receipt of the IND that the investigational studies were allowed to proceed.

2. *The date the application was initially submitted with respect to the human biological product under section 351 of the Public Health Service Act (42 U.S.C. 262):* November 24, 2020. FDA has verified the applicant's claim that the biologics license application (BLA) for Rybrevant (BLA B761210) was initially submitted on November 24, 2020.

3. *The date the application was approved:* May 21, 2021. FDA has verified the applicant's claim that BLA B761210 was approved on May 21, 2021.

This determination of the regulatory review period establishes the maximum potential length of a patent extension. However, the USPTO applies several statutory limitations in its calculations of the actual period for patent extension. In its application for patent extension, this applicant seeks 546 days of patent term extension.

III. Petitions

Anyone with knowledge that any of the dates as published are incorrect may submit either electronic or written comments and, under 21 CFR 60.24, ask for a redetermination (see **DATES**). Furthermore, as specified in § 60.30 (21 CFR 60.30), any interested person may petition FDA for a determination regarding whether the applicant for extension acted with due diligence during the regulatory review period. To meet its burden, the petition must comply with all the requirements of § 60.30, including but not limited to: must be timely (see **DATES**), must be filed in accordance with § 10.20, must contain sufficient facts to merit an FDA investigation, and must certify that a true and complete copy of the petition has been served upon the patent applicant. (See H. Rept. 857, part 1, 98th Cong., 2d sess., pp. 41–42, 1984.) Petitions should be in the format specified in 21 CFR 10.30.

Submit petitions electronically to *https://www.regulations.gov* at Docket No. FDA–2013–S–0610. Submit written petitions (two copies are required) to the Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

Dated: February 22, 2024.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2024–03961 Filed 2–26–24; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

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

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 ICR should be received no later than April 29, 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 or to obtain a copy of the data collection plans and draft instruments, 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: Ryan White HIV/AIDS Program Core Medical Services Waiver Form, OMB No. 0915–0065—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 with HIV identified and eligible under the statute, after reserving permissible amounts for administrative and clinical quality management (CQM) costs. The statute also grants the Secretary of Health and Human Services 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, 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 their 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.

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 requires 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 prior 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 adds a requirement to include the proposed percentages of HIV service dollars allocated to core medical and support services on the form. The table on the prior 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.

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 with HIV identified and eligible under Title XXVI of the Public Health Service Act.[1]

Likely Respondents: HRSA expects responses from RWHAP Parts A, B, and C grant applicants and recipients. The number of grant recipients requesting waivers has fluctuated annually and 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	1	23	0.49	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. 2024–03952 Filed 2–26–24; 8:45 am]

BILLING CODE 4165–15–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center for Scientific Review; Notice of Closed Meetings

Pursuant to section 1009 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: Risk, Prevention and Health Behavior Integrated Review Group; HIV/AIDS Intra- and Inter-personal Determinants and Behavioral Interventions Study Section.

Date: March 20–21, 2024.

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

Agenda: To review and evaluate grant applications.

Place: St. Gregory Hotel, 2033 M Street NW, Washington, DC 20036.

Contact Person: Mark P Rubert, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5218, MSC 7852, Bethesda, MD 20892, 301–806–6596, *rubertm@csr.nih.gov.*

Name of Committee: Center for Scientific Review Special Emphasis Panel; Small Business: Aging and Development, Auditory Vision and Low Vision Technologies.

Date: March 20–21, 2024.

Time: 9:00 a.m. to 8:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Canopy by Hilton, 940 Rose Avenue, North Bethesda, MD 20852.

Contact Person: Barbara Susanne Mallon, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, (301) 480–8992, *mallonb@mail.nih.gov.*

[1] Sections 2604(c)(2), 2612(b)(2), and 2651(c)(2) of the PHS Act.