

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

JUSTIFICATION

1. Circumstances of Information Collection

This is a request by the Health Resources and Services Administration (HRSA) for extension with revision 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 April 30, 2014. 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 grantees expend 75 percent of Parts A, B, and C funds on core medical services, including antiretroviral drugs for individuals with HIV/AIDS, identified and eligible under the legislation. In order for grantees under Parts A, B, and C to be exempted from the 75 percent core medical services requirement, they must request and receive a waiver from HRSA, as required in the Act.

The waiver process was revised in 2013 to clarify and streamline the application requirements. The revised uniform standards also expand the application period. Previously grantees were only allowed to submit a waiver with their annual grant application. Now grantees 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. The final notice of these revised uniform waiver standards to be utilized by grantees requesting core medical services waivers for fiscal year (FY) 2014 and beyond was published in the *Federal Register* on October 25, 2013 (78 FR 63990).

These revised standards will allow grantees more flexibility to adjust resource allocation based on the current situation in their local environment. In addition, the revised standards ensure that grantees receiving waivers clearly demonstrate the availability of core medical services, including antiretroviral drugs, for persons with HIV/AIDS served under Title XXVI of the PHS Act. Core medical services waivers will be effective for a 1-year period that is consistent with the grant award period.

2. Purpose and Use of Information

Grantees 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 individuals with HIV/AIDS 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/grantee 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 individuals with HIV/AIDS 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 policy document in Appendix A outlines the revised procedure for requesting a waiver of the Core Medical Services requirement.

3. Use of Improved Information Technology

Requests for waivers and supporting documentation must be submitted electronically, 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 will be posted at <http://www.hab.hrsa.gov/affordablecareact/index.html>.

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 grantees' requests to waive the requirement that they expend at least 75% of Ryan White HIV/AIDS Program funds on core medical services.

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 grantees who request a waiver. This would decrease the grantee'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 November 12, 2013 (78 FR 67367). No comments were received on the Agency Information Collection notice.

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 grantees will request the waiver. There are approximately 466 grantees eligible to apply for this waiver, however most grantees will be able to meet the statutory requirement that 75 percent of their funds be spent on core medical services.

To request a waiver, grantees provide the documentation and evidence that the statutory criteria are fulfilled. Much of this information is routinely available as it is required for grantee 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/AIDS Core Medical Services Waiver	20	1	5.5	110	\$35.00	\$3,850.00

HRSA anticipated that the number of grantees requesting waivers may fluctuate annually as requests have ranged up to 10 per year since its implementation in FY 2007. Given recent changes in the health care system, 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 grantees varies by type of grantee. 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 \$3,055.20. 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 - \$50.92 ¹ Average number of hours per respondent - 2	\$2,036.80
(2)	Notifying the Ryan White HIV/AIDS Program Grantee – \$50.92 ¹ Number awarded out of respondents – 20 Average number of hours per respondent - 1	\$1,018.40
	Total	\$3,055.20

1 – \$50.92 is hourly rate of a Public Health Analyst, GS-14, step 1 (2014).

15. Changes in Burden

Until recently, there has been a decrease in the number core medical services waiver requests from grantees, but beginning in 2014, grantees may require additional flexibility with the 75 percent requirement, in part due to implementation of the Affordable Care Act. In addition, the revised requirements may make it more convenient for grantees to request a waiver, so more grantees may apply. Considering these facts, the program anticipates a slight increase in the number of waiver applicants. Even with the projected increase, the program estimates that only a limited number of grantees will request the waiver, since most grantees will be able to meet the requirement that 75 percent of their funds be spent on core medical services.

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.