le: 4165-15-P

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Health Resources and Services Administration**

**Agency Information Collection Activities: Proposed Collection: Public Comment Request; Information Collection Request Title: 340B Rebate Model Pilot Program Application, Implementation, and Evaluation, OMB Number 0906-0111 - Extension**

**AGENCY:** Health Resources and Services Administration (HRSA), Department of Health and Human Services.

**ACTION:** Notice.

**SUMMARY:** In compliance with the requirement for opportunity for public comment on proposed data collection projects of the Paperwork Reduction Act of 1995, HRSA announces plans to submit an Information Collection Request (ICR), described below, to the Office of Management and Budget (OMB). Prior to submitting the ICR to OMB, HRSA seeks comments from the public regarding the burden estimate, below, or any other aspect of the ICR.

**DATES:** Comments on this ICR should be received no later than **[INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]**.

**ADDRESSES:** Submit your comments to paperwork@hrsa.gov or mail the HRSA Information Collection Clearance Officer, Room 14NWH04, 5600 Fishers Lane, Rockville, Maryland 20857.

**FOR FURTHER INFORMATION CONTACT:** To request more information on the proposed project or to obtain a copy of the data collection plans and draft instruments, email paperwork@hrsa.gov or call Samantha Miller, the HRSA Information Collection Clearance Officer, at (301) 443-3983.

**SUPPLEMENTARY INFORMATION:** When submitting comments or requesting information, please include the ICR title for reference.

*Information Collection Request Title:* 340B Rebate Model Pilot Program Application, Implementation, and Evaluation, OMB No. 0906-0111 - Extension

*Abstract:* HRSA's Office of Pharmacy Affairs (OPA) is introducing a 340B Rebate Model Pilot Program as a voluntary mechanism for qualifying drug manufacturers to effectuate the 340B ceiling price on select drugs to covered entities, as outlined in a *Federal Register Notice* (90 Fed. Reg., 38,165; herein referred to as the "Notice") issued on August 7, 2025. This information collection request includes the collection of 340B Rebate Model Pilot Program plans from drug manufacturers, the collection of reports from drug manufacturers for OPA's evaluation of the pilot program and for overall 340B Program surveillance, and the collection of data submitted by covered entities to manufacturers to request a rebate.

*Need and Proposed Use of the Information*: The scope of the 340B Rebate Model Pilot Program will be limited to manufacturers with Medicare Drug Price Negotiation Program Agreements with the Centers for Medicare & Medicaid Services' for the initial price applicability year 2026.[1] Once selected plans are approved in accordance with the Notice, manufacturers may then begin to effectuate the 340B rebate starting January 1, 2026. This information collection request includes the collection of 340B Rebate Model Pilot Program plans from drug manufacturers, the collection of sales data from drug manufacturers for OPA's evaluation of the pilot program and for overall 340B Program surveillance, and the collection of data submitted by covered entities to manufacturers to request a rebate.

*Collection of Drug Manufacturer Applications:* OPA will evaluate and approve plans for participation in the 340B Rebate Pilot Program based on the elements required in the Notice (90 Fed. Reg., 38,166-67).

*Collection of Reporting Data from Manufacturers:* Manufacturers will be required to submit data to the 340B Prime Vendor on a monthly basis to ensure program integrity and to provide

[1] The Fact Sheet for Negotiated Prices for Applicability Year 2026 includes the list of Primary Manufacturers with selected drugs, available at https://www.cms.gov/files/document/fact-sheetnegotiated-prices-initial-price-applicability-year2026.pdf.

transparency in the 340B Program. Monthly submissions will provide better data for tracking 340B data and reduce lag time in assessing Program metrics. The data submitted is also being collected to support the assessment of the 340B Rebate Model Pilot Program.

*Collection of Data Submitted by Covered Entities to Manufacturers:* Covered entities are required to provide specific data to participating manufacturers in order for the manufacturers to provide rebates to effectuate the 340B discount on the entities' covered outpatient drug purchases. Specific requirements that detail the type of and frequency of such submittals can be found in the Notice (Fed. Reg., 38,166). The data collected will be kept private to the extent permitted by the law.

HRSA received an emergency clearance from OMB on August 26, 2025. The emergency clearance will ensure that the agency will collect drug manufacturer applications by September 15, 2025. This 60-day *Federal Register Notice* will allow HRSA to fully consider all public comments on its burden statement. HRSA has taken all practicable steps to consult with the public to minimize burden (including a 30-day comment period in the Notice).

*Likely Respondents:* Pharmaceutical manufacturers and 340B covered entities.

*Burden Statement:* Burden in this context means the time expended by persons to generate, maintain, retain, disclose, or provide the information requested. This includes the time needed to review instructions; to develop, acquire, install, and utilize technology and systems for the purpose of collecting, validating, and verifying information, processing and maintaining information, and disclosing and providing information; to train personnel and to be able to respond to a collection of information; to search data sources; to complete and review the collection of information; and to transmit or otherwise disclose the information. The total annual burden hours estimated for this ICR are summarized in the table below.

**Total Estimated Annualized Burden Hours:**

| Name | Number of Respondents* | Number of Responses per Respondent | Total Responses | Average Burden per Response (in hours) | Total Burden Hours |
|---|---|---|---|---|---|

| | | | | | |
|---|---|---|---|---|---|
| 340B Program Rebate Model Pilot Program Plan Submission | 9 | 1 | 9 | 8 | 72 |
| Monthly purchase reports | 9 | 12 | 108 | 2 | 216 |
| Covered Entities reporting claims data to third party platform | 14,600 | 52 | 759,200 | 2 | 1,518,400 |
| Total | 14,609 | | 759,317 | | 1,518,688 |

***** The same nine manufacturers will submit Plans and Monthly Purchase Reports (first two rows, above), while the 14,600 Covered Entities will submit Claims Data (third row, above). Therefore, the total number of respondents is 14,609.

HRSA specifically requests comments on (1) the necessity and utility of the proposed information collection for the proper performance of the agency's functions; (2) the accuracy of the estimated burden; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

**Maria G. Button,**

*Director, Executive Secretariat.*

[FR Doc. 2025-17641 Filed: 9/11/2025 8:45 am; Publication Date: 9/12/2025]