

TABLE 1—LIST OF INFORMATION COLLECTIONS APPROVED BY OMB

Title of collection	OMB control No.	Date approval expires
Blood Establishment Registration and Product Listing for Manufacturers of Blood and Blood Products and Licensed Devices	0910–0052	7/31/2024
Current Good Manufacturing Practice: Manufacturing, Processing, Packing, and Holding of Drugs; GMP for Finished Pharmaceuticals (Including Gases and Active Pharmaceutical Ingredients)	0910–0139	7/31/2024
Irradiation in the Production, Processing, and Handling of Food	0910–0186	7/31/2024
State Enforcement Notifications	0910–0275	7/31/2024
Veterinary Feed Directive	0910–0363	7/31/2024
Record Retention Requirements for the Soy Protein/Coronary Heart Disease Health Claim	0910–0428	7/31/2024
Prescription Drug Marketing: Administrative Procedures, Policies, and Requirements	0910–0435	7/31/2024
Generic Clearance for the Collection of Qualitative Data on Tobacco Products and Communications	0910–0796	7/31/2024
Survey of Drug Product Manufacturing, Processing, and Packing Facilities	0910–0899	7/31/2024
Current Good Manufacturing Practices for Blood and Related Regulations for Blood Components; and Requirements for Donor Testing, Donor Notification and “Lookback”	0910–0116	8/31/2024
New Animal Drugs for Investigational Use	0910–0117	8/31/2024
Regulations Under the Federal Import Milk Act	0910–0212	8/31/2024
Medical Device Reporting	0910–0437	8/31/2024
New Plant Varieties Intended for Food Use	0910–0583	8/31/2024
Guidance for Industry and FDA Staff; Class II Special Controls: Automated Blood Cell Separator Device Operating by Centrifugal or Filtration Separation Principle	0910–0594	8/31/2024
Prescription Drug Advertisements	0910–0686	8/31/2024
Animal Food Labeling; Declaration of Certifiable Color Additives	0910–0721	8/31/2024
Survey on the Occurrence of Foodborne Illness Risk Factors in Selected Retail and Food Service Facility Types	0910–0744	8/31/2024
Food and Cosmetic Export Certificates	0910–0793	8/31/2024
National Agriculture and Food Defense Strategy Survey	0910–0855	8/31/2024
Medical Product Communications That are Consistent With the Food and Drug Administration Required Labeling—Questions and Answers	0910–0856	8/31/2024
Drug and Device Manufacturer Communications with Payors, Formulary Committees, and Similar Entities Questions and Answers	0910–0857	8/31/2024
Study of Disclosures to Health Care Providers Regarding Data That Do Not Support Unapproved Use of an Approved Prescription Drug	0910–0900	8/31/2024
Medical Conference Attendees’ Observations About Prescription Drug Promotion	0910–0901	8/31/2024

Dated: September 24, 2021.

Lauren K. Roth,

Acting Principal Associate Commissioner for Policy.

[FR Doc. 2021–21386 Filed 9–30–21; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Final Policy: Updates to Uniform Standard for Waiver of the Ryan White HIV/AIDS Program Core Medical Services Expenditure Requirement

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

ACTION: Notice of final policy.

SUMMARY: The Ryan White HIV/AIDS Program (RWHAP) statute of the Public Health Services Act requires that RWHAP Part A, B, and C recipients expend not less than 75 percent of Parts A, B, and C grant funds on core medical services for individuals with HIV/AIDS identified and eligible under the statute, after reserving statutory permissible

amounts for administrative and clinical quality management (CQM) costs. The statute also grants the Secretary of HHS authority to waive this requirement if certain requirements are met. HRSA has simplified the process for RWHAP Part A, B, and C recipients to request a waiver of the core medical services expenditure amount requirement by replacing HRSA Policy Number 13–07, “Uniform Standard for Waiver of Core Medical Services Requirement for Grantees Under Parts, A, B, and C” with Policy Notice 21–01, “Waiver of the Ryan White HIV/AIDS Program Core Medical Services Expenditure Requirement.”

DATES: The final policy is effective on October 1, 2021.

FOR FURTHER INFORMATION CONTACT: Lieutenant Commander Emeka Egwim, U.S. Public Health Service, Senior Policy Analyst, Division of Policy & Data, HRSA, HIV/AIDS Bureau, 5600 Fishers Lane, Rockville, MD 20857, Phone: (301) 945–9637 or by emailing RWHAPPolicy@hrsa.gov. When requesting information, please include this **Federal Register** notice title for reference.

