

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

JUSTIFICATION

1. Circumstances of Information Collection

The Health Resources and Services Administration (HRSA), HIV/AIDS Bureau (HAB) is requesting Office of Management and Budget (OMB) review and approval for the Core Medical Services Waiver request process for grantees of the Ryan White HIV/AIDS Treatment Modernization Act of 2006. HRSA is requesting emergency processing procedures for this activity because the requests and reporting of this information are needed before the expiration of the normal time limits under regulations at 5 CFR Part 1320 to ensure the timely availability of data as necessary to ensure determinations of waiver requests to eligible grantees. Emergency processing is needed because of the timing of the application cycle for grantees. The program application for FY 2008 must be made available on August 1, 2007, in order to allow 60 days for grantees to prepare the application materials, which are due on October 1, 2007. The waiver request must be submitted with the program application and budget information required on the SF 424A (OMB No. 4040-0006), and information on the process and documentation must be available for grantees when the application is made available.

On December 19, 2006, the President signed the Ryan White HIV/AIDS Treatment Modernization Act of 2006. The predecessor statute was the Ryan White Comprehensive AIDS Resources Emergency (CARE) Act. The 2006 Act requires that grantees receiving funds under Parts A, B, and C expend 75 percent of funding on core medical services, including antiretroviral drugs, for individuals with HIV/AIDS identified and eligible under the legislation, retroactive to the beginning of the 2007 Fiscal Year.

Sections 2604(c)(2), 2612(b)(2), and 2651(c)(2) of Title XXVI of the Public Health Service (PHS) Act, as amended by the 2006 Act, permit a waiver with respect to the required portion of funding for core medical services. The Act, signed in December, 2006, was made retroactive to the beginning of the 2007 Fiscal Year regarding this statute. For the FY 2007 grantees, the waiver request did not require data collection due to the immediate implementation. Grantees made the waiver request by sending a written request for the waiver stating that they met the legislative criteria; a total of three requests were submitted and granted in FY 2007.

The program has worked to determine the standard data elements and information required for making the annual waiver request in order to ensure that HRSA has documentation that all requests meet the criteria specified in the Act. For FY 2008, HRSA seeks to require documentation of waiver criteria for grantees under Parts A, B, and C of Title XXVI of the PHS Act for FY 2008. Beginning in FY 2008, HRSA will utilize these new requirements for granting waivers of the core medical services requirement for Ryan White HIV/AIDS Programs. These standards meet the intent of the

Ryan White HIV/AIDS Treatment Modernization Act of 2006 to increase access to core medical services, including antiretroviral drugs, for persons with HIV/AIDS and to ensure that grantees receiving waivers demonstrate the availability of such services for individuals with HIV/AIDS identified and eligible under Title XXVI of the PHS Act. The core medical services waiver uniform standard and waiver request process will apply to Ryan White HIV/AIDS Program grant awards under Parts A, B, and C of Title XXVI of the PHS Act.

We are requesting OMB's emergency review and approval of this data collection with a 180-day approval period. During this 180-day approval period, HRSA will publish a *Federal Register* notice announcing the initiation on an extensive 60-day public comment period and begin the process for a routine information collection request.

2. Purpose and Use of Information

HRSA will use the Core Medical Services requests and documentation 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.

Proposed Uniform Standard for Waiver of Core Medical Services Requirements for Grantees under Parts A, B, and C

Grantees must submit a waiver request with the annual grant application 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 within 30 days 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 within 30 days. 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

Upon receipt of core medical services waiver request with grantees' annual grant application, HRSA/HAB will review requests and notify grantees of waiver approval no later than the date of issuance of Notice of Grant Award (NOGA). 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 uniform standards 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

For FY 2007, three grantees provided written requests and have received core medical services waivers, as the Act signed by the President was retroactive to the beginning of the 2007 Fiscal Year. Grantees provided signed written requests by letter stating that they met the criteria stated in the legislation. Copies of these letters are provided. HRSA, HAB has received written correspondence expressing interest in the implementation of the core medical services provision in the Ryan White HIV/AIDS Treatment Modernization Act of 2006 from the Honorable Vernon J. Ehlers and the Honorable Jerrold Nadler, House of Representatives; Donald Blair, MD, SUNY Upstate Medical University; Daniel Brown, V.P. of Client Services, Inland AIDS Project; Michael Caldwell, MD, MPH, Commissioner of Health Dutchess County Department of Health; S. Deidre Kelley, Administrator of Thursday's Child, Inc.; Ram Yogev, MD, Director, Section of Pediatric, Adolescent and Maternal HIV Infection, Children's Memorial Hospital; and M. Gerardo Ramos of 381 Belmont Street #303, Oakland, CA.

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 473 grantees are eligible). The majority of the grantees are Community Health Centers that are already expending at least 75% of Ryan White funds on core medical services, and have no need to request a waiver. With only 3 requests made in 2007, the program estimates a possible increase of up to 20 requests in 2008.

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	20	6.5	130	\$35.00	\$4,550.00

In FY 2007, only three grantees requested the waiver; however, it is anticipated that this number might increase in the next year as the legislation is new. Application burden for grantees may vary by type of grantee. We expect some States and municipalities will have more burden in providing the information than others; however, the 6.5 hour estimate has been calculated as the average burden per respondent. HRSA estimates that the burden of the waiver request will diminish after the first year of preparation of waiver requests by grantees.

13. Estimates of Annualized Cost Burden to Respondents

There are no capital or start up costs. The information will be posted on the HRSA, HAB 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 \$1461.73. 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 - \$36.54	\$730.86
(2)	Notifying the Ryan White HIV/AIDS Program Grantee – \$36.54 Number awarded out of respondents – 20	\$730.86
	Total	\$1461.73

15. Changes in Burden

This is a new project.

16. Time Schedule, Publication and Analysis Plans

There will be no statistical analysis done on the information received on these application forms. In addition, there will be no publication of the information being reported on the application forms.

17. Exemption for Display of Expiration Date

The expiration date will be displayed.

18. Certifications

This project fully complies with CFR 1320.9. The certifications are included in this package.