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Client Alert

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Final Rule on VBP, Patient Assistance and Line Extensions Presents Opportunity and Risk for Drug Manufacturers

Trump Administration Finalizes Rulemaking on Value-Based Purchasing, Multiple Best Prices, Expanded Alternative URA, and other MDRP Drug Pricing Changes

On December 21, 2020, the Centers for Medicare & Medicaid Services finalized its June 17, 2020 proposed rule ("Proposed Rule") updating and expanding several key regulations governing the Medicaid Drug Rebate Program. The Final Rule largely adopts the regulations as originally proposed, with significant consequences for manufacturers' commercial strategies, government payer program liabilities, lifecycle management plans, and patient assistance regimes.

As discussed in our June 23 Client Alert on the Proposed Rule, CMS used the rulemaking process to consider new proposals to expand value-based purchasing ("VBP") arrangements between manufacturers and commercial insurers and amend the Medicaid Drug Rebate Program, including: (1) altering the MDRP Best Price rules, including authorizing the use of multiple Best Prices for a single drug in a single quarter; (2) dramatically increasing the number of drugs subject to an "alternative URA" calculation; (3) limiting the ability of manufacturers to exclude supplemental rebates paid to Medicaid MCOs from calculations of AMP and Best Price; (4) requiring manufacturers to "ensure" that patient assistance is fully passed on to a consumer in order to qualify for exclusion from Best Price; and others. Many of these proposals have been adopted in the Final Rule without modification, while others have been modified in response to stakeholder comments.

To aid analysis, we will soon provide a redlined version of the Medicaid Drug Rebate Program regulations to illustrate how they are amended by the Final Rule.

The Final Rule was published in the Federal Register on December 31. It will be effective on March 1, 2021, 60 days after publication in the Federal Register. Because the Final Rule becomes effective after January 20, 2021 (*i.e.*, Inauguration Day), it may be subject to the "freeze" an incoming administration typically imposes on regulations issued by a prior administration that are not yet effective. Importantly, certain provisions of the Final Rule have delayed effective dates:

- January 1, 2022: reporting of multiple Best Prices for VBP arrangements and revised definitions of "line extension" and "new formulation" and related provisions.
- January 1, 2023: revisions to the Best Price and AMP exclusions of manufacturer-sponsored patient benefit programs.

1. Value-Based Purchasing Arrangements

For several years, drug manufacturers and payers (both public and commercial) have struggled to enter into VBP arrangements under which payment for a prescription drug or biologic could vary depending on its outcome in a particular patient or group. VBP arrangements are particularly attractive to manufacturers, patients and payers for very high cost, potentially curative gene and orphan drug therapies, as well as to commercial payers with multiple products in a therapeutic class. While these arrangements have generally been successful overseas, they have not fully developed in the United States due to manufacturers' concerns about establishing unsustainably low Best Prices or running afoul of the Anti-Kickback Statute. In recent years, nine state Medicaid programs have entered into VBP contracts with drug manufacturers. Yet, the federal regulatory standards have not adapted to these new pricing strategies for commercial arrangements. Until now.

CMS Finalized the Proposed Rule Without Material Modification: Under the Final Rule, manufacturers will be permitted to continue to account for VBP pricing within bundled sales arrangements. More noteworthy, however, is that the Agency will, in the near future, permit reporting multiple Best Prices for the same product and dosage strength, if qualifying VBP arrangements are used. This is a significant modernization of government price reporting rules, and although it will take time to implement the new process, CMS has allowed the coming year to do so.

CMS received numerous comments both for and against the proposed VBP concepts, ranging from those who claimed that the Rule would increase drug prices (or at least not reduce drug prices) to those who urged the delay of the Rule until implementation could be addressed, to those in favor of the proposal. CMS responded that the Rule was less a framework to address drug pricing concerns than it was to accommodate what stakeholders (including Medicaid programs) desire to implement and in some cases are already doing. For that reason, the Agency was unwilling to eliminate or even delay the proposal. Other commenters suggested that CMS attempt a VBP demonstration project through the Center for Medicare and Medicaid Innovation, but CMS rejected that idea as insufficiently immediate. CMS openly acknowledged that implementation would take some time and that the Final Rule did not address the specifics of exactly how multiple Best Price reporting could be implemented, but the Agency promised that it would address implementation concerns in the coming months[1] and that further detail would be issued through sub-regulatory guidance.

