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Multiple Best Price Points Contemplated by the Proposed Rule…

A Bold Step Toward Innovation?

The Medicaid Program proposed rule published on June 19, 2020 ("CMS-2842-P" or the "Proposed Rule") includes several proposed revisions to program regulations, each of which present different legal, strategic, and operational challenges for manufacturers.

At Riparian, our mission is to empower our clients by delivering innovative solutions that provide efficiency, clarity, and accelerated insights. In this second article in our series on the Proposed Rule, we address the revisions that pave the way for increased adoption of value-based purchasing ("VBP") arrangements, along with some potential operational impact and change management challenges that manufacturers may need to address as a result.

Best Price: A Hurdle for Value-Based Purchasing Arrangements

The basic premise of a VBP arrangement is to link drug prices to patient outcomes – whereby a payer pays a higher price for a drug when the desired outcome is achieved and a lower price for a drug (in some cases nothing at all) when the desired outcome is not achieved.

At present, manufacturers report a single Best Price ("BP") for each dosage form and strength of a covered outpatient drug, which is then used to establish a single Medicaid Unit Rebate Amount ("URA") that is payable on Medicaid utilization across all package sizes of the dosage form and strength of the covered outpatient drug. A single sale of a single unit may set BP.

As a result, a VBP arrangement presents a significant financial risk; due to its variable pricing structure, a poor outcome for a *single* patient has the potential to set a very low BP, and as a result, yield a significant rebate amount on *every* unit reimbursed by Medicaid.

Modernizing the Medicaid Drug Rebate Program: Changes to BP Reporting

In the Proposed Rule, CMS appears to acknowledge that the current BP construct presents a significant hurdle to manufacturers' adoption of VBP arrangements. Notably, the Proposed Rule includes various revisions that may pave the way for increased adoption of VBP arrangements.

Multiple Best Price Points

The revised BP definition states that the lowest price available from a manufacturer may include "*varying best price points* for a single dosage form and strength as a result of a value based purchasing arrangement." The preamble to the Proposed Rule indicates that a manufacturer would report the following BPs and pay Medicaid rebates as follows:

- VBP BPs: Distinct price points available based on the range of evidence-based or outcomes measures possible under VBP arrangements. These VBP BPs would be applied to units dispensed to Medicaid patients that participate in a VBP, based on each patient's outcome.
- "Standard" BP: Lowest price available outside of VBP arrangements. This "standard" BP would be applied to units dispensed to Medicaid patients that do not participate in a VBP.

VBP Arrangement as a Bundled Sale

The revised Bundled Sale definition states that VBP arrangements "may *qualify as a bundled sale*, if the arrangement contains a performance requirement such as an outcome(s) measurement metric."

The bundled sale definition directs manufacturers to allocate the discounts in a bundled sale proportionally to the total dollar value of the units of all drugs or products sold under the bundled arrangement, and to use the resulting reallocated discount amounts (rather than the actual discount assigned to each sale) to calculate net prices that go into consideration for BP. "Unbundling" has the net effect of generating a weighted average discount rate for all units sold in a bundled arrangement, dampening the impact that a single, heavily discounted unit would otherwise have on BP.

Extension to Deadline for Reporting Revisions to Pricing

The Proposed Rule includes a new exemption to the 12-quarter period currently allotted to manufacturers to report revisions to pricing – specifically in the event a VBP arrangement includes an outcome that must be evaluated outside of the 12-quarter period.

The Proposed Rule recognizes that VBP arrangements may include patient outcomes that are measured over a greater-than 12-quarter period; the proposed exception that allows more time for manufacturers to true up prices reported using estimated discounts addresses a tactical matter that is critical to getting BP right.

Sounds Good So Far… What's the Catch?

These proposed changes to BP reporting represent real progress toward addressing manufacturers' gross-to-net and operational concerns that may have caused many manufacturers to balk at VBP arrangements. The notion that there are multiple BPs (and URAs as a result) for a single dosage form

and strength of a covered outpatient drug is a dramatic change from the current pricing regime, and represents an attempt get the Medicaid Drug Rebate Program caught up to some of the exciting breakthroughs in healthcare that have occurred since the start of the Program. However, there are several matters that will need to be addressed before this goal can be achieved.

The BP Reporting Conundrum

Two of the proposed changes to BP reporting – 1) that the lowest price available from the manufacturer may include multiple BPs for a single dosage form and strength of a covered outpatient drug, and 2) that a VBP may qualify as a bundled sale arrangement – address the fundamental inequity that occurs when a significant discount on a single commercial unit resulting from a poor patient outcome must be applied to all Medicaid units, regardless of patient outcomes. However, these concepts, when considered collectively, result in a BP reporting conundrum. The requirement that a manufacturer report a *distinct set of BPs available* based on the range of evidence-based or outcomes measures possible under the VBP arrangement is at odds with the revision to the bundled sale definition, which would result in a *single VBP BP* based on the weighted average discount rate of all units sold in the arrangement.

