PRA Disclosure Statement

According to the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number. The valid OMB control number for this information collection is [0938-TBD]. This information collection is for the Centers for Medicare & Medicaid Services (CMS) to collect information to implement regulatory requirements of Medicare Part D Drug Inflation Rebate Program as proposed in CY 2026 Physician Fee Schedule (PFS) proposed and calculate a rebate amount for a manufacturer of a Part D rebatable drug if the annual manufacturer price exceeds the inflation-adjusted payment amount.

The time required to complete this information collection ranges per response, including the time to review instructions, search existing data resources, gather the data needed, to review and complete the information collection. The time required to complete this information collection for the attached appendix, per year, is as follows:

- 340B Repository Data Elements Instructions and Collection Form (Appendix A)- 208,000 hours

The purpose of this ICR is for CMS to collect information to implement the Medicare Part D Drug Inflation Rebate Program as proposed in CY 2026 Physician Fee Schedule (PFS) proposed rule. Specifically, section 1860D-14B(b)(1)(B) of the Act requires that beginning with plan year 2026, CMS shall exclude from the total number of units for a Part D rebatable drug, with respect to an applicable period, those units for which a manufacturer provides a discount under the 340B Program. In the CY 2026 PFS proposed rule, CMS proposed to establish a 340B repository to receive voluntary submissions from covered entities of certain data elements from Part D 340B claims to allow CMS to assess such data for use in identifying units of Part D rebatable drugs for which a manufacturer provides a discount under the 340B Program in a future applicable period. CMS proposed to allow covered entities to submit data on units of Part D rebatable drugs for which a manufacturer provides a discount under the 340B Program beginning in 2026 to begin testing the usability of the 340B repository. This ICR will enable CMS to collect information to implement this voluntary collection.

This information collection contains voluntary elements, as follows:

- 340B Repository Data Elements Instructions and Collection Form (Appendix A)- Voluntary

If you have comments concerning the accuracy of the time estimate(s) or suggestions for improving this form, please write to: CMS, 7500 Security Boulevard, Attn: PRA Reports Clearance Officer, Mail Stop C4-26-05, Baltimore, Maryland 21244-1850.