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.

Amy P. McNulty,

Deputy Director, Executive Secretariat.

[FR Doc. 2026–00104 Filed 1–7–26; 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: Enrollment and Re-Certification of Entities in the 340B Drug Pricing Program, OMB No. 0915–0327—Revision

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

ACTION: Notice.

SUMMARY: In compliance with the Paperwork Reduction Act 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 February 9, 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: When submitting comments or requesting information, please include the information collection request title for reference.

Information Collection Request Title: Enrollment and Re-Certification of Entities in the 340B Drug Pricing Program, OMB No. 0915–0327—Revision.

Abstract: Section 602 of Public Law 102–585, the Veterans Health Care Act of 1992, enacted section 340B of the Public Health Service (PHS) Act, which instructs HHS to enter into a Pharmaceutical Pricing Agreement (PPA) with manufacturers of covered outpatient drugs. Manufacturers are also required by section 1927(a)(5)(A) of the Social Security Act to enter into agreements with the Secretary of HHS (Secretary) that comply with section 340B of the PHS Act if they participate in the Medicaid Drug Rebate Program. When a drug manufacturer signs a PPA, it is opting into the 340B Drug Pricing Program (340B Program), and it agrees to the statutory requirement that prices charged for covered outpatient drugs to covered entities will not exceed statutorily defined 340B ceiling prices. When an eligible covered entity voluntarily decides to enroll and participate in the 340B Program, it accepts responsibility for ensuring compliance with all provisions of the 340B Program, including all associated costs. Covered entities that choose to participate in the 340B Program must comply with the requirements of section 340B(a)(5) of the PHS Act. Section 340B(a)(5)(A) of the PHS Act prohibits a covered entity from accepting a discount for a drug that would also generate a Medicaid rebate. Further, section 340B(a)(5)(B) of the PHS Act prohibits a covered entity from reselling or otherwise transferring a discounted drug to a person who is not a patient of the covered entity.

A 60-day notice published in the **Federal Register** on August 7, 2025, vol. 90, No. 150; pp. 38167–38169. There were 14 public comments.

Issue	Summary of comments	Actions to address comments
Shipping Address Clarifications.	Some covered entities disagree with the additional clarifying questions identifying wholly owned pharmacies and health care service delivery sites.	HRSA developed the new shipping address submission process to streamline communication with covered entities and improve efficiency. The policy on what qualifies as a shipping address remains unchanged.
New documentation requirements for Sexually Transmitted Disease (STD) entities.	Some covered entities are concerned that the proposed documentation to support STD eligibility will strain small and community-based STD clinics with limited administrative staff and funding.	The new requirements for STD covered entities are intended to improve transparency, program integrity, and enable HRSA to more effectively confirm and maintain eligibility for all stakeholders.
Request for technical assistance to implement STD written agreements.	Some entities are concerned about the timeline and support needed to comply with the STD written agreements. Therefore, they request that technical assistance be provided by the Office of Pharmacy Affairs and/or Apexus to help implement these new requirements and an implementation period to execute the changes.	HRSA understands the operational challenges described in the comments and will take these concerns into account; however, this documentation is necessary for HRSA to provide oversight. HRSA will continue to provide outreach and technical assistance to ensure covered entities understand documentation requirements and can comply with them in a timely manner.
Trial Balance Language.	Some stakeholders are concerned with the language update regarding entities that should submit a trial balance that clearly indicates unique and separate reimbursable outpatient costs and charges for each service being requested. They are concerned this will create a burden or result in inappropriate modification or termination.	HRSA is clarifying the required elements of a trial balance for hospitals registering a child site to ensure compliance with program requirements. The criteria for what qualifies as a child site remain unchanged.

Need and Proposed Use of the Information: To ensure the ongoing responsibility to administer the 340B Program while maintaining efficiency, transparency, and integrity, HRSA developed a process of registration for covered entities to enable it to address specific statutory mandates. Specifically, section 340B(a)(9) of the PHS Act requires HRSA to notify manufacturers of the identities of covered entities and of their status pertaining to certification and annual recertification in the 340B Program pursuant to section 340B(a)(7) and the establishment of a mechanism to prevent duplicate discounts as outlined at section 340B(a)(5)(A)(ii) of the PHS Act.

