66. Emily Dworkin, Seattle, Washington, Court of Federal Claims No: 26–0609V
67. Paula Taylor, Washington, DC, Court of Federal Claims No: 26–0610V
68. Dariane Walker, Dresher, Pennsylvania, Court of Federal Claims No: 26–0612V
69. Jenny Gentry, Moscow, Idaho, Court of Federal Claims No: 26–0615V
70. Robert Deal, Phoenix, Arizona, Court of Federal Claims No: 26–0617V
71. Tom Thomas, Beverly Hills, Florida, Court of Federal Claims No: 26–0618V
72. James Hoy, Cottonwood, Arizona, Court of Federal Claims No: 26–0620V
73. Jody Anzalone, Las Vegas, Nevada, Court of Federal Claims No: 26–0625V
74. Eric Margolin, Washington, DC, Court of Federal Claims No: 26–0626V
75. Adam Rolnick, Chicago, Illinois, Court of Federal Claims No: 26–0627V
76. Neta-Li Almagor-Friedlander, Charlotte, North Carolina, Court of Federal Claims No: 26–0628V
77. Parvin Farahani, Beverly Hills, California, Court of Federal Claims No: 26–0629V
78. Sharon Dennard, Woodridge, Illinois, Court of Federal Claims No: 26–0631V
79. Christopher Wright, Chicago, Illinois, Court of Federal Claims No: 26–0633V
80. Marylex Lopez-Sarraff, Washington, DC, Court of Federal Claims No: 26–0634V
81. Alethea Harris, Dresher, Pennsylvania, Court of Federal Claims No: 26–0635V
82. Steven Klobucarich, Milwaukee, Wisconsin, Court of Federal Claims No: 26–0636V

[FR Doc. 2026–11972 Filed 6–12–26; 8:45 am]

BILLING CODE 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–NEW

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

ACTION: Notice.

SUMMARY: In compliance with the Paperwork Reduction Act (PRA) of 1995, HRSA submitted an Information Collection Request (ICR) to the Office of Management and Budget (OMB) for review and approval. Comments submitted during the first public review of this ICR will be provided to OMB. OMB will accept further comments from the public during the review and approval period. OMB may act on HRSA's ICR only after the 30-day comment period for this notice has closed.

DATES: Comments on this ICR should be received no later than July 15, 2026.

ADDRESSES: Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to *www.reginfo.gov/public/do/PRAMain.* Find this particular information collection by selecting ''Currently under Review—Open for Public Comments'' or by using the search function.

FOR FURTHER INFORMATION CONTACT: To request a copy of the clearance requests submitted to OMB for review, email Samantha Miller, the HRSA Information Collection Clearance Officer, at *paperwork@hrsa.gov* or call (301) 443–3983.

SUPPLEMENTARY INFORMATION:

Information Collection Request Title: 340B Rebate Model Pilot Program Application, Implementation, and Evaluation, OMB No. 0906–NEW.

Abstract: HRSA's Office of Pharmacy Affairs (OPA) intends to introduce a revised 340B Rebate Model Pilot Program (Pilot) as a mechanism for qualifying drug manufacturers, who wish to participate, to effectuate the 340B ceiling price on a limited set of drugs sold to covered entities using rebates. OPA plans to publish a **Federal Register** Notice to notify 340B stakeholders of criteria and standards for implementation of the Pilot. This ICR includes the collection of Pilot plans from drug manufacturers, the collection of purchase data reports from drug manufacturers for OPA's monitoring of the Pilot and for overall 340B Program surveillance and program integrity monitoring, and the collection of data submitted by covered entities to manufacturers to request rebates.

A 60-day notice was published in the **Federal Register** for this ICR on February 26, 2026, vol. 91, No. 2026–03833, pp. 9632–9633. There were 180 timely public comments. Commenters included hospitals, health systems, community health centers, pharmacies, manufacturers, vendors, and national associations. HRSA accepted comments on the following topics: (1) burden on drug manufacturers to submit 340B Rebate Pilot Plans to OPA; (2) burden on drug manufacturers to submit reports to OPA; and (3) burden on covered entities to submit data to manufacturers. HRSA also received comments including general opposition to implementing a rebate model and requests to maintain the current upfront discount structure; concerns about financial impacts such as cash flow constraints, increased drug acquisition costs, and loss of 340B savings; potential downstream effects on patient care, including reduced access to medications and elimination of services supported by 340B savings; legal and statutory arguments regarding HRSA's authority to implement a rebate model; and recommendations for alternative program designs, such as use of a centralized clearinghouse or other approaches to address duplicate discount concerns. While HRSA acknowledges these concerns, they do not directly address the necessity, practical utility, or burden of the information collection under the PRA and therefore were not considered in revising burden estimates or data collection requirements. Other out of scope comments were related to manufacturer contract pharmacy policies, third-party platforms, and broader program integrity issues. The concerns raised that are not directly related to burden as outlined in this ICR will be addressed in a separate **Federal Register** notice.

