

State of Ohio



Ohio Department  
of Health

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| SUBJECT:  | PAGE 1 OF 6   |
| RYAN WHITE PART B<br>PROGRAM ELIGIBILITY: HIV Status  | NUMBER:<br>11-RWB-01  |
| RELATED RULE/CODE:<br>ORC 121.07, OAC 3701.241, HRSA Policy<br>Notice 10-02, HRSA Monitoring Standards,<br>HRSA Policy Clarification Notice 13-02, and<br>HRSA Program Letter (February 25, 2013) | SUPERSEDES:<br>10-1-2003 Policy                             |
| RELATED PHAB STANDARDS:<br>NA   | EFFECTIVE DATE:<br>To be assigned 30 days from<br>issuance. |
| RELATED FORMS:  | APPROVED:   |

## I. AUTHORITY

This directive is issued in compliance with Ohio Revised Code 121.07, which delegates to the Director of the Department of Health the authority to manage and direct the operations of the Department and to establish such rules and regulations as the Director prescribes. Further, section 3701.241 of the Ohio Administrative Code requires the Director to develop and administer AIDS and HIV-related programs. In addition, this policy is supported by HRSA Policy Notice 10-02, the 2011 HRSA National Monitoring Standards, HRSA Policy Clarification Notice (PCN) 13-02, and HRSA Program Letter (February 25, 2013).

## II. PURPOSE

The purpose of this directive is to establish the medical eligibility requirement for participation in the Ryan White Part B programs.

## III. APPLICABILITY

This policy applies to all Ryan White Part B program clients and is to be used by Ryan White Part B-funded medical case managers and ODH staff who review client applications for Part B program services.

## IV. DEFINITIONS

**ADAPs—AIDS Drug Assistance Programs:** This state-administered program is authorized under Part B of the Ryan White HIV/AIDS Program (RWHAP) and provides FDA-approved medications for HIV and related conditions to low-income individuals with HIV disease who have no/limited coverage from private insurance or Medicaid. ADAPs are designed to provide medication/medication assistance even in areas where other Ryan White programs are present. In Ohio, the program is known as OHDAP (Ohio HIV Drug Assistance Program).

**AIDS—Acquired Immune Deficiency Syndrome:** AIDS is the term used for a recognized constellation of infections, cancers, and other illnesses resulting from late stage infection with the human immunodeficiency virus (HIV). It is also referred to as HIV Disease Stage 3. In the U.S., the Centers for Disease Control and Prevention are responsible for creating the AIDS definition based on pathogenic organisms present in the United States. The World Health Organization (WHO) determines the AIDS definition for much of the rest of the world.

**Antibody:** An antibody is a protein generated in response to the invasion of a foreign molecule (antigen) into the body. Antibodies are found in blood and tissue fluids and will bind to the antigen whenever it is encountered.

**CD4+ T-Lymphocyte:** These are the thymus-derived white blood cells that are positive for the 4-type glycoprotein cluster differentiation (CD) on their surfaces. Also known as CD4+T Cells, these cells play a central role in cell-mediated immunity. HIV selects CD4+ T-lymphocytes as the viral host cell. Depletion of these cells over time due to HIV infection can result in AIDS. CD4+ T-Lymphocytes include both T helper cells and memory T cells (antigen-specific T cells that persist after resolution of infection).

**CD4+ T-Lymphocyte Count:** The CD4+ T-Lymphocyte or T-cell count is a measure of the number of CD4+ white blood cells in a sample of blood ( $\text{mm}^3$ ). The typical T-cell count in a healthy adult/adolescent ranges from  $500 \text{ mm}^3$  to  $1200 \text{ mm}^3$ .

**CDC—Centers for Disease Control and Prevention:** The CDC was founded on July 1, 1946 as the Communicable Disease Center in Atlanta, GA. The CDC is the leading national public health institute of the United States and is a part of the Department of Health and Human Services (HHS).

**EIA—Enzyme-linked Immunosorbent Assay:** Abbreviated ELISA or EIA, an enzyme-linked immunosorbent assay is the most widely used screening test for HIV-1 infection. It is a type of laboratory test used to detect the presence of a substance in a liquid sample. A positive EIA or series of positive EIA test results are then confirmed with a more specific test called a Western blot (using the same sample of blood already provided). The EIA tests for the presence of antibodies the individual's body has made in response to HIV antigens. Because it can take some time for the body to build up enough antibodies to show up on the EIA, there is a period of time shortly after infection that an HIV+ person can still test negative on an EIA. This is referred to as the “window period.”

**HAB--HIV/AIDS Bureau:** Within HRSA, the HIV/AIDS Bureau has responsibility for oversight of the Ryan White HIV/AIDS Program (RWHAP).

