collections are available on the internet at *https://www.reginfo.gov/public/do/PRAMain.* An Agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.

TABLE 1—LIST OF INFORMATION COLLECTIONS APPROVED BY OMB

Title of collection	OMB control No.	Date approval expires
Infant Formula Requirements	0910–0256	3/31/2023
Export of Medical Devices; Foreign Letters of Approval	0910–0264	10/31/2025
Center for Devices and Radiological Health Appeals Processes	0910–0738	10/31/2025
Review Transparency & Communication for New Molecular Entity NDAs & Original BLAs	0910–0746	10/31/2025

Dated: October 24, 2022.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2022–23510 Filed 10–27–22; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Agency Information Collection Activities: Submission to OMB for Review and Approval; Public Comment Request; Enrollment and Re-Certification of Covered Entities in the 340B Drug Pricing Program, OMB Number 0915–0327—Revision.

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

ACTION: Notice.

SUMMARY: In compliance with of the Paperwork Reduction Act of 1995, HRSA has 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 November 28, 2022.

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 Acting HRSA Information Collection Clearance Officer, at *paperwork@hrsa.gov* or call (301) 443–9094.

SUPPLEMENTARY INFORMATION:

Information Collection Request Title: Enrollment and Re-Certification of Covered 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 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 was published in the **Federal Register** on June 14, 2022, vol. 87, No. 114; pp. 35983–85. There were five comments. Some comments addressed policy issues that are outside the scope of this information collection request. HRSA responded to technical comments that pertained to the ICR and revised the draft instruments based on the comments received.

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 in order 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 several forms have been revised to increase program efficiency and integrity. Below are descriptions of each of the forms and 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 covered entity level authorizing officials and primary contacts. To maintain accurate records, HRSA requests covered 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. No less than on an annual basis, covered entities need to certify the accuracy of the information provided and continued maintenance of their eligibility and to comply with statutory mandates of the 340B Program.

Registration and annual recertification information is entered into the 340B OPAIS by covered entities and verified by HRSA staff according to 340B Program requirements. In response to the comments received, HRSA has made technical and other revisions to the draft instruments and discusses the revisions below.

1. 340B Program Registrations & Recertifications for Hospitals (applies to all hospital types): In September 2017, HRSA launched 340B OPAIS, which among other things, removed the attestation requirement from the Government Official for the classification of a parent hospital, but it was still required for the covered entity to enter the Government Official contact information. As covered entities are no longer required to obtain this attestation, HRSA is removing the requirement for the covered entity to enter the Government Official contact information in 340B OPAIS. During the first public review of this ICR, commenters agreed with removing the Government Official contact information for a parent hospital.

2. 340B Registrations & Recertifications for Ryan White Covered Entities: Previously, HRSA requested that Ryan White covered entities provide a Notice of Funding Opportunity (NOFO) number at the time of registration and recertification. After reevaluation, HRSA has determined that the NOFO number is an unnecessary component to determine the eligibility of a Ryan White covered entity's registration. Since the NOFO number correlates to the Ryan White covered entity's Federal Grant Number, which is already required to be entered in 340B OPAIS during registration, the NOFO number is not needed. During the first public review of this ICR, commenters agreed with removing the requirement for Ryan White covered entities to provide a NOFO number at the time of registration and recertification.

3. 340B Registration, Recertification & Change Requests for Shipping Address: In the 60-day notice (87 FR 35,983, June 14, 2022), HRSA proposed to include clarifying information for covered entities to complete the shipping address section in 340B OPAIS. This information was added to assist covered entities in determining the exact shipping address location and relationship to the covered entity. In response to comments submitted during the first public review of this ICR, HRSA is removing this section from the instrument and will plan to release guidance on shipping address locations in the future.

4. 340B Program Registrations, Recertifications & Change Requests for Hospitals (applies to rural referral centers and sole community hospital covered entity types): HRSA proposed to revise the 340B OPAIS registration for the rural referral centers and sole community hospital covered entity types. If applicable, 340B OPAIS will prompt the covered entity for documentation that supports eligibility, which will be attached as part of its registration, recertification or change request submission. Currently, the request for the supporting eligibility documentation is obtained during the submission review process; therefore, this requirement would not change the burden on the covered entities.