The Definition of a VBP Arrangement: In addressing the critically-important definition of a VBP arrangement, CMS has adopted its proposal to condition prices on either "evidence-based measures" or "outcomes-based measures." Some commenters were in favor of one definition, others favored the other, a third group favored requiring a VBP to condition payment on both, and a fourth group urged rejection of both. In the end, the Agency retained the two core definitions, but clarified that an arrangement could meet the definition if either set of criteria is satisfied. The Agency

rejected comments recommending that CMS define what types of evidence or outcomes would be acceptable, opting to leave those details to the contracting parties (manufacturers, plans, patients and providers).

One of the more controversial concepts CMS had proposed was that the price of a VBP arrangement be "substantially" based upon an evidence-based or outcomes-based measure. In the Proposed Rule, CMS had suggested that "substantially" could mean 90% or greater than 50%. The Final Rule declined to set any specific threshold, permitting flexibility in contracting, while noting that as CMS gained experience in the field it may in the future clarify the term in sub-regulatory guidance.

The Agency acknowledged concerns that a VBP arrangement could result in calculated state rebates below the statutory minimums (i.e, 13%, 17.1% and 23.1%). The Final Rule clarified that states would never receive less than these percentages as a rebate, even under VBP arrangements.

As important as the flexibility that CMS adopted in its definition were the criteria suggested by commenters that the Agency rejected. CMS declined to adopt definitions of "substantially" that referred to work productivity, patient satisfaction with treatment, medical spending, healthcare utilization like reduction in hospitalization rates and emergency department visits, laboratory tests or screenings or use of electronic health records, reduced pricing for an individual patient for greater-than-expected usage based on available evidence, discounts based on the achievement of patient-testing benchmarks, patient-reported measures that signal improvement in patient health or quality of life as an indicator of a drug's value and expected therapeutic, clinical, or patient centric value in a population, and even drug to drug comparisons. CMS was clear that while it would not adopt these proposed definitions to preserve flexibility in VBP arrangements, they could be used as part of a set of outcome measures by contracting parties. The Agency did, however, make clear that measures that would unlawfully discriminate on the basis of disability or age in violation of federal anti-discrimination laws, including the use of Qualified Life Adjusted Year (QALY) metrics, are not appropriate for use. The Agency also noted that VBP agreements in effect before the Final Rule that do not meet the new regulatory definition of a VBP arrangement would need to be restructured to take advantage of the pricing rules set out in the Final Rule.

Several commenters suggested that CMS mandate VBP transparency requirements, including making commercial VBP contracts directly available to the states, making the details of the arrangements available to states, and having CMS collect contracting information and provide it to states and others in public reports. CMS resisted these ideas, indicating that states were not required to participate in VBP arrangements and that only the different "Best Prices" would be required to be provided. CMS also clarified that, unlike state supplemental rebate agreements, it would not pre-review state VBP arrangements for compliance purposes.

Commenters suggested that CMS promulgate rules around issues such as increased data collection responsibilities, monitoring burden, patient-specific portability challenges, and patient monitoring associated with the outcomes or evidence-based evaluation under the VBP arrangement. CMS declined to do so, although it noted the importance of these issues and recommended that manufacturers, plans, and Medicaid programs consider these issues when contracting.

Price Reporting for VBP Arrangements:

CMS did not modify reporting of Average Manufacturer Price ("AMP") in the context of VBP arrangements. AMP, including base date AMP, will take into account the full price paid to the manufacturer even if the payment is made in installments. That is, a unit sold for $100 in month 1 will count in AMP as a $100 sale in month 1 even if the payer pays $25 per quarter for four quarters. Installment payments not made due to outcomes failures, however, will be treated as lagged price concessions and included in AMP's 12-month rolling average methodology. 85 Fed. Reg. 87019.

