If you do not wish your name and contact information be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify the information as ''confidential.'' Any information marked as ''confidential'' will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: *https://www.govinfo.gov/content/pkg/FR-2015-09-18/pdf/2015-23389.pdf*.

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to *https://www.regulations.gov* and insert the docket number, found in brackets in the heading of this document, into the ''Search'' box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 240–402–7500.

FOR FURTHER INFORMATION CONTACT: Letise Williams, Center for Devices & Radiological Health, Food and Drug Administration, 10903 New Hampshire Avenue, Building 66, Room 5407, Silver Spring, MD 20993, *Letise.Williams@fda.hhs.gov,* 301–796–8398, or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area). A notice in the **Federal Register** about last-minute modifications that impact a previously announced advisory committee meeting cannot always be published quickly enough to provide timely notice. Therefore, you should always check FDA's website at *https://www.fda.gov/AdvisoryCommittees/default.htm* and scroll down to the appropriate advisory committee meeting link or call the advisory committee information line to learn about possible modifications before the meeting.

SUPPLEMENTARY INFORMATION:

Agenda: The meeting presentations will be heard, viewed, captioned, and recorded through an online teleconferencing and/or video conferencing platform.

On November 6, 2025, the Committee will discuss and make recommendations on the topic of ''Generative Artificial Intelligence-Enabled Digital Mental Health Medical Devices.'' Many of these medical devices pose novel risks and, as mental health devices continue to evolve in complexity, regulatory approaches ideally will also evolve to accommodate these novel challenges and opportunities to provide a reasonable assurance of their safety and effectiveness while promoting innovation to support public health. There is an increasing demand for mental health services in the US and insufficient access to mental health care providers. These new devices may be one way to help address this gap in care for people, potentially improving outcomes and access. The committee will discuss the benefits, risks to health, and risk mitigations that might be considered for these new digital mental health devices, including premarket evidence and postmarket monitoring considerations.

FDA intends to make background material and the link to the live webcast available to the public no later than (2) business days before the meeting. If FDA is unable to post the background material on its website prior to the meeting, the background material will be made publicly available on FDA's website at the time of the advisory committee meeting. Background materials and the link to the online teleconference and/or video conference meeting will be available at *https://www.fda.gov/AdvisoryCommittees/Calendar/default.htm.* Scroll down to the appropriate advisory committee meeting link.

The meeting will include slide presentations with audio and video components to allow the presentation of materials in a manner that most closely resembles an in-person advisory committee meeting.

Procedure: Interested persons may present data, information, or views, orally or in writing, on issues pending before the Committee. All electronic and written submissions to the Docket (see **ADDRESSES**) on or before October 17, 2025, will be provided to the Committee. Oral presentations from the public will be scheduled between approximately between 10:30 a.m. and 12:30 p.m. Eastern Time. Those individuals interested in making formal oral presentations should notify the contact person and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation on or before October 9, 2025. Time allotted for each presentation may be limited. If the number of registrants requesting to speak is greater than can be reasonably accommodated during the scheduled open public hearing session, FDA may conduct a lottery to determine the speakers for the scheduled open public hearing session. The contact person will notify interested persons regarding their request to speak by October 10, 2025.

For press inquiries, please contact the HHS Press Room at *www.hhs.gov/press-room/index.html* or 202–690–6343. FDA welcomes the attendance of the public at its advisory committee meetings and will make every effort to accommodate persons with disabilities. If you require accommodations due to a disability, please contact CDR Daniel Bailey, M.S., M.B.A, M.DIV, at *Daniel.bailey@fda.hhs.gov* or 301–529–54505 at least 7 days in advance of the meeting.

FDA is committed to the orderly conduct of its advisory committee meetings. Please visit our website at *https://www.fda.gov/AdvisoryCommittees/AboutAdvisoryCommittees/ucm111462.htm* for procedures on public conduct during advisory committee meetings.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. 1001 *et seq.*). This meeting notice also serves as notice that, pursuant to 21 CFR 10.19, the requirements in 21 CFR 14.22(b), (f), and (g) relating to the location of advisory committee meetings are hereby waived to allow for this meeting to take place using an online meeting platform. This waiver is in the interest of allowing greater transparency and opportunities for public participation, in addition to convenience for advisory committee members, speakers, and guest speakers. The conditions for issuance of a waiver under 21 CFR 10.19 are met.