5. 340B Program Registrations and Recertification for Authorizing Official Certification/Attestation: In the 60-day notice (87 FR 35,983, June 14, 2022), HRSA proposed to make revisions to the Authorizing Official certification by removing the requirement that any contract pharmacy arrangement is performed in accordance with OPA requirements and guidelines. Several commenters questioned why HRSA was removing this statement from the Authorizing Official's certification of a covered entity's registration or recertification in the 340B Program. HRSA removed this information as it was duplicative with information found on other instruments (*e.g.,* the contract pharmacy registration form) and already existed on the registration and recertification documentation. HRSA believes that this revision will reduce burden on covered entities.

6. 340B Program Change Requests for Hospitals: HRSA proposed inclusion of hospital qualification information such as, the Disproportionate Share Adjustment Percentage, control type, hospital classification, and contract start date to be changed under a change request submission as well as during recertification. This requirement would not change the burden on the covered entities, as this is an option to change the information by the hospital.

7. 340B Primary Contact and Authorizing Official Information: HRSA removed the FAX number field. This does not change the burden on covered entities, as this was an optional field.

8. 340B Program Recertifications & Change Requests for Hospitals: HRSA proposed clarifying when a covered entity would initiate a name change in 340B OPAIS. If applicable, 340B OPAIS will prompt the covered entity for documentation that supports the name change, which will be attached as part of its recertification or change request submission. In response to comments received, HRSA has made general technical and editorial revisions to this instrument.

9. Medicaid Billing Information: In the 60-day notice (87 FR 35,983, June 14, 2022), HRSA proposed to make a minor clarification regarding whether a 340B drug to an outpatient at a pharmacy or as part of a medical encounter. In response to comments submitted during the first public review of this ICR and after further consideration, HRSA is removing this section from the instrument and will plan to release future guidance on this issue.

Contract Pharmacy Certification

In order to ensure that drug manufacturers and drug wholesalers recognize contract pharmacy arrangements, covered entities that elect to utilize one or more contract pharmacies are required to submit general information about their contract pharmacy arrangements and certify that signed agreements are in place with those contract pharmacies.

Pharmaceutical Pricing Agreement and Addendum

Section 340B(a)(1) of the PHS Act provides that a manufacturer who sells covered outpatient drugs to eligible covered entities must sign a Pharmaceutical Pricing Agreement (the ''Agreement'') with the Secretary in which the manufacturer agrees to charge a price for covered outpatient drugs that

will not exceed the average manufacturer price (''AMP'') decreased by a rebate percentage. In addition, section 340B(a)(1) of the PHS Act includes specific requirements, which have been incorporated in the PPA with manufacturers of covered outpatient drugs. In particular, section 340B(a)(1) includes the following requirements:

I. ''Each such agreement shall require that the manufacturer furnish the Secretary with reports, on a quarterly basis, of the price for each covered outpatient drug subject to the agreement that, according to the manufacturer, represents the maximum price that covered entities may permissibly be required to pay for the drug (referred to in this section as the ''ceiling price'') and

II. ''. . . shall require that the manufacturer offer each covered entity covered outpatient drugs for purchase at or below the applicable ceiling price if such drug is made available to any other purchaser at any price.''

The burden imposed on manufacturers by submission of the PPA and PPA Addendum is low as the information is readily available.

Pricing Data Submission, Validation and Dissemination

In order to implement section 340B(d)(1)(B)(i)(II) of the PHS Act, HRSA developed a system to calculate 340B ceiling prices prospectively from data obtained from the Centers for Medicare & Medicaid Services as well as a third-party commercial database. However, in order to conduct the comparison required under the statute, manufacturers must submit the quarterly pricing data as required by section 340B(d)(1)(B)(i)(II). The 340B OPAIS securely collects the following data from manufacturers on a quarterly basis: AMP, unit rebate amount, package size, case pack size, unit type, national drug code, labeler code, product code, period of sale (year and quarter), Food and Drug Administration product name, labeler name, wholesale acquisition cost, and the manufacturer determined ceiling price for each covered outpatient drug produced by a manufacturer subject to a PPA. The burden imposed on manufacturers is low because the information requested is readily available and utilized by manufacturers in other areas.

