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Client Alert

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Major Shift in Best Price Proposed in Grab Bag of MDRP Reforms

The title of CMS's May 26 proposed rule, "Misclassification of Drugs, Program Administration and Program Integrity Updates Under the MDRP," buries the lede. Amid *twenty* Medicaid Drug Rebate Program-related proposals—some consequential, others mechanical—lies one that would require manufacturers to follow-the-pill and aggregate independent discounts when determining Best Price, reversing thirty years' experience with the critical government pricing metric. There is truly something for everyone in the 59-page proposed rule. But it is the government's position that discounts to independent entities must be stacked that strikes us as the most aggressive and impactful of the bunch (see number 8, below).

The proposed rule (88 Fed. Reg. 34,238 (May 26, 2023)) presents for comment a great variety of ideas to modify the MDRP, and in no discernible order. It appears that CMS has been keeping a list for the last three years of items it hadn't had time to get around to, until now. We summarize each of the proposals below for your review, including those that would punish drug misclassification; expand the definition of "manufacturer" to include all affiliated entities; establish an MFP-like "survey" on high cost Medicaid drugs; and impose limitations on AMP and Best Price restatements.

Interesting too is what is *not* included in the grab bag: there is no "crack drug" AMP fix, for which the industry has been waiting for years.

Comments on the proposed rule (PR) are due on July 25. This Client Alert is designed to give in-house counsel, government pricing specialists, and market access personnel an at-a-glance overview and initial insight into the PR. As always, we at King & Spalding stand ready to help you understand the proposals, evaluate their implications, and draft persuasive comments for CMS's consideration.

In the order presented in the PR (generally), CMS proposes to:

1. Clarify "Covered Outpatient Drug"
2. Define "Drug Product Information"
3. Limit Manufacturers' Ability to Restate Beyond 12 Quarters
4. Modify "Manufacturer" to Include All Affiliates
5. Define "Market Date"
6. Slightly Modify Definition of N Drug
7. Define "Vaccine" for MDRP Purposes
8. Require Stacking of Concessions to Unaffiliated Entities in Best Price
9. Limit Manufacturers' Ability to Audit State Utilization
10. Impose an Extensive "Survey" on Selected High-Cost Drugs
11. Require Additional Data from States to Change Pharmacy Reimbursement
12. Require States to Collect NDCs on Physician Administered Drugs
13. Provide for Suspension of NDRA for Late Reporting
14. Modify Managed Care Plan Standard Contract Requirements
15. Rescind Accumulator Rule Changes in Light of Court Decision
16. Amend Regulations Relating to Drug Misclassification
17. Conform Regulations to Reflect Removal of URA Cap on January 1, 2024
18. Clarify That Not All "N" Drugs are Noninnovator Multiple Source
19. Request Information on Requiring Diagnosis on Medicaid Script
20. Correct a Coordination of Benefits Regulation Error

Here are our thoughts and suggestions as to each. We hope they are helpful as you model the potential impacts to your business and compliance efforts.

1. Clarify the Definition of COD

The Medicaid statute sets out the definition of "Covered Outpatient Drug." §1927(k)(2). Drugs and biologics that qualify are subject to manufacturer price reporting and rebating and must be covered by state Medicaid programs. The statute affirmatively excludes products provided "as part of, or as incident to and in the same setting as" certain services, but only if "payment may be made under this subchapter as part of payment for the [services] and not as direct reimbursement for the drug." §1927(k)(3).

To address confusion around when a drug is "directly reimbursed," and therefore not subject to the COD exclusion, CMS proposes to add to the regulatory definition of COD the following sentence: "Direct reimbursement for a drug may include both reimbursement for a drug alone, or reimbursement for a drug plus the service, in one inclusive payment if the drug and the itemized cost of the drug are separately identified on the claim." See p. 34,291.

