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MDRP: CMS issues new rebate agreement; all current agreements terminate October 1, 2018

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On March 23, 2018, the Centers for Medicare and Medicaid Services (CMS) published a Final Notice that implements a substantially revised Medicaid National Drug Rebate Agreement (NDRA). ***All agreements currently in place will expire on October 1, 2018, and CMS is requiring participating manufacturers to execute and return the new NDRA no later than September 30, 2018, as a condition of remaining in the Medicaid Drug Rebate Program (MDRP)***. CMS also has sent an e-mail to participating manufacturers including instructions on how to execute the new NDRA electronically (noting that hard copies are no longer required to be sent to CMS, and also stating that manufacturers should submit an updated 367d Labeler Contact Form as part of the process). On March 26, 2018, CMS published MDRP Manufacturer Release No. 108, which largely mirrors the information contained in the e-mail sent to participating manufacturers.

The updated NDRA reflects the first substantive changes to the NDRA since CMS originally published the agreement in February 1991, at the inception of the MDRP. CMS proposed revisions to the NDRA in the November 9, 2016 Federal Register, and now has finalized a number of those proposed revisions, as well as certain other changes described below. Please refer to our prior client alert for a discussion of the 2016 proposed revisions. We also attach two blacklines for your reference: the first compares the revised NDRA to the original 1991 NDRA (as revised in 2001 to reflect the agency's name change to "CMS"), and the second compares the final revised NDRA to the 2016 proposed NDRA.

According to CMS, the finalized NDRA revisions serve two purposes: they "incorporate legislative and regulatory changes that have occurred since the Agreement was [originally] published" and "make editorial and structural revisions, such as references to the updated Office of Management and Budget (OMB)-approved data collection forms and electronic data reporting." We summarize below key changes as compared to the original NDRA.

Definitions: As proposed, CMS replaced the definitions from the 1991 agreement with references to the Medicaid statute and the Covered Outpatient Drugs Final Rule (Final Rule). Other changes include:

- *Retention of Certain Terms CMS Proposed to Delete.* CMS did not delete the original definitions of "**Depot Price**," "**Single Award Contract**," and "**Single-Award Contract Price**," as had been proposed, acknowledging that these terms "are used in determination of best price and AMP but are not defined anywhere except for the NDRA."

- *Clarification with Respect to "State Drug Utilization Data."* CMS finalized its proposal to replace the former term "**Medicaid Utilization Information**" with "**State Drug Utilization Data**," and CMS updated the definition. Specifically, CMS clarified that "State Drug Utilization Data" includes units "dispensed and/or paid for, as applicable" under Medicaid. The proposed definition had referred instead to units "reimbursed" under Medicaid. One commenter noted that reference to units "reimbursed" could be misinterpreted to apply only to fee-for-service (FFS) rebate claims, and not to Medicaid managed care claims as well. CMS agreed and consequently replaced the term "reimbursed" with the phrase "dispensed and/or paid for, as applicable," in order to clarify that State Medicaid agencies' responsibilities with respect to reporting State Drug Utilization Data to manufacturers "apply to both FFS and MCO rebate claims."

- *Definition of "Best Price."* CMS replaced the Best Price definition from the 1991 agreement with references to the Medicaid statute and Final Rule. That results in the deletion of the phrase "the lowest price at which the manufacturer *sells* the Covered Outpatient Drug to any purchaser in the United States in any pricing structure" (emphasis added). This phrase is not included in the Medicaid statute or the Final Rule definition of Best Price.

Manufacturer's Responsibilities:

- *Points of Contact*. CMS revised the NDRA to require manufacturers to identify three main points of contact by requiring "one main contact for each of the following issues: Legal, Invoice, and Technical," in order "to facilitate the necessary communications with states with respect to rebate invoice issues."

- *URA Calculation*. CMS added language making clear that the manufacturer is obligated to calculate the URA and use that amount when paying state invoices. The revised NDRA states that while "CMS may calculate a URA based on manufacturer-submitted product and pricing data and provide the URA to states in order to facilitate rebate billing," CMS's calculation "does not relieve the manufacturer of its responsibility to calculate the URA." This has been CMS's position historically, but it previously was not included in the NDRA.

