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 Drug Pricing Program; Initiation of the Administrative Dispute Resolution Process

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) 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 October 7, 2024.

ADDRESSES: Submit your comments to *paperwork@hrsa.gov* or mail the HRSA Information Collection Clearance Officer, Room 14N39, 5600 Fishers Lane, Rockville, Maryland, 20857.

FOR FURTHER INFORMATION CONTACT: To request more information on the proposed project, email *paperwork@hrsa.gov* or call Joella Roland, 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 Drug Pricing Program; Initiation of the Administrative Dispute Resolution Process, OMB No. 0906–xxxx—New.

Abstract: Section 602 of Public Law 102–585, the Veterans Health Care Act of 1992, created the 340B Drug Pricing Program in section 340B of the Public Health Service (PHS) Act. The Secretary of HHS (Secretary) has delegated the authority to administer the 340B Drug Pricing Program to the HRSA Administrator, who has further delegated authority to the Office of Pharmacy Affairs (OPA), within HRSA, which oversees the 340B Drug Pricing Program. Eligible covered entity types are defined in section 340B(a)(4) of the PHS Act, as amended. Section 340B(a)(1) of the PHS Act instructs HHS to enter into pharmaceutical pricing agreements with manufacturers of covered outpatient drugs. Under section 1927(a)(5)(A) of the Social Security Act, a manufacturer must enter into an agreement with the Secretary that complies with section 340B of the PHS Act to receive payments from Medicaid or Medicare Part B for the manufacturer's covered outpatient drugs. When a manufacturer signs a pharmaceutical pricing agreement, it agrees that the prices charged for covered outpatient drugs to covered entities will not exceed statutorily defined 340B ceiling prices. Such prices are based on quarterly pricing reports that manufacturers must provide to the Secretary which are calculated and verified by HRSA.

Section 340B(d)(3) to the PHS Act requires HHS to promulgate regulations establishing and implementing a binding 340B Administrative Dispute Resolution (ADR) process for certain disputes arising under the 340B Drug Pricing Program. Pursuant to the statute, the 340B ADR process is intended to resolve (1) claims by covered entities that they have been overcharged for covered outpatient drugs by manufacturers and (2) claims by manufacturers, after a manufacturer has conducted an audit as authorized by section 340B(a)(5)(C) of the PHS Act, that a covered entity has violated the prohibition on diversion or duplicate discounts.

On April 19, 2024, HRSA published the 340B Drug Pricing Program; Administrative Dispute Resolution Regulation Final Rule (340B ADR Final Rule) (89 FR 28643 (Apr. 19, 2024) (to be codified at 42 CFR part 10)). The 340B ADR Final Rule provides the requirements for filing a 340B ADR claim. The 340B ADR Final Rule requires the submission of a 340B ADR claim within 3 years of the date of the alleged violation and specifies that it is a remedy open to all manufacturers and covered entities that participate in the 340B Drug Pricing Program. To initiate the 340B ADR process, a petitioner will email OPA's designated mailbox with its 340B ID or Labeler code and contact information, the 340B ID or Labeler code and contact information of the opposing party, and a brief description of the claim. Once a petition is filed, OPA reviews the petition to make sure the claim meets the requirements for the 340B ADR process, including whether: (1) the claim alleges a violation of an overcharge, duplicate discount, or diversion; (2) the claim has been filed within 3 years of the alleged violation; and (3) the petitioner has engaged in good faith efforts to resolve the claim. Both the petitioner and opposing party will be required to upload certain documentation to a secure 340B ADR workspace in the 340B OPA Information System to substantiate the claim. After an initial review of the claim and any supporting documentation, OPA staff will determine whether the requirements for filing a claim have been met, and if the claim is deemed complete, OPA will notify the parties. If the claim is deemed complete and all filing requirements are met, the claim will be assigned to a 340B ADR Panel. If the claim does not meet the filing requirements, OPA will dismiss the claim. Specific details concerning the 340B ADR Panel and requirements for filing a claim are outlined in the 340B ADR Final Rule and can be reviewed at *https://www.hrsa.gov/opa/340b-administrative-dispute-resolution.*

This information collection request is limited to the initiation of the 340B ADR process and the uploading of the related documents. Filing a claim though the 340B ADR process is a remedy open to all manufacturers and covered entities that participate in the 340B Drug Pricing Program, which can constitute a standardized federal information collection. Once the claim is assigned to a 340B ADR Panel for review, these subsequent steps, which encompass the 340B ADR process itself and ensuing correspondence with the parties involved in the process, are exempt from Paperwork Reduction Act requirements, pursuant to the Paperwork Reduction Act exception listed at 44 U.S.C. 3518(c), which exempts administrative actions or investigations involving an agency against specific individuals or entities.

Need and Proposed Use of the Information: HRSA is requesting approval for the initiation of the 340B ADR process and uploading of the related documents outlined in the 340B ADR Final Rule. The 340B ADR process is conducted pursuant to the requirements under section 340B(d)(3) of the PHS Act, which requires the establishment and implementation of the 340B ADR process for certain disputes arising under the 340B Drug Pricing Program. HRSA uses the information gathered in the 340B ADR initiation process to determine if the claim submitted meets the statutory requirements for filing a 340B claim and accessing the 340B ADR process.

Likely Respondents: Covered entities and manufacturers and organizations representing these groups.

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. To estimate the burden to initiate the 340B ADR process, HRSA reviewed the amount of petitions received under a prior 340B ADR process and estimated the amount of time it took petitioners to initiate the 340B ADR process up until the claim was assigned to a 340B ADR Panel for review. 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
340B Claim Submission	10	1	10	2.5	25
Total	10		10		25

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. 2024–17380 Filed 8–6–24; 8:45 am]

BILLING CODE 4165–15–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of General Medical Sciences; 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: National Institute of General Medical Sciences Special Emphasis Panel; Review of Center of Biomedical Research Excellence—COBRE (P20) Phase-2 Applications.

Date: November 21–22, 2024.

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

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, National Institute of General Medical Sciences, Natcher Building, 45 Center Drive, Bethesda, Maryland 20892 (Virtual Meeting).

Contact Person: Manas Chattopadhyay, Ph.D., Scientific Review Officer, Office of Scientific Review, National Institute of General Medical Sciences, National Institutes of Health, 45 Center Drive, Room 3AN12N, Bethesda, Maryland 20892, 301–827–5320, *manasc@mail.nih.gov*.

(Catalogue of Federal Domestic Assistance Program No. 93.859, Biomedical Research and Research Training, National Institutes of Health, HHS)

Dated: August 1, 2024.

Miguelina Perez,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2024–17408 Filed 8–6–24; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Diabetes and Digestive and Kidney Diseases; 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: National Institute of Diabetes and Digestive and Kidney Diseases Initial Review Group; Kidney, Urologic and Hematologic Diseases D Study Section.

Date: October 15–17, 2024.

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

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, NIDDK Democracy II, Suite 7000A, 6707 Democracy Boulevard, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Jason D. Hoffert, Ph.D., Scientific Review Officer, National Institute of Diabetes and Digestive and Kidney, National Institute of Health, 6707 Democracy Boulevard, Rm. 7343, Bethesda, MD 20817, 301–496–9010, *hoffertj@niddk.nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.847, Diabetes, Endocrinology and Metabolic Research; 93.848, Digestive Diseases and Nutrition Research; 93.849, Kidney Diseases, Urology and Hematology Research, National Institutes of Health, HHS)

Dated: August 1, 2024.

Miguelina Perez,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2024–17376 Filed 8–6–24; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute on Aging; 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