manufacturer of the IVD is a laboratory. The final rule, which is codified at 21 CFR 809.3, is effective July 5, 2024. In conjunction with this amendment, the FDA is phasing out its general enforcement discretion approach for LDTs so that IVDs manufactured by a laboratory will generally fall under the same enforcement approach as other IVDs. This phaseout policy includes enforcement discretion policies for specific categories of IVDs manufactured by a laboratory, including currently marketed IVDs offered as LDTs and LDTs for unmet needs. This phaseout policy is intended to better protect the public health by helping to assure the safety and effectiveness of IVDs offered as LDTs, while also accounting for other important public health considerations such as patient access and reliance. FDA has prepared this SECG to assist small entities in complying with the requirements established in FDA regulations, as they apply to IVDs, including LDTs.

This level 2 guidance is being issued consistent with our good guidance practices regulation (21 CFR 10.115(c)(2)). The SECG represents the current thinking of FDA on this topic. It does not establish any rights for any person and is not binding on FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statutes and regulations.

II. Electronic Access

Persons interested in obtaining a copy of the guidance may do so by downloading an electronic copy from the internet. A search capability for all Center for Devices and Radiological Health guidance documents is available at *https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/guidance-documents-medical-devices-and-radiation-emitting-products.* This guidance document is also available at *https://www.regulations.gov, https://www.fda.gov/regulatory-information/search-fda-guidance-documents, or https://www.fda.gov/vaccines-blood-biologics/guidance-compliance-regulatory-information-biologics.* Persons unable to download an electronic copy of ''Laboratory Developed Tests: Small Entity Compliance Guide; Guidance for Laboratory Manufacturers and Food and Drug Administration Staff'' may send an email request to *CDRH-Guidance@fda.hhs.gov* to receive an electronic copy of the document. Please use the document number GUI00007036 and complete title to identify the guidance you are requesting.

III. Paperwork Reduction Act of 1995

While this guidance contains no new collection of information, it does refer to previously approved FDA collections of information. The previously approved collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501–3521). The following collections of information have been approved by OMB: OMB control number 0910–0437, Medical Device Reporting; OMB control number 0910–0359, Corrections and Removals; OMB control number 0910–0625, Device Registration and Listing; OMB control number 0910–0485, Device Labeling; OMB control number 0910–0078, Investigational Device Exemption; OMB control number 0910–0073, Quality Systems, including § 820.198 (complaint files); OMB control number 0910–0231, Premarket Approval; OMB control number 0910–0332, Humanitarian Device Exemption; OMB control number 0910–0120, Premarket Notification; OMB control number 0910–0844 De Novo Requests; OMB control number 0910–0338, Biologics License Applications Procedures & Requirements; OMB control number 0910–0052, Blood Establishment Registration and Product Listing for Manufacturers of Human Blood and Blood Products and Licensed Devices; OMB control number 0910–0014, Investigational use requirements under 42 U.S.C. 262 and 21 CFR part 312 for certain devices that are biological products; and OMB control number 0910–0756, FDA's final guidance document entitled ''Requests for Feedback and Meetings for Medical Device Submissions: The Q-Submission Program.''

Dated: June 18, 2024.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2024–13872 Filed 6–24–24; 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; Ryan White HIV/AIDS Program Core Medical Services Waiver Form

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

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 July 25, 2024. The form will become effective on October 1, 2024.

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 Joella Roland, the HRSA Information Collection Clearance Officer, at *paperwork@hrsa.gov* or call (301) 443–3983.

SUPPLEMENTARY INFORMATION:

Information Collection Request Title: Ryan White HIV/AIDS Program Core Medical Services Waiver Form, OMB No. 0906–0065—Revision

Abstract: In accordance with sections 2604(c), 2612(b), and 2651(c) of the Public Health Service Act, recipients are required to spend not less than 75 percent of funds on core medical services for individuals identified with HIV and who are eligible under the statute, after reserving permissible amounts for administrative and clinical quality management (CQM) costs. The statute also grants the Secretary authority to waive this requirement for a Ryan White HIV/AIDS Program (RWHAP) Part A, B, or C recipient if certain requirements are met, and a waiver request is submitted to HRSA for approval.

As currently implemented by HRSA, in order to be approved, (1) core medical services must be available and accessible to all individuals identified and eligible for the RWHAP in the recipient's service area within 30 days. This access must be without regard to payer source, and without the need to spend at least 75 percent of funds

remaining from the recipient's RWHAP award after statutorily permissible amounts for administrative and CQM costs are reserved; (2) the recipient must ensure there are no AIDS Drug Assistance Program (ADAP) waiting lists in its service area; and (3) a public process to obtain input on the waiver request must have occurred. This process must seek input from impacted communities, including clients and RWHAP-funded core medical services providers, on the availability of core medical services, and the decision to request the waiver. The public process may be a part of the same one used by recipients to seek input on community needs as part of the annual priority setting and resource allocation, comprehensive planning, statewide coordinated statement of need, public planning, and/or needs assessment processes. RWHAP Parts A, B, and C core medical services waiver requests must include funds awarded under the Minority AIDS Initiative. Core medical services waivers are effective for a 1-year period.

The process for RWHAP Parts A, B, and C grant recipients to request a waiver of the minimum expenditure amount requirements for core medical services is outlined in Policy Notice 21–01, Waiver of the Ryan White HIV/AIDS Program Core Medical Services Expenditure Requirement. Policy Notice 21–01 is currently being revised and will be effective October 1, 2024.

HRSA proposes to modify the one-page form to include the proposed percentages of HIV service dollars allocated to core medical and support services. Under the proposed changes, a field will be added to the form to capture the proposed percentages. This information will inform HRSA whether recipients are able to meet the statutory requirements in sections 2604(c), 2612(b), and 2651(c) of the Public Health Service Act and will clarify what proposed portion of funds will be allocated to core medical and support services. Minor changes will also be made to the form to increase readability.