**HHS—Health and Human Services:** In the US, HHS is the government's principal agency for protecting the health of all Americans and providing essential services, especially for those who are least able to help themselves. Health and Human Services includes HRSA (where the Ryan White program is located) and the CDC.

**HIPP—Health Insurance Premium Payment Program:** The HIPP program is a specialized program within OHDAP whereby an eligible client who has or could obtain health insurance may receive assistance with wrap-around health insurance costs such as premiums, medication copayments, and co-insurance.

**HIV—Human Immunodeficiency Virus:** HIV is a retrovirus (lentivirus) that is known to cause AIDS.

**HIV-1 and HIV-2:** Both types of HIV (HIV-1 and HIV-2) are transmitted in the same ways (through sexual contact, through contact with blood, and from mother to child). HIV-2 may be less easily transmitted and the period between initial infection and illness is longer in the case of HIV-2. HIV-1 is the most common type of HIV, with HIV-2 being concentrated in West Africa. HIV-2 is between 40-60% genetically similar to HIV-1 so antibodies to HIV-1 and to HIV-2 can cross-react with each other, making it difficult to differentiate between the two viruses using conventional HIV tests (*see Enzyme-linked immunosorbent assay and Western blot*).

**HIV RNA Testing:** Plasma HIV-1 RNA testing is also known as viral load testing and measures the amount of HIV-1 circulating in the bloodstream.

**HRSA—Health Resources and Services Administration:** HRSA is an agency within the US Department of Health and Human Services (HHS) and is the federal agency that funds the Ryan White programs in the United States.

**Immunoassay:** This is a quick and accurate biochemical test to detect the presence of specific molecules. Immunoassays rely on the inherent ability of an antibody to bind to the specific structure of a molecule. (*See also EIA--Enzyme-linked Immunosorbent Assay*)

**Indeterminate:** Used to describe results of an antibody test for HIV. Also referred to as inconclusive, non-diagnostic, and pending validation, an indeterminate test result is a term used to describe preliminary test results that cannot be classified definitively.

**ODRC—Ohio Department of Rehabilitation and Correction:** ODRC is the agency responsible for operation of the state prison system.

**OHDAP—Ohio HIV Drug Assistance Program:** OHDAP is the mechanism by which eligible Ohioans with HIV are able to receive prescription medication to treat their HIV disease and related conditions. The program includes distribution of formulary medications directly to eligible program clients (formulary client) or as a result of providing wrap-around services (e.g., paying insurance premiums, payment of medication copayments, etc.), most commonly referred to as a HIPP (health insurance premium payment) client. (*See also ADAP—AIDS Drug Assistance Programs*)

**OHDAP Coordinator:** Ohio HIV Drug Assistance Program (OHDAP) Coordinators are the ODH employees who work in the Ohio HIV Drug Assistance Program to determine client eligibility and enrollment.

**PLWHA:** Person living with HIV/AIDS.

**Ryan White:** Ryan White was diagnosed with AIDS at age 13 (December 17, 1984). He and his mother, Jeanne White Ginder fought for his right to attend school, gaining international attention as a voice of reason about HIV/AIDS. Ryan was one of the first children with hemophilia to be diagnosed with AIDS. At the age of 18, Ryan died on April 8, 1990, just months before Congress passed the AIDS bill that bears his name—the Ryan White Comprehensive AIDS Resources Emergency (CARE) Act. The legislation has been reauthorized four times since—in 1996, 2000, 2006, and 2009 and is now called the Ryan White HIV/AIDS Program (RWHAP).

**RWAD—Ryan White Application Database:** This ODH web-based system (also known as RWAD) is designed to document client eligibility and enrollment in any of the Ryan White Part B programs in Ohio.

**Ryan White Case Manager:** Ryan White Parts A and B provide medical case management services within Ohio. Potential clients for any of the Ryan White programs are able to receive assistance from a Ryan White case manager at no cost to the client.

**RWHAP—Ryan White HIV/AIDS Program:** This is the name of the program within the HIV/AIDS Bureau (HAB) at the Health Resources and Services Administration (HRSA). Originally named the Ryan White Comprehensive AIDS Resources Emergency (CARE) Act, the program had several name changes when reauthorized in 1996, 2000, 2006, and 2009 (as the Ryan White HIV/AIDS Treatment Extension Act of 2009) and is now called the Ryan White HIV/AIDS Program (RWHAP).

**Ryan White Part B Administrator:** Also referred to as the HIV Care Services Section Administrator, this individual is responsible for all operations and programs with the HIV Care Services Section at the Ohio Department of Health. This is the role designated as the Principle Investigator on the HRSA program grant.

**Ryan White Part B Program:** This refers to the federal program established by the Ryan White HIV/AIDS Treatment Modernization Act, 42 USC 300ff et seq (as in effect on January 1, 2009) and administered by the Director of health under division (D) of section 3701.241 of the Revised Code. Part B.