In addition, section 340B(a)(1) of the PHS Act requires each participating manufacturer to enter into an agreement with the Secretary to offer covered outpatient drugs to 340B covered entities.

Finally, section 340B(d)(1)(B)(i) of the PHS Act requires the development of a system to enable the Secretary to verify the accuracy of ceiling prices calculated by manufacturers under subsection (a)(1) and charged to covered entities.

HRSA is requesting approval for existing information collections. HRSA notes that the previously approved collections are mostly unchanged, except some forms have been revised to increase program efficiency and integrity. Below are descriptions of each form and any resulting revisions that are captured in both the registration and pricing component of the 340B Office of Pharmacy Affairs Information System (OPAIS).

Enrollment/Registration/Recertification

To enroll and certify the eligibility of federally funded grantees and other safety net health care providers, HRSA requires covered entities to submit administrative information (*e.g.,* shipping and billing arrangements, Medicaid participation), certifying information (*e.g.,* Medicare Cost Report information, documentation supporting the hospital's selected classification), and attestation from appropriate grantee-level or entity-level authorizing officials and primary contacts. To maintain accurate records, HRSA requests entities submit modifications to any administrative information that they submitted when initially enrolling into the 340B Program. Covered entities participating in the 340B Program have an ongoing responsibility to immediately notify HRSA in the event of any change in eligibility for the 340B Program. Covered entities must comply with the statutory mandates of the 340B Program and, at least annually, need to certify the accuracy of the information provided and continued maintenance of their eligibility.

Registration and annual recertification information is entered into the 340B OPAIS by covered entities and verified by HRSA staff according to 340B Program requirements. The following forms are being revised:

(1) *340B Registration, Recertification and Change Requests for Shipping Address:* HRSA is providing additional clarification for covered entities to complete the shipping address section in 340B OPAIS to improve transparency and assist in determining the exact shipping address location and relationship to the covered entity. The information collected will help determine whether the shipping address is a pharmacy, health care delivery site, or other receiving location. The information collected will also help determine if the location should be listed as a shipping address or potentially registered separately in OPAIS as a contract pharmacy or covered entity. Reviewing shipping addresses has become difficult and inefficient for both the covered entity and HRSA because it can involve sending the task back to the covered entity, sometimes multiple times, before HRSA can appropriately act on the task. The burden will not be significantly affected since the requested language facilitates a more efficient review with fewer exchanges between the covered entity and HRSA.

(2) *340B Registration and Recertification for STD and Tuberculosis (TB) Grantees:* HRSA is requesting that STD and TB grantees provide supporting documentation to demonstrate 340B eligibility pursuant to section 340B(a)(4)(K) of the PHS Act during initial registration as well as during recertification if requested to ensure compliance. The requested documentation will include a copy of the federal grant notice of award that identifies the grantor, grant number, period of funding, and recipient information. If the entity is a subgrantee, they will also need to provide a copy of the executed written subrecipient agreement that includes the name and address of the recipient and subrecipient, the grant and notice of funding opportunity number, and the terms and conditions of support. This new requirement streamlines the verification process and enhances program integrity for STD and TB entity types. This requirement will slightly increase the burden on covered entities since eligible covered entities should already have this documentation readily available prior to registering and recertifying for the 340B Program.

(3) *340B Program Registrations, Recertifications, and Change Requests for Family Planning (Title X):* HRSA is requesting to collect the time period that assistance was received for Family Planning (Title X) covered entities. The addition of these fields is consistent with information collected from Ryan White, STD, and TB entities at registration and recertification and will support HRSA's ability to verify a Family Planning covered entity's eligibility in the 340B Program as outlined in section 340B(a)(4)(C) of the PHS Act. This collection of time period information is a minor addition that will not significantly affect the burden on covered entities, as the time period when assistance was received is a readily available data point for Family Planning (Title X) covered entities.

(4) *340B Recertification and Change Requests for Street Address:* HRSA is providing additional clarification for covered entities that revise their street address in 340B OPAIS to assist in determining continued eligibility as outlined in section 340B(a)(4) of the PHS Act. OPAIS will prompt the covered entity to state if they are still receiving federal funding that makes them eligible for the 340B Program and/or if the service remains open at the old address. The answers to these questions will help determine the next appropriate action taken by the covered entity and HRSA. The collection of this information will not increase the burden on covered entities because it provides increased transparency and facilitates a more efficient review with fewer exchanges between the covered entity and HRSA.