SUPPLEMENTARY INFORMATION: The RWHAP statute also grants the Secretary

of HHS authority to waive this requirement for RWHAP Parts A, B, or C recipients if a number of requirements are met and a waiver request is submitted to HRSA for approval. RWHAP Part A, B, and C core medical services waiver requests—if approved—are effective for a 1-year budget period, and apply to funds awarded under the Minority AIDS Initiative.

Currently, for a core medical services waiver request 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, without regard to payer source; (2) there cannot be any AIDS Drug Assistance Program (ADAP) waiting lists in the recipient’s service area; and (3) a public process to obtain input on the waiver request 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 must have occurred. The public process may be a part of the same one used 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.

HRSA has simplified the waiver request process for RWHAP Parts A, B, and C recipients by revising and replacing HRSA Policy Number 13–07: Uniform Standard for Waiver of Core Medical Services Requirement for Grantees Under Part, A, B, and C. The changes reduce the administrative burden for recipients by lessening the documentation they must submit to HRSA when requesting a waiver. Under this final policy, recipients are required to submit a one-page “HRSA RWHAP Core Medical Services Waiver Request Attestation Form” to HRSA in lieu of the multiple documents previously required to submit a waiver request.

HRSA also revised the waiver request submission deadlines. This final policy, “Waiver of the Ryan White HIV/AIDS Program Core Medical Services Expenditure Requirement,” replaces HRSA Policy Number 13–07 effective October 1, 2021.

In administering the RWHAP, HRSA continually evaluates its policies and processes, and considers making updates where necessary to ensure programmatic efficiency while facilitating recipients’ ability to provide care and support services to people with HIV. To inform its policy evaluation and development processes with perspectives representative of the communities served by the RWHAP, HRSA welcomes and considers input from stakeholders of the RWHAP, including recipients, providers, people with HIV, and the general public. To that end, on April 20, 2021, HRSA sought public input when it published the proposed updates to the waiver request process for RWHAP Parts A, B, and C recipients in the **Federal Register** (86 FR 20500), and released a listserv message informing stakeholders where to access and review the **Federal Register** notice. In addition, during the April 27, 2021, “HAB You Heard” RWHAP recipient webinar, HRSA conducted a walkthrough of the proposed policy, comparing and contrasting it to the existent policy outlined in HRSA Policy Number 13–07. Subsequently, on August 20, 2021, HRSA published a **Federal Register** notice for 30-day public comment period, and submitted the ICR to OMB for review and approval.

Overview of Public Comments

In response to the proposed policy published in 86 FR 20500, HRSA received 52 responses from stakeholders. The vast majority of respondents were individuals from the general public, followed by RWHAP

recipients and HIV patient care advocacy organizations. HRSA considered all feedback in the finalization of the policy, and a discussion of the public comments is included below.

Discussion of Public Comments on the Proposed Policy

Availability of Core Medical Services, ADAP Waiting Lists, and Evidence of a Public Process

Public Comment: Commenters were unanimously supportive of submitting a one-page attestation form in lieu of the multiple pages of supporting documentation required per HRSA Policy Number 13–07 because it would reduce administrative burden. They were equally supportive of the stipulation that, if requested, recipients would need to submit supportive documentation to HRSA if requested.

Response: HRSA appreciates the comments and agrees the new policy will reduce burden for recipients, as well as for HRSA as it reviews the waiver applications. HRSA is finalizing the policy as proposed. As such, when submitting waiver requests, RWHAP recipients will only need to submit the one-page “HRSA RWHAP Core Medical Services Waiver Request Attestation Form” to HRSA in lieu of multiple documents currently required to submit a waiver request. HRSA may request additional information or supporting documentation. HRSA approximates this process would require 4 hours per response, representing a reduction of 1.5 hours when compared to the current process, or a total of 88 hours across all recipients expected to submit a waiver application.

Submission Deadlines

Public Comment: Commenters were supportive of the proposed changes regarding waiver request submissions deadlines. One commenter expressed some concern that specific submission deadlines may reduce flexibility for some recipients and may not take into account the urgency of a potential waiver in the case of an emergency or unexpected situation on the part of the recipient. The commenter recommended that HRSA adequately advertise this tenet of the policy and evaluate the deadlines to ensure this change does not adversely impact recipients.