Manufacturers regularly wonder whether products administered incident to the enumerated services qualify for the COD exclusion. CMS's proposal addresses when a product is subject to direct reimbursement: if the drug and its cost are separately identified on a provider's Medicaid claim form. But that operational clarification does not provide a means by which manufacturers can know if direct reimbursement *may not* be made by any state, which seems to be a prerequisite to claiming the exclusion. Manufacturers with products stuck in this quandary may want to press CMS for a more useful change to the regulation.

2. Define "Drug Product Information"

The Medicaid statute requires that participating manufacturers submit AMP, Best Price, ASP, and other data monthly and quarterly. It also requires that we submit and certify "drug product information." §1927(b)(3)(A)(v). This drug product information (often called "baseline information") is not specifically identified in the statute or regulation. CMS guidance (in the form of Labeler Guides and Program Releases) lists a number of pieces of drug-specific information subject to this reporting requirement.

CMS proposes to define "drug pricing information" at §447.502 to include "National Drug Code (NDC), drug name, units per package size (UPPS), drug category ("S", "I", "N"), unit type (for example, TAB, CAP, ML, EA), drug product type (prescription, over-the-counter), base date AMP, therapeutic equivalent code (TEC), line extension indicator, 5i indicator and route of administration, if applicable, FDA approval date, FDA application number or OTC monograph citation as applicable, market date, COD status, and any other information deemed necessary by the agency to perform accurate unit rebate amount (URA) calculations." *See* p. 34,252. Generally, CMS points out, manufacturers cannot make changes to drug product information on their own but must seek the assistance of CMS to execute revisions. *Id.*

This proposal seems innocuous because it generally tracks the baseline information already required in the MDP system. However, the catchall at the end raises the possibility of mischief. By codifying the required data fields in regulation, erroneous or late reporting of which could result in civil monetary penalties or termination from the program, CMS increases the pressure on manufacturers to get them right. But by leaving the list open ended, and arguably not subject to subsequent notice and comment rulemaking, one wonders if CMS will inappropriately try to enlarge it.

3. Limit Manufacturers' Ability to Restate Beyond 12 Quarters

MDRP regulations generally limit a manufacturer's ability to restate AMP and Best Price to a 12 quarter/36 month window. §447.510. There are several exceptions to this rule. Relevant here, CMS will consider changes to pricing outside the 12 quarter window that arise out of a manufacturer's internal investigation. Evidently, manufacturers' "broad interpretation" of the internal investigation exception has led to more submissions than CMS wants to consider.

CMS proposes to require that any request to reopen MDP beyond the 12 quarter window based on the internal investigation exception must include "a finding made by the manufacturer of fraud, abuse, or violation of law or regulation" in support. *See* p. 34,254. This crime/fraud requirement is intended to crowd out benign—but equally meritorious—reasons for seeking restatement: "[m]anufacturers should not use the internal investigation exception to permit restatements to allow manufacturers to apply a different methodology or reasonable assumption to determine AMP and best price to its favor when the methodology originally applied was consistent with statute and regulation…" *Id.*

It is well and good to set reasonable requirements around when CMS will and will not approve restatements. What is strange about this proposal is that CMS assumes that requests to restate only occur when a manufacturer seeks recoupment from states, when the restatement would be "to its favor." How does CMS square its demand for admissions of fraud or violations of law with attempts to restate *in the states' favor*? Are those not barred, or even required, because they would benefit the government? Or what about final resolution of disputes with pricing-eligible entities that affect historic submissions, but do not amount to fraud/violations of law? Or when errors are discovered that

are not fraud or lawbreaking but nonetheless undermine the accuracy of the certification previously made? There is nothing in the PR regarding restatement of base date AMP to match prospective changes in AMP methodology, which can occur with no fraud or violation of law. CMS proposes to create a standard of self-incrimination that acts as a bar to reasonable requests to restate complicated pricing metrics (but only, apparently, if the government does not benefit financially). Internal investigations are costly, difficult affairs consistent with compliant participation in the MDRP that should be encouraged, not punished. They are not pre-ordained to come out one way or another and are, in our experience, just as likely to result in payments owed to the government as the other way around.