It is unclear how both concepts will peacefully coexist, because the purpose of reporting distinct VBP BPs tied to specific evidence-based or outcomes measures is to determine the Medicaid rebate payable on units dispensed to each Medicaid patient, based on each patient's outcome, whereas "unbundling" would essentially disregard the net price of each individual sale in a VBP arrangement. Perhaps manufacturers will have the choice of the "bundled sale" option vs. the multiple BPs option. In that case, it may be up to manufacturers to evaluate the potential cost-benefit of each option.

VBP Arrangements with State Medicaid Programs

At present, manufacturers may enter into VBP arrangements with State Medicaid programs by executing Supplemental Rebate Arrangements ("SRAs") with the States (generally on a State-by-State basis). Although CMS does not specifically propose changing the use of SRAs as the means for manufacturers to negotiate VBP arrangements with the States, it is conceivable that the current State-by-State contracting model will evolve over time so as to abolish any administrative (or other) barriers that could otherwise prevent States from generating additional savings from VBP supplemental rebates.

This could result in a scenario in which manufacturers would need to extend the terms of any VBP arrangement to *all* States, rather than make that election on a State-by-State basis. Under this scenario, manufacturers would have to evaluate the potential Medicaid impact of any VBP arrangement for *all* States, rather than the few States that have CMS-approved state plan amendments permitting them to negotiate SRAs based on evidence or outcomes-based measures.

Buried Alive in a Medicaid Avalanche

At present, a manufacturer may receive hundreds of Medicaid invoice types on a quarterly basis. In general, States invoice manufacturers by labeler code, and invoice FFS and MCO utilization separately. Many States invoice at a more granular level by MCO or by specific waivers. Finally, States invoice for supplemental rebates separate and apart from the drug rebates set forth under the National Drug Rebate Agreement.

The number of invoice types a manufacturer receives per quarter is likely to increase significantly to support the application of multiple URAs for a single dosage form and strength of a covered outpatient drug, as there will likely need to be additional invoice types for each level of rebates payable based on VBP patient outcomes. Further, the introduction of multiple BPs will likely lead to a significant increase in rebate amounts subject to dispute, since manufacturers will have URA-based disputes when units are not correctly categorized by patient outcome, in addition to unit-based disputes (a very common occurrence for manufacturers of specialty/ 5i products).

Such an increase in Medicaid invoices and potential dispute activity will require manufacturers to invest in additional resources and better Medicaid processing systems to support the additional level of effort needed to complete the invoice and claims level detail data acquisition, URA and unit dispute identification, and A/P coordination activities needed to adjudicate and pay each Medicaid invoice in a timely manner. Additionally, there will likely also be more resource and system requirements to work with the States on dispute resolution, accrue for Medicaid rebates, and support the overall gross-to-net process.

340B Drug Discount Program Complication

No analysis of the revisions to BP can be complete without giving some consideration to the 340B Drug Discount Program, since 340B ceiling prices are established based on Medicaid pricing.

Pursuant to the "duplicate discount" provision, manufacturers are not required to provide a discounted 340B price and a Medicaid drug rebate on the same unit of drug. However, there could be a true-up in a scenario where a 340B drug (where the ceiling price is established on the basis of the "standard" BP) is dispensed to a Medicaid patient participating in a VBP, depending on the patient's outcome. This scenario could necessitate yet another Medicaid invoice type that would be used to invoice manufacturers for the supplemental VBP rebate amount (so that the manufacturer does not pay a duplicate discount on the rebate set by the "standard" BP) – further adding on to the Medicaid avalanche.

Challenge Accepted: Prepare for Change

Clearly, there is a lot of work to be done before a system in which multiple BPs can be used to determine Medicaid rebates based on evidence or outcomes-based measures can be operationalized. Bringing this idea to reality will undoubtably require significant additional investment in people and

technology on the part of manufacturers that have products for which VBP arrangements are the best fit from a pricing perspective.

Manufacturers may increasingly need to re-evaluate their enterprise systems (e.g., GP calculations and Medicaid rebates processing), as well as their resource allocation to ensure they will be able to meet any new price-reporting and rebate claims adjudication requirements as a result of entering into VBP arrangements. From a technology standpoint, manufacturers may need to consider alternative solutions in addition to evaluating the upgrades that will need to be made to existing systems to comply with new requirements. From a people standpoint, manufacturers may need to consider (or reconsider) outsourcing certain business functions to hone their operational focus. For example, manufacturers may consider outsourcing basic Medicaid rebate processing activities such as managing invoice intake, invoice data entry, and claims level detail acquisition, to reallocate company resources to more complex activities and/or strategic initiatives.

As our body of scientific knowledge continues to grow and medical breakthroughs continue to be made, there is no telling what advances in medicine will come next. The pricing mechanisms used by the Medicaid Drug Rebate Program must evolve to make the next wave of innovative therapies and cures available to Medicaid patients; it is not a matter of if, but when that will happen, and manufacturers need to be prepared to meet the operational challenges head on.

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This article is a part of the Riparian and Hayden Consulting Group Article Series:

Proposed Rule for 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

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