

**WEST VIRGINIA
SECRETARY OF STATE
NATALIE E. TENNANT
ADMINISTRATIVE LAW DIVISION**

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OFFICE WEST VIRGINIA
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Form #6

**NOTICE OF FINAL FILING AND ADOPTION OF A LEGISLATIVE RULE AUTHORIZED
BY THE WEST VIRGINIA LEGISLATURE**

AGENCY: HEALTH - Bureau for Public Health TITLE NUMBER: 64

AMENDMENT TO AN EXISTING RULE: YES NO

IF YES, SERIES NUMBER OF RULE BEING AMENDED: 64

TITLE OF RULE BEING AMENDED: Aids - Related Medical Testing and Confidentiality

IF NO, SERIES NUMBER OF RULE BEING PROPOSED: _____

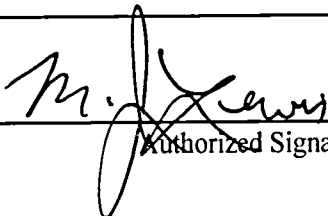
TITLE OF RULE BEING PROPOSED: _____

THE ABOVE RULE HAS BEEN AUTHORIZED BY THE WEST VIRGINIA LEGISLATURE.

AUTHORIZATION IS CITED IN (house or senate bill number) SB 245

SECTION §64-5-2(f), PASSED ON March 10, 2012

THIS RULE IS FILED WITH THE SECRETARY OF STATE. THIS RULE BECOMES EFFECTIVE ON THE
FOLLOWING DATE: May 2, 2012



Authorized Signature

FILED

TITLE 64

2012 MAY -2 PM 1:06

LEGISLATIVE RULE
BUREAU FOR PUBLIC HEALTH
DEPARTMENT OF HEALTH AND HUMAN RESOURCES

OFFICE WEST VIRGINIA
SECRETARY OF STATE

SERIES 64

AIDS-RELATED MEDICAL TESTING AND CONFIDENTIALITY

§64-64-1. General.

1.1. Scope. -- This legislative rule establishes specific standards and procedures concerning AIDS-related medical testing; record confidentiality and disclosure; consent for testing by a legal representative; exclusion from schools; reporting requirements for physicians, laboratories and other health care providers; the approval of laboratories for HIV testing; and other matters pertinent and necessary for the implementation of the AIDS-Related Medical Testing and Records Confidentiality Act, WV Code §16-3C-1, et seq.

This rule supplements the AIDS-Related Medical Testing and Records Confidentiality Act, WV Code §16-3C-1 et seq., and should be read in conjunction with the Act.

1.2. Authority. -- WV Code §§16-1-4, 16-3C-8, and 16-5J-3.

1.3. Filing Date. -- May 2, 2012.

1.4. Effective Date. -- May 2, 2012.

§64-64-2. Application and Enforcement.

2.1. Application. -- This rule applies to:

2.1.a. Health facilities;

2.1.b. Health care providers;

2.1.c. Funeral service providers and personnel;

2.1.d. Schools;

2.1.e. Persons with access to or in charge of medical records or other sources of information regarding AIDS-related testing information;

2.1.f. Laboratories seeking approval to conduct AIDS-related tests to be used in this State;

2.1.g. Health care providers or emergency responders and their employers; and

2.1.h. Spouses, sexual contacts and intravenous (IV) drug contacts who may be at risk of having acquired the HIV infection as a result of the possible exchange of body fluids.

2.2. Enforcement. -- This rule is enforced by the Commissioner of the Bureau for Public Health or his or her lawful designee.

§64-64-3. Definitions.

The following definitions of terms are in addition to those in WV Code §16-3C-1.

3.1. Anonymous HIV Testing. -- HIV testing performed on a voluntary patient by a health care provider with no knowledge of the person's identity.

3.2. Body Fluids. -- Substances that have been implicated in the transmission of HIV that include:

3.2.a. Blood, semen, vaginal secretions or other body fluids contaminated with visible blood; and

3.2.b. Cerebrospinal, oral, synovial, pleural, peritoneal, pericardial, and amniotic fluids, which have an undetermined risk for transmitting HIV.

3.3. Bureau. -- The Bureau for Public Health in the Department of Health and Human Resources.

3.4. CLIA-88. -- Clinical Laboratory Improvement Amendments of 1988 (Public Law 100-578) to Section 353 of the Public Health Service Act (Title 42 United States Code Section 263a).

3.5. Commissioner. -- Commissioner of the Bureau for Public Health.

3.6. Confidential HIV Testing. -- HIV testing performed by a health care provider identifying the patient by name. The use of test results is limited by law.