Although CMS received numerous creative comments about alternative ways in which VBP arrangements could be excluded or otherwise included in Best Price calculations, the Agency opted to stay with its original proposal and require the reporting of "multiple" Best Prices: one for non-VBP arrangements, and one for each discrete VBP arrangement.

CMS considered, but ultimately rejected, allowing "payment over time" pricing that was not contingent on outcomes to meet the definition of a VBP arrangement. Similarly, CMS considered how to treat "warranty" arrangements where a premium was paid to a third party to guarantee a particular financial outcome. Surprisingly, CMS opted to require the manufacturer premium payment to be included in Best Price calculations, although the warranty payment made by the third party to a provider or plan in the event that the drug did not meet certain clinical or performance measures is exempt from Best Price and AMP calculations. 85 Fed. Reg. 87020.

As was expected, CMS received many comments on its controversial proposal to require that multiple Best Prices be reported. CMS analyzed its statutory and regulatory authority to permit the concept, and as noted above, adopted the Proposed Rule without material modification. Many comments challenged the complexity and costs associated with creating VBP models, but CMS noted that these arrangements were voluntary for manufacturers, plans, providers, and states, and expressed its view that if the arrangements were too complex or costly they would not have to be used.

CMS further noted that states that enter into VBP arrangements with manufacturers as part of the multiple Best Price approach would not be required to seek State Plan Amendments for these contracts, as these arrangements are not CMS-authorized Supplemental Rebate Agreements. Any VBP arrangements that propose to exclude pricing from Best Price, however, would still be viewed by CMS as Supplemental Rebate Agreements and require a State Plan Amendment.

CMS rejected concerns that VBP arrangements would contribute to increasing drug prices, noting that the MDRP inflation penalty would still apply to drugs in VBP arrangements. Importantly, CMS clarified that all VBP Best Prices reported to States would still remain confidential under the provisions of Section 1927(b)(3)(C).

Summary: The VBP provisions of the Final Rule represent a major opportunity for manufacturers who wish to pursue novel pricing arrangements. For the first time, manufacturers who were unable to adopt bundled pricing arrangements to accommodate value-based arrangements in drug pricing will be able to able to enter into Best Price-aware VBP arrangements. CMS has given manufacturers, patients and plans significant flexibility to design their VBP arrangements. We expect a wide range of arrangements to emerge in the coming years, implementing a number of different VBP models. The details of actual price reporting and its impact on MDRP liability will be critical to manufacturers, and we will monitor CMS's sub-regulatory guidance announcements for specifics on how reporting will occur.

2. New Formulations and the Alternative URA

As described in our June 23 Client Alert, CMS's proposed plan to expand the definition of "new formulation" would have highly consequential effects on many drug manufacturers. The Final Rule makes good on that plan. Manufacturers of oral solid dosage form products will very likely see increased MDRP rebates and lower 340B ceiling prices on many NDCs beginning January 1, 2022, when application of the alternative URA calculation is significantly expanded.

CMS repeatedly claims that its changes to the definition of "new formulation" will not "categorically" increase rebate liability. Indeed, the agency suggests that its new "clarification" is a boon to manufacturers that merely "assist[s]… in ensuring their compliance with Section 1927(c)(2)(C) of the Act." There is no doubt, however, that increased Medicaid URAs are the intended and natural consequence of this rule. We foresee significant changes to lifecycle

planning, perhaps even reduced enthusiasm for new strengths and dosage forms, as a result of these changes to the MDRP regulations.

The Final Rule expands the definition of a "new formulation" subject to the alternative URA calculation. New formulations will include any "change to [a] drug, including, but not limited to: an extended release formulation or other *change in release mechanism*, a change in *dosage form, strength, route of administration*, or *ingredients*." 42 C.F.R. §447.502 (emphasis added). The Proposed Rule also had included new combination drugs, new drug/device combinations, and new indications in its redefinition of "new formulation," but the Final Rule appropriately does not include them.