Response: HRSA will finalize the policy as proposed by requiring specific submission deadlines. RWHAP Part A recipients will need to submit the waiver request as an attachment with the grant application or non-competing

continuation (NCC) progress report. RWHAP Part B recipients will need to submit the waiver request either in advance of the grant application, with the grant application, with the mandatory NCC progress report, or up to 4 months into the grant award budget period for which the waiver is being requested. RWHAP Part C recipients will need to submit the waiver request as an attachment with the grant application or the mandatory NCC progress report. HRSA thanks the commenters for their input, and will monitor the impact of the new policy on the RWHAP in order to ensure recipients’ ability to timely submit waiver requests and their ability to provide care and support services to people with HIV.

Concluding Points

HRSA continues to find opportunities to streamline its policies and processes to facilitate RWHAP recipients’ ability to continue to deliver quality care and support services to people with HIV, while increasing HRSA’s efficiency in administering the program. Given the participation of RWHAP stakeholders in the public process, HRSA believes HRSA Policy Number 21–01 titled “Waiver of the Ryan White HIV/AIDS Program Core Medical Services Expenditure Requirement” meets the overall goal and objective of the RWHAP, and is inclusive of the perspectives of stakeholders, while reducing burden to RWHAP recipients. HRSA expects a period of adjustment to the new process. To that end, HRSA will provide timely technical assistance and other resources to assist recipients with the transition to and implementation of the final policy. Recipients are encouraged to contact HRSA at RWHAPPolicy@hrsa.gov for questions or feedback on the new process.

HRSA remains committed to supporting RWHAP recipients in their provision of care and support services to people with HIV. The finalization of HRSA Policy Number 21–01, which reduces burden for recipients requesting a waiver of the Core Medical Services expenditure requirement, is another step indicative of this commitment.

The final policy is set forth below. Upon its Effective Date of October 1, 2021, the policy replaces HRSA Policy Number 13–07.

*Waiver of the Ryan White HIV/AIDS
Program Core Medical Services
Expenditure Requirement*

Policy Notice 21–01

Replaces Policy Number 13–07

Scope of Coverage

HRSA HIV/AIDS Bureau RWHAP Parts A, B, and C

Requirements

A HRSA RWHAP Part A, B, or C recipient must meet a number of requirements and submit a waiver request to HRSA to receive a waiver of the core medical services expenditure requirement. First, 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. Access to core medical services 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 statutory permissible amounts for administrative and CQM are reserved. Second, the HRSA RWHAP recipient must ensure there are no ADAP waiting lists in its service area. Third, 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 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.

Requesting a Waiver

To request a waiver, the Chief Elected Official, Chief Executive Officer, or a

designee of either must complete and submit the HRSA RWHAP Core Medical Services Waiver Request Attestation Form (appended below) to HRSA. The form should be submitted according to the applicable deadlines and methods for submission outlined below. By completing and submitting this form, the Chief Elected Official, Chief Executive Officer, or a designee of either attests to meeting the requirements outlined above and agrees to provide supportive evidence to HRSA upon request. No other documentation is required to be submitted with the HRSA RWHAP Core Medical Services Waiver Request Attestation Form.

Deadlines for Submitting Waiver Requests

HRSA RWHAP Part A Waiver Requests

A HRSA RWHAP Part A recipient's request for a waiver should be submitted as an attachment with the grant application or the mandatory NCC progress report, if applicable. In each case, waiver requests do not count towards the submission page limit. Requests for waivers should not be submitted prior to the grant application or mandatory NCC progress report, nor should they be submitted after the start of the grant award budget period for which the waiver is being requested.

HRSA RWHAP Part B Waiver Requests

A HRSA RWHAP Part B recipient's request for a waiver may be submitted either in advance of the grant application, as an attachment to the grant application, with the mandatory NCC progress report, or up to 4 months into the grant award budget period for which the waiver is being requested.

HRSA RWHAP Part C Waiver Requests

A HRSA RWHAP Part C recipient's request for a waiver should be submitted as an attachment to the grant application or the mandatory NCC progress report. Requests for waivers

should not be submitted prior to the grant application or mandatory NCC progress report, nor should they be submitted after the start of the grant award budget period for which the waiver is being requested.