Summary of Proposed Changes: Sections 2604(c), 2612(b), and 2651(c) of the Public Health Service Act require recipients to spend not less than 75 percent of funds on core medical services after reserving statutorily permissible amounts for administrative and CQM costs. However, on the current version of the form, the portion of HIV service dollars to be allocated to core medical and support services was sometimes unclear. The suggested change to the form adds a requirement to include the proposed percentages of HIV service dollars allocated to core medical and support services. The table on the current form is expanded to allow for the insertion of the proposed percentages for core medical and support services. Instructions at the top of the new form are updated to indicate where to insert the proposed percentages. Language within the table is also updated to increase readability.

The proposed changes do not modify the underlying requirements necessary to obtain a waiver: all core medical services are available and accessible within 30 days in the jurisdiction or service area; ensuring that the state ADAP has no waiting lists; and that the recipient has used a public process to determine the need for a waiver. Recipients may still need to provide supportive evidence to HRSA upon request.

A 60-day notice published in the **Federal Register** on February 27, 2024, vol. 89, No. 39; pp. 14507–14508. There were no public comments.

Need and Proposed Use of the Information: HRSA uses the documentation submitted in core medical services waiver requests to determine if the RWHAP Parts A, B, and C grant applicant or recipient meets the statutory requirements for waiver eligibility including: (1) no waiting lists for ADAP services; and (2) evidence of core medical services availability within the grant recipient's jurisdiction, state, or service area to all persons identified with HIV and eligible under Title XXVI of the Public Health Service Act.

Likely Respondents: HRSA expects responses from RWHAP Parts A, B, and C grant applicants and recipients. The number of grant recipients requesting waivers fluctuates annually and has ranged up to 23 per year since its implementation in fiscal year 2007. In light of recent trends, HRSA anticipates receiving possibly up to 23 applications in a given year.

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
RWHAP Core medical Services Waiver request Attestation Form	23	1	23	0.49	11.27
Total	23		23		11.27

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. 2024–13857 Filed 6–24–24; 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; 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 Allergy and Infectious Diseases Special Emphasis Panel; NIAID Investigator Initiated Program Project Applications (P01 Clinical Trial Not Allowed).

Date: July 18, 2024.

Time: 1:00 p.m. to 4:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institute of Allergy and Infectious Diseases, National Institutes of Health, 5601 Fishers Lane, Room 3G21A, Rockville, MD 20852 (Video Assisted Meeting).

Contact Person: Shiv A. Prasad, Ph.D., Scientific Review Officer, Scientific Review Program, Division of Extramural Activities, National Institute of Allergy and Infectious Diseases, National Institutes of Health, 5601 Fishers Lane, Room 3G21A, Rockville, MD 20852, 240.627.3219, *shiv.prasad@nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.855, Allergy, Immunology, and Transplantation Research; 93.856, Microbiology and Infectious Diseases Research, National Institutes of Health, HHS)

Dated: June 18, 2024.

Lauren A. Fleck,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2024–13838 Filed 6–24–24; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Submission for OMB Review; 30-Day Comment Request Generic Clearance for the Collection of Qualitative Feedback on Agency Service Delivery (NIH)

AGENCY: National Institutes of Health, HHS.

ACTION: Notice.

SUMMARY: In compliance with the Paperwork Reduction Act of 1995, the National Institutes of Health (NIH) has submitted to the Office of Management and Budget (OMB) a request for review and approval of the information collection listed below.

DATES: Comments regarding this information collection are best assured of having their full effect if received within 30-days of the date of this publication.

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 30-day Review—Open for Public Comments'' or by using the search function.

FOR FURTHER INFORMATION CONTACT: To request more information on the proposed project or to obtain a copy of the data collection plans and instruments, contact: Ms. Mikia Currie, Project Clearance Officer, Office of Policy for Extramural Research Administration, 6705 Rockledge Drive, Suite 350, Bethesda, Maryland 20892 or call non-toll-free number (301) 435–0941 or email your request, including your address to: *curriem@mail.nih.gov.*

SUPPLEMENTARY INFORMATION: This proposed information collection was previously published in the **Federal Register** on April 10th, 2024 (89 FR 25275) and allowed 60 days for public comment. No public comments were received. The purpose of this notice is to allow an additional 30 days for public comment.

The National Institutes of Health (NIH) may not conduct or sponsor, and the respondent is not required to respond to, an information collection that has been extended, revised, or implemented on or after October 1, 1995, unless it displays a currently valid Office of Management and Budget (OMB) control number.

In compliance with section 3507(a)(1)(D) of the Paperwork Reduction Act of 1995, NIH has submitted to OMB a request for review and approval of the information collection listed below.

Proposed Collection: Generic Clearance for the Collection of Qualitative Feedback on Agency Service Delivery, EXTENSION, 0925–0648, expiration date 06/30/2024, National Institutes of Health (NIH).

Need and Use of Information Collection: There are no substantive changes being requested for this submission. The information collection activity will garner qualitative customer and stakeholder feedback in an efficient, timely manner, in accordance with the Administration's commitment to improving service delivery. This generic clearance will continue to provide information about the NIH Institutes and Centers customer or stakeholder perceptions, experiences, and expectations, provide an early warning of issues with service, or focus attention on areas where communication, training, or changes in operations might improve delivery of products or services. It will also allow feedback to contribute directly to the improvement of program management. Feedback collected under this generic clearance will provide useful information, but it will not yield data that can be generalized to the overall population.

OMB approval is requested for 3 years. There are no costs to respondents other than their time. The total estimated annualized burden hours are 103,083.