

OMB No. 0915-0307

Exp. Date:

**U.S. Department of Health and Human Services
Health Resources and Services Administration**

HIV/AIDS Bureau

Public Burden Statement: An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a valid OMB control number. The OMB control number for this project is 0915-0307. Public reporting burden for this collection of information is estimated to average 6.5 hours per response, including the time for reviewing instructions, searching existing data sources, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to: HRSA Reports Clearance Officer, 5600 Fishers Lane, Room 10-33, Rockville, Maryland, 20857.

Authority: Section 2651 et seq., of the Public Health Service Act, 42 USC § 300ff -51 et seq.

HIV/AIDS Bureau Core Medical Services Waiver Request

Applicants will find information on core medical services waiver requests as part of the grantee application package. Information for the waiver request will be available electronically using Grants.gov when submitting applications using the Public Health Service (PHS) Application Form 5161-1 and Standard Form 424. These grant application forms contain general information and instructions for grant applications, proposal narratives, and budgets. These standard forms may be obtained from the following site by downloading from <http://www.hrsa.gov/grants/forms.htm>. Grantees request a waiver for core medical services by providing documentation assuring that the legislative criteria for such a waiver are met. The legislation requires an annual request for a waiver of core medical services.

Part A, B, and/or C Grantees may request a waiver of the 75% requirement for core medical services if the following conditions are met:

1. There are no waiting lists for AIDS Drug Assistance Program (ADAP) services in the State, and
2. Core medical services are available to all individuals with HIV/AIDS identified and eligible under this title.

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:

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 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).

Waiver Request Documentation

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. 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.

Core Medical Services: Definitions

Core Medical Services

- a. *Outpatient/Ambulatory medical care (health services)*** is the provision of professional diagnostic and therapeutic services rendered by a physician, physician's assistant, clinical nurse specialist, or nurse practitioner in an outpatient setting. Settings include clinics, medical offices, and mobile vans where clients generally do not stay overnight. Emergency room services are not outpatient settings. Services

includes diagnostic testing, early intervention and risk assessment, preventive care and screening, practitioner examination, medical history taking, diagnosis and treatment of common physical and mental conditions, prescribing and managing medication therapy, education and counseling on health issues, well-baby care, continuing care and management of chronic conditions, and referral to and provision of specialty care (includes all medical subspecialties). *Primary medical care* for the treatment of HIV infection includes the provision of care that is consistent with the Public Health Service's guidelines. Such care must include access to antiretroviral and other drug therapies, including prophylaxis and treatment of opportunistic infections and combination antiretroviral therapies. **NOTE: Early Intervention Services provided by Ryan White HIV/AIDS Program Part C and Part D should be included here under *Outpatient/ Ambulatory medical care*.**

- b. *AIDS Drug Assistance Program (ADAP treatments)*** is a State-administered program authorized under Part B of the Ryan White HIV/AIDS Program that provides FDA-approved medications to low-income individuals with HIV disease who have limited or no coverage from private insurance, Medicaid, or Medicare.
- c. *AIDS Pharmaceutical Assistance (local)*** includes local pharmacy assistance programs implemented by Part A or Part B Grantees to provide HIV/AIDS medications to clients. This assistance can be funded with Part A grant funds and/or Part B base award funds. Local pharmacy assistance programs are **not** funded with ADAP earmark funding.
- d. *Oral health care*** includes diagnostic, preventive, and therapeutic services provided by general dental practitioners, dental specialists, dental hygienists and auxiliaries, and other trained primary care providers.
- e. *Early intervention services (EIS)*** include counseling individuals with respect to HIV/AIDS; testing (including tests to confirm the presence of the disease, tests to diagnose to extent of immune deficiency, tests to provide information on appropriate therapeutic measures); referrals; other clinical and diagnostic services regarding HIV/AIDS; periodic medical evaluations for individuals with HIV/AIDS; and providing therapeutic measures.

NOTE: EIS provided by Ryan White HIV/AIDS Program Part C and Part D should NOT be reported here. Part C and Part D EIS should be included under *Outpatient/ Ambulatory medical care*.

- f. *Health Insurance Premium & Cost Sharing Assistance*** is the provision of financial assistance for eligible individuals living with HIV to maintain a continuity of health insurance or to receive medical benefits under a health insurance program. This includes premium payments, risk pools, co-payments, and deductibles.
- g. *Home Health Care*** includes the provision of services in the home by licensed health care workers such as nurses and the administration of intravenous and aerosolized treatment, parenteral feeding, diagnostic testing, and other medical therapies.
- h. *Home and Community-based Health Services*** include skilled health services furnished to the individual in the individual's home based on a written plan of care established by a case management team that includes appropriate health care

professionals. Services include durable medical equipment; home health aide services and personal care services in the home; day treatment or other partial hospitalization services; home intravenous and aerosolized drug therapy (including prescription drugs administered as part of such therapy); routine diagnostics testing administered in the home; and appropriate mental health, developmental, and rehabilitation services. Inpatient hospitals services, nursing home and other long term care facilities are **NOT** included.

- i. *Hospice services*** include room, board, nursing care, counseling, physician services, and palliative therapeutics provided to clients in the terminal stages of illness in a residential setting, including a non-acute-care section of a hospital that has been designated and staffed to provide hospice services for terminal clients.
- j. *Mental health services*** are psychological and psychiatric treatment and counseling services offered to individuals with a diagnosed mental illness, conducted in a group or individual setting, and provided by a mental health professional licensed or authorized within the State to render such services. This typically includes psychiatrists, psychologists, and licensed clinical social workers.
- k. *Medical nutrition therapy*** is provided by a licensed registered dietitian outside of a primary care visit and includes the provision of nutritional supplements. Medical nutrition therapy provided by someone other than a licensed/registered dietitian should be recorded under psychosocial support services.
- l. *Medical Case management services (including treatment adherence)*** are a range of client-centered services that link clients with health care, psychosocial, and other services. The coordination and follow-up of medical treatments is a component of medical case management. These services ensure timely and coordinated access to medically appropriate levels of health and support services and continuity of care, through ongoing assessment of the client's and other key family members' needs and personal support systems. Medical case management includes the provision of treatment adherence counseling to ensure readiness for, and adherence to, complex HIV/AIDS treatments. Key activities include (1) initial assessment of service needs; (2) development of a comprehensive, individualized service plan; (3) coordination of services required to implement the plan; (4) client monitoring to assess the efficacy of the plan; and (5) periodic re-evaluation and adaptation of the plan as necessary over the life of the client. It includes client-specific advocacy and/or review of utilization of services. This includes all types of case management including face-to-face, phone contact, and any other forms of communication.
- m. *Substance abuse services outpatient*** is the provision of medical or other treatment and/or counseling to address substance abuse problems (i.e., alcohol and/or legal and illegal drugs) in an outpatient setting, rendered by a physician or under the supervision of a physician, or by other qualified personnel.