

**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 without change 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) Core Medical Services Waiver request process. The OMB number for this activity is 0915-0307 and the current expiration date is 02/28/2011.

Title XXVI, Section 2671 of the Public Health Services (PHS) Act, as amended by the Ryan White HIV/AIDS Treatment Extension Act of 2009, Public Law 111-87, 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 who are identified and eligible under the legislation. In order for grantees under Parts A, B, and C to be exempt from the 75 percent core medical services requirement, they must request and receive a waiver from HRSA. The final notice of the Ryan White HIV/AIDS Program uniform waiver standards to be utilized by grantees requesting core medical services waivers for fiscal year (FY) 2009 and beyond was published in the *Federal Register*, Vol. 73, No. 113, dated Wednesday June 11, 2008. Use of these standards and the core medical services waiver process meet the intent of the Ryan White HIV/AIDS Program to increase access to core medical services including antiretroviral drugs, for persons with HIV/AIDS and to ensure that grantees receiving waivers demonstrate that availability of such services for individuals with HIV/AIDS who are identified and eligible for services under Title XXVI of the PHS Act.

The core medical services waiver uniform standard and waiver request process applies to Ryan White HIV/AIDS Program Grant awards under Parts A, B, and C of Title XXVI of the PHS Act. Waiver requests that include the required certifications and documentation must be submitted by grantees with the annual grant application. 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. The waiver request certifications and documentation will be utilized by HRSA in making waiver determinations. Core medical services waivers are effective for a 1-year period that is consistent with the grant award period.

Grantees must submit a waiver request with their annual grant application. Grantees no longer receive waiver application instruction letters from the HIV/AIDS Bureau regarding this matter. Application guidance documents for Parts A, B, and C refer to the final notice of the HIV/AIDS Bureau; Ryan White HIV/AIDS Program Core Medical Services Waiver Application Requirements, published in the *Federal Register* notice, Vol. 73, No. 113, dated Wednesday

June 11, 2008 and may be found at <http://edocket.access.gpo.gov/2008/pdf/E8-13102.pdf>.

2. Purpose and Use of Information

HRSA uses the certifications and 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.

Criteria for Waiver of Core Medical Services Requirements for Grantees under Parts A, B, and C

Grantees must submit a waiver request containing the following certifications and documentation which will be utilized by HRSA in determining whether to grant a waiver. The waiver must be signed by the chief elected official or the fiscally responsible agent, and include:

- a. Certification from the Part B state grantee that there are no current or anticipated ADAP services waiting lists in the state for the year in which such waiver request is made. This certification must also specify that there are no waiting lists for a particular core class of antiretroviral therapeutics established by the Secretary, e.g., fusion inhibitors;
- b. Certification that all core medical services listed in the statute (Part A section 2604(c)(3), Part B section 2612(b)(3), and Part C section 2651(c)(3)), regardless of whether such services are funded by the Ryan White HIV/AIDS Program, are available for all identified and eligible individuals with HIV/AIDS in the service area;
- c. Evidence that a public process was conducted to seek public input on availability of core medical services;
- d. Evidence that receipt of the core medical services waiver is consistent with the grantee's Ryan White HIV/AIDS Program application.

Types of Documentation and Evidence Required for Core Medical Services Waiver Consideration

Grantees must provide documentation 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 identified and eligible under Title XXVI of the PHS Act in the service area. Such documentation may include one or more of the following types of information for the service area for the prior fiscal year: HIV/AIDS care and treatment services inventories including funding sources, HIV/AIDS met and unmet need assessments, HIV/AIDS client/patient service utilization data, planning council core medical services priority setting and funding allocations documents, and letters from Medicaid and other state and local HIV/AIDS entitlement and benefits programs including private insurers. Information provided by grantees must show specific verifiable evidence that all listed core medical services are available and are being utilized to meet the needs of persons with HIV/AIDS who are identified and eligible for Ryan White HIV/AIDS Program services without further infusion of Ryan White HIV/AIDS

Program dollars. Such documentation must also describe which specific core services are available, from whom, and through what funding source.

Grantees must have evidence of a public process for the dissemination of information and must seek input from affected communities related to the availability of core medical services and the decision to request a waiver. This public process may be the same one utilized for obtaining input on community needs as part of the comprehensive planning process. In addition, grantees must describe in narrative form the following:

1. Local/state underlying issues that influenced the grantee's decision to request a waiver and how the submitted documentation supports the assertion that such services are available and accessible to all individuals with HIV/AIDS identified and eligible under Title XXVI in the service area.
2. How the approval of a waiver will impact the grantee's ability to address unmet need for HIV/AIDS services and perform outreach to HIV-positive individuals not currently in care.
3. The consistency of the waiver request with the grantee's grant application, including proposed service priorities and funding allocations.

Waiver Review and Notification Process

Grantees include their request for a core medical service waiver when they submit their application for funding. Upon receipt of the core medical services waiver request from the grantee, HRSA/HAB will review the request and provide notification to grantees of waiver approval. Core medical services waivers will be effective for a one-year period consistent with the grant award period.

3. Use of Improved Information Technology

Requests for waivers and supporting documentation can be submitted electronically. The core medical services uniform standards and guidance on documentation and evidence requirements will be available in the HAB application guidance for Parts A, B, C, and will also be posted at the following web address: <http://www.hrsa.gov/grants/>

4. Efforts to Identify Duplication

The core medical services waiver request and documentation and evidence requirements are unique to this waiver statute. The information requested is specific to this activity and is needed to determine whether to approve grantees' requests to expend less than 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 and CFR, grantees requesting core medical services waiver consideration must submit required documentation and evidence annually. If such information is not submitted, grantees will be required to expend 75% of grant funds for core medical services for that year.

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 30, 2010 (Volume 75, Number 25, Pages 74065-74066). 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

The program estimates that only a limited number of grantees will request the waiver out of the total number of eligible grantees (approximately 477 grantees are eligible). The majority of the Part C grantees are already expending at least 75% of Ryan White funds on core medical services, and have no need to request a waiver. The program estimates approximately 10 requests in 2010.

To request a waiver, grantees provide the documentation and evidence that the legislative criteria are fulfilled. Much of this information is routinely utilized by grantee applicants when preparing and completing sections of the grantee application Form 5161-1 and SF 424A budget information, but the waiver request requires the submission of additional documentation indicating that the legislative criteria have been met by the grantee applicant.

The annual estimate of burden is as follows:

Type of Form	Number of Respondents	Hours per Response	Total Burden Hours	Total Wage Rate	Total Cost Burden Hours
HIV/AIDS Core Medical Services Waiver	10	6.5	65	\$35.00	\$2,275.00

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. 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 6.5 hour estimate has been calculated as the average burden per respondent.

13. Estimates of Annualized Cost Burden to Respondents

There is no capital or start up costs. The information will be posted on the HRSA web site for easy access by Ryan White HIV/AIDS Program grantees.

14. Estimated Cost to the Federal Government

The estimated annual cost to the federal government for data processing is \$730.80. 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 – 10 Average cost per hour - \$36.54	\$365.40
(2)	Notifying the Ryan White HIV/AIDS Program Grantee – \$36.54 Number awarded out of respondents – 10	\$365.40
	Total	\$730.80

15. Changes in Burden

There has been a decrease amount of core medical services waiver requests from grantees due to the lack of need for a waiver. The program estimates that only a limited number of grantees will request the waiver out of the total number of eligible grantees (approximately 477 grantees are eligible). The majority of the Part C grantees are already expending at least 75% of Ryan White funds 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 information being reported.

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.