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	Hours per respondent	Total burden hours
Hospital Enrollment, Additions & Recertifications					
340B Program Registrations & Certifications for Hospitals *	131	1	131	2.00	262
Certifications to Enroll Hospital Outpatient Facilities *	620	7	4340	0.50	2170
Hospital Annual Recertifications *	2618	10	26180	0.25	6545
Registrations and Recertifications for Covered Entities Other Than Hospitals					
340B Registrations for Community Health Centers *	679	1	679	1.00	679
340B Registrations for STD/TB Clinics *	864	1	864	1.00	864
340B Registrations for Various Other Eligible Covered Entity Types *	166	1	166	1.00	166
Community Health Center Annual Recertifications *	1277	7	8939	0.25	2235
STD & TB Annual Recertifications *	4033	1	4033	0.25	1008
Annual Recertification for covered entities other than Hospitals, Community Health Centers, and STD/TB Clinics *	4472	1	4472	0.25	1118
Contracted Pharmacy Services Registration & Recertifications					
Contracted Pharmacy Services Registration	3446	11	37906	1.00	37906
Other Information Collections					
Submission of Administrative Changes for any Covered Entity *	19322	1	19322	0.25	4831
Submission of Administrative Changes for any Manufacturer *	350	1	350	0.50	175
Pharmaceutical Pricing Agreement and PPA Addendum	200	1	200	1.00	200
Total	38,178		99,542		58,159

* Minor revisions since last the OMB submission, but burden was not affected.

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. 2022–23518 Filed 10–27–22; 8:45 am]

BILLING CODE 4165–15–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Allergy and Infectious Diseases Amended Notice of Meeting

Notice is hereby given of a change in the meeting of the National Institute of Allergy and Infectious Diseases Special Emphasis Panel, which was published in the **Federal Register** on October 11, 2022, FR Doc 2022–22017, 87 FR 61342.

Amendment to change panel name from NIAID Clinical Trial Planning Grant (R34 Clinical Trial Not Allowed) to NIAID Clinical Trial Planning Grant (R34 Clinical Trial Not Allowed) and Implementation Cooperative Agreement (U01 Clinical Trial Required). The meeting is closed to the public.

Dated: October 25, 2022.

Tyeshia M. Roberson-Curtis,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2022–23541 Filed 10–27–22; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Allergy and Infectious Diseases; Amended Notice of Closed Meeting

Notice is hereby given of a change in the meeting of the National Institute of Allergy and Infectious Diseases Special Emphasis Panel NIAID Investigator Initiated Program Project Applications (P01 Clinical Trial Not Allowed) which was published in the **Federal Register** on September 30, 2022, FR Doc 2022–21261, 87 FR 59446.

Amendment to change meeting date from October 26, 2022, to November 14, 2022. The meeting is closed to the public.

Dated: October 25, 2022.

Tyeshia M. Roberson-Curtis,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2022–23540 Filed 10–27–22; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Environmental Health Sciences; Notice of Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of a meeting of the Board of Scientific Counselors, NIEHS.

The meeting will be open to the public as indicated below, with attendance limited to space available. Individuals who plan to attend as well as those who need special assistance, such as sign language interpretation or other reasonable accommodations, should notify the Contact Person listed below in advance of the meeting. The open session will be videocast and can be accessed from the NIH Videocasting website (*http://videocast.nih.gov/*).

The meeting will be closed to the public as indicated below in accordance with the provisions set forth in section 552b(c)(6), Title 5 U.S.C., as amended for the consideration of personnel qualifications and performance, and the competence of individual investigators, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: Board of Scientific Counselors, NIEHS.

Date: December 4, 2022.

