely require updates if this proposed rule is adopted. Similarly, gross-to-net calculations should be examined to factor in any greater likelihood of the alternative URA methodology being used over the standard URA for line extension products. The higher liability presented by these rebates will present a more significant impact to bottom-line revenue for any manufacturers with products that would be considered new formulations.

## Conclusion

At this early stage, a manufacturer's best course of action is to stay apprised of updates around this new proposed rule to ensure they remain compliant and can adapt their systems and processes effectively. In addition, manufacturers should work with their legal counsel to ensure comments are submitted to CMS by the comment period end date of July 20, 2020. After this point, the potential impact of this proposed rule can be more fully analyzed, and a path forward can be more clearly determined.