Methods for Submitting Waiver Requests

Waiver requests submitted with grant applications must be submitted through www.grants.gov. Waiver requests submitted with the mandatory NCC progress report must be submitted through the HRSA Electronic Handbooks (EHB). For waiver requests that are not submitted with grant applications, and not submitted with the mandatory NCC progress report, a recipient must notify its HRSA project officer of its intention to request a waiver. The project officer will initiate a Request for Information in the EHB. The recipient must respond to the EHB task consistent with the deadlines for submitting waiver requests outlined above.

Waiver Review and Notification Process

HRSA will review requests and notify recipients of waiver approval or denial within 4 weeks of receipt of the request.

Approved core medical services waivers will be effective for the 1-year budget period for which it is approved; recipients must submit a new request for each budget period. A recipient approved for a core medical services waiver is not required to implement the approved waiver if it is no longer needed.

This guidance does not have the force and effect of law and is not meant to bind the public in any way, except as authorized by law or as incorporated into a contract. It is intended only to provide clarity to the public regarding existing requirements under the law or agency policies.

BILLING CODE 4165–01–P

HRSA Ryan White HIV/AIDS Program (RWHAP) Core Medical Services Waiver Request Attestation Form

This form is to be completed by the Chief Elected Official, Chief Executive Officer, or a designee of either.

Please initial to attest to meeting each requirement after reading and understanding the explanation.

Name of recipient _____

☐

RWHAP Part A recipient

☐

RWHAP Part B recipient

☐

RWHAP Part C recipient

☐

Initial request

☐

Renewal request

Year of request _____

REQUIREMENT	EXPLANATION
No ADAP waiting lists	By initialing here and signing this document, you attest there are no AIDS Drug Assistance Program (ADAP) waiting lists in the service area. ☐
Availability of, and accessibility to core medical services to all eligible individuals	By initialing here and signing this document, you attest to the availability of and access to core medical services for all HRSA RWHAP eligible individuals in the service area within 30 days. Such access is without regard to funding source, and without the need to spend on these services, at least 75 percent of funds remaining from your RWHAP award after reserving statutory permissible amounts for administrative and clinical quality management. You also agree to provide HRSA HAB supportive evidence of meeting this requirement upon request. ☐
Evidence of a public process	By initialing here and signing this document, you attest to having had a public process during which input related to the availability of core medical services and the decision to request this waiver was sought from impacted communities, including clients and RWHAP funded core medical services providers. You also agree to provide supportive evidence of such process to HRSA HAB upon request. ☐

SIGNATURE OF CHIEF ELECTED OFFICIAL OR CHIEF EXECUTIVE OFFICER (OR DESIGNEE)

PRINT NAME

TITLE

DATE

Public Burden Statement: An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. The OMB control number for this project is 0906-0065 and is valid until 09/30/2024. Public reporting burden for this collection of information is estimated to average 4 hours per response, including the time for reviewing instructions, searching existing data sources, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to HRSA Reports Clearance Officer, 5600 Fishers Lane, Room 14N39, Rockville, Maryland, 20857.

Diana Espinosa,
Acting Administrator.

[FR Doc. 2021–21241 Filed 9–30–21; 8:45 am]

BILLING CODE 4165–15–C

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Center for Indigenous Innovation and Health Equity Tribal Advisory Committee; Solicitation of Nominations for Delegates

AGENCY: Office of Minority Health, Office of the Secretary, Department of Health and Human Services.

ACTION: Notice of solicitation of nominations for delegates for the Center for Indigenous Innovation and Health Equity Tribal Advisory Committee.

SUMMARY: The U.S. Department of Health and Human Services (HHS) Office of Minority Health (OMH) hereby gives notice that OMH is establishing a Center for Indigenous Innovation and Health Equity Tribal Advisory Committee (CIIHE TAC) and accepting nominations of qualified candidates to serve as primary and alternate delegates for the CIIHE TAC, in alignment with the 12 geographic areas served by the Indian Health Service (IHS).

DATES: Nomination letters for the CIIHE TAC must be sent to the address noted below no later than 6:00 p.m. EST on October 29, 2021.

ADDRESSES: All nominations should be emailed to: Violet Woo, Designated Federal Officer for the CIIHE TAC, at Violet.Woo@hhs.gov. Please use the subject line “OMH CIIHE Tribal Advisory Committee”.