4. Modify "Manufacturer" to Include All Affiliates

The cornerstone of the MDRP "grand bargain" is that in exchange for rebates, states will provide coverage for all of a participating manufacturer's CODs. "[A] manufacturer has to be 'all in' for all its drugs, or 'all out.'" *See* p. 34,255. Central to this proposition is understanding what it means to be a "participating manufacturer," particularly as it relates to multiple labeler codes held by a single or affiliated corporate entities. There is currently no binding definition of what level of corporate relationship defines a "single manufacturer," leading some to wonder if entities within an attenuated corporate structure could take different positions on MDRP participation.

The PR sets out a very broad definition of "manufacturer," meant to bind together in participation (or non-participation) far-flung labelers or entities. Specifically, CMS proposes to add the following at §447.502: "the term 'manufacturer' means that all associated entities of the manufacturer that sell prescription drugs, including, but not limited to, owned, acquired, affiliates, brother or sister corporations, operating subsidiaries, franchises, business segments, part of holding companies, divisions, or entities under common corporate ownership or control, must each maintain an effectuated rebate agreement." Further, the PR proposes to require manufacturers to have signed rebate agreements consistent with that definition (at §447.510(h)(1)) and to have such agreements in place very shortly after any acquisition, purchase, asset transfer, or creation of a subsidiary has occurred (at §447.510(h)(1)).

Given the rapidly increasing costs of participating in the MDRP, it is not surprising that CMS would propose to firmly tie as many labelers into rebate requirements as possible. A good case could be made, however, that entities that are truly independent of one another, even if they are related in some way, should be entitled to determine for themselves whether or not to participate in the Program. The MDRP is a *voluntary* program, after all. Manufacturers may want to press CMS on some of its language: what constitutes an "affiliate"? Or a "franchise" of a drug manufacturer? What does it mean to be "part" of a holding company? Is it reasonable to compel participation by all sibling entities if only one (and not the parent) chooses to be part of the MDRP? Surely there must be adequate objective criteria of independence that would permit manufacturers greater certainty as they organize their businesses.

5. Define "Market Date"

When a COD is first marketed is an important piece of baseline information, as it determines base date AMP and therefore the inflation penalty portion of the COD's Medicaid rebate. The market date follows the dosage form and strength of the product for its lifetime, whatever manufacturer may sell it. For these reasons, getting the market date right is an important part of MDRP compliance.

CMS proposes to add a definition of "market date" to §447.502: "the date on which the covered outpatient drug was first sold by any manufacturer," rejecting "first available for sale," which CMS thinks is too susceptible to varying interpretation. The PR seeks comment on what would qualify as being "sold," suggesting that it be read to men "transferred (or in transit) to a purchasing entity." *See* p. 34,257.

This proposal strikes us as thoughtful and generally benign, intended to provide clarity without pushing an agenda. The preamble to the PR is confusing, however, because it suggests a manufacturer without *AMP-eligible* sales might need to

resort to reasonable assumptions, where the text of the proposed definition does not distinguish between first AMP-eligible sales and first AMP-ineligible sales. *Id.* The text of the regulation would lead us to think that a single sale to a 340B covered entity, for example, would set the market date, but the preamble suggests not. If there is a reasoned distinction to be found based on the character of the "purchasing entity," it is not articulated in the PR. In addition, manufacturers with concerns about CMS's recent proposal to ignore generic or biosimilar competition for an MFP eligible product (*see* March 15, 2023, Medicare Drug Price Negotiation Program guidance memorandum) might find a way to leverage this proposed bright-line definition of "Market Date."