Many commenters argued that expanding "new formulation" to include new strengths, dosage forms, routes of administration, and ingredients went beyond the intent of Congress. Legislative history shows that Congress intended the line extension provision to apply only to "slight alterations" of existing products, and the proposed new line extensions were often major changes or significant alterations. CMS brushed that concern aside:

> "[T]he statute does not require that in order for a drug to be a line extension, the change to a drug must be a slight alteration. Had Congress intended to limit the definition of line extension to only those drugs for which a slight alteration had been made, we believe they would have included that requirement in the statute… Congress could have included language that excluded new formulations that were innovative or provided significant benefits to patients…. [S]uch language was not included in the statute…" 85 Fed. Reg. 87033.

CMS appropriately recognized that under the Medicaid statute, a new strength or dosage form of a drug is entitled to a new base date AMP. We would argue that this explicit statutory arrangement entitles new strengths and new dosage forms to be beyond the reach of an aggressive interpretation of the vague alternative URA provision. The former insulates new strengths and dosage forms from the inflation penalties of earlier products; the latter ties products' additional rebates to one another. The Final Rule, however, embraces an expansion of "new formulation" to include new strengths and dosage forms, explicitly as a means of disincentivizing manufacturer avoidance of inflation-based rebate liability. Whether courts will agree with CMS's logic remains to be seen.

Despite the fact that the alternative URA calculation requires consideration of all strengths of the original drug, the Final Rule makes new strengths themselves line extensions. Commenters rightly noted the circular tension of conflating calculation inputs and results. Offering staff to provide operational support, the Final Rule states that CMS understands "that the statutory requirement to apply the alternative rebate calculation to a drug that is a line extension may be operationally confusing and difficult, but we do not believe that that it is illogical or impossible."

It is important to note that the initial brand name listed drug used to calculate the alternative URA is not necessarily the *first* version of a drug to enter the market (the "truly original drug," in the Final Rule). Instead,

> "[t]o apply the alternative formula … for each line extension and rebate period, the manufacturer must determine which NDC represents the initial brand name listed drug that will be used to calculate the alternative URA. First, the manufacturer must identify *all* potential initial brand name listed drugs by their respective NDCs by considering *all* strengths of the initial brand name listed drug…. In order to perform the calculation as instructed, *all* strengths of potential initial drugs must be considered, regardless of the chronology of a drug's approval, or date first marketed." 85 Fed. Reg. 87003

The initial brand name listed drug may therefore change quarter-to-quarter for a line extension. Implementation of the Final Rule will be operationally complex and burdensome.

The Final Rule reaffirms that a line extension is only subject to the alternative URA if an initial brand name listed drug is manufactured by the labeler of the line extension, or by a company in a "corporate relationship" with the labeler of

the line extension. CMS refused to define "in a corporate relationship," so manufacturers will have to develop and apply reasonable assumptions in this area.

The Final Rule codifies CMS's interpretation that for the alternative URA to apply, only the initial brand name listed drug—and not the line extension product—must be an oral solid dosage form (specifically, an orally administered product that is neither a gas nor a liquid when it enters the oral cavity). Thus, a liquid solution dosage form may be a line extension of a pill or tablet.

These definitional changes are applicable prospectively from January 1, 2022. Until that time, CMS writes, manufacturers are to rely on reasonable assumptions to determine if their products are line extensions (one wonders, however, if the publication of this Final Rule at the end of 2020 will sway a subsequent determination of what assumptions were "reasonable" in 2021). Importantly, this prospective application applies only to when the *rebate calculation* is conducted, not to when initial brand name listed drugs or line extensions are *introduced*. Specifically:

> "We do not agree that only products introduced on or after the effective date of the final rule should be subject to the [final rule requirements]…. Although manufacturers will not be required to apply the regulatory definitions and oral solid dosage form requirement when calculating rebates for periods prior to the effective date of the final rule, the definitions become effective for all drugs that are on the market as of and following that effective date." 85 Fed. Reg. 87045.

Thus, beginning with the first quarter of 2022, products introduced years ago may be deemed to be initial brand name listed drugs and line extensions subject to the alternative URA. Short of divesting or withdrawing one or both of the products from the market before 2022, manufacturers may not be able to avoid the increased MDRP and 340B liability that flows from these amendments to the regulations.