3.7. Contact. --When used as a noun, a sexual or needle-sharing partner.

3.8. Convicted. -- Pleas of guilty and pleas of nolo contendere accepted by the court having jurisdiction of the criminal prosecution, a finding of guilty following a jury trial to a court, and a juvenile delinquent or status offender as defined in WV Code §49-1-4.

3.9. Funeral Director. -- Any person engaged, or holding himself or herself out as engaged, in the business of funeral directing as defined in WV Code §30-6-3(o) and (p), and who uses in connection with his or her name or business the words or terms "funeral director," "undertaker," "mortician," or any other word, term, or title to imply or designate himself or herself as a funeral director, undertaker, or mortician.

3.10. Funeral Establishment. -- A licensed place of business devoted to: the care, preparation and arrangements for the transporting, embalming, funeral, burial or other disposition of a deceased. A funeral establishment includes a licensed crematory.

3.11. HIV-Infected Person. -- A person who has been diagnosed with AIDS or who has a positive confirmatory test for HIV.

3.12. Legal Representative. -- A person from whom substituted consent may be obtained as provided for in WV Code §16-3C-4 for HIV-related testing or for the authorization of the release of test results.

3.13. Person charged with a sexual crime -- Any person charged with a sexual offense, which triggers a mandatory HIV test to be performed in accordance with WV Code §16-3C-2(f)(2), including, persons charged with; prostitution, sexual abuse, sexual assault, rape, incest or sexual molestation.

3.14. Physician. -- A person licensed under Chapter 30 of the WV Code to practice medicine.

3.15. Post-Exposure Care. -- Care including an initial HIV test following exposure and United States Centers for Disease Control and Prevention (CDC) currently recommended follow-up HIV testing, counseling, medical evaluation and provision for post-exposure prophylactic treatment.

3.16. Source Patient. -- Any person whose body fluids have been the source of a significant exposure to a health care provider or emergency responder or other person.

§64-64-4. Testing.

4.1. Voluntary Consent.

4.1.a. All health-care providers shall recommend HIV-related testing on a voluntary basis as part of a routine screening for treatable conditions and as a part of routine prenatal and perinatal care. The HIV-related testing provided for in WV Code §§16-3C-2(a) through (d) may also be requested by a health care provider acting within the scope of his or her professional license.

4.1.b. The provisions of WV Code §§16-3C-2(b) through (d) shall also be followed when a patient, without a request from a physician, dentist, other health care provider acting within the scope of his or her professional practice, or the Bureau, voluntarily seeks an HIV test from any physician, dentist, other health care provider, or from the Bureau.

4.1.b.1. Patients shall be informed either orally or in writing that HIV-related testing is performed as a part of routine care, that HIV-related testing is voluntary and that the patient may decline HIV-related testing (opt-out); or

4.1.b.2. Patients shall be informed that his or her general consent for medical care includes consent for HIV-related testing.

4.1.c. Nothing in this rule shall be construed to provide grounds for any physician, dentist, other health care provider or the Commissioner to refuse to treat a patient, nor shall the testing provisions of this rule be used by health care providers to screen patients.

4.1.d. HIV screening for pregnant women and their infants.

4.1.d.1. Health care providers shall notify a pregnant patient that HIV screening is recommended and that she will be tested for HIV as part of the routine panel of prenatal tests, unless she declines through the mechanism of opting out.

4.1.d.2. HIV testing of pregnant women should be voluntary and free from coercion. No woman shall be tested without her knowledge, unless in accordance with subdivision 4.2.c. of this section.

4.1.d.3. Pregnant women shall receive oral or written information that includes an explanation of HIV infection, a description of interventions that can reduce HIV transmission from mother to infant, and the meanings of positive and negative test results and she shall be offered an opportunity to ask questions and to decline testing.

4.1.d.4. It is recommended that health care providers test women as early as possible during

each pregnancy. Women who decline the test early in prenatal care may be encouraged to be tested at subsequent visits.

4.1.d.5. A second HIV test during the third trimester, preferably prior to the 36th week of gestation, is cost-effective even in areas of low HIV prevalence and may be considered for all pregnant women. A second HIV test during the third trimester is also recommended for a woman who meets one or more of the following criteria:

4.1.d.5.A. The women received health care in facilities in which prenatal screening identifies at least one HIV-infected pregnant woman per 1,000 women screened;

4.1.d.5.B. The women is known to be at high risk for acquiring HIV, for example, injection- drug users and their sexual partners, women who exchange sex for money or drugs, women who are sex partners of HIV-infected persons and women who have had a new or more than one sex partner during the pregnancy; or

4.1.d.5.C. A woman who has signs or symptoms consistent with acute HIV infection.

