

## **Policy Notice – Notice 07-02**

Document Title: The Use of Ryan White HIV/AIDS Program Funds for HIV Diagnostics and Laboratory Tests Policy

DATE:

TO: All Ryan White HIV/AIDS Program Grantees

Attached is the HIV/AIDS Bureau (HAB) updated policy describing the use of Ryan White HIV/AIDS Program funds for HIV diagnostics and laboratory tests. This policy was previously published as “Policy Notice 99-03.” This updated policy reflects the 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 funds for HIV diagnostics and laboratory tests for Parts A through D of the Ryan White HIV/AIDS Program.

This policy is consistent with the “Public Health Service Guidelines for the Use of Antiretroviral Agents in HIV-1-Infected Adults and Adolescents”, “Public Health Service Guidelines for the Use of Antiretroviral Agents in Pediatric HIV Infection”, “Revised Recommendations for HIV Testing of Adults, Adolescents, and Pregnant Women in Health-Care Settings”, and other standards, supported by professional associations.

The attached policy emphasizes the importance of diagnostics and laboratory tests as clinical tools in medical assessment and treatment decision-making, related to HIV/AIDS antiretroviral agents and other medications that treat HIV/AIDS or opportunistic infections related to HIV disease.

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

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Attachment

## **Policy Notice 07-02: The Use of Ryan White HIV/AIDS Program Funds for HIV Diagnostics and Laboratory Tests Policy**

The purpose of all Ryan White HIV/AIDS Program funds is to ensure that eligible HIV-infected persons and families gain and/or maintain access to medical care. 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 guidelines for the use of Ryan White HIV/AIDS Program funds for HIV diagnostics and laboratory tests.

I. Ryan White HIV/AIDS Program funds for Parts A, B (including ADAP funds), C, and D may be used by grantees for support of diagnostic and laboratory tests integral to the treatment of HIV infection and related complications (for example, but not limited to, CD4 counts, viral load tests, genotype assays) under the following conditions:

A. The tests are consistent with medical and laboratory standards, as established by scientific evidence and supported by professional panels, associations, or organizations. Types of standards include, but are not limited to:

- “Public Health Service Guidelines for the Use of Antiretroviral Agents in HIV-1-Infected Adults and Adolescents”;
- “Public Health Service Guidelines for the Use of Antiretroviral Agents in Pediatric HIV Infection”;
- “Revised Recommendations for HIV Testing of Adults, Adolescents, and Pregnant Women in Health-Care Settings”, and
- Other standards supported by professional associations, such as the Infectious Diseases Society of America, American Medical Association, American Pediatric Association, and American College of Obstetricians and Gynecologists.

B. Such diagnostics and laboratory tests (1) are approved by the Food and Drug Administration (FDA), when required under the FDA Medical Devices Act and/or (2) are performed in an approved Clinical Laboratory Improvement Amendments of 1988 (CLIA) certified laboratory or State-exempt laboratory.

C. Such diagnostics and laboratory tests (1) are ordered by a registered, certified, or licensed medical provider and (2) are necessary and appropriate, based on established clinical practice standards (refer to Section 1) and professional clinical judgment.

D. Ryan White HIV/AIDS Program funds are the payer of last resort by statute; therefore, grantees must demonstrate a procedural mechanism for purposes of identification and billing of liable payers. Funds for diagnostics and laboratory tests cannot be expended without such a procedure in place.

Diagnostic and laboratory tests, ordered in accordance with this policy, constitute core medical services, as that term is defined in Parts A, B, and C of the PHS Act.