3. CMS-Authorized State Supplemental Rebate Agreements

The Final Rule prohibits manufacturers from excluding rebates paid to Medicaid MCOs under certain state supplemental rebate agreements from calculations of AMP, 5i AMP, and Best Price. The Rule accomplishes this change by creating a new definition of "CMS-Authorized State Supplemental Rebate Agreement" that would specifically exclude any supplemental rebate agreement between a manufacturer and Medicaid MCO that results in rebates that are not paid directly to the state under a CMS-authorized State Plan Amendment (SPA). Previously, manufacturers were permitted to make reasonable assumptions about whether to exclude supplemental rebates paid to Medicaid MCOs from AMP, 5i AMP, and Best Price as discounts "arising under" Section 1927. Many manufacturers assumed that all rebates paid under supplemental rebate agreements were excludable. CMS held in the Final Rule that supplemental rebates paid outside of a CMS-authorized SRA are not shared with the state or eventually used to offset state drug expenditures prior to claiming FFP from the federal government. As such, CMS argues that such rebates are not deserving of AMP, 5i AMP, and Best Price exclusion.

Importantly, in the Final Rule, CMS clarifies that the new definition of "CMS-Authorized State Supplemental Rebate Agreement" applies equally to both VBP SRAs and traditional non-VBP SRAs. Once CMS approves either template, rebates provided for under agreements entered into between states and manufacturers are exempt from Best Price.

Manufacturers should be aware that common arrangements in place today with Medicaid MCOs may result in erosion of Best Price and increased Medicaid rebate liability. Before these provisions become effective on January 1, 2022, manufacturers should analyze existing Medicaid SRAs and ensure that any agreements that would negatively impact Best Price are approved under a CMS-authorized SPA.

4. Patient Assistance Program Exclusions and PBM Accumulator Programs

The Final Rule adopts the changes to the Best Price and AMP exclusions for PAP payments as proposed in June. Specifically, those exclusions (at 42 C.F.R. §§447.504(c), 504(e), and 505(c)) are modified to require that manufacturers *ensure* that the entire value of their patient assistance be passed on to patients in order to be excluded from Best Price and AMP. To give industry adequate time to develop implementation strategies, the effective date of these changes is delayed two years, to **January 1, 2023**.

CMS appears to be deeply committed to requiring manufacturers to bear responsibility for how plans and PBMs penalize patients who benefit from manufacturer assistance. Each of dozens of thoughtful policy and implementation objections to the proposed rule provided in comments was summarily rejected. Given a two-year ramp-up, CMS believes, manufacturers will be able to figure out a way to ensure that patient assistance remains with patients, no matter what plans or PBMs might invent to thwart them. Whether this is indeed attainable—or if manufacturers will significantly scale back patient assistance—remains to be seen.

The Final Rule groups comments received about this proposal into five categories: impact on patients, CMS's legal authority, existence of mechanisms to assist manufacturers with compliance, viability of manufacturer assistance programs, and impact on other federal programs and policies. In response to each and every comment critical of the proposal, CMS rejected the concerns expressed, asserted its authority to establish the "ensure" standard, and expressed a belief that manufacturers can contract their way to compliance (despite imposing no parallel obligations on PBMs or plans). In CMS's view, the rule does not create an insurmountable burden for manufacturers, because they are already required to hold a reasonable belief that PAP dollars are not price concessions to any entity other than the patient.

Many of CMS's responses to reasonable objections to the "ensure" proposal border on the naïve, but several detail solutions that the Agency would support. For example, CMS suggests contracting with third parties to track assistance when provided at the point of sale ("switches and brokers"), or changing the structure of patient assistance to require full-pay by patients at the point of sale that is then offset by direct manufacturer payments to patients. CMS even goes so far as to promote the latter approach because it "will allow a patient's cost sharing at the point of sale to apply to the patient's deductible *because the pharmacy and PBM will be unable to identify that the patient used manufacturer-sponsored assistance."* 85 Fed. Reg. 87053 (emphasis added). Are we at the point where manufacturers are now obliged to better conceal patient assistance from players that would steal it from patients, or be penalized for the theft?

