during the regulatory review period. To meet its burden, the petition must comply with all the requirements of § 60.30, including but not limited to: must be timely (see **DATES**), must be filed in accordance with § 10.20, must contain sufficient facts to merit an FDA investigation, and must certify that a true and complete copy of the petition has been served upon the patent applicant. (See H. Rept. 857, part 1, 98th Cong., 2d sess., pp. 41–42, 1984.) Petitions should be in the format specified in 21 CFR 10.30.

Submit petitions electronically to *https://www.regulations.gov* at Docket No. FDA–2013–S–0610. Submit written petitions (two copies are required) to the Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

Grace R. Graham,

Deputy Commissioner for Policy, Legislation, and International Affairs.

[FR Doc. 2026–03851 Filed 2–25–26; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Request for Information: 340B Rebate Model Pilot Program Extension

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

ACTION: Notice of extension for the comment period for the Request for Information: 340B Rebate Model Pilot Program (91 FR 7287).

SUMMARY: The Health Resources and Services Administration (HRSA) is extending the comment period for Request for Information: 340B Rebate Model Pilot Program from 30 days to 60 days. The change will provide stakeholders additional time to submit meaningful comments for HRSA's review in evaluating operational, financial, and potential impacts on access to drugs for patients under a rebate model.

DATES: Comments on this notice should be received no later than April 20, 2026.

FOR FURTHER INFORMATION CONTACT: Chantelle Britton, Director, Office of Pharmacy Affairs (OPA), Office of Special Health Initiatives, HRSA, 5600 Fishers Lane, Mail Stop 10W29, Rockville, MD 20857; email: *340Bpricing@hrsa.gov;* telephone: 301–594–4353.

SUPPLEMENTARY INFORMATION: None.

Thomas J. Engels,

Administrator.

[FR Doc. 2026–03838 Filed 2–25–26; 8:45 am]

BILLING CODE 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–NEW

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 April 27, 2026.

ADDRESSES: Submit your comments to *paperwork@hrsa.gov* or mail the HRSA Information Collection Clearance Officer, Room 13N82, 5600 Fishers Lane, Rockville, Maryland 20857.

FOR FURTHER INFORMATION CONTACT: To request more information on the proposed collection or to obtain a copy of the information 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–XXXX.

Abstract: HRSA's Office of Pharmacy Affairs (OPA) is considering a potential 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, and is requesting information from 340B stakeholders and others as described in a Request for Information (91 FR, 7287) issued on February 17, 2026.[1] This ICR includes the collection of proposed rebate model plans from qualifying drug manufacturers, the collection of reports from drug manufacturers approved for participation to allow OPA to evaluate the Pilot Program and enhance 340B Program integrity and compliance monitoring, and the collection of data submitted by covered entities to participating drug manufacturers to request a rebate in connection with a potential 340B Rebate Model Pilot Program.

Need and Proposed Use of the Information: This new proposed information collection request will replace an emergency clearance ICR, OMB No: 0906–0111 (Reference No: 202508–0906–002),[2] which HRSA discontinued. The scope of the potential 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 years 2026 and 2027.[3] This information collection request includes the collection of proposed rebate model plans from qualifying drug manufacturers, the ongoing collection of sales data from drug manufacturers to allow OPA to evaluate the pilot program and enhance 340B Program integrity and compliance monitoring, and the collection of data submitted by covered entities to manufacturers to request a rebate in connection with a potential 340B Rebate Model Pilot Program.

Collection of Drug Manufacturer Applications: OPA anticipates evaluating and approving manufacturer plans for participation in a potential 340B Rebate Model Pilot Program based on requirements published by OPA in future guidance.

Collection of Reporting Data from Manufacturers: In a potential 340B Rebate Model Pilot Program, manufacturers will be required to

[1] *Request for Information* (91 FR, 7287) issued on February 17, 2026, available at *https://www.federalregister.gov/documents/2026/02/17/2026-03042/request-for-information-340b-rebate-model-pilot-program.*

[2] 340B Rebate Model Pilot Program Application, Implementation, and Evaluation (0906–0111) available at *https://www.reginfo.gov/public/do/PRAViewICR?ref_nbr=202508-0906-002.*

[3] The Fact Sheets for Negotiated Prices for Applicability Years 2026 and 2027 includes the list of Primary Manufacturers with selected drugs, available at *https://www.cms.gov/files/document/fact-sheet-negotiated-prices-initial-price-applicability-year-2026.pdf* and *https://www.cms.gov/files/document/fact-sheet-negotiated-prices-ipay-2027.pdf* respectively.

submit data to the 340B Prime Vendor monthly to evaluate program integrity and to provide greater transparency in the 340B Program. Monthly data submissions will enhance 340B Program compliance monitoring and reduce lag time in assessing 340B Program metrics. The monthly data will also support the ongoing assessment of any 340B Rebate Model Pilot Program.

Collection of Data Submitted by Covered Entities to Manufacturers: In a potential 340B Rebate Model Pilot Program, covered entities will be required to provide specific data to participating manufacturers for the manufacturers to provide rebates to effectuate the 340B price on the entities' covered outpatient drug purchases. OPA expects that specific requirements that detail the type and frequency of such submittals will be defined in future guidance to include claims level data elements for 340B-eligible dispenses. OPA expects that data submitted by covered entities to manufacturers will be comparable to data already being collected and maintained by covered entities through existing third-party vendor relationships or data that is already being provided to manufacturers with respect to certain contract pharmacy policies, in-house pharmacy claims requests, and data elements provided for claims with drugs dispensed under the Medicare Drug Price Negotiation Program. Therefore, the burden associated with a potential 340B Rebate Model Pilot Program data requests may not be significant.

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 60-day comment period in the Request for Information).

Likely Respondents: Pharmaceutical manufacturers and covered entities.

Burden Statement: Burden in the context of this information collection 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, if necessary, 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 and were analyzed based on implementation of a potential 340B Rebate Model Pilot Program compared to current data collection practices in the market.

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 Rebate Model Pilot Program Plan Submission	13	1	13	8	104
Manufacturer monthly purchase reports	13	12	156	2	312
Covered Entities reporting claims data to third party platform	14,600	52	759,200	5	3,796,000
Total	14,613		759,369		3,796,416

* Potentially 13 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 14,613.

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. 2026–03833 Filed 2–25–26; 8:45 am]

BILLING CODE 4165–15–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center For Scientific Review; Amended Notice of Meeting

Notice is hereby given of a change in the meeting of the Center for Scientific Review Special Emphasis Panel, March 10, 2026, 09:00 a.m. to March 11, 2026, 07:00 p.m., National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892 which was published in the **Federal Register** on January 30, 2026, 91 FR 4088 Doc No. 2026–01836.

Change in contact person from Dr. Sharon Isern to Vishakha Sharma, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, (301) 594–2297, *sharmav3@nih.gov.* The meeting is closed to the public.

Dated: February 23, 2026.

Bruce A. George,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2026–03817 Filed 2–25–26; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center for Scientific Review; Notice of Closed Meetings

Pursuant to section 1009 of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material,