HRSA received a few comments related to the burden on manufacturers to submit Pilot plans to OPA. These commenters generally focused on administrative considerations associated with OPA's collection and review of such plans rather than on actual burden on drug manufacturers. HRSA did not receive any comments on the burden associated with drug manufacturers submitting reports to OPA. While some commenters provided input on reporting structure and data processes, these comments did not address the estimated burden hours for manufacturer reporting.

A significant number of commenters raised concerns about the burden on covered entities to submit data to manufacturers. Commenters consistently indicated that the proposed data submission requirements would impose substantial administrative, operational, and systems-related burdens. Specifically, commenters noted that compliance would require additional staffing, new or modified information technology systems, increased data tracking and reconciliation efforts, and ongoing

auditing and reporting activities. Several commenters also raised concerns about the complexity of claims-level data submission, potential for errors, and the need to manage denials and disputes, all of which would increase burden. In addition, some commenters highlighted privacy and data-sharing concerns associated with transmitting patient-level information to manufacturers.

Some commenters, including hospital associations, provided substantially higher burden estimates, including estimates requiring dedicated staff resources or full-time equivalent employees to manage reporting, reconciliation, and compliance activities. Commenters provided a wide range of estimates, from modest incremental burden where automated systems are used, to substantially higher burden reflecting manual processes, system integration challenges, and ongoing reconciliation activities.

Many commenters stated that HRSA underestimated the burden hours associated with these activities and recommended that the estimated hours be increased to better reflect the operational realities faced by covered entities. Commenters frequently cited that processing and managing rebate-related data could take significantly more time per claim than estimated and would require dedicated staff resources. HRSA also notes that other commenters indicated that required data elements are already being collected by covered entities and that automation may reduce burden for certain entities.

After careful consideration of the comments, HRSA acknowledges that commenters identified potential administrative, operational, and systems-related burdens associated with covered entities submitting data to manufacturers. Commenters described multiple activities involved in the reporting process, including claims identification, extraction, validation, formatting, submission, reconciliation, denial management, and ongoing auditing. Several commenters also indicated that these activities may require additional staffing, system modifications, or coordination across departments.

At the same time, other commenters asserted that the cost estimates by covered entities are overstated or unsupported and noted that many of the required data elements are already collected and maintained by covered entities as part of routine billing, compliance, and audit processes, and that existing systems and third-party administrators may be leveraged to support data submission and reporting. In their view, the data sharing requirements contemplated with rebates are materially similar to existing obligations imposed by Medicare, Medicaid, and commercial payers. These commenters indicated that, particularly after initial implementation, ongoing reporting activities may be automated or integrated into existing workflows, thereby reducing incremental burden on covered entities.

To estimate burden, HRSA applied a task-based methodology that considers the discrete activities required to complete a reporting cycle, including: (1) identifying and extracting eligible claims data; (2) formatting and validating data to meet manufacturer specifications; (3) submitting the data; (4) reconciling submissions and tracking rebate status; and (5) addressing errors, denials, or follow-up requests. HRSA evaluated the range of estimates provided by commenters, including higher-end estimates reflecting total operational workload and lower-end estimates reflecting use of existing systems and automation, and normalized these inputs into a per-response estimate consistent with PRA requirements.

HRSA considered higher estimates provided by some commenters, including those based on full-time equivalent staffing or total weekly workload, but determined that these estimates reflect overall operational impacts rather than the incremental time required to complete individual reporting responses under the PRA framework. HRSA also considered that the Pilot will implement a rebate approach for a limited set of drugs and is designed to utilize a targeted and limited set of claims-level data elements necessary to administer rebate eligibility and prevent duplicate discounts and diversion. These standardized data elements are commonly available and already generated, maintained, and transmitted by covered entities or their vendors.

HRSA recognizes that covered entities vary in size, patient volume, staffing capacity, and technical infrastructure. As a result, the time required to submit data to manufacturers will differ across entities, with some smaller or less complex entities initially experiencing lower burden and larger or more complex entities initially experiencing higher burden. Alternatively, the more complex entities may have a more sophisticated operations infrastructure that will lower the burden of adopting reporting requirements. The estimate of 5 hours per response reflects a reasonable median burden across this range of entities and is consistent with PRA guidance to estimate typical respondent effort.

