Policy Notice - 07- 03 The Use of Ryan White HIV/AIDS Program, Part B (formerly Title II), AIDS Drug Assistance Program (ADAP) Funds for Access, Adherence, and Monitoring Services

September 2007

TO: All Ryan White HIV/AIDS Program Grantees

Attached is the HIV/AIDS Bureau's (HAB) updated policy describing the use of Ryan White HIV/AIDS Program Part B funds for access, adherence, and monitoring services. This policy was previously published as "Policy Notice 00-02" and was amended April 26, 2001. This updated policy reflects the technical changes in Title XXVI of the Public Health Service Act as amended by the Ryan White HIV/AIDS Treatment Modernization Act of 2006 (Ryan White HIV/AIDS Program) and establishes updated guidelines for the use of Ryan White HIV/AIDS Program Part B Funds for Access, Adherence and Monitoring Services affecting the AIDS Drug Assistance Program (ADAP). In essence, the previous policy has not undergone any substantive changes and is being re-issued to reflect the technical changes as a result of the newly reauthorized Ryan White HIV/AIDS Program, including a reference to the provision requiring States to have certain classes of core antiretroviral medications on their formularies.

On July 26, 2000, the HIV/AIDS Bureau (HAB) issued a policy clarifying how Ryan White HIV/AIDS Program funds from the ADAP appropriation could be used to provide services to increase access to medications, adherence to medication regimens, and monitoring of progress to therapy. Specifically, the Ryan White HIV/AIDS Program Section 2616(c)(6) of the Public Health Service Act contains language that permits ADAP funds to be used to "encourage, support, and enhance adherence to and compliance with treatment regimens, including related medical monitoring." However, the law places some limits on the use of ADAP funds for these purposes. It states, "Of the amount reserved by a State for a fiscal year for use under this section, the State may not use more than 5 percent to carry out services under [this] paragraph, except that the percentage applicable with respect to such paragraph is 10 percent if the State demonstrates to the Secretary that such additional services are essential and in no way diminish access to the therapeutics described in subsection 2616(a)."

HAB interprets this provision to say that the criteria for using ADAP funds for services related to access, adherence, and monitoring are still appropriate and in force, and that no more than 5 percent of a State's ADAP funding in a given year may be used for these services unless there are extraordinary circumstances that would warrant up to10 percent of a State's ADAP funding being used. We have included some examples of extraordinary circumstances.

If you have any questions regarding the content of this HAB Policy Notice, please contact your project officer. Thank you for your attention in this important matter.

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

The Use of Ryan White HIV/AIDS Program, Part B, AIDS Drug Assistance Program (ADAP) Funds for Access, Adherence, and Monitoring Services

In accordance with the provisions of Title XXVI of the Public Health Service Act, as amended by the Ryan White HIV/AIDS Treatment Modernization Act of 2006 (Ryan White HIV/AIDS Program), the following policy establishes updated guidelines for the use of Ryan White HIV/AIDS Program funds for allowable ADAP-related expenditures. The purpose of all Ryan White HIV/AIDS Program ADAP funds is to ensure that eligible HIV-infected persons gain or maintain access to HIV-related medications. This policy continues to provide grantees greater flexibility in the use of ADAP funds and permits expenditures of ADAP funds for services that improve access to medications, increase adherence to medication regiments, and help clients monitor their progress in taking HIV-related medications. This policy further clarifies the use of ADAP funds under Section I, item A specified below.

I. Federal funds received under the Ryan White HIV/AIDS Program, ADAP, as established by Section 2612(b)(3)(B) of the Public Health Service (PHS) Act, in accordance with Section 2616 of the PHS Act, may be used for access, adherence, and monitoring services under the following conditions.

A. No more than 5 percent of ADAP funds may be used for the following services, except that under extraordinary circumstances, no more than 10 percent of ADAP funds may be used to fund: (1) enabling eligible individuals to gain access to drugs; (2) supporting adherence to the drug regiment necessary to experience the full health benefits afforded by the medications; and (3) services to monitor the client's progress in taking HIV-related medications (refer to HAB Policy Notice 07-02, "The Use of Ryan White HIV/AIDS Program Funds for HIV Diagnostics and Laboratory Tests Policy").