- *Other Labeler Codes*. CMS added language indicating that the NDRA must be signed and applied to "all covered outpatient drugs of all labeler codes of a manufacturer." CMS stated in the preamble to the Final Notice that "manufacturers must ensure that *all associated labeler codes* with covered outpatient drugs enter into a rebate agreement in order to comply with the terms of the NDRA" (emphasis added). CMS did not further elaborate on this requirement, but we note that in its e-mail to manufacturers, CMS stated: "If your company has any associated labeler codes that meet the requirements of section 1927 of the Social Security Act and do not have an active NDRA, a new NDRA or reinstatement (if applicable) must be requested and will be subject to the new NDRA or reinstatement process."

- *Listing NDCs with FDA*. CMS finalized its proposal that manufacturers should ensure their drugs are listed electronically with the Food and Drug Administration (FDA). Specifically, CMS revised the NDRA to state that "CMS uses drug information listed with FDA . . . to be able to verify that an NDC meets the definition of covered outpatient drug." CMS indicated that this revision is intended to clarify for manufacturers how CMS uses "drug information listed with FDA, and why it is in a manufacturer's best interests to ensure that their NDCs are electronically listed with FDA."

- *Quarterly Pricing Adjustment Reporting*. CMS revised Section II(d) to mirror the Final Rule and state that "adjustments to all prior quarterly pricing data must be reported for a period

not to exceed 12 quarters from when the pricing data were originally due as required under § 447.50(b)."

- *Increases and Decreases of Rebate Payment Amounts*. The proposed revisions to the NDRA addressed URA increases resulting from "changes in product, pricing, or related data," but failed to reference decreased URA amounts. In response to comments highlighting this omission, CMS added the following new sentence to Section II(f): "To the extent that changes in product, pricing, or related data cause decreases to previously-submitted total rebate amounts, the manufacturer should communicate with the states regarding where to apply the line-item (NDC-level) credit."

- *CMS Guidance*. As had been proposed, the revised NDRA requires manufacturers to agree to comply with "agency guidance" in addition to applicable statutory and regulatory requirements (as well as the NDRA itself). CMS declined to remove this new language regarding "guidance," despite comments expressing concern that the Administrative Procedure Act does not permit CMS to require manufacturers by contract to agree to be bound by current or future guidance, particularly where such guidance otherwise may not be binding on the manufacturer.

- *Reasonable Assumptions*. CMS finalized its proposal to require manufacturers to make reasonable assumptions available upon request. CMS also finalized its proposed reasonable assumption description, which has been revised from the 1991 agreement to now refer to assumptions being consistent with the "purpose," rather than the "intent," of the relevant legal requirements, and to require that the written record of assumptions should "explain" rather than "outline" such assumptions.

- *Notice of Bankruptcy*. CMS finalized its proposal to require manufacturers to notify CMS within seven days of any filing of bankruptcy.

Secretary's Responsibilities:
- CMS finalized its proposal to permit audits of all "manufacturer information" reported under the Medicaid statute, as opposed to audits of AMP and BP as permitted under the 1991 agreement. Under the adopted provision, audits may include all applicable information reported under Section 1927(b)(3)(A) of the Social Security Act, which includes AMP units, Average Sales Price, Wholesale Acquisition Cost, and sales at a nominal price.

Penalty Provisions:
- CMS finalized the addition of a provision indicating that the government's remedies under the NDRA are not exclusive.

Dispute Resolution:
- *Timing to Resolve a Dispute*. CMS revised the time provided in both the 1991 and proposed agreements for a state and a manufacturer to resolve state invoiced drug utilization disputes from "within 60 days" of the state receiving notice of the dispute to "within a reasonable time frame" after receiving such notice.

- *Hearing Mechanism*. Under the 1991 agreement, Section V(c) provided that CMS would "require" states to make available to manufacturers certain state hearing mechanisms. Under the updated agreement, CMS has revised this language to state that "CMS will employ best efforts to ensure" that states make such state hearing mechanisms available to manufacturers.

