December 20, 2025

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Russell Vought
Director
Office of Management and Budget
Executive Office of the President
Attention: OMB Control No. 0938-1485
725 17th St NW
Washington, DC 20503

Re: OMB Control No. 0938-1485: Medicare Prescription Drug Inflation Rebate Program: Sections 11101 and 11102 of the Inflation Reduction Act (IRA) (CMS-10930)

Dear Director Vought:

RWC-340B appreciates the opportunity to comment on the Centers for Medicare and Medicaid Services' (CMS's) Paperwork Reduction Act submission to the Office of Management and Budget (OMB) entitled, *Medicare Prescription Drug Inflation Rebate Program: Sections 11101 and 11102 of the Inflation Reduction Act (IRA) (CMS-10930)*. We commend OMB's commitment to protecting the public from unduly burdensome agency information collection requests, and CMS's commitment to implementing the IRA in a manner that accurately excludes 340B drug prices from Medicare Part D inflation rebate calculations.

RWC-340B is a national association of HIV/AIDS health care clinics and service providers funded under the Ryan White Comprehensive AIDS Resources Emergency (CARE) Act. Our members provide essential primary care, case management, medication management, and supportive services to low-income and vulnerable patients living with HIV/AIDS. Ryan White clinics participate as "covered entities" in the federal 340B drug discount program (340B program), which allows them to access medications at discounted rates to extend care to underserved populations.

RWC-340B Supports CMS's Overall Objectives

CMS explains in its Supporting Statement to OMB that the purpose of the information collection request is to implement the exclusion of 340B units from the total number of units for a Part D

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rebateable drug.[1] RWC-340B agrees that accurate exclusion of 340B drugs is consistent with statutory requirements under the IRA and is critical to protecting manufacturers and other stakeholders, including covered entities. Because 340B ceiling prices already incorporate an inflationary penalty through the 340B program's statutory formula, including them in the Part D inflation rebate calculation would distort the Part D rebate amount, potentially resulting in inflated manufacturer liability and other unintended consequences.[2] By recognizing the need to exclude 340B claims, CMS has taken an essential step toward ensuring the equitable application of the inflation rebate program.

While RWC-340B strongly supports CMS's stated objective, we believe the 340B repository approach detailed in its Supporting Statement falls short of adequately excluding 340B pricing, minimizing administrative burden, and ensuring impartiality in data handling. A better alternative, in our view, is to establish a neutral third-party clearinghouse.

CMS's Approach Is Flawed as the Agency Acknowledges

The voluntary 340B data repository would require covered entities to submit certain data elements from Part D 340B claims, including date of service, prescription number, fill number, pharmacy NPI, and NDC.[3] CMS would allow retrospective identification of 340B claims, which aligns with a longstanding priority of covered entities. CMS encourages covered entities to participate voluntarily during the testing period, which it expects to be available in Fall 2026, with submission covering dates of service on or after January 1, 2026.[4] While the repository represents progress in the right direction, it would still give manufacturers access to covered entities' 340B claims data. RWC-340B and other 340B provider groups have consistently opposed any IRA implementation proposal that allows manufacturers to review 340B claims data. As an alternative, they have advocated that the Medicare Transaction Facilitator (MTF) be charged with reviewing and excluding 340B claims submitted by covered entities and their third party administrators (TPAs). In addition, the voluntary nature of the proposed repository raises concerns regarding completeness, consistency, and neutrality, and it does not provide a standardized, centralized mechanism to validate 340B claims uniformly across all participants.

CMS has previously recognized that accurately identifying 340B claims is critical to program integrity and has stated that it "will monitor this approach and will continue to explore the feasibility of incorporating 340B-related transactional data from 340B covered entities or their TPAs identifying claims eligible under section 1193(d)(1) of the Act into MTF processes in the

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[1] Supporting Statement – Part A, Medicare Prescription Drug Inflation Rebate Program Under Sections 11101 and 11102 of the Inflation Reduction Act (IRA) 2 (Nov. 21, 2025) ("Supporting Statement").

[2] *See* 42 U.S.C. § 1396r-8(c)(2) (Medicaid Drug Rebate Program inflationary rebate formula, which caps price increases by requiring manufacturers to provide additional rebates when AMP increases faster than inflation). The 340B ceiling price is calculated as AMP minus the Medicaid unit rebate amount, meaning it already incorporates this inflation penalty. *See also* 42 U.S.C. § 256b(a)(1) (establishing 340B ceiling price formula). Including these inflation-adjusted prices in the Part D rebate calculation under IRA § 11101 (codified at 42 U.S.C. § 1395w–114c) would therefore double-count inflationary penalties and distort rebate liability.

[3] Supporting Statement at 4.

[4] *Id.* at 3.

future."[5] This acknowledgment underscores the value of a neutral third-party clearinghouse to ensure accurate, reliable, and impartial exclusion of 340B claims in Part D rebate calculations.