Grace R. Graham,

Deputy Commissioner for Policy, Legislation, and International Affairs.

[FR Doc. 2025–17651 Filed 9–11–25; 8:45 am]

BILLING CODE 4164–01–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 November 12, 2025.

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 FR 38165; 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 FR 38166–67).

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 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 (FR 38166). 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.

[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.*

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 9–11–25; 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: Nurse Faculty Loan Program Forms OMB No. 0915–0314—Revision

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

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 November 12, 2025.

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: Nurse Faculty Loan Program Forms OMB No. 0915–0314—Revision.

Abstract: This clearance request seeks approval for the Nurse Faculty Loan Program (NFLP) Forms. The forms included are the NFLP—Program Specific Data Form, NFLP—Annual Performance Report (APR) Financial Data Form, and the NFLP Due Diligence Form. They are currently approved under OMB Approval No. 0915–0314, with the expiration date of August 31, 2026. For greater clarity and consistency, the only change to this information collection request is to change the title from the ''Nurse Faculty Loan Program—Program Specific Data Form, Annual Performance Report Financial Data Form, and NFLP Due Diligence Form'' to the ''Nurse Faculty Loan Program Forms.''

Need and Proposed Use of the Information: Section 846A of the Public Health Service Act provides the Secretary of HHS with the authority to provide grants to accredited schools of nursing for the establishment and operation of student loan funds to increase the number of qualified nurse faculty. HRSA makes awards to accredited schools of nursing and the schools provide loans to students enrolled in advanced education nursing degree programs who are committed to becoming nurse faculty. Following graduation from the NFLP grant recipient school, NFLP borrowers may receive up to 85 percent of loan cancellation over a 4-year period in exchange for service as full-time faculty at a school of nursing. The NFLP grant recipient school collects any portion of the loan that is not cancelled and any loans that go into repayment and deposits these monies into the NFLP loan fund to make additional NFLP loans.

The NFLP—Program Specific Data Form is a required electronic attachment within the NFLP application materials. The data provided in the form is an essential component of the formula-based criteria used to determine the amount awarded to the applicant schools. The form collects application-related data from applicants such as the amount requested, number of students to be funded, tuition information, and projected unused loan fund balance. This data collection assists HRSA in streamlining the application submission process, enabling an efficient award determination process, and facilitating reporting on the use of funds and analysis of program outcomes. There are no changes to this form.

The NFLP—APR Financial Data Form is an online form that collects outcome and financial data to capture the NFLP loan fund account activity related to financial receivables, disbursements, and borrower account data related to employment status, loan cancellation, loan repayment and collections. NFLP grant recipient schools will provide HHS with current and cumulative information on (1) NFLP loan funds received, (2) number and amount of NFLP loans made, (3) number and amount of loans cancelled, (4) number and amount of loans in repayment, (5) loan default rate percent, (6) number of NFLP graduates employed as nurse faculty, and (7) other related loan fund costs and activities. The NFLP—APR Financial Data Form is used to monitor grantee performance by collecting information related to the NFLP loan fund operations and financial activities for a specified reporting period (July 1 through June 30 of the academic year). NFLP grant recipient schools are required to complete and submit the NFLP—APR Financial Data Form annually. The data provided in the form is essential for HRSA to effectively monitor the school's use of NFLP funds in accordance with the statute and program guidelines. There are no changes to this form.

The NFLP Due Diligence Form is a required form that is completed and submitted electronically by NFLP grant recipient schools. This form indicates that due diligence has been exercised in the cancellation of any remaining loan funds for NFLP borrowers due to permanent/total disability, death, and uncollectible/bad debt write-offs. The data collected on the due diligence form will include the student borrower's unique ID number, reason for cancellation, the amount of principal loaned, the total amount of principal loan funds and corresponding interest canceled, and the outstanding amount of principal/interest that would be canceled because of death or permanent disability or written-off as uncollectible/bad debt. The NFLP Due Diligence Form is essential for monitoring performance measure outcomes and to verify and validate accuracy of information submitted on the NFLP Annual Performance Reports. There have been no changes to this form.

Likely Respondents: NFLP grant recipient schools and applicants to the NFLP program.

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