(5) *340B Program Registrations, Recertifications, and Change Requests for Urban Indian and Tribal Contract/Compact with Indian Health Service (FQHC628) Covered Entities:* HRSA is requesting the Tribal Agreement number in OPAIS for registrations and recertifications for Urban Indian and FQHC638 covered entities. This helps increase program integrity by providing information that can be used to verify the eligibility of a specific grant for a specific entity. This collection of information is not expected to significantly increase burden as this information is readily available to covered entities on the agreements they have with their granting organization.

(6) *340B Program Registrations, Recertifications, and Change Requests for Hospitals:* HRSA is revising a hospital qualification field in OPAIS from the language ''File Date'' to ''Date/Time Prepared'' to match Centers for

Medicare & Medicaid Services (CMS) language on Worksheet S of a hospital's most recently filed Medicare Cost Report (MCR). This eliminates confusion for covered entities and clarifies what HRSA considers the ''file date.'' This update will not change the burden on covered entities.

(7) *340B Program Registrations, Recertifications, and Change Requests for Hospitals:* HRSA is revising a hospital qualification field in OPAIS from the language ''Medicare Provider Number'' to ''CMS Certification Number'' to match CMS language on Worksheet S of the hospital's most recently filed MCR. This provides consistency with CMS language as they no longer use the term ''Medicare Provider Number.'' This update does not impact burden on covered entities as there is no action needed to be taken on the covered entities' part for this change to occur.

(8) *340B Program Registrations for Hospitals:* HRSA is clarifying Worksheet S instructions for hospitals to include a copy of their signed, dated, and electronically encrypted Worksheet S from the latest filed MCR. This language will be updated on the initial registration instructions as well as in the actual registration. This updated language clarifies the exact documentation required for submission which results in fewer exchanges with covered entities. This update does not impact burden on covered entities.

(9) *340B Program Registrations for Hospitals:* HRSA is revising an instructional update and clarifying the registration form language for trial balance and cost center information to clarify that entities should submit a trial balance that clearly indicates unique and separate reimbursable outpatient costs and charges for each service being registered. This update will not change the burden on covered entities as there is no new or revised collection requirement.

Contract Pharmacy Certification

There are no changes being made to Contract Pharmacy Certification from prior submissions. There is no change in burden on the covered entities.

PPA and Addendum

There are no changes being made to PPA and Addendum from prior submissions. There is no change in burden on the manufacturers.

Pricing Data Submission, Validation, and Dissemination

There are no changes being made to Pricing Data Submission, Validation, and Dissemination from prior submissions. There is no change in burden on the manufacturers.

Likely Respondents: Drug manufacturers and 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

Form name	Number of respondents	Number of responses per respondent	Total responses	Average burden per response (in hours)	Total burden hours****
Hospital Enrollment, Additions & Recertifications					
340B Program Registrations & Certifications for Hospitals*	172	1	172	2.00	344
Certifications to Enroll Hospital Outpatient Facilities*	1,036	6	6,216	0.50	3,108
Hospital Annual Recertifications*	2,699	13	35,087	0.25	8,772
Registrations and Recertifications for Covered Entities Other Than Hospitals					
340B Registrations for Community Health Centers*	350	3	1,050	1.00	1,050
340B Registrations for STD/TB Clinics**	341	1	341	1.25	426
340B Registrations for Various Other Eligible Entity Types***	177	1	177	1.25	221
Community Health Center Annual Recertifications*	1,840	7	12,880	0.25	3,220
STD and TB Annual Recertifications*	6,412	1	6,412	0.25	1,603
Annual Recertification for entities other than Hospitals, Community Health Centers, and STD/TB Clinics*	3,407	1	3,407	0.25	852
Contracted Pharmacy Services Registration & Recertifications					
Contracted Pharmacy Services Registration	4,376	11	48,136	1.00	48,136
Other Information Collections					
Submission of Administrative Changes for any Covered Entity*	24,829	1	24,829	0.25	6,207
Submission of Administrative Changes for any Manufacturer	471	1	471	0.50	236
PPA and Addendum	73	1	73	1.00	73
Total	46,183		139,251		74,248

* Minor revisions to the language on the forms since the last OMB submission, but burden has not been impacted.
** Average Burden was increased from 1 to 1.25, compared to the prior version of this package.

