performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology. Consideration will be given to comments and suggestions submitted within 60 days of this publication.

*Authority:* Section 5(a) of the ''Torture Victims Relief Act of 1998,'' Public Law 105–320 (22 U.S.C. 2152 note) Assistance for Treatment of Torture Victims.

**Mary B. Jones,**

*ACF/OPRE Certifying Officer.*

[FR Doc. 2022–12816 Filed 6–13–22; 8:45 am]

**BILLING CODE 4184–46–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Health Resources and Services Administration

**[OMB Number 0915–0327—Revision]**

### 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

**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 August 15, 2022.

**ADDRESSES:** Submit your comments to *paperwork@hrsa.gov* or by mail to the HRSA Information Collection Clearance Officer, Room 14N136B, 5600 Fishers Lane, Rockville, MD 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 acting HRSA Information Collection Clearance Officer at (301) 443–9094.

**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 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.

*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 some of the forms have been revised to increase program efficiency and integrity. Below are descriptions of each of the forms 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 to submit modifications to any administrative information that they submitted when initially enrolling into the 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 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. The following forms are being revised:

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. This will not change the burden on the entities.

2. *340B Registrations & Recertifications for Ryan White Entities:* Previously, HRSA requested that any Ryan White entity provide its 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 entity's registration. Since the NOFO number correlates to the Ryan White entity's Federal Grant Number, which is already required to be entered in 340B OPAIS during registration, the NOFO number is not needed. This will not change the burden on the covered entities.

3. *340B Registration, Recertification & Change Requests for Shipping Address:* HRSA is providing additional clarification for covered entities to complete the shipping address section in 340B OPAIS to assist in determining the exact shipping address location and relationship to the covered entity. This clarification will not change burden on entities.

4. *340B Program Registrations, Recertifications & Change Requests for Hospitals (applies to rural referral centers and sole community hospital entity types):* HRSA is revising the 340B OPAIS registration for the rural referral centers and sole community hospital types, in an effort to provide guidance that determines the eligibility criteria. 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 entities.

5. *340B Program Change Requests for Hospitals:* HRSA will allow 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 entities, as this is an option to change the information by the hospital.

6. *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.

7. *340B Program Recertifications & Change Requests for Hospitals:* HRSA is clarifying when the 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. Currently, the request for the supporting name change documentation is obtained during the submission review process, therefore, this requirement would not change the burden on covered entities.

**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. There is no change in burden on the entities.

**Pharmaceutical Pricing Agreement and Addendum**

In accordance with the 340B Program guidance issued in the May 7, 1993, **Federal Register**, section 340B(a)(1) of the PHS Act provides that a manufacturer who sells covered outpatient drugs to eligible entities must sign a Pharmaceutical Pricing Agreement (the ''Agreement'') with the Secretary of Health and Human Services (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 required components of 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), FDA 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 | 4,340 | 0.50 | 2,170 |
| Hospital Annual Recertifications * | 2,618 | 10 | 26,180 | 0.25 | 6,545 |
| **Registrations and Recertifications for 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 Entity Types * | 166 | 1 | 166 | 1.00 | 166 |
| Community Health Center Annual Recertifications * | 1,277 | 7 | 8,939 | 0.25 | 2,235 |
| STD & TB Annual Recertifications * | 4,033 | 1 | 4,033 | 0.25 | 1,008 |
| Annual Recertification for entities other than Hospitals, Community Health Centers, and STD/TB Clinics * | 4,472 | 1 | 4,472 | 0.25 | 1,118 |
| **Contracted Pharmacy Services Registration & Recertifications** | | | | | |
| Contracted Pharmacy Services Registration | 3,446 | 11 | 37,906 | 1.00 | 37,906 |
| **Other Information Collections** | | | | | |
| Submission of Administrative Changes for any Covered Entity * | 19,322 | 1 | 19,322 | 0.25 | 4,831 |
| Submission of Administrative Changes for any Manufacturer * | 350 | 1 | 350 | .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. 2022–12776 Filed 6–13–22; 8:45 am]

**BILLING CODE 4165–15–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

### Eunice Kennedy Shriver National Institute of Child Health and Human Development; Notice of Closed Meeting

Pursuant to section 10(d) 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:* National Institute of Child Health and Human Development Initial Review Group; Biobehavioral and Behavioral Sciences Study Section.

*Date:* July 22, 2022.

*Time:* 10:00 a.m. to 6:00 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* Eunice Kennedy Shriver National Institute of Child Health and Human Development, National Institutes of Health, 6710B Rockledge Drive, Room 2131B, Bethesda, MD 20892 (Video Assisted Meeting).

*Contact Person:* Luis E. Dettin, Ph.D., M.S., M.A., Scientific Review Officer, Scientific Review Branch, Eunice Kennedy Shriver National Institute of Child Health and Human Development, National Institutes of Health, 6710B Rockledge Drive, Room 2131B, Bethesda, MD 20892, (301) 219–3044, *luis.dettin@nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.865, Research for Mothers and Children, National Institutes of Health, HHS)

Dated: June 8, 2022.

**David W. Freeman,**

*Program Analyst, Office of Federal Advisory Committee Policy.*

[FR Doc. 2022–12800 Filed 6–13–22; 8:45 am]

**BILLING CODE 4140–01–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, Small Business: Health Informatics, June 29, 2022, 10:00 a.m. to June 29, 2022, 7:00 p.m., National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD, 20892 which was published in the **Federal Register** on June 03, 2022, FR Doc 2022–11873, 87 FR 33799.

This notice is being amended to change the meeting date from June 29, 2022, to June 29, 2022—June 30, 2022. The meeting is closed to the public.