FOR FURTHER INFORMATION CONTACT: For information and guidance about the nomination process for CIIHE TAC delegates, please contact Violet Woo, Designated Federal Officer at Violet.Woo@hhs.gov. CIIHE TAC nomination guidance and sample nomination letters also are available on the OMH website’s Tribal Leader Letters section: <https://www.minorityhealth.hhs.gov/omh/browse.aspx?lvl=3&lvlid=62#tribal-leader-letters>.

SUPPLEMENTARY INFORMATION:

Authorized under Section 1707 of the Public Health Service Act, 42 U.S.C. 300u–6, as amended, the mission of OMH is to improve the health of racial and ethnic minority populations through the development of health policies and programs that help eliminate health disparities. OMH awards and other activities are intended to support the identification of effective policies, programs, and practices for

improving health outcomes and to promote the sustainability and dissemination of these approaches.

Under the authority of Public Law 116–260 (2021 Consolidated Appropriations Act), Congress directed OMH to create a CIIHE to support research, education, service, and policy development advancing Indigenous solutions that ultimately address health disparities in American Indian/Alaska Native (AI/AN) and Native Hawaiian and Pacific Islander (NHPI) populations. OMH is establishing the CIIHE TAC to ensure that Tribal Leaders have meaningful and timely input in the development of the priorities and activities established to address the focus areas of the CIIHE. The CIIHE TAC shall support, but not supplant, government-to-government consultation activities that OMH undertakes.

TAC Membership: The CIIHE TAC will consist of 16 delegate positions: One from each of the 12 geographic areas served by the Indian Health Service and four National At-Large Member positions.

Alaska Area
Albuquerque Area
Bemidji Area
Billings Area
California Area
Great Plains Area
Nashville Area
Navajo Area
Oklahoma Area
Phoenix Area
Portland Area
Tucson Area
National At-Large Members (4)

OMH recommends a two (2) year term length for each delegate, but delegates’ term length will be established by the TAC’s charter.

Eligibility: The CIIHE TAC delegates must be: (1) Elected tribal officials from a federally recognized tribe acting in their official capacity as elected officials of their tribe, with authority to act on behalf of the tribe; or (2) individuals designated by an elected tribal official. Designees must have the authority to act on behalf of the tribal official and the tribe and be qualified to represent the views of the AI/AN tribes in the area from which they are nominated. No delegate of the CIIHE TAC may be an employee of the federal government.

Nomination Procedures: CIIHE TAC candidates must be nominated by an elected tribal leader. The nomination letter must be on tribal letterhead and signed by an elected tribal leader, and must include the following information:

- Name of the nominee
- Nominee’s official title
- Name of the nominee’s tribe

- Date of nominee’s election to official tribal position and term length
- Nominee’s contact information (mailing address, phone, and email)
- Nominee’s expertise that is relevant to the CIIHE TAC
- Name of tribal leader submitting the nomination
- Official title of tribal leader submitting the nomination
- Contact information for tribal leader submitting the nomination and/or administrative office for tribal government

CIIHE TAC nomination guidance and sample nomination letters are available on the OMH website’s Tribal Leader Letters section: <https://www.minorityhealth.hhs.gov/omh/browse.aspx?lvl=3&lvlid=62#tribal-leader-letters>.

Selection Process: OMH is responsible for selecting and finalizing CIIHE TAC members.

Eligible nominees will be considered in the following priority order:

1. Tribal President/Chairperson/Governor
2. Tribal Vice-President/Vice-Chairperson/Lt. Governor
3. Elected or Appointed Tribal Official
4. Designated Tribal Official with authority to act on behalf of Tribal leader

In the event that there is more than one nomination for a given IHS area, OMH will make a determination of representation based on submitted nomination materials.

Nominees will be notified of the status of delegate selection in November 2021.

Dated: September 24, 2021.

Violet Woo,

Designated Federal Officer, Center for Indigenous Innovation and Health Equity Tribal Advisory Committee.

[FR Doc. 2021–21253 Filed 9–30–21; 8:45 am]

BILLING CODE 4150–29–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Indian Health Service

Request for Public Comment: 60 Day Notice for Extension of Fast Track Generic Clearance for the Collection of Qualitative Feedback on Agency Service Delivery: IHS Customer Service Satisfaction and Similar Surveys

AGENCY: Indian Health Service, HHS.

ACTION: Notice and request for comments. Request for extension of approval.