

HIV/AIDS BUREAU

Law & Policy: Policy Notice - 08-02

Title: UNIFORM STANDARD FOR WAIVER OF CORE MEDICAL SERVICES REQUIREMENTS FOR GRANTEEES UNDER PARTS A, B, and C

Date: JUL 31 2008

To: All Ryan White HIV/AIDS Program Grantees

Attached is the HIV/AIDS Bureau (HAB) policy describing the uniform waiver standards for Ryan White HIV/AIDS Program grantees. The Health Resources and Services Administration (HRSA) has issued waiver standards for grantees under Parts A, B, and C of Title XXVI of the Public Health Service Act, as amended by the Ryan White HIV/AIDS Treatment Modernization Act of 2006. The statute in Sections 2604 (c) (2), 2612 (b) (2), and 2651 (c) (2) 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.

On November 26, 2007, *Federal Register* notice 60 FR 66181 solicited comments on the proposed uniform waiver standards. During the 30-day public comment period, which ended on December 26, 2007, HRSA received many comments from the public. There were several comments in strong support of the policy stating that the proposed changes allow for more funds to be allocated to life-saving core medical services, including medications.

Of the comments, three main issues of concern were identified and addressed. 1) Types of documentation and evidence required as part of the waiver request, 2) Core medical services waiver requests submitted as part of the annual grant application, and 3) Requests that obtaining a core medical services waiver be further strengthened to require more stringent documentation than that proposed. After much consideration of the public comments, HRSA responded and addressed these concerns in the June 11, 2008 *Federal Register* notice 73 FR 33097. The revised policy provides guidance and sets forth the criteria to be used to evaluate waiver requests.

This policy becomes effective for fiscal year 2009 and beyond. If you have any questions regarding the content of this Policy Notice, please contact your project officer.

A handwritten signature in cursive script, reading "Deborah Parham Hopson".

Deborah Parham Hopson, Ph.D., R.N.
Assistant Surgeon General
Associate Administrator

Attachment

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Health Resources and Services Administration
HIV/AIDS Bureau

Ryan White HIV/AIDS Program Core Medical Services Waiver
Application Requirements

AGENCY: Health Resources and Services Administration, HHS.

ACTION: Final Notice.

SUMMARY: The Health Resources and Services Administration (HRSA) is amending the uniform waiver standards for Ryan White HIV/AIDS Program Grantees requesting a core medical services waiver for fiscal year (FY) 2009 and beyond. Title XXVI of the Public Health Service Act (PHS) Act, as amended by the Ryan White HIV/AIDS Treatment Modernization Act of 2006 (Ryan White HIV/AIDS Program) 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. HRSA has issued waiver standards for grantees under Parts A, B, and C of Title XXVI of the PHS Act. This *Federal Register* notice seeks to make public the

final notice of Uniform Standard for Waiver of Core Medical Services Requirements for Grantees Under Parts A, B, and C effective FY 2009.

SUPPLEMENTARY INFORMATION: The Ryan White HIV/AIDS Program imposes two criteria for waiver eligibility: (1) no waiting lists for AIDS Drug Assistance Program (ADAP) services; and (2) 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. HRSA's HIV/AIDS Bureau (HAB) issued interim waiver eligibility guidance for FY 2007 to provide immediate implementation of these waiver provisions. The final Uniform Standard for Waiver of the Core Medical Services Requirements for Grantees Under Parts A, B, and C, reflects modifications based on public comment received in response to the guidance published in the *Federal Register* on November 27, 2007. During the 30-day comment period, ending December 26, 2007, HAB received comments from the public.

Beginning in FY 2009, HRSA will utilize new standards for granting waivers of the core medical services requirement for Ryan White HIV/AIDS Program grantees. 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 purposes of this notice are: 1) to establish a uniform standard for core medical services waiver eligibility for grantees under Parts A, B, and C of Title XXVI of the PHS Act; and 2) to establish a process for waiver request submission, review and notification. The core medical services waiver uniform standard and waiver request process in this notice apply to Ryan White HIV/AIDS Program grant awards under Parts A, B, and C of Title XXVI of the PHS Act effective for the FY 2009 grant year.

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

There were several public comments in strong support of the draft policy stating that the proposed changes allow more funds to be allocated to life-saving core medical services, including medications. The following suggestions and

concerns were the main issues raised in the public comments.

Issue (1): Types of documentation and evidence required as part of the waiver request

(Comment) Submission of documentation letters from private payers should be optional, not required.

(Response) HRSA concurs with the suggestion and changed the sentence regarding private insurers to "letters from Medicaid and other State and local HIV/AIDS entitlement and benefits programs, which may include private insurers".

(Comment) Requiring submission of data demonstrating that services are "being utilized" is unreasonable and falls outside the provisions of the statute.

(Response) HRSA concurs with the comment. As amended, the standard requires grantees to provide specific verifiable evidence that all listed core medical services are available and *accessible* 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.

(Comment) "Verifiable evidence" that core services are available and accessible is not replicable across jurisdictions and would not result in "uniform waiver standards".