*** Average Burden was increased from 1 to 1.25, compared to the prior version of this package. This is due to an additional field being added for Family Planning covered entities.
**** Total Burden Hours are rounded up to the nearest whole number.

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.

Amy P. McNulty,

Deputy Director, Executive Secretariat.

[FR Doc. 2026–00179 Filed 1–7–26; 8:45 am]

BILLING CODE 4165–15–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center for Scientific Review; Notice of Closed Meeting

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

The meeting 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, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Immunological Mechanisms of Autoimmunity.

Date: January 20, 2026.

Time: 9:30 a.m. to 1:00 p.m.

Agenda: To review and evaluate grant applications.

Address: National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892.

Meeting Format: Virtual Meeting.

Contact Person: Maria Chiara G. Monaco-kushner, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Dr., Bethesda, MD 20892, (301) 555–1212, *monaco@csr.nih.gov.*

Late Notice Text: This notice is being published less than 15 days from the meeting date due to exceptional circumstances. As a result of the 43-day government shutdown, due to lapsed appropriations, the above meeting was canceled. This meeting was to assess the scientific and technical merit of NIH grant applications, required by statute to disburse NIH funds. The meeting must take place urgently so that evaluations of biomedical research applications addressing multiple major public health priorities can be submitted to the national advisory councils for timely funding recommendations.

Dated: January 6, 2026.

Sterlyn H. Gibson,

Program Specialist, Office of Federal Advisory Committee Policy.

[FR Doc. 2026–00205 Filed 1–7–26; 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 Meeting

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

The meeting 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, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Fellowships: Physiology and Pathobiology of Cardiovascular and Respiratory Systems.

Date: January 21, 2026.

Time: 9:00 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Address: National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892.

Meeting Format: Virtual Meeting.

Contact Person: Yuanyi Feng, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, (301) 594–1180, *fengy7@csr.nih.gov.*

Late Notice Text: This notice is being published less than 15 days from the meeting date due to exceptional circumstances. As a result of the 43-day government shutdown, due to lapsed appropriations, the above meeting was canceled. This meeting was to assess the scientific and technical merit of NIH grant applications, required by statute to disburse NIH funds. The meeting must take place urgently so that evaluations of biomedical research applications addressing multiple major public health priorities can be submitted to the national advisory councils for timely funding recommendations.

Dated: January 6, 2026.

Rosalind M Niamke,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2026–00204 Filed 1–7–26; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HOMELAND SECURITY

U.S. Immigration and Customs Enforcement

Departure Notification Record

AGENCY: U.S. Immigration and Customs Enforcement.

ACTION: 60-Day notice.

SUMMARY: The information collection Departure Notification Record (DNR), OMB Control Number 1653–0057, was reinstated on December 22, 2025. In accordance with the Paperwork Reduction Act (PRA) of 1995, the Department of Homeland Security (DHS), U.S. Immigration and Customs Enforcement (ICE) will submit the following Information Collection Request (ICR) to the Office of Management and Budget (OMB) to extend this currently approved collection. DHS is soliciting comments for this collection.

DATES: Comments are encouraged and must be submitted March 9, 2026 to be assured of consideration.

ADDRESSES: All submissions received must include the OMB Control Number 1653–0057 in the body of the correspondence, the agency name and Docket ID ICEB–XXXX–XXXX. All comments received will be posted without change to *http://www.regulations.gov,* including any personal information provided. Submit comments via the Federal eRulemaking Portal website at *http://www.regulations.gov* under e-Docket ID number ICEB XXXX–XXXX.

FOR FURTHER INFORMATION CONTACT: If you have questions related to this collection please contact: Omar Charris, 202–200–1988, *Omar.A.Charris@ice.dhs.gov,* U.S. Immigration and Customs Enforcement. (This is not a toll-free number. Comments are not accepted via telephone message.)

SUPPLEMENTARY INFORMATION: