C. Selection Criteria and Process

FDA intends to select participant CBER and CDER INDs based on the criteria outlined below. Review of requests is planned to occur quarterly, or as needed, depending upon the requests to participate in the pilot that are received during the period. FDA intends to issue a letter to notify each sponsor of FDA's decision on their request to participate within 180 days of receipt.

In selecting INDs for the pilot program, FDA intends to consider factors such as (1) anticipated clinical benefits of facilitating earlier patient access to the product, (2) novelty of the product, (3) complexity of the product or its manufacturing process, including technology, (4) sponsor's overall manufacturing experience, as well as (5) sponsor's experience with the particular product type, class, or the type of manufacturing process. FDA may give additional consideration to less experienced sponsors. Overall, FDA intends to seek balance and diversity in product types, sponsors, and therapeutic indications to obtain a variety of relevant experience and learnings from the pilot.

D. FDA-Sponsor Interactions During the Pilot

During this CDRP program, sponsors will have the ability to discuss their product development strategies and goals with FDA review staff during predesignated Type B meetings and a limited number of additional CMC-focused discussions. As part of the CMC readiness pilot, two dedicated CMC meetings will be granted, and sponsors will have an opportunity for followup discussions to address questions arising from the meeting or meeting minutes, or if additional clarifications are needed.

In preparation for a meeting, sponsors should submit written questions along with a background information package clearly marked as a ''PDUFA VII CDRP meeting'' as part of the cover letter to enable FDA review staff to address the questions. The briefing package should be submitted to the corresponding IND. Meetings associated with the pilot should be requested by sponsors. For additional information on meetings and other communications between the sponsors and FDA, see the FDA guidance for industry entitled ''Formal Meetings Between the FDA and Sponsors or Applicants of PDUFA Products'' (December 2017) (Ref. 6), CDER MAPP 6025.6: *Good Review Practice: Management of Breakthrough Therapy-Designated Drugs and Biologics* (July 29, 2014) (Ref. 7), CBER SOPP 8101: *Regulatory Meetings with Sponsors and Applicants for Drugs and Biological Products* (February 27, 2022) (Ref. 8), and CBER SOPP 8212.3: *Management of Breakthrough Therapy-Designated Products: Sponsor Interactions and Status Assessment Including Rescinding* (February 3, 2022) (Ref. 9).

III. Paperwork Reduction Act of 1995

Collections of information from fewer than 10 respondents within any 12-month period are not subject to the Paperwork Reduction Act of 1995 (PRA) (5 CFR 1320.3(c)(4)). To the extent this information collection involves 10 or more respondents, this notice refers to previously approved collections of information. These collections of information are subject to review by the Office of Management and Budget (OMB) under the PRA (44 U.S.C. 3501–3521). The collections of information for NDAs, formal meetings with sponsors and applicants for PDUFA products, and PDUFA VII Commitment Letter have been approved under OMB control number 0910–0001. The collections of information for INDs have been approved under OMB control number 0910–0014. The collections of information for BLAs have been approved under OMB control number 0910–0338. The collections of information pertaining to CGMP requirements have been approved under OMB control number 0910–0139. The collections of information pertaining to expedited programs for serious conditions for drugs and biologics and breakthrough therapy-designation for drugs and biologics have been approved under OMB control number 0910–0765.

IV. References

The following references are on display at the Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 240–402–7500, and are available for viewing by interested persons between 9 a.m. and 4 p.m., Monday through Friday; they are also available electronically at *https://www.regulations.gov.* FDA has verified the website addresses, as of the date this document publishes in the **Federal Register**, but websites are subject to change over time.

1. PDUFA Reauthorization Performance Goals and Procedures—Fiscal Years 2023 through 2027 at *https://www.fda.gov/media/151712/download.*
2. FDA guidance for industry ''Expedited Programs for Serious Conditions—Drugs and Biologics'' (May 2014): *https://www.fda.gov/media/86377/download.*
3. FDA guidance for industry ''Providing Regulatory Submissions in Electronic Format—Certain Human Pharmaceutical Product Applications and Related Submissions using the eCTD Specifications'' (February 2020): *https://www.fda.gov/media/135373/download.*
4. FDA guidance for industry ''Process Validation: General Principles and Practices'' (January 2011): *https://www.fda.gov/files/drugs/published/Process-Validation—General-Principles-and-Practices.pdf.*
5. CDER MAPP 5015.13: *Quality Assessment for Products in Expedited Programs* (in clearance).
6. FDA guidance for industry ''Formal Meetings Between the FDA and Sponsors or Applicants of PDUFA Products'' (December 2017): *https://www.fda.gov/media/109951/download.*
7. CDER MAPP 6025.6: *Good Review Practice: Management of Breakthrough Therapy-Designated Drugs and Biologics* (July 2014).
8. CBER SOPP 8101: *Regulatory Meetings with Sponsors and Applicants for Drugs and Biological Products* (February 2022).
9. CBER SOPP 8212.3: *Management of Breakthrough Therapy-Designated Products: Sponsor Interactions and Status Assessment Including Rescinding* (February 2022).

Dated: October 25, 2022.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2022–23575 Filed 10–28–22; 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; The National Health Service Corps Loan Repayment Programs

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 Information Collection Request must be received no later than December 30, 2022.

ADDRESSES: Submit your comments to *paperwork@hrsa.gov* or mail them to HRSA Information Collection Clearance Officer, Room 14N136B, 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 acting HRSA Information Collection Clearance Officer, at (301) 443–9094.

SUPPLEMENTARY INFORMATION:

Information Collection Request Title: The National Health Service Corps (NHSC) Loan Repayment Programs (LRP) OMB No. 0915–0127—Revision.

Abstract: The NHSC LRP was established to assure an adequate supply of trained primary care health professionals to provide services in the neediest Health Professional Shortage Areas (HPSAs) of the United States. The NHSC Substance Use Disorder Workforce LRP and the NHSC Rural Community LRP were established to recruit and retain a health professional workforce with specific training and credentials to provide evidence-based substance use disorder treatment in HPSAs. Under these programs, the Department of Health and Human Services agrees to repay the qualifying educational loans of selected primary care health professionals. In return, the health professionals agree to serve for a specified period of time in an NHSC-approved site located in a federally-designated HPSA approved by the Secretary for LRP participants.

The forms utilized by each LRP include the following: (1) the NHSC LRP Application, (2) the Authorization for Disclosure of Loan Information form, (3) the Privacy Act Release Authorization form, and if applicable, (4) the Verification of Disadvantaged Background form, and (5) the Private Practice Option form. The first four of the NHSC LRP forms collect information that is needed for selecting participants and repaying qualifying educational loans. The last referenced form, the Private Practice Option Form, is needed to collect information for all participants who have applied for that service option.

NHSC-approved sites are health care facilities that provide comprehensive outpatient, ambulatory, primary health care services to populations residing in HPSAs. Related in-patient services may be provided by NHSC-approved Critical Access Hospitals and Indian Health Service hospitals. In order to become an NHSC-approved site, new sites must submit a Site Application for review and approval. Existing NHSC-approved sites are required to complete a Site Recertification Application every 3 years in order to maintain their NHSC-approved status. Both the NHSC Site Application and Site Recertification Application request information on the clinical service site, sponsoring agency, recruitment contact, staffing levels, service users, charges for services, employment policies, and fiscal management capabilities. Assistance in completing these applications may be obtained through the appropriate State Primary Care Offices and the NHSC. The information collected on the applications is used for determining the eligibility of sites for the assignment of NHSC health professionals and to verify the need for NHSC clinicians. NHSC service site approval is valid for 3 years.

Need and Proposed Use of the Information: The need and purpose of this information collection is to assess an LRP applicant's eligibility and qualifications for the LRP, and to obtain information for NHSC site applicants. The NHSC LRP application asks for personal, professional, and financial/loan information.

The proposed revisions in this ICR include asking applicants to provide their educational information on the completion of post graduate training. The NHSC will use this information to identify graduates or completers of the following HRSA-funded programs: the Primary Care Training and Enhancement: Training Primary Care Champions Program, the Addiction Medicine Fellowship, the Teaching Health Center Graduate Medical Education Program, the Advanced Nursing Education Nurse Practitioner Residency Program, or the Advanced Nursing Education Nurse Practitioner Residency Integration Program. To identify the graduates or completers of these HRSA-funded programs, the NHSC will require applicants to respond to the following additional questions:

(1) Have you completed a post graduate training?