6. Slightly Modify Definition of N Drug

The current regulatory definition of a noninnovator multiple source drug (an "N" drug) includes "A covered outpatient drug that entered the market before 1962 that *was not originally* marketed under an NDA." §447.502 (emphasis added).

When CMS last amended the definition of covered outpatient drug in 2020 to conform to changes in the statute relating to the "narrow exception," it removed references to marketing under an "original NDA" in the single source ("S") and innovator multiple source ("I") drug definitions. The PR seeks to make the same correction in the N definition. If finalized, the regulatory language would read: "A covered outpatient drug that entered the market before 1962 that *is not* marketed under an NDA." Emphasis added.

This change is ministerial and likely not consequential. It is designed to align the structure of the statutory and regulatory definitions of an I drug. "Original NDA" is not a concept regularly tripping up manufacturers of N drugs.

7. Define "Vaccine" for MDRP Purposes

"Vaccines" are specifically excluded from the statutory definition of COD for purposes of the MDRP. §1927(k)(2)(b). State Medicaid coverage for vaccines is generally optional, and manufacturers of vaccines need not price report or pay rebates on vaccines. There is no definition of the term "vaccine" in any HHS agency statute or regulation (according to CMS). *See* p. 34,258. The PR claims that when the MDRP was created, only "preventive vaccines" were on the market. In recent years, so-called "therapeutic vaccines"— biological products intended to induce antigen-specific immune responses to established diseases—have been introduced that treat, rather than prevent, disease. *Id.*

CMS proposes to add a definition of "vaccine" to §447.502 to ensure (i) that only the "appropriate" products are excluded from the definition of COD, (ii) that manufacturers have certainty about their reporting and rebating obligations, and (iii) that Medicaid beneficiaries have access to important non-"vaccine" therapies. Specifically, CMS seeks to define "vaccine" to be "a product that is [1] administered prophylactically to induce active, antigen-specific immunity for the prevention of one or more specific infectious diseases and [2] is included in a current or previous FDA published list of vaccines licensed for use in the United States." "Therapeutic vaccines" would not be subject to the COD exclusion.

Manufacturers of immunotherapies and other "therapeutic vaccines" will want to take a close look at evidence that might reflect Congressional intent regarding §1927(k)(2)(b). CMS suggests that its proposal to limit the vaccines subject to the COD exclusion follows all known sources of legislative and regulatory text and history. If it is important to claim that a therapeutic vaccine is not a COD, manufacturers must marshal support to rebut CMS's claim that this distinction is the natural interpretation of the statute's text. In addition, such a manufacturer will want to review the FDA-published list of vaccines to see if its methodology departs from that set out in the PR.

8. Require Stacking of Concessions to Unaffiliated Entities in Best Price

The Medicaid statute defines Best Price to be "the lowest price available from the manufacturer during the rebate period to *any*" Best Price eligible entity. §1927(c)(1)(C)(i)(emphasis added). The current regulation mirrors that language. §477.505(a). For over 30 years, Best Price has been understood to be the lowest price available to any individual entity.

"Stacking" of discounts is required only when multiple concessions are extended to the same entity on the same unit of product. Where multiple concessions are extended on the same unit to separate entities (e.g., they are not passed through to a common entity), they are *not* aggregated because the measurement of Best Price is at the "any entity" level, not the manufacturer level. This principle was very clearly articulated by a panel of the Fourth Circuit in the *Sheldon v. Allergan* case. 24 F.4th 340 (4th Cir. 2022)(vacated *en banc*, petition for cert. pending).

The PR seeks to reverse this interpretation, requiring manufacturers to follow-the-pill and stack every discount in the chain of purchase or payment into one single Best Price eligible price point, even if the recipients of those concessions are entirely independent of one another. CMS makes this momentous case in a scant seven paragraphs. Specifically, CMS would revise §477.505(d)(3) as follows:

> The manufacturer must adjust the best price for a drug for a rebate period if cumulative discounts, rebates, or other arrangements to best price eligible entities subsequently adjust the price~~s~~ available from the manufacturer ~~to the extent that such c~~. Cumulative discounts, rebates, or other arrangements ~~are not excluded from the determination of best price by statute or regulation~~ must be stacked to determine a final price realized by the manufacturer for a covered outpatient drug, including discounts, rebates, or other arrangements provided to different best price eligible entities.