Taken together, the comments demonstrate that the reporting process involves multiple steps beyond a simple transmission of data. However, based on the task-based methodology, the limited scope of the Pilot, and the ability of many covered entities to leverage existing systems and processes, HRSA has determined that maintaining the estimated burden of 5 hours per week to respond provides a reasonable and appropriate estimate of the time required for covered entities to comply with the data submission requirements.

Need and Proposed Use of the Information: The scope of the anticipated Pilot will be limited to manufacturers with current Medicare Drug Price Negotiation Program Agreements with the Centers for Medicare & Medicaid Services for the initial price applicability years (IPAY) 2026 and 2027.[1] This ICR 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 monitor implementation of the Pilot and enhance 340B program integrity and compliance monitoring, and the collection of data submitted by covered entities to manufacturers to request a rebate under a potential Pilot.

Collection of Drug Manufacturer Applications: OPA will review, evaluate and approve manufacturer plans for participation in the Pilot based on requirements to be published in the **Federal Register** at a future date.

Collection of Reporting Data from Manufacturers: Under the Pilot, approved manufacturers will be required to submit data to the 340B Prime Vendor on a monthly basis to monitor Pilot implementation and to provide greater transparency into 340B claims transactions. Monthly data submissions will enhance overall 340B Program compliance monitoring and reduce lag time in assessing 340B Program metrics. The monthly data will also support the ongoing monitoring of the Pilot.

Collection of Data Submitted by Covered Entities to Manufacturers: Under a Pilot, covered entities will be required to provide specific data to participating manufacturers in order for the manufacturers to provide rebates to

[1] 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.

effectuate the 340B price on the covered entities' eligible covered outpatient drug purchases. Specific requirements detailing the type and frequency of such submittals will be defined in a **Federal Register** notice, to include claims level data elements for 340B-eligible dispenses. The data submitted by covered entities to manufacturers is comparable to data already being collected and maintained by covered entities through existing third-party vendor relationships.

Likely Respondents: Drug 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 Pilot compared to current data collection practices in the market.

The total annual burden hours estimated for this ICR reflect the number of respondents once an anticipated Pilot is implemented. This includes 11 manufacturers of IPAY 2026 and IPAY 2027 drugs.

Total Estimated Annualized Burden Hours:

TABLE 1

Form 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	11	1	11	8	88
Monthly purchase reports	11	12	132	2	264
Covered Entities reporting claims data to third party platform	** 15,249	52	792,948	5	3,964,740
Total	15,260		793,080		3,965,092

The 11 manufacturers will submit Plans and Monthly Purchase Reports (first two rows, above), while the 15,249 Covered Entities will submit Claims Data (third row, above). Therefore, the total number of respondents is 15,260

** As of April 1, 2026.

Amy P. McNulty,

Deputy Director, Executive Secretariat.

[FR Doc. 2026–11989 Filed 6–12–26; 8:45 am]

BILLING CODE 4165–15–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Diabetes and Digestive and Kidney Diseases; Amended Notice of Meeting

Notice is hereby given of a change in the meeting of the National Diabetes and Digestive and Kidney Diseases Advisory Council, July 01, 2026, 01:00 p.m. to July 01, 2026, 03:00 p.m., National Institutes of Health, Democracy II, National Institutes of Diabetes and Digestive and, 6707 Democracy Boulevard, Bethesda, MD 20892 which was published in the **Federal Register** published on March 19, 2026, FR Doc. 91 FR 13316.

This notice is being amended to add a one-hour open session from 1 p.m. to 2 p.m. The meeting is partially closed to the public.

Dated: June 10, 2026.

Margaret N. Vardanian,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2026–11936 Filed 6–12–26; 8:45 am]

BILLING CODE 4167–05–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, June 29, 2026, 10:00 a.m. to June 30, 2026, 06:00 p.m., National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892 which was published in the **Federal Register** on June 01, 2026, 91 FR 32404, FR Doc No. 2026–10931.

The meeting is being amended to change the SRO/contact person from Konrad J. Krzewski to John Laity. The meeting is closed to the public.

Dated: June 11, 2026.

Bruce A. George,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2026–11999 Filed 6–12–26; 8:45 am]

BILLING CODE 4167–05–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Government Owned Inventions Available for License: Fluorophthalimides as Anti-Inflammatory Agents for Systemic and Neurodegenerative Disorders

AGENCY: National Institutes of Health, HHS.

ACTION: Notice.

SUMMARY: The National Institute on Aging (NIA) seeks research co-development partners and/or licensees for the pre-clinical and clinical development of the compounds as anti-inflammatory therapeutics for systemic and neurodegenerative disorders.

FOR FURTHER INFORMATION CONTACT: Inquiries related to this license opportunity should be directed to: Nikki Guyton, Ph.D., Unit Supervisor, NCI, Technology Transfer Center, Email: