

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

**0915-0307
Extension**

JUSTIFICATION

1. Circumstances of Information Collection

This is a request by the Health Resources and Services Administration (HRSA) for extension of Office of Management and Budget (OMB) approval to continue to collect information for the Ryan White HIV/AIDS Treatment Act of 2009 (Ryan White HIV/AIDS Program or RWHAP) Core Medical Services Waiver request process. The OMB number for this activity is 0915-0307 and the current expiration date is March 31, 2020. The Title XXVI of the Public Health Service (PHS) Act, as amended by the Ryan White HIV/AIDS Treatment Extension Act of 2009, Part A section 2604(c), Part B section 2612(b), and Part C section 2651(c), requires that grant recipients expend on core medical services, including antiretroviral drugs for individuals with HIV who are eligible under the legislation, no less than 75 percent of the remainder of their total award amount after reserving statutory permissible amounts for administrative and clinical quality management costs. In accordance with statute, for a grant recipient under the RWHAP Parts A, B, and C to be exempted from this requirement, they must request and receive a waiver from HRSA.

The waiver process was revised in 2013 to clarify and streamline the application requirements. Previously grant recipients were only allowed to submit a waiver with their annual grant application. Now, the uniform standards expanded the application period, and grant recipients may submit a waiver request before the annual grant application, with the application, or up to four months after the grant award has been made.

These standards allow grant recipients more flexibility to adjust resource allocation based on the service mix needed to reach health outcomes related to retention and viral suppression. In addition, the standards ensure that grant recipients receiving waivers clearly demonstrate the availability of core medical services, including antiretroviral drugs, for people with HIV served under Title XXVI of the PHS Act. Core medical services waivers are effective for a 1-year period.

2. Purpose and Use of Information

Grant recipients must provide evidence that all of the core medical services listed in the statute, regardless of whether such services are funded by the Ryan White HIV/AIDS Program, are available to all people with HIV who are identified and eligible under Title XXVI of the PHS Act in the service area within 30 days. HRSA uses the documentation submitted in core medical

services waiver requests to determine if the applicant/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. See sections 2604(c)(2), 2612(b)(2), and 2651(c)(2) of the PHS Act.

The attached policy document outlines the procedure for requesting a waiver of the Core Medical Services requirement.

3. Use of Improved Information Technology

Requests for waivers and supporting documentation, either with the annual grant application or through HRSA's Electronic Handbook (EHB) Prior Approval portal. The core medical services uniform standards and guidance on documentation and evidence requirements is posted at <http://hab.hrsa.gov/sites/default/files/hab/Global/13-07waiver.pdf>

4. Efforts to Identify Duplication

There is no duplication of the required documentation for the core medical services waiver request. 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 award amount after reserving statutory permissible amounts for administrative and clinical quality management costs. See sections 2604(c)(1), 2612(b)(1), and 2651(c)(1) of the PHS Act.

5. Involvement of Small Entities

This activity does not have a significant impact on small entities.

6. Consequences if Information Collected Less Frequently

As required by the statute, waivers may only be awarded for a single grant year. If this information is collected less than annually, HRSA will not be able to determine whether the applicant meets the statutory and programmatic requirements of the waiver and will not be able to award waivers to eligible grant recipients who request a waiver. This would decrease the grant recipient's flexibility to meet its patients' needs.

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

The data are collected in a manner consistent with guidelines contained in 5 CFR 1320.5(d)(2).

8. Consultation Outside the Agency

The notice required in 5 CFR 1320.8(d) was published in the *Federal Register* on August 15, 2019, Vol. 84, No. 158, pages 41726-41727. No comments were received.

9. Remuneration of Respondents

Respondents will not be remunerated.

10. Assurance of Confidentiality

The waiver request does not involve the collection of individual level or personally identifiable information.

11. Questions of a Sensitive Nature

There are no questions of a sensitive nature.

12. Estimates of Annualized Hour Burden

Of the total number of eligible grantees, the program estimates that only a limited number of grant recipients will request the waiver. There are approximately 466 grant recipients eligible to apply for this waiver, however most grant recipients will be able to meet the statutory requirement that they expend on core medical services, no less than 75 percent of the remainder of their total award amount after reserving statutory permissible amounts for administrative and clinical quality management costs.

To request a waiver, grant recipients provide the documentation and evidence that the statutory criteria are fulfilled. Much of this information is routinely available as it is required for grant recipient planning and application process, but the waiver request may require the submission of additional documentation to prove that the statutory and programmatic criteria have been met by the applicant.

The annual estimate of burden is as follows:

| Type of Form | Number of Respondents | Number of Responses per Respondent | Hours per Response | Total Burden Hours | Total Wage Rate | Total Cost Burden Hours |
|---|-----------------------|------------------------------------|--------------------|--------------------|-----------------|-------------------------|
| HIV Core Medical Services Waiver | 20 | 1 | 5.5 | 110 | \$35.00 | \$3,850.00 |

HRSA anticipated that the number of grant recipients requesting waivers might fluctuate annually as requests have ranged up to 14 per year since its implementation in FY 2007. Given recent changes in the health care environment, HRSA anticipates receiving a slightly larger number of applications than in past years, possibly up to 20 applications in a given year. The

burden of application for grant recipients varies by type of grant recipient. Some states and municipalities may have more burden in providing the information than others; however, the 5.5 hour estimate has been calculated as the average burden per respondent.

13. Estimates of Annualized Cost Burden to Respondents

There are no capital or start-up costs.

14. Estimated Cost to the Federal Government

The estimated annual cost to the federal government for data processing is \$3369.00. 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 – 20 Average cost per hour - \$56.15 ¹ Average number of hours per respondent – 2 | \$2246.00 |
| (2) | Notifying the Ryan White HIV/AIDS Program Grant Recipient – \$56.15 ¹ Number awarded out of respondents – 20 Average number of hours per respondent – 1 | \$1123.00 |
| | Total | \$3369.00 |

¹ – \$56.15 is hourly rate of a Public Health Analyst, GS-14, step 1 (2019).

15. Changes in Burden

There is no change from the currently approved burden of 110 hours.

16. Time Schedule, Publication and Analysis Plans

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. Exemption for Display of Expiration Date

The expiration date will be displayed.

18. Certifications

This information collection fully complies with the guidelines in 5 CFR 1320.9. The necessary certifications are included in the package.