The State can use ADAP funds to purchase these services referenced only if the State demonstrates to the Secretary that such additional services are essential and in no way diminish access to the therapeutics described in subsection 2616(a) of the PHS Act.

Extraordinary circumstances may include such factors as demonstrated exceptionally low compliance and adherence rates among targeted segments of the clients receiving ADAP medications (e.g. active substance users, persons with serious mental illnesses, etc.), or significant new numbers of clients entering

ADAP who are new recipients of drug therapies (as a result of other outreach activities) that necessitate devoting added resources to these activities. The State must work with HAB to ensure that any requested use of ADAP funds for these services above 5 percent is necessary and appropriate and that existing ADAP services to clients will not be diminished or disrupted.

B. There are no current limitations to accessing ADAP in the State, including: (1) no client waiting list or limits on client enrollment; (2) no restrictions or limitation on HIV medications, such as caps on the number of prescriptions or cost to the client (such as co-pays), except for purposes of clinical quality assurance or the prevention of fraud and abuse; and (3) administrative support is maintained (e.g., administrative support and eligibility staff.)

C. There is current, comprehensive coverage of antiretroviral and opportunistic infection (OI)/preventive therapies including: (1) an ADAP formulary that includes a full complement of PHS recommended antiretroviral medications; and (2) medication necessary for the prophylaxis and treatment of opportunistic infections. Compliance with formulary coverage may be adjusted or modified based on the State's alternative methods of providing comprehensive pharmacy coverage (e.g., health insurance, or Stated-funded pharmacy assistance program). Section 2616(c)(1) of the PHS Act requires that the State *"shall ensure that the therapeutics included on the list of classes of core antiretroviral therapeutics established by the Secretary under subsection (e) are, at a minimum, the treatments provided by the State pursuant to this section;"* Under subsection (e) of that same section, it states *"For purposes of subsection (c)(1), the Secretary shall develop and maintain a list of classes of core antiretroviral therapeutics, which list shall be based on the therapeutics included in the guidelines of the Secretary known as the Clinical Practice Guidelines for Use of HIV/AIDS drugs, relating to drugs needed to manage symptoms associated with HIV."* In a letter dated February 15, 2007 (see attachment) from Dr. Deborah Parham Hopson, Associate Administrator of HAB, Part B Program Directors were informed that the current United States PHS Clinical Practice Guidelines identify 1) Non-nucleoside Reverse Transcriptase Inhibitors; 2) Nucleoside/Nucleotide Analogues; 3) Protease Inhibitors; and 4) Fusion Inhibitors as the classes of approved antiretrovirals for the treatment of HIV infection and that all ADAPs must include agents from each of the classes in their FY 2007 formulary. (The PHS Guidelines can be found at the following website: http://aidsinfo.nih.gov/Guidelines/Default.aspx?MenuItem=Guidelines).

II. It is expected that no more than 5 percent of ADAP funds will be used to purchase services referenced in I. A, items (1) – (3) above; and up to 10 percent under extraordinary circumstances and in agreement with HAB staff.

III. In addition:

A. The grantee will work with HAB staff to ensure the grantee's plan to redirect ADAP funds still meets the core purposes of ADAP.

B. The Ryan White HIV/AIDS Program must be the payer of last resort. Grantees must be capable of providing the HAB with documentation related to the use of funds as payer of last resort and the coordination of such funds with other local, State, and Federal funds. For example, the grantee should back bill Medicaid for Ryan White HIV/AIDS Program services provided to Medicaid eligible individuals. In addition, funds received under the Ryan White HIV/AIDS Program, including ADAP, must be used to supplement, but not supplant, funds currently being used from local, State, and Federal agency programs.

C. The grantee must have a mechanism to report on the use of redirected funds. For example, an estimation of unspent funds, including carryover, the impact of such services in improving access and use of ADAP-funded medications, and any procedural plans to shift funds back to purchasing medications.

D. The request to provide additional services with ADAP funds must be submitted on an annual basis either through the grant application process or by requesting prior approval from Resources and Services Administration's Division of Grants Management Operations during the year.