

**Supporting Statement
Health Resources and Services Administration, HIV/AIDS Bureau
Core Medical Services Waiver**

New Package

JUSTIFICATION

1. Circumstances of Information Collection

This is a request by the Health Resources and Services Administration (HRSA) for the Office of Management and Budget's (OMB) approval to collect information for the Ryan White HIV/AIDS Program (RWHAP) core medical services waiver requests using a new information collection tool. Title XXVI of the Public Health Service Act (RWHAP statute) 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 RWHAP statute also grants the Secretary 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 HIV/AIDS Bureau (HAB) for approval.

HRSA HAB is proposing to simplify the process for RWHAP Part A, B, and C recipients to request a waiver of the core medical services expenditure amount requirement. The Federal Register Notice (FRN) outlined in [86 FR 20500](#) published on April 20, 2021 introduced the proposed policy and provided a 60 day period for public comments. In compliance with the Paperwork Reduction Act of 1995, HRSA HAB submitted the Information Collection Request (ICR) pertinent to this proposed policy to the Office of Management and Budget (OMB). In addition to submitting the ICR to OMB, HAB sought comments from the public regarding the burden estimate or any other aspect of the ICR.

The proposed policy changes would reduce the administrative burden for recipients by lessening the documentation that must be submitted to HRSA HAB when recipients request waivers. Under the proposed policy, recipients would be required to submit a one-page "HRSA RWHAP Core Medical Services Waiver Request Attestation Form" to HRSA HAB in lieu of multiple documents currently required to submit a waiver request. Also, the deadlines to submit waiver requests would be revised to better align with programmatic processes, and allow HRSA HAB to better manage the review and processing of the requests.

When finalized, the policy would be effective on October 1, 2021. It would replace HRSA HAB Policy Number 13-07, "[Uniform Standard for Waiver of Core Medical Services Requirement for Grantees Under Parts, A, B, and C,](#)" and would be named "Waiver of the Ryan White HIV/AIDS Program Core Medical Services Expenditure Requirement."

HRSA HAB is seeking a new and separate OMB approval for this proposed new collection of information tool that is different from the OMB approval (OMB 0915-0307) granted for the policy outlined in HRSA HAB Policy Number 13-07. This approach will safeguard against interruptions in HRSA HAB's authority to accept applications from RWHAP recipients for core medical services waivers, and seamlessly transition to the proposed policy outlined in the Federal Register Notice ([86 FR 20500](#)) if finalized. In the event the proposed policy is not finalized, HRSA HAB will maintain its authority to accept applications from RWHAP grant recipients for core medical services waivers.

Currently, all waiver requests must be signed by the Chief Elected Official or the project director, and include several documents, regardless of when they are submitted relative to the annual grant application. The documents required under the current waiver request process are: 1) a letter signed by the Director of the RWHAP Part B State/Territory Recipient indicating that there is no current or anticipated AIDS Drug Assistance Program (ADAP) services waiting list in the State/Territory; 2) evidence that all core medical services listed in the statute are available and accessible within 30 days for all identified and eligible individuals with HIV in the service area; 3) evidence of a public process; and 4) a narrative of no more than 10 pages.

Under the proposed policy, the Chief Elected Official, or Chief Executive Officer, or a designee of either, would complete and submit the one page HRSA Ryan White HIV/AIDS Program (RWHAP) Core Medical Services Waiver Request Attestation Form to HRSA HAB indicating the requirements outlined in statute and the policy have been met. The revised policy proposal does not change the underlying requirements necessary to obtain a waiver: ensuring that the state ADAP has no waiting lists, all core medical services are available and accessible within 30 days in the jurisdiction or service area, and that the recipient has used a public process to determine the need for a waiver. HRSA HAB may request additional information or supporting documentation from the recipient.

The proposed policy would continue to allow grant recipients flexibility to adjust resource allocation based on the current situation and mix of services needed to achieve desired health outcomes related to retention and viral suppression in their local environments. It would also continue to ensure grant recipients receiving waivers demonstrate availability of core medical services, including antiretroviral drugs for persons with HIV served under the HRSA RWHAP. RWHAP Part A, B, and C core medical services waiver requests – if approved – are effective for a 1-year period, and apply to funds awarded under the Minority AIDS Initiative (MAI).

In addition to shortening the application length, HRSA HAB is also proposing changes to the timeframes for submitting waiver requests. Currently, RWHAP Parts A, B, and C recipients may choose to submit a waiver request any time prior to submission of the grant application, or along with the grant application, or up to four months after the start of the grant year for which a waiver is being requested.

The proposed changes would require waiver requests to be submitted according to specific programmatic deadlines. Under the new proposal, A RWHAP Part A recipient's request for a waiver must be submitted as an attachment to the grant application or the mandatory non-

competing continuation (NCC) progress report, if applicable. Because RWHAP Part B recipients submit their final budget 90 days after the Notice of Award (NoA) is received, the need for a waiver may not be identified until the final budget is approved. Therefore, a RWHAP Part B recipient's request for a waiver must be submitted either in advance of the grant application, or as an attachment with the grant application, or the mandatory NCC progress report, or up to four months into the grant award budget period for which the waiver is being requested. A RWHAP Part C recipient's request for a waiver must be submitted as an attachment with the grant application, or the mandatory NCC progress report. The proposed changes better align waiver requests with programmatic processes and will allow HRSA HAB to better manage the review and processing of waiver requests.

The proposed policy maintains that 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 Electronic Handbooks (EHB). The proposed policy revises the process for submitting waiver requests that are not submitted with grant applications or mandatory NCC progress reports. For these requests, a recipient must notify its HRSA HAB project officer (PO) of its intention to request a waiver. The PO will initiate a Request for Information in the EHB, and the recipient must respond to the EHB task consistent with the deadlines for submitting the waiver requests outlined above.

Under the current process, HRSA HAB reviews the waiver request and notifies the recipient of waiver approval or denial no later than the date of issuance of the NoA. Under the proposed process, HRSA HAB will notify a recipient of waiver approval or denial within four weeks of receipt of the request. As before, approved core medical services waivers will be effective for the one-year budget period for which they are approved; recipients must submit a new request for each budget period. Also as before, a recipient approved for a core medical services waiver is not required to implement an approved waiver if it is no longer needed.

2. Purpose and Use of Information

HRSA HAB will use the documentation submitted in core medical services waiver requests to determine if the grant recipient meets the statutory requirements for waiver eligibility including: (1) no waiting lists for AIDS Drug Assistance Program (ADAP) services; and (2) evidence of core medical services availability within the relevant service area to all people with HIV identified and eligible under Title XXVI of the PHS Act without regard to whether such services are funded by the RWHAP. See sections 2604(c)(2), 2612(b)(2), and 2651(c)(2) of the PHS Act. Additionally, HRSA HAB will use the documentation to determine that the grant recipient has engaged in a public process that allows input into the decision to seek a waiver.

3. Use of Improved Information Technology

Currently, consistent with HRSA HAB Policy Number 13-07, all requests for waivers and supporting documentation are submitted either with the grant application through www.grants.gov or through HRSA's Electronic Handbook (EHB) Prior Approval portal. If finalized, the proposed policy outlined in [86 FR 20500](#) would maintain these submission

modalities and would be posted at <https://hab.hrsa.gov/program-grants-management/policy-notice-and-program-letters>.

4. Efforts to Identify Duplication

There is no duplication of the required information for the core medical services waiver request in another information collection. The information requested is specific to this activity. It is used only to determine whether to approve grant recipients' requests to waive the requirement that they expend on core medical services no less than 75 percent of the remainder of their total RWHAP award amount after reserving statutory permissible amounts for administrative and clinical quality management. See sections 2604(c)(1), 2612(b)(1), and 2651(c)(1) of the PHS Act. HRSA HAB is the sole federal bureau or office that administers the RWHAP and reviews core medical services expenditure waiver requests.

5. Involvement of Small Entities

This activity does not have a significant impact on small entities. To the extent that small organizations need to submit core medical services expenditure waiver requests, the information requested under the proposed policy is limited to the absolute minimum required for its intended use, thus minimizing burden.

6. Consequences if Information Collected Less Frequently

As required by the statute, waivers – if approved – are effective for a single grant year. If this information is collected less than annually, HRSA HAB will not be able to determine whether the recipient meets the statutory and programmatic requirements for the waiver and will not be able to award waivers to eligible grant recipients who request a waiver. This would decrease the grant recipients' flexibility to meet patients' needs.

7. Consistency with Guidelines in 5 CFR 1320.5(d)(2)

The request fully complies with 5 CFR 1320.5(d)(2).

8. Comments in Response to the Federal Register Notice/Outside Consultation

A 60-day Federal Register Notice soliciting comments from the public regarding the burden estimate or any other aspect of the Information Collection Request (ICR) was published in the Federal Register on April 20, 2021 ([86 FR 20499](#)). Concurrently, HRSA HAB published a Federal Register Notice ([86 FR 20500](#)) regarding the proposed policy and provided a 60-day period for public comments. On the same day, HRSA HAB released a listserv message informing stakeholders on where to access and review the Federal Register Notice. In addition, during the April 27, 2021 "HAB You Heard" RWHAP recipient webinar, HRSA HAB conducted a walkthrough of the proposed policy, comparing and contrasting it to the current policy outlined in Policy Number 13-07.

