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

HIV/AIDS Bureau

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/ADIS 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 service****s)* includes the provision of professional diagnostic and therapeutic services rendered by a physician, physician's assistant, clinical nurse specialist, nurse practitioner, or other health care professional who is certified in his or her jurisdiction to prescribe antiretroviral (ARV) therapy in an outpatient setting. These settings include clinics, medical offices, and mobile vans where clients generally do not stay

overnight. Emergency room services are not considered outpatient settings. Services include 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 PHS's guidelines. Such care must include access to ARV and other drug therapies, including prophylaxis and treatment of opportunistic infections and combination ARV therapies. **NOTE: Early Intervention Services provided by Ryan White Parts C and D program 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 (APA, not ADAP)*** 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. These organizations may or may not provide other services (e.g., primary care or case management) to the clients they serve through an RWHAP contract with their grantee.

Programs are considered APAs if they provide HIV/AIDS medications to clients and meet all of the following criteria:

- Have a client enrollment process;
- Have uniform benefits for all enrolled clients;
- Have a record system for distributed medications; and
- Have a drug distribution system.

Programs are not APAs if they dispense medications in one of the following situations:

- As a result or component of a primary medical visit;
- On an emergency basis (defined as a single occurrence of short duration); or
- By giving vouchers to a client to procure medications.

Local APAs are similar to AIDS Drug Assistance Programs (ADAPs) in that they provide medications for the treatment of HIV disease. However, local APAs are not paid for with Part B funds "earmarked" for ADAP.

d. ***Oral health care*** includes diagnostic, preventive, and therapeutic services provided by a dental health care professional licensed to provide health care in

the State or jurisdiction, including general dental practitioners, dental specialists, and dental hygienists, as well as licensed and trained and dental assistants.

e. ***Early intervention services (EIS)*** for Parts A and B include counseling individuals with respect to HIV/AIDS; testing (including tests to confirm the presence of the disease, to diagnose the extent of immune deficiency, and 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 provision of therapeutic measures.

f. ***Health insurance premium and cost sharing assistance*** is the provision of financial assistance for eligible individuals living with HIV to maintain 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*** is 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*** includes 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. **NOTE: Inpatient hospitals services, nursing home and other long term care facilities are NOT included as home and community-based health services.**

i. ***Hospice services*** are end-of-life care provided to clients in the terminal stage of an illness. They include room, board, nursing care, counseling, physician services, and palliative therapeutics. Services may be provided in a residential setting, including a non-acute-care section of a hospital that has been designated and staffed to provide hospice services.

j. ***Mental health services*** are psychological and psychiatric treatment and counseling services for individuals with a diagnosed mental illness. They are conducted in a group or individual setting, and provided by a mental health professional licensed or authorized within the State to render such services. Such professionals typically include psychiatrists, psychologists, and licensed clinical social workers.

k. ***Medical nutrition therapy including nutritional supplements*** is provided by a licensed registered dietitian outside of a primary care visit. The provision of food may be provided pursuant to a physician's recommendation and a nutritional plan developed by a licensed, registered dietician.

Nutritional services and nutritional supplements not provided by a licensed, registered dietician shall be considered a support service. Food not provided pursuant to a physician's recommendation and a nutritional plan developed by a licensed, registered dietician also shall be considered a support service.

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 are 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 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 reevaluation and adaptation of the plan as necessary over the life of the client. It includes client-specific advocacy and review of utilization of services. This includes all types of case management, including face-to-face, telephone, and any other forms of communication.

m. ***Substance abuse services (outpatient)*** are 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 by a physician or under the supervision of a physician, or by other qualified personnel.