The 340B repository approach outlined by CMS in the Supporting Statement does not fully address the need for accuracy, neutrality, and administrative efficiency in calculating Part D rebates. To the contrary, it would likely lead to gaps or inconsistencies in rebate calculations under the IRA.

RWC-340B Recommendation: Adopt a Neutral Third-Party Clearinghouse

RWC-340B strongly recommends that CMS implement a neutral third-party clearinghouse to identify and validate 340B claims for Part D rebate calculations. Such a clearinghouse would be operated by the MTF or another government contractor that is independent from both manufacturers and covered entities, ensuring impartial, standardized, and consistent application of rules across the program. Centralized submissions and uniform data formats would enhance accuracy, reduce administrative burden for CMS and covered entities, and protect sensitive claims information. Covered entities would submit data directly to the clearinghouse, which would exclude 340B prices from rebate calculations and transmit only validated results to CMS, minimizing exposure of proprietary or patient-specific data.

The proposed third-party clearinghouse is designed to implement and enhance the statutory requirements outlined in section 1193(d)(1) of the IRA, as previously referenced by CMS,[6] by ensuring operational efficiency, data accuracy, and compliance with regulatory standards. The neutral clearinghouse would operate independently from both manufacturers, covered entities and Part D plans, thereby guaranteeing impartiality and consistency in the application of the rebate mechanism across the program. By centralizing submissions and using uniform data formats, the clearinghouse enhances accuracy and reduces the administrative burden for both CMS and covered entities. It would incorporate strong privacy and security safeguards, ensuring that sensitive 340B claims data is transmitted, stored, and used solely for Part D rebate calculations. Furthermore, the neutral clearinghouse would allow for retrospective submission of data, which ensures the accuracy of 340B claims identification and validation. This approach not only aligns with the applicable statutory requirements but also surpasses them by providing a reliable, administratively feasible, and legally neutral solution that upholds the integrity of the program. It could also incorporate safeguards utilized in other areas of the 340B program,

[5] CMS, *Medicare Drug Price Negotiation Program: Final Guidance*, at 55–56 (October 2, 2024) available at https://www.cms.gov/files/document/medicare-drug-price-negotiation-final-guidance-ipay-2027-and-manufacturer-effectuation-mfp-2026-2027.pdf.

[6] *See, e.g.*, CMS, *Medicare Drug Price Negotiation Program: Final Guidance*, at 15 (October 2, 2024), available at https://www.cms.gov/files/document/medicare-drug-price-negotiation-final-guidance-ipay-2027-and-manufacturer-effectuation-mfp-2026-2027.pdf.

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including strict neutrality of the operator,[7] secure handling of sensitive claims data,[8] and assurances against discriminatory treatment of participating covered entities or pharmacies.[9] CMS's statement regarding future feasibility of TPA data integration underscores the importance of piloting such a neutral structure now to address MFP and 340B overlap issues effectively.

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RWC-340B appreciates OMB's and CMS's efforts to implement the IRA in a way that ensures the accuracy of rebate calculations and safeguards program integrity while recognizing the critical role of safety-net providers. We strongly support CMS's goal of accurately excluding 340B claims but respectfully urge the agency to adopt a neutral third-party clearinghouse model. This alternative would provide a reliable, administratively feasible, and legally neutral solution that aligns with the IRA and ensures program integrity.

We thank OMB for its consideration of these comments. For further information, please contact Peggy.Tighe@PowersLaw.com, Legislative Counsel to RWC-340B.

Sincerely,

Shannon Burger, MBA, CPA
President
Ryan White Clinics for 340B Access

[7] *See, e.g.*, Final Notice Regarding Section 602 of the Veterans Health Care Act of 1992 Entity Guidance, 59 Fed. Reg. 25110, 2511 –25112 (May 13, 1994) ("Manufacturers may not single out covered entities from their other customers for restrictive conditions that would undermine the statutory objective" and "must not place limitations on the transactions... which would have the effect of discouraging entities from participating in the discount program.") *see also Clarification of Non-Discriminatory Policy*, HRSA, Release No. 2011-1.1 (May 23, 2012), available at https://www.hrsa.gov/sites/default/files/hrsa/opa/non-discrimination-05-23-2012.pdf

[8] *See, e.g.*, HRSA's Program Integrity Guidelines require covered entities to: "Maintain accurate records to ensure compliance" and be subject to audits under section 340B(a)(5)(C) of the PHSA. *See* https://www.hrsa.gov/opa/program-integrity.

[9] *See, e.g.*, *Clarification of Non-Discriminatory Policy*, HRSA, Release No. 2011-1.1 (May 23, 2012) ("Manufacturers must not place limitations... which would have the effect of discouraging entities from participating in the discount program."), available at https://www.hrsa.gov/sites/default/files/hrsa/opa/non-discrimination-05-23-2012.pdf.