(2) Applicants who selected ''yes'' to the question above are required to submit the National Practitioner Identifier number.

(3) Further, if applicable, applicants are asked to enter the residency identification number and their residency completion certificate, if available.

NHSC policy requires behavioral health providers to practice in a community-based setting that provides access to comprehensive behavioral health services. Accordingly, for those sites seeking to be assigned behavioral health NHSC participants, additional site information will be collected from an NHSC Comprehensive Behavioral Health Services Checklist. NHSC sites that do not directly offer all required behavioral health services must demonstrate a formal affiliation with a comprehensive, community-based primary behavioral health setting or facility to provide these services.

Likely Respondents: Likely respondents include: (1) Licensed primary care medical, dental, and mental and behavioral health providers who are employed or seeking employment, and are interested in serving underserved populations; (2) health care facilities interested in participating in the NHSC and becoming an NHSC-approved service site; and (3) NHSC sites providing behavioral health care services directly, or through a formal affiliation with a comprehensive community-based primary behavioral health setting or facility providing comprehensive behavioral health services.

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 Information Collection Request 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
NHSC LRP Application	9,020	1	9,020	1.00	9,020
Authorization for Disclosure of Loan Information Form	7,150	1	7,150	.10	715
Privacy Act Release Authorization Form	303	1	303	.10	30.0
Verification of Disadvantaged Background Form	660	1	660	.50	330
Private Practice Option Form	330	1	330	.10	33
NHSC Comprehensive Behavioral Health Services Checklist	4,400	1	4,400	.13	572
NHSC Site Application (including recertification)	4,070	1	4,070	.50	2,035
Total	25,933		25,933		12,735

Maria G. Button,

Director, Executive Secretariat.

[FR Doc. 2022–23574 Filed 10–28–22; 8:45 am]

BILLING CODE 4165–15–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 Member Conflict: Cell Biology, Biochemistry, and Aging, November 21, 2022, 12:00 p.m. to November 21, 2022, 6:00 p.m., National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, which was published in the **Federal Register** on October 24, 2022, 87 FR 64241 Doc 2022–23066.

This meeting is being amended to change the meeting start date from November 21, 2022, to November 22, 2022. The meeting is closed to the public.

Dated: October 26, 2022.

Tyeshia M. Roberson-Curtis,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2022–23638 Filed 10–28–22; 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 Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meetings.

The meetings 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; Small Business: Respiratory Sciences.

Date: November 29–30, 2022.

Time: 9:00 a.m. to 7:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Imoh S Okon, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20817, 301–347–8881, *imoh.okon@nih.gov*.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Member Conflict: Conflicts in hepatology, pharmacology and toxicology.

Date: November 29, 2022.

Time: 9:30 a.m. to 6:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Frederique Yiannikouris, Ph.D., Scientific Review Officer, The Center for Scientific Review, The National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, 301–594–3313, *frederique.yiannikouris@nih.gov*.

Name of Committee: Center for Scientific Review Special Emphasis Panel; PAR–21–120: Global Infectious Disease Research Training Program [D43 Clinical Trial Optional].

Date: November 29, 2022.

Time: 11:00 a.m. to 8:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Dayadevi Jirage, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4422, Bethesda, MD 20892, (301) 867–5309, *jiragedb@csr.nih.gov*.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Member Conflict: Cancer Prevention and Immunotherapy.

Date: November 30, 2022.

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

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Laurie Ann Shuman Moss, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, (301) 867–5309, *laurie.shumanmoss@nih.gov*.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Small Business: Computational, Modeling, and Biodata Management.

Date: November 30, 2022.

Time: 10:00 a.m. to 8:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Marie-Jose Belanger, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Rm 6188 MSC 7804, Bethesda, MD 20892, 301–435–1267, *belangerm@csr.nih.gov*.

(Catalogue of Federal Domestic Assistance Program Nos. 93.306, Comparative Medicine; 93.333, Clinical Research, 93.306, 93.333, 93.337, 93.393–93.396, 93.837–93.844, 93.846–93.878, 93.892, 93.893, National Institutes of Health, HHS)

Dated: October 25, 2022.

Tyeshia M. Roberson-Curtis,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2022–23608 Filed 10–28–22; 8:45 am]

BILLING CODE 4140–01–P