Note how the proposed revision creates a new perspective on Best Price that is not present in the statute. By adding "realized by the manufacturer," the PR attempts to reorient Best Price around its aggregated conception, rather than follow the statutory language to determine the Best Price to "any" single entity. It is disappointing that CMS would try to rewrite Best Price in this way, particularly during the pendency of the cert petition in the *Sheldon* case. Manufacturers should give careful thought to the economic, legal, and operational implications were such a rule to become final. CMS should consider the perverse incentive of this proposal, which if finalized would encourage manufacturers to pull back on discounts throughout the supply chain. Are fewer and smaller drug discounts the legacy this administration wants to leave behind? Between this proposal and the unlamentedly late, wrongheaded accumulator rule, one could be forgiven for believing so.

9. Limit Manufacturers' Ability to Audit State Utilization

The Medicaid statute lets manufacturers dispute and audit state rebate invoices and supporting information. §1927(b)(2)(B). There is currently no regulatory (or contractual) limitation on the time between receipt of the invoice and initiation of a manufacturer audit. CMS guidance suggests that manufacturers should dispute state invoices within 38 days of receipt. See State Release No. 45 (Nov. 30, 1994). CMS claims that states have received new disputes on invoices from over 30 years ago. *See* p. 34,267.

The PR would add a new subparagraph to §447.510 limiting manufacturers' right to initiate audits and other processes to seek adjustments to utilization data to 12 quarters from the last day of the quarter of the state invoice. *See* p. 34,267. This limitation would only apply to disputes regarding drug utilization data; other appropriate change requests (e.g., COD status change requests, Market Date change requests) would not be subject to the restriction.

On its face, a 12 quarter limitation on *initiating* new audits seems reasonable if the clock only begins to run with the receipt by the manufacturer of the invoice. Manufacturers have reported receiving rebate invoices relating to decades-old utilization (contrary to the 60-day requirement in §1927(b)(2)(A) and §447.511(a)). Perhaps the better use of CMS's time would be to develop a mechanism to address that violation of the statute and regulation. Regardless, manufacturers should consult with their rebate invoice processing teams to consider whether commenting on this proposal is warranted.

10. Impose an Extensive "Survey" on Selected High Cost Drugs

CMS is authorized by the Medicaid statute to survey (i) wholesalers, and (ii) manufacturers that directly distribute their CODs, to verify the prices reported to the government (AMP, Best Price, ASP, WAC). §1927(b)(3)(B). The purpose of the surveys is to confirm the reported prices and, according to the PR, to understand if the reimbursements paid based on those prices are adequate and appropriate. "[T]here is little or no public information available about the factors that influence the pricing of drugs dispensed in non-retail community pharmacy settings in Medicaid, the prices that pharmacies or wholesalers pay for these CODs, whether the prices or charges bear any relationship to the cost components of the COD, or whether the costs of distribution or preparation methods are included in the prices reported to us." *See* p. 34,269-70.

Despite the limited purpose of the statutory survey requirement, CMS proposes in the PR to annually collect, explicitly under the authority of §1927(b)(3)(B), very extensive pricing and other information from selected high-cost MDRP-participating manufacturers. Specifically, CMS proposes a new §447.510(k) that would identify high-cost CODs (under a number of different criteria), exclude CODs of manufacturers that provide voluntary additional discounts (those with a "willingness to negotiate"), and exclude CODs of manufacturers who have engaged in other "effort[s] to lower drug prices for the Medicaid program" to arrive at a list of 10 drugs to survey. *See* p. 34,271-72. Selected CODs would be subjected to an extensive "drug price verification survey" demanding (i) pricing, charges, distribution, and utilization information, (ii) product and clinical information, (iii) costs of production, research, and marketing, and (iv) other information as determined by the Secretary. *See* p. 34,273. Non-proprietary data will be made available to the states and the public, and CMS may "request" that a manufacturer address the published information "in a public forum." Manufacturers that refuse to provide demanded information would be subject to civil monetary penalties. *Id.*