**Viral Load:** Also known as viral burden, a patient's viral load is a measure of the severity of a viral infection and is an assessment of the level of HIV in an individual's bloodstream.

**Western Blot:** The Western blot is a type of laboratory test. After an individual receives a positive result on an EIA screening, a western blot is performed to confirm the positive test result. Western blots also work by detecting HIV antibodies, but the western blot looks at specific proteins known to be present with HIV antibodies so the test is considered to be more specific. Because HIV-2 is very rare in the United States, Western blot testing is designed to look for the presence of HIV-1 (there are no FDA approved western blot tests for HIV-2).

## V. POLICY

It is the policy of the Ohio Department of Health (ODH) to identify eligibility requirements for participants in the Ohio Ryan White Part B programs. The ODH requirements are in line with HRSA requirements and ensure that interested PLWHAs provide appropriate documentation to illustrate that they meet these established eligibility requirements in order to receive program services.

## VI. PROCEDURE

A. **Medical Eligibility:** According to HRSA Policy Notice 10-02, the principal intent of the Ryan White HIV/AIDS Treatment Extension Act of 2009 (Ryan White HIV/AIDS Program--RWHAP) is

to provide services to persons infected with the Human Immunodeficiency Virus (HIV), including those whose illness has progressed to the point of clinically defined Acquired Immune Deficiency Syndrome (AIDS).

HRSA Program Letter (February 25, 2013) states: In order to be eligible for any Ryan White Part B program services, an individual must have a “medical diagnosis of HIV disease” (Section 2616 of the Public Health Service (PHS) Act). An individual may be infected with HIV-1, HIV-2, or both. An individual with a documented AIDS diagnosis is presumed to be infected with HIV. There is no legislative requirement for a “confirmed” diagnosis prior to linkage to RWHAP-funded medical care, nor is there any specific statutory or program requirement related to the use of Western blot testing as the only means of confirmatory testing. According to HRSA, tests to confirm the diagnosis of HIV disease could include the following:

1. Positive HIV immunoassay and positive Western blot
2. Positive HIV immunoassay and detectable HIV RNA
3. Two positive HIV immunoassays (should be different assays based on different antigens or different principles)

**B. Proof of HIV-Positive Status:** There are a variety of documents that can serve as proof of the individual’s positive HIV status. These include:

1. Any ODH form developed for this purpose and completed by the individual’s healthcare provider including CD-4+ T-lymphocyte count with date of test and viral load measures with date of test. This document must be signed by the individual’s treating physician or other authorized individual including advanced practice nurse.
2. An official report from Ohio Department of Rehabilitation and Corrections (ODRC) to administrative personnel in the Ryan White Part B program indicating an inmate’s positive HIV status.
3. A positive HIV-test result that includes the patient’s name, the location where the test was performed, and the date of the positive test result.
4. A documented diagnosis of AIDS that includes the patient’s name and the name and address of the physician making the diagnosis, as well as the date of the diagnosis and documentation of the AIDS-defining illness or a laboratory test result indicating the patient has a CD4+ T-lymphocyte count of 200 or below and is being treated for HIV infection.
5. Hospital discharge letter indicating diagnosis/es.
6. Documentation from the ODH HIV/AIDS Surveillance Unit.
7. Documented history of treatment with antiretroviral medications specific to HIV disease.

The HRSA Program Letter (February 25, 2013) acknowledges that “standards of HIV confirmation will continue to evolve with improving technology” and indicates that “the overarching goal is to diagnose and quickly link persons with HIV into high quality medical care.” As such, the above list is not considered exhaustive and the Ryan White Part B program administrator has the Director’s

delegated authority to review other proofs of HIV positive status on a case-by-case basis for a client to be considered for program enrollment.

**C. Documentation:** The Ryan White Part B medical case manager or OHDAP Coordinator/Secretary entering a client program application into RWAD must attach documentation of the client's HIV-positive status [using the naming convention Lab-HIV for the document(s)]. This documentation is required one time and HIV-status will be assumed for all subsequent program applications.

- Indeterminate results would not allow an individual to be enrolled in Ryan White Part B programs. In this case, a confirmed positive HIV test result would be required.

**D. Review:** The case manager and/or OHDAP Coordinator reviewing the client's application for program participation will review the documentation provided and will specifically review the information provided for proof of positive HIV status or AIDS diagnosis. Any questions about an individual's HIV status will be referred to the Ryan White Part B Administrator (or designee) for clarification/review.

#### Table of Effective Changes

| Version | Effective Date | Superseded/Modified | Significant Changes   |
|---------|----------------|---------------------|---|
| 0001    | 10/1/2003      | NA                  | First Issuance  |
|         |                | V1 10/1/2003        | <ul style="list-style-type: none"> <li>• Restating the policy in the new ODH format.</li> <li>• Adding updated information from the HRSA letter.</li> </ul> |