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Comments to CMS Guidance on the Medicare Prescription Drug Inflation Rebate Program Due March 11, 2023

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On February 9, 2023, the Centers for Medicare & Medicaid Services ("CMS") issued a fact sheet and its initial guidance documents addressing the Medicare Prescription Drug Inflation Rebate Program for Medicare Parts B and D (the "Inflation Rebates")—a critical component of the sweeping prescription drug pricing changes enacted through the Inflation Reduction Act of 2022 (the "IRA"). In addition to providing substantial detail regarding CMS's intended implementation of the Inflation Rebates, the initial program guidance documents (the "Initial Inflation Rebate Guidances" highlight areas where CMS seeks specific feedback. This feedback must be submitted to CMS by **March 11, 2023** via email (IRARebateandNegotiation@cms.hhs.gov).

Stakeholders can view CMS's issuance of the Initial Inflation Rebate Guidances as an early step in the complex, multi-year process CMS must undertake to implement the various IRA provisions. To advance these efforts, CMS established a Medicare Drug Rebate and Negotiations Group dedicated to the IRA and set forth the agency's intended overarching timeline to implement the various IRA provisions, such as the Medicare Drug Price Negotiation Program and the Part D redesign. CMS has also held some meetings with drug manufacturers and issued a few high-level documents on IRA implementation—including a notice to drug manufacturers impacts of the Medicare Prescription Drug Rebate Program on the average manufacturer price and Medicaid "Best Price," guidance about the IRA's Medicare Drug Price Negotiation Program, and an information collection request regarding the Small Biotech Exemption under the Medicare Drug Price Negotiation Program (with comments due **March 27, 2023**). However, CMS's release of the Initial Rebate Guidances represents the agency's first significant opportunity to submit substantive and specific input from the broader stakeholder community with regard to one of the most significant components of the prescription drug pricing changes of the IRA.

The Medicare Prescription Drug Inflation Rebate Program

Under the Medicare Prescription Drug Inflation Rebate Program, manufacturers must pay a penalty "rebate amount" for a "rebatable drug," which is a drug under Part B or Part D with a price that has increased by more than the rate of inflation over a specific period of time. Manufacturers must pay a rebate amount within thirty (30) days of receiving an invoice from CMS or face a civil money penalty

of 125% of the rebate amount. The following provides a high-level overview of the Inflation Rebates:

The Initial Inflation Rebate Guidances

Stakeholders have anxiously awaited further details about the Medicare Prescription Drug Inflation Rebate Program, particularly as the April 1, 2023 implementation date for the Part B coinsurance protections approaches. On February 1, 2023, Senator Ron Wyden (D-OR), Chair of the Senate Finance Committee, sent a letter to CMS requesting details on CMS's intended timeline for implementation, illustrations of the rebate calculation methodologies, and CMS's plans to issue invoices on a timely basis to ensure manufacturers are penalized promptly. Manufacturers reportedly met with CMS on February 27, 2023, after the release of the Initial Inflation Rebate Guidances, to provide additional feedback on the rebate program. CMS "expects to issue revised guidance to implement the Medicare Prescription Drug Inflation Rebate Program" in the 4th quarter of 2023, but has specified that timing may be adjusted as necessary.[1]

Part B Rebates

The Initial Inflation Rebate Guidance for Part B was released only two days after the Office of the Inspector General ("OIG") at the U.S. Department of Health and Human Services ("HHS") issued a report detailing the administrative hurdles CMS might face when implementing the Part B provisions. Yet, notably, CMS specifies that its coverage of several topics is considered "final, without a comment solicitation" due to the "timing constraints to implement the adjustment to beneficiary cost sharing for April 2023."[2] CMS stated the agency "may, in revised guidance, make changes to any policies in this memorandum, including policies on which CMS has not expressly solicited comment, based on the agency's further consideration of the relevant issue."[3]

The following highlights issues CMS addresses in the Part B Initial Inflation Rebate Guidance, specific guidance designated as "final guidance" by CMS, and particular areas where CMS seeks stakeholder feedback:[4]

Part D Rebates

The Part D Initial Rebate Guidance addresses similar issues as the Part B Initial Rebate Guidance. However, as CMS does not face similar time constraints for the Part D provisions, the Part D Initial Rebate Guidance does not contain "final guidance." The following highlights topics addressed by CMS and specific areas where CMS seeks stakeholder feedback.[5]