CMS Medicaid appears to be taking a page from its colleagues in Medicare, trying to impose an invasive price justification information demand on manufacturers of products deemed to be "high cost" if they have not shown an appropriately eager willingness to provide greater discounts to Medicaid than the law demands. At least on the Medicare side of the house, CMS has the patina of Congressional authority to engage in this kind of shame and blame in the "maximum fair price" provisions of the SSA. No such authority exists in Medicaid. The PR attempts to significantly expand the purpose of the statutory survey provision to construct an MFP-type mechanism to force manufacturers to "voluntarily" provide supplemental rebates and other Medicaid concessions. This proposal goes far beyond the verification of the accuracy of reported pricing. Manufacturers of "high cost" Medicaid products will want to study this proposal closely and marshal arguments in opposition in their comments.

11. Require Additional Data from States to Change Pharmacy Reimbursement

State Medicaid agencies must ensure that their payments to dispensing pharmacies are sufficient to enlist enough providers to serve their populations. §1902(a)(30)(A). Federal Medicaid regulations require pharmacy reimbursement to consist of (i) ingredient cost (based on actual acquisition cost), and (ii) a professional dispensing fee. §447.502, §447.512, and §447.518.

CMS proposes to add new subpart §447.518(d) to require states to provide more thoughtful and extensive data to CMS when proposing changes to the state's ingredient costs or professional dispensing fees. *See* pp. 34,273-75. States would have to, for example, periodically assess whether current rates being paid to pharmacies reflect current costs and could not rely on general market-based research to establish dispensing fee amounts.

This requirement does not seem unreasonable. Manufacturers that have faced difficulty obtaining adequate state pharmacy reimbursement for their products may be heartened by the proposed change.

12. Require States to Collect NDCs on Physician Administered Drugs

Physician-administered drugs, like self-administered drugs, may be CODs, subject to manufacturer rebates. §1927(k)(2)-(3). For many years, however, states did not require from providers, and did not collect, NDC-specific information on physician-administered CODs. Because of this, states were unable to submit utilization for rebates on these drugs. In 2005 Congress began a slow program to incentivize collection of NDC data such that rebates could be sought on physician-administered drugs, denying states Federal matching payments as an incentive. See pp. 34,275-76.

CMS proposes to push the states even harder by affirmatively requiring that providers (including those reporting utilization to managed care plans) identify NDC numbers when submitting claims for physician-administered CODs. This will let states secure Federal Financial Participation and manufacturer rebates on those drugs. CMS proposes to continue to annually publish the list of the top 20 multiple source physician administered drugs (by Medicaid utilization).

13. Provide for Suspension of NDRA for Late Reporting

The MDRP statute permits the government to fine and suspend manufacturers that do not timely provide price and drug product information to CMS. §1927(b)(3)(C)(i).

CMS proposes to rename ("Requirements and Penalties for Manufacturers") and add a new subparagraph to §447.510 describing the process by which a manufacturer's NDRA would be suspended due to late reporting. Specifically, if the data and information is not reported and certified within the 30 day deadlines, CMS will inform the manufacturer and set a new deadline to come into compliance. If the manufacturer has not complied within 90 calendar days of that notice, suspension will occur. The suspension will be lifted only after all required information is received and reviewed (no earlier than after 30 days' suspension), and continued suspension could result in termination of the NDRA for cause. Here's the interesting kicker: any suspension under this provision will deny the manufacturer Medicaid coverage, but not remove its 340B obligations. CMS gives no rationale for this position other than to say, "while suspended for purposes of the MDRP, the Medicaid drug rebate agreement with the manufacturer would remain in effect for purposes of Medicare Part B reimbursement and the 340B Drug Pricing Program." *See* p. 34,264.