Closed: 7:00 p.m. to 8:30 p.m.

Agenda: Discussion of BSC Reviews.

Place: National Institute of Environmental Health Science, 111 T. W. Alexander Drive, Research Triangle Park, NC 27709 (Hybrid Meeting).

Open: December 5, 2022, 9:00 a.m. to 12:05 p.m.

Agenda: Meeting Overview and Q & A Sessions (Calcium Signaling in Health & Disease Group, Inositol Signaling Group, and Molecular Endocrinology Group).

Place: National Institute of Environmental Health Science, 111 T. W. Alexander Drive, Research Triangle Park, NC 27709 (Hybrid Meeting).

Closed: December 5, 2022, 12:05 p.m. to 1:05 p.m.

Agenda: To review and evaluate personnel qualifications and performance, and competence of individual investigators.

Place: National Institute of Environmental Health Science, 111 T. W. Alexander Drive, Research Triangle Park, NC 27709 (Hybrid Meeting).

Open: December 5, 2022, 1:05 p.m. to 2:45 p.m.

Agenda: Q & A Sessions (Nucleolar Integrity Group and Metabolism, Genes and Environment Group).

Place: National Institute of Environmental Health Science, 111 T. W. Alexander Drive, Research Triangle Park, NC 27709 (Hybrid Meeting).

Closed: December 5, 2022, 3:00 p.m. to 4:00 p.m.

Agenda: To review and evaluate personnel qualifications and performance, and competence of individual investigators.

Place: National Institute of Environmental Health Science, 111 T. W. Alexander Drive, Research Triangle Park, NC 27709 (Hybrid Meeting).

Open: December 5, 2022, 4:00 p.m. to 4:50 p.m.

Agenda: Q & A Sessions (In Vivo Neurobiology Group and Neurobiology Group).

Place: National Institute of Environmental Health Science, 111 T. W. Alexander Drive, Research Triangle Park, NC 27709 (Hybrid Meeting).

Closed: December 5, 2022, 4:50 p.m. to 5:05 p.m.

Agenda: To review and evaluate personnel qualifications and performance, and competence of individual investigators.

Place: National Institute of Environmental Health Science, 111 T. W. Alexander Drive, Research Triangle Park, NC 27709 (Hybrid Meeting).

Open: December 6, 2022, 8:45 a.m. to 9:35 a.m.

Agenda: Q & A Session (Mechanism of Mutation Group and Genome Integrity & Structural Biology Group).

Place: National Institute of Environmental Health Science, 111 T. W. Alexander Drive, Research Triangle Park, NC 27709 (Hybrid Meeting).

Closed: December 6, 2022, 9:50 a.m. to 10:05 a.m.

Agenda: To review and evaluate personnel qualifications and performance, and competence of individual investigators.

Place: National Institute of Environmental Health Science, 111 T. W. Alexander Drive, Research Triangle Park, NC 27709 (Hybrid Meeting).

Open: December 6, 2022, 10:05 a.m. to 12:00 p.m.

Agenda: Poster Session.

Place: National Institute of Environmental Health Science, 111 T. W. Alexander Drive, Research Triangle Park, NC 27709 (Hybrid Meeting).

Closed: December 6, 2022, 1:00 p.m. to 5:30 p.m.

Agenda: Session with Fellows and Staff Scientists; Review of Flow Cytometry Center Molecular Genomics Core Laboratory and Fluorescence Microscopy and Imaging Center; BSC Discussion & completion of Individual Review Assignments; Debriefing to NIEHS/DIR Leadership.

Place: National Institute of Environmental Health Science, 111 T. W. Alexander Drive, Research Triangle Park, NC 27709 (Hybrid Meeting).

Contact Person: Darryl C. Zeldin, Scientific Director & Principal Investigator, Division of Intramural Research, National Institute of Environmental Sciences, NIH, 111 T. W. Alexander Drive, Mail drop MSC A2–09, Research Triangle Park, NC 27709, 919–541–1169, *zeldin@niehs.nih.gov*.

Any interested person may file written comments with the committee by forwarding