

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
<b>Total .....</b>	<b>14,613</b>		<b>759,369</b>		<b>3,796,416</b>

\* 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.*

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**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.*

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**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,