In general, spelling out an enforcement mechanism for recalcitrant manufacturers is a good thing. In addition to questioning CMS's belief that 340B obligations remain during a period of suspension from the MDRP, however, manufacturers should consider whether the notice provisions are adequate, and sufficient due process is afforded to accused labelers. There is no allowance for dispute resolution with CMS during the 90-day period (for instance, to hammer out disagreements over reasonable assumptions), nor is there any formal opportunity to be heard before suspension kicks in.

14. Modify Managed Care Plan Standard Contract Requirements

CMS proposes to require Medicaid managed care plans to use unique Medicaid-specific BIN, PCN, and group identifiers on all Medicaid managed care beneficiary identification cards. The change would make the MDRP more efficient, CMS claims, and reduce the incidence of 340B duplicate discounts. *See* p. 43,248-49.

The PR further proposes to require that Medicaid managed care plans provide to the state's greater transparency into subcontractor costs, fees, and amounts. This proposal is driven by a concern that PBMs administering MCO plans engage in spread pricing that generates revenue for the PBMs not captured accurately in the plans' medical loss ratios. *See* p. 43,249-52. "Greater transparency and accountability by Medicaid managed care plans (and their subcontractors) to the States for how Medicaid benefits are paid compared to how administrative fees or services are paid are necessary for efficient and proper operation of Medicaid programs." *See* p. 43,249.

15. Rescind Accumulator Rule Changes in Light of Court Decision

In 2020, CMS proposed and finalized an ill-considered change to the numerous regulatory provisions that exclude patient assistance from AMP and Best Price, and that in turn encourage manufacturers to offer that assistance. Misconstruing both the market and its authority, CMS required that manufacturers "ensure" that the full value of patient assistance is passed on to the patient, and not stolen from the manufacturer and patient by intermediaries through "accumulator" programs that operate out of sight and beyond manufacturers' control. On May 17, 2022, a federal judge quickly rejected the changes as inconsistent with the terms of the Medicaid statute and vacated the so-called "accumulator adjustment rule of 2020." *See* p. 34,261. The government did not appeal.

In response to the court order, CMS proposes to withdraw "the manufacturer ensures" changes made to AMP and Best Price in 2020 and restore the pre-2021 text. §§447.504(c)(25)-(29), (e)(13)-(17), and 447.505(c)(8)-(12).

Good riddance to this bad policy.

16. Amend Regulations Relating to Drug Misclassification

In 2019 Congress amended the Medicaid statute to combat perceived manipulation of the MDRP through drug misclassification, specifically, the misreporting of S or I drugs as N drugs to take advantage of lower rebate obligations. §1927(c)(4) (*inter alia*). CMS published guidance in 2020 regarding how manufacturers should comply with the misclassification law. Program Release No. 113 (June 5, 2020).

CMS considers much of the law to be self-implementing, but nonetheless proposes regulatory amendments to §447.509 and §447.510 to implement and codify the changes in regulation. *See* p. 34,261-64. Those amendments address:

Identifying a misclassification (which would include an incorrect base date AMP)

- Notifying a manufacturer of misclassification
- Indicating the penalties/past rebates that may apply
- Describing the process by which past rebates are to be paid
- Allowing CMS to correct misclassifications
- Providing for referral to OIG and termination from the Program
- Publishing an annual report on drugs identified as misclassified

Congress' concern about drug misclassification in the MDRP may be overblown. Still, CMS must implement the statute's directives to identify and punish instances of misclassification. The proposed regulations do a fair job of reflecting the requirements of the statute. Manufacturers should be keenly aware of the attention being paid to misclassification, and to the severe costs of allowing misclassification to persist.