Nonrenewal and Termination:
- CMS finalized its proposed revisions to Section VII(d) to clarify the timing for a terminated manufacturer's re-entrance into the MDRP. Specifically, the updated NDRA prohibits a

manufacturer from executing another rebate agreement "for at least one rebate period from the effective date of the termination," and the manufacturer "must also address to the satisfaction of CMS any outstanding violations from any previous rebate agreement(s)."

General Provisions:

- *Authorization*. CMS added language that "[t]his agreement is authorized by the applicable provisions of sections 1902, 1903, 1905, and 1927 of the Act, and the implementing regulations at 42 CFR Part 447." CMS stated that this new language is intended to clarify that the NDRA incorporates "statutory requirements not explicitly referenced in other sections of the NDRA."

- *Assignment of Liability After Ownership Transfer*. The 1991 agreement provided that a transfer in ownership of the manufacturer results in the automatic assignment of the agreement to the new owner. In the revised NDRA, CMS finalized its proposal that "any outstanding rebate liability" is automatically assigned to the new owner as well.

Additional Observations:

- *Status of the NDRA as a "Contract."* In the preamble to the Final Notice, CMS stated that "[t]he NDRA is not a contract. Rather, it should be viewed as an opt-in agreement that memorializes the statute and regulations." While the preamble language is not determinative as to whether the NDRA is, in fact, a "contract," CMS's position has potential implications for any contract-based legal theories a manufacturer or other party my seek to rely upon to enforce obligations under the NDRA.

- *CMS MDRP Releases*. The preamble to the Final Notice ratifies a number of prior CMS MDRP releases on key issues, including the following:

  - Manufacturer Release No. 7, and State Releases No. 29 and No. 166, regarding permissible timing of rebate payments;

  - Manufacturer Release No. 69, regarding "Market Date;"

  - Manufacturer Release No. 95 and State Release No. 173, regarding claims-level data; and

  - Manufacturer Release No. 106 and State Release No. 183, regarding inner and outer NDCs.

- *Applicability to States*. The preamble reiterates in several instances that CMS does not consider states to be a party to the NDRA, and, as such, CMS rejected commenters' requests to add state-specific provisions to the NDRA. CMS noted its belief that such revisions are unnecessary because states remain bound by those provisions of the Medicaid statute that apply to the states.

- *Dispute Resolution Process*. CMS declined to add the term "or manufacturers" where indicated below, as requested by multiple stakeholders, to the new language regarding Dispute Resolution, which now states: "[n]othing in this Agreement shall be construed to limit the remedies available to the United States government or the states ~~or manufactures~~ for a violation of this Agreement or any other provision of law." CMS stated that "[m]anufacturers are afforded protections under section V. of the NDRA, which addresses dispute resolution procedures in the event a manufacturer wishes to dispute state drug utilization data on the rebate invoice."

Next Steps

The Final Notice states that manufacturers with a current NDRA will have "at least 2 full calendar quarters as of the effective date of this notice to sign and submit the updated NDRA," but the CMS e-mail to manufacturers makes clear that CMS is requiring participating manufactures to execute and return the new NDRA no later than September 30, 2018, in order to remain in the program.

Other considerations include the following:

- If your organization currently has multiple NDRAs in place or is part of a larger corporate family with other manufacturers, consider whether one or more new NDRAs will be appropriate.
- Review your "reasonable assumptions" documentation to confirm whether it will continue to comply with the new NDRA provisions.
- Also review your government price reporting documentation more generally for references to NDRA provisions that may need to be updated. Consider whether the final changes to the NDRA may substantively impact any current processes or approaches your organization has in place regarding the MDRP, but also with respect to obligations under related programs (e.g., Medicare Part B Average Sales Price).
- CMS stated in the Final Notice that it will publish further guidance on the termination of existing NDRAs and the execution of updated NDRAs "soon." It is not clear whether that was in reference to something other than the e-mail CMS has already sent to manufacturers.

As always, it is important to review the final revised NDRA in detail to identify any issues relevant to your organization. Please feel free to contact the Hogan Lovells price reporting team if you have any questions or would like to discuss the revised NDRA.

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