No public comments were received regarding the ICR ([86 FR 20499](#)). In response to the Federal Register Notice regarding the proposed policy ([86 FR 20500](#)), 52 comments were received. Comments were overwhelmingly supportive of the proposed policy, and expressed particular support for the reduction in burden, reduced documentation for submission, and elimination of duplication. Commenters were supportive of this proposed change, and noted that it would amount to a reduction in burden, and increase in efficiency for all entities involved. One commenter expressed support for the stipulation that if required, recipients would need to submit supportive documentation to HRSA HAB if requested, and noted it was reasonable.

Commenters also expressed support for the proposed specific submission deadlines. While expressing strong support for the policy as a whole, one commenter expressed concern that specific submission deadlines may create less flexibility for 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 HAB adequately advertise the waiver request submission deadlines to recipients and evaluate the deadlines to ensure recipients are not adversely impacted by this change.

HRSA HAB appreciates all feedback received in response to [86 FR 20500](#) and notes that it was remarkably positive. HRSA HAB agrees that requiring only the one-page attestation form would reduce burden and increase efficiency, and will consider all comments when it finalizes the updated policy. HRSA HAB will closely monitor the implementation of the revised submission deadlines to ensure recipients' ability to timely request waivers while continuing to provide care, treatment, and support services to people with HIV is not undermined.

9. Remuneration of Respondents

Respondents will not be remunerated.

10. Assurance of Confidentiality

The waiver request does not involve the collection of individual or personally identifiable information. Data will be kept private to the extent allowed by law.

11. Questions of a Sensitive Nature

There are no questions of a sensitive nature.

12. Estimates of Annualized Hour and Cost Burden

Of the total number of eligible recipients, the program estimates that only a limited number of grant recipients will request the waiver. Although this statutory provision applies to approximately 466 grant recipients, most grant recipients will not have sufficient alternate resources available to provide these needed core medical services, and therefore most grant recipients will not be eligible for a waiver.

The estimated annualized burden hours is as follows:

Form Name	Number of Respondents	Number of Responses per Respondent	Total Responses	Average Burden per Response (in hours)	Total Burden Hours
Waiver Request	22	1	22	4	88
Total	22		22		88

The estimated annualized burden cost is as follows:

Type of Respondent	Number of Respondents	Number of Responses per Respondent	Hours per Response	Total Burden Hours	Total Wage Rate	Total Cost Burden Hours
RWHAP Recipients	22	1	4	88	\$37.22	\$3275.36

HRSA HAB anticipates that the number of recipients requesting waivers might fluctuate annually as requests have ranged from 15 to 22 since HRSA HAB implemented a waiver request process in FY 2007. Given recent changes in the health care environment, HRSA HAB anticipates receiving up to 22 applications in a given year. The burden of application for recipients varies by type of recipient. Some states and municipalities may have more burden than others; however, the 4-hour estimate has been calculated as the average burden per response. This represents a 1.5-hour reduction when compared to the current process, which is estimated at 5.5 hours per response. The total wage rate was determined using the national median hourly wage rate for 2020 for Project Management Specialist available at <http://www.bls.gov/bls/blswage.htm>

13. Estimates of Annualized Cost Burden to Respondents

Consistent with the proposed policy, HRSA HAB expects recipients to use existing public processes 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. That is, 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 (SCSN), public planning, and/or needs assessment processes. Therefore, other than their time, there is no cost to respondents.

14. Annualized Cost to the Federal Government

The estimated annual cost to the federal government for data processing is \$3874.86. This figure is the sum of the following cost categories:

(1)	Data entry, review, processing of the waiver requests and notification Total number of respondents – 22 Average cost per hour - \$58.71 ¹ Average number of hours per respondent – 2	\$2583.24
(2)	Notifying the Ryan White HIV/AIDS Program Grant Recipient – \$58.71 ¹ Number awarded out of respondents – 22 Average number of hours per respondent – 1	\$1291.62
	Total	\$3874.86

1 – \$58.71 is hourly rate of a Public Health Analyst, GS-14 - Step 1 (2021) for Washington DC-MD-VA-WV-PA.

15. Changes in Burden

This is a new information collection request.

16. Plans for Tabulation, Publication, and Project Time Schedule

There will be no statistical analysis done on the information received for the core medical services waiver requests. In addition, there will be no publication of the reported information.

17. Reason(s) Display of OMB Expiration Date Is Inappropriate

The OMB number and expiration date will be displayed on every page of every form/instrument.

18. Certifications

There are no exceptions to the certification.