17. Conform Regulations to Reflect Removal of URA Cap on January 1, 2024

Congress in 2021 changed the Medicaid statute to sunset the 100% of AMP cap on URA as of January 1, 2024. §1927(c)(2)(D). For periods beginning with 1Q2024, Medicaid URA can exceed AMP, and for many products, it will. No longer will URAs be capped at the price at which the manufacturer sold the product to the Medicaid dispensing pharmacy but may exceed it. We call this phenomenon "negative pricing."

To conform the regulation with this statutory change, CMS proposes to amend §447.509(a)(5) and (9) to state that the limit on maximum URAs applies only during the time frames set out in the statute. For all drugs (S, I, and N), the maximum URA limitation will end on December 31, 2023.

As a matter of regulatory housekeeping, this proposal is unassailable. The regulation needs to track the statute. Comments critical of the substantive change made by Congress will fall on deaf ears at CMS. Nevertheless, manufacturers should carefully model what the removal of the URA cap will do to the gross-to-net of their legacy product portfolios. Products with low Best Prices and significant inflation penalties may soon find themselves in a world where every unit dispensed to a Medicaid patient is a loss, where the MDRP can be used by states as a profit center. Consideration should be given to strategies that lower current AMP (e.g., by extending discounts to AMP-eligible entities) and/or remove the product from the Program (e.g., by divesting the product to a nonparticipating manufacturer or leaving the program all together).

18. Clarify That Not All "N" Drugs are Noninnovator Multiple Source

The PR takes pains to explain that while all CODs other than S or I drugs should be categorized as N drugs (whether or not they satisfy the definition of a noninnovator multiple source drug at §447.502), not all N drugs are multiple source. *See* pp. 34,265-66. Therefore, CMS proposes to replace each appearance of "noninnovator multiple source drug(s)" in §447.509 with "drug other than a single source drug or innovator multiple source drug(s)."

We have read and summarized this proposal, so you don't have to. You're welcome.

19. Request Information on Requiring Diagnosis on Medicaid Script

Generally, a COD is subject to Medicaid reimbursement and rebating when used for a medically accepted indication. §1927(k)(6). But Medicaid COD claims do not require the submission of a diagnosis code as a condition for payment. There is no mechanism to cross-reference a drug's use with a patient's medical diagnoses to ensure that the drug is being used for a medically accepted indication. Therefore, CMS states, it is difficult for the states to determine if a product is subject to reimbursement and a manufacturer rebate. *See* p, 34.276.

To permit states to appropriately identify rebatable utilization (and become eligible for certain federal matching funds that require diagnosis-specific data), promote safer prescribing, and understand state-level needs, CMS seeks comment on requiring that a diagnosis code be identified on all Medicaid prescriptions. CMS wants to hear about burden, the impact of such a requirement on stakeholders, operational implications, and impact on program integrity. There is no specific proposal made in the PR, just a request that manufacturers and others submit comments to help the agency consider such a requirement in the future.

20. Correct a Coordination of Benefits Regulation Error

Medicaid is generally the payor of last resort. State Medicaid programs must identify and seek payment from third party sources before billing Medicaid. Congress changed the law governing this requirement in 2018. §1902(a)(25). CMS finalized regulatory updates incorporating the new statutory requirements in 2020. §433.139(b)(3). CMS proposes to correct some technical language in the regulations that would permit states to pay claims sooner than the specified waiting periods, when appropriate. Manufacturers that receive Medicaid payment claims complaints from providers may want to evaluate CMS's proposal to see if it provides any relief. *See* p. 34,248.

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Please let us know if we can help as you consider and evaluate these potentially consequential changes to the MDRP regulations.

ABOUT KING & SPALDING

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BRUSSELS	DUBAI	LONDON	NORTHERN VIRGINIA	SILICON VALLEY	