Looking Forward

The attentions of industry stakeholders, consumers, and policymakers should and likely ***will*** remain fixed on CMS as the agency implements the Medicare Prescription Drug Inflation Rebate Program—particularly to identify signals informative of CMS' intentions with regard to implementing other IRA provisions and to assess potential legal challenges that could arise and disrupt implementation—similar to the No Surprises Act.[6] For example, CMS intends to roll out certain guidance for the Drug Price Negotiation Program using the same short, 30-day time-frame and email submission process used by the Initial Inflation Rebate Guidances. Beyond the practical issues presented by requiring stakeholders to meet such a quick timeline, using such a process outside the scope of normal notice and comment rulemaking raises procedural issues, including with regard to timing, transparency concerns due to emailed stakeholder feedback being unavailable for review by the public, and the lack of oversight with regard to how CMS addresses comments received.

CMS's identification of "final guidance" adds further complexity to the analysis—particularly as the areas for which CMS issued guidance for Part B appears far more extensive than the areas in which the IRA's statutory language expressly defers to the Secretary. Additionally, although the IRA's statutory language permits the HHS Secretary to implement the Part D rebates for "2022, 2023, and 2024 by program instruction or other forms of program guidance," the statutory language of Part B includes no such similar language to indicate notice and rulemaking would not be required for the Part B rebates.[7] Despite the impending deadline to implement the Part B coinsurance provisions, it is notable that CMS and stakeholders still benefited from notice and comment rulemaking procedures during implementation of other industry-shifting health care legislation with similarly tight timelines through federal agencies' use of "interim final rule(s) with request for comment" issuances with 60-day comment periods, such as in 2021 when federal agencies issued two interim final rules five months and—the second—less than two months prior to the date in which all providers, facilities, commercial health plans, and associated stakeholders in the healthcare industry needed to comply with most requirements under the sweeping No Surprises Act.[8]

FOOTNOTES

[1] CMS, Fact Sheet: Medicare Prescription Drug Inflation Rebate Program Initial Guidance (Feb. 9, 2023), https://www.cms.gov/sites/default/files/2023-02/Inflation%20Rebate%20Fact%20Sheet%202.9.23.pdf (hereinafter, "Initial Rebate Guidance Factsheet").

[2] CMS, Medicare Part B Drug Inflation Rebates Paid by Manufacturers: Initial Memorandum, Implementation of Section 1847A(i) of the Social Security Act, and Solicitation of Comments (Feb. 9, 2023), https://www.cms.gov/files/document/medicare-part-b-inflation-rebate-program-initial-guidance.pdf (hereinafter, "Part B Initial Rebate Guidance").

[3] *Id.*

[4] *See* CMS, Initial Rebate Guidance Factsheet; Part B Initial Rebate Guidance. https://www.cms.gov/sites/default/files/2023-02/Inflation%20Rebate%20Fact%20Sheet%202.9.23.pdf , https://www.cms.gov/files/document/medicare-part-b-inflation-rebate-program-initial-guidance.pdf

[5] *See* CMS, Initial Rebate Guidance Factsheet; CMS, Medicare Part D Drug Inflation Rebates Paid by Manufacturers: Initial Memorandum, Implementation of Section 1860D-14B of Social Security Act, and Solicitation of Comments (Feb. 9, 2023), https://www.cms.gov/sites/default/files/2023-02/Inflation%20Rebate%20Fact%20Sheet%202.9.23.pdf , https://www.cms.gov/files/document/medicare-part-d-inflation-rebate-program-initial-guidance.pdf.

[6] *See* Texas Medical Association, et al. v. United States Department of Health and Human Services, Case No. 6:22-cv-372 (TMA II); CMS, February 24, 2023 Notice, Payment Disputes Between Providers and Health Plans, https://www.cms.gov/nosurprises/help-resolve-payment-disputes/payment-disputes-between-providers-and-health-plans.

[7] 42 U.S.C. § 1395w-114b(h); *see* 42 U.S.C. § 1395w-3a.

[8] Requirements Related to Surprise Billing; Part I, 86 Fed. Reg. 36872 (July 13, 2021); Requirements Related to Surprise Billing; Part II, 86 Fed. Reg. 55980 (Oct. 7, 2021).

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