CMS affirmatively rejected an option under which patients would be required to attest to the lack of an accumulator in order to be eligible for patient assistance. "Prohibiting patients from accepting assistance unless they know that an accumulator program does not apply in their plan places undue burden on patients." 85 Fed. Reg. 87055.

5. Authorized Generics and Standard AMP

The Final Rule adopts the changes to 42 C.F.R. §§ 447.502, 504 and 506 proposed in June. In short, in accordance with statutory changes made in 2019, manufacturers must calculate separate AMPs for brand drugs and authorized generics. For a detailed discussion of those changes, please refer to our Client Alert. The comments and responses published in the Final Rule do not add much to our understanding of the changes, with the exception of CMS' "clarifying revision" to the existing regulatory definition of "secondary manufacturer." The Agency removed the language "but does not hold the NDA" from the definition, noting that the Medicaid statute does not "distinguish among the different business or corporate relationships, if any, that might exist among the manufacturer of the brand name drug and the entity that that manufacturer approves, allows, or otherwise permits to sell such drug under the same NDA," and "this is likely because in some cases, the primary and secondary manufacturers are one in the same." 85 Fed. Reg. 87060. As is the case with the line extension provisions, CMS does not define "business or corporate relationships." This clears the path for AMPs of authorized generics to be calculated independently from

those of brand drugs, even if the secondary manufacturer has a corporate relationship with the primary manufacturer.

CMS also disagreed with commenters that the Medicaid statute continues to support the blending of AG sales and brand sales when calculating AMP in certain situations. CMS indicated that it has also interpreted the statute to apply beyond AG cases to other situations where the manufacturer approves, allows or otherwise permits the drug to be sold under the manufacturer's NDA, citing as an example its recent guidance on importation of drugs under Section 801 of the Federal Food, Drug, and Cosmetic Act. CMS does not address whether there might be any (non-AG) situations where it would view blending of AMP across NDC-9s as permissible.

The Final Rule does not address the concern raised in our Client Alert regarding the breadth of the definition of "authorized generic," or the distinction in AMP treatment between authorized generics and other situations in which one manufacturer might market two versions of the same product under different NDCs.

6. Other Final Rule Provisions Align MDRP Regulations with Statutory Language

In the Final Rule, CMS amends the existing regulatory definitions of "innovator multiple source drug," "multiple source drug," and "single source drug" to align with recently updated statutory definitions in the MDRP statute. As discussed in detail in our earlier Client Alert, Congress amended the MDRP statute to address drug misclassification in the Medicaid program.

7. State Submissions of Drug Utilization Data

State Medicaid programs are required to submit accurate and up-to-date reports to CMS reflecting the reimbursed unit data for which they have sought rebates from manufacturers. These reports are known as "State Drug Utilization Data" reports, or "SDUDs." According to CMS, some states have been submitting inaccurate, unedited, or inconsistent copies to CMS, resulting in discrepancies that have prevented CMS from accurately accounting for rebates billed in the MDRP. As a result, CMS is requiring states to identify and exclude utilization of certain drugs, update CMS of data changes, and certify, on a quarterly basis, that SDUD data submitted to CMS is identical to information submitted to manufacturers.

Importantly, CMS has found that some states may have overbilled manufacturers because they do not have sufficient edits in place to detect, reject, and investigate SDUD outliers, which may distort manufacturer rebate liability.

8. Changes to State Medicaid Program Opioid Drug Utilization Review Programs

CMS changed certain state Medicaid Program opioid Drug Utilization Review Programs addressed at 42 C.F.R. Parts 438 and 456 that are beyond the scope of this Client Alert. If you have questions about these areas, please contact one of the authors and we will direct you to a King & Spalding subject matter expert.

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We at King & Spalding stand ready to help you understand and interpret the Final Rule, and to apply it to your commercial, government price reporting, and reimbursement practices and strategies.

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[1] CMS also noted that it was in the midst of overhauling the MDRP reporting database for other reasons, and expected a new system to be operational in July 2021. Rule at 34 ("We are also developing a new Medicaid Drug Program (MDP) system that will replace both the current Drug Data Reporting (DDR) and Medicaid Drug Reporting (MDR) systems, and this new system is expected to be fully functional in July 2021").