(Response) HRSA does not concur with the comment. The core medical services waiver standards do not require that methods of providing "verifiable evidence" of service availability and accessibility be replicable across jurisdictions. When submitting a waiver request, each jurisdiction must submit clear and concise verifiable documentation as to the availability and accessibility of all core medical services in their service area. Each waiver request will be reviewed and assessed individually on its merits.

(Comment) There is no basis for the proposed standard that all core medical services must be available within 30 days.

(Response) The Ryan White HIV/AIDS Program legislation specifies that core medical services must be "available." Access to routine medical and preventive care services within 30 days has been cited as an example of a reasonable availability standard for Medicare Coordinated Care Plans by the Department of Health and Human Services/Centers for Medicare and Medicaid Services (HHS/CMS). (See Medicare Managed Care Manual, Chapter 4 Benefits and Beneficiary Protections, section 120.2 Access and Availability Rules for Coordinated Care Plans

(<http://www.cms.hhs.gov/manuals/downloads/mc86c04.pdf>)

Therefore, HRSA will maintain the requirement that all core medical services are available to individuals identified in the service area within 30-days, as this requirement serves as a benchmark for the availability of core medical services.

Issue (2): Core medical services waiver requests submitted as part of the annual grant application

(Comment) Core medical services waiver requests should be allowed to be submitted after awards are received, to better respond to fluctuations in funding.

(Response) HRSA does not agree with the recommendation to submit waiver request after receipt of a Notice of Grant Awards (NGA). By law, the waiver will be granted at the time the award is made (See sections 2604(c)(2)(B), 2612(b)(2)(B), and 2651(c)(2)(B) of the PHS Act.

Issue (3): Requests for obtaining a core medical services waiver need to be strengthened to require more stringent documentation than that proposed.

(Comment) Requests for obtaining a core medical service waiver should include assurances that core services are available and accessible to those most in need. Documentation should include information about average waiting times for first appointments, average travel time to service locations as well as cost-sharing or services limits related to core services. Grantees should be required to, identify all eligible people, including those not yet diagnosed.

(Response) HRSA acknowledges the commenters' emphasis on the importance of access to services and follow-up, however, disagrees with the suggestion for additional documentation as this would be overly burdensome to

grantees seeking core medical service waivers.

Furthermore, the documentation imposed by this final notice is sufficiently detailed for HRSA to approve or deny core medical services waiver requests.

(Comment) Require that Ryan White HIV/AIDS Program-funded core medical services providers be included in the public process.

(Response) HRSA concurs. Grantees will be required to provide evidence of a public process for the dissemination of information and must document that they have sought input from affected communities; including Ryan White HIV/AIDS Program-funded core medical services providers,

(Comment) Public input should be independent of routine community planning.

(Response) HRSA does not concur. Requiring a public input process independent of routine community planning would be burdensome given Ryan White HIV/AIDS Program administrative cost caps.

(Comment) Require documentation demonstrating that grantees applying for waivers have made reasonable

efforts to identify all eligible persons including those not yet diagnosed and link them to care. This should include using at least 25 percent of Ryan White HIV/AIDS Program funding on outreach and testing.

(Response) HRSA agrees with the commenter's emphasis on the importance of ensuring that all cases of HIV and AIDS are identified and brought into care, but disagrees with the proposal. HRSA urges all of the Ryan White HIV/AIDS Program grantees to utilize available outreach funding, including those available from the Centers for Disease Control and Prevention, to identify HIV-positive individuals and provide linkages to HIV care and treatment.

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:

1. 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;
2. 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;
3. Evidence that a public process was conducted to seek public input on availability of core medical services;
 4. Evidence that receipt of the core medical services waiver is consistent with the grantee's Ryan White HIV/AIDS Program application (e.g., "Description of Priority Setting and Resource Allocation Processes" and "Unmet Need Estimate and Assessment", sections of the application for Parts A, "Needs Assessment and Unmet Need", section of the application under Part B, and "Description of the Local HIV Service Delivery System," and "Current and Projected Sources of Funding", sections of the application under Part C).

TYPES OF DOCUMENTATION AND EVIDENCE

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, 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, which may include private insurers. Information provided by grantees must show specific verifiable evidence that all listed core medical services are available and accessible 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 medical 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 document that they have sought input from affected communities; including Ryan White HIV/AIDS Program-funded core medical services providers, 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 needs 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

As indicated, grantees must submit a waiver request with their annual grant application. No waiver requests will be accepted at any other time (other than with the annual grant application). Application guidance documents will be amended to include this requirement. HRSA/HAB will review requests for waiver of the core medical services

requirement and will notify grantees of waiver approval no later than the date of issuance of NOGA. Core medical services waivers will be effective for a one-year period consistent with the grant award period.

THE PAPERWORK REDUCTION ACT OF 1995

This activity has been reviewed and approved by the Office of Management and Budget, under the Paperwork Reduction Act of 1995 (Control number 0915-0307).