4.2. Consent Not Required.

4.2.a. Consent for testing is not required and the provisions of WV Code §16-3C-2(b) and Subsection 4.1. of this rule does not apply for the performance of an HIV test:

4.2.a.1. On a human body part as provided in WV Code §16-3C-2(e)(1). HIV testing shall be required of the donor and recipient of the human body part.

4.2.a.1.A. All confidentiality restrictions contained in Section 8 of this rule and in WV Code §16-3C-3 apply to information obtained through the testing of human body parts, tissue, blood, blood products, or semen;

4.2.a.1.B. Consent for HIV-related testing is required for donors of routine blood transfusions, and the provisions of WV Code §16-3C-2(e)(1) do not apply to those transfusions;

4.2.a.2. In documented bona fide medical emergencies as provided for in WV Code §16-3C-2(e)(2) and as determined by a treating physician taking into account the nature and extent of the exposure to another person, whether the source patient's blood is to be obtained or is already available: Provided, That:

4.2.a.2.A. The source patient is unable or unwilling to grant or withhold consent, and if the source patient is unable to grant or withhold consent, substituted consent is not obtained after a reasonable attempt is made to obtain consent from a legal representative of the source patient in accordance with WV Code §16-3C-4. For the purposes of this section a reasonable attempt includes but is not limited to: a telephone call or personal contact;

4.2.a.2.B. The test results are necessary for medical diagnostic purposes to provide appropriate emergency care or treatment, and the HIV testing for a source patient is conducted only after a health care provider, as qualified in Subsection 7.1. of this rule, documents in the medical record of a health care provider or emergency responder or another person who has come into contact with a source patient that there has been a significant exposure of the emergency responder or person and that in the medical judgment of that health care provider the results are medically necessary to determine the course of treatment for the exposed emergency responder or person; and

4.2.a.2.B.1. A reasonable attempt is made to contact the source patient, or the source patient's legal representative if the source patient is unable to grant or withhold consent, to inform him or her that the test will be performed using a pseudonym;

4.2.a.2.B.2. The test results are offered to the source patient, and any refusal of acceptance is documented only in the medical record of the exposed health care provider or emergency responder or other exposed person;

4.2.a.2.B.3. None of the activities set forth in this subsection are documented in the source patient's medical record. The health care facility and the health care provider or emergency responder shall maintain confidentiality. If any improper disclosure occurs, the source patient may invoke the remedies and penalties of WV Code §16-3C-5; and

4.2.a.3. For the purpose of research in accordance with WV Code §16-3C-2(e)(3).

4.2.b. For a test performed under the authority of WV Code §16-3C-2(f)(9), the Commissioner may, at his or her discretion, release the test result to the physician or other health care provider who requested the test: Provided, That the provisions of Section 8 of this rule and WV Code §16-3C-3 regarding confidentiality and disclosure apply. The Commissioner may establish a list of health care providers who are approved to authorize HIV testing in emergency medical aid circumstances.

4.2.c. If the pregnant woman's HIV status is unknown at the time she presents for delivery, an HIV test shall be offered and if she refuses the test, the infant may be tested and the mother shall be informed of the testing and the results.

4.2.c.1. The rapid testing of newborns is recommended as soon as possible after birth so antiretroviral prophylaxis can be offered to HIV-exposed infants when the woman's HIV status is unknown postpartum. The woman shall be informed that identifying HIV antibodies in the newborn indicates that the woman is infected.

4.2.c.2. For infants whose HIV exposure status is unknown and who are in foster care, the person legally authorized to provide consent shall be informed that HIV testing is recommended for infants whose biologic mothers have not been tested.

4.3. Mandated HIV Testing

4.3.a. The testing of a person charged with or convicted of a sex-related crime as specified in WV Code §16-3C-2(f) does not require consent of that person and is under the direction of the court having jurisdiction of the criminal prosecution. Counseling may be offered.

4.3.b. The court having jurisdiction of the criminal prosecution or the prosecuting attorney of the county shall order that an HIV-related test be performed on any person charged with a sexual crime. The testing shall occur as follows:

4.3.b.1. A court shall order a defendant charged with an offense set forth in subdivision two, subsection f, section two, article three-c, chapter sixteen of the code, to undergo an oral test for HIV not later than 48 hours after the date on which the information or indictment is presented;

4.3.b.1.A. A person charged with a sexual crime shall be tested for HIV by qualified personnel in the jail or correctional facility where he or she is detained, by a private health care provider

or by the local health department.

4.3.b.2. As soon as practical, the victim, the parents or guardians of the victim and the person charged with the crime or offense shall be notified of the test result;

4.3.b.3. Follow-up tests for HIV are authorized as may be medically appropriate, and the results of any follow-up tests shall be made available in accordance with paragraph 4.3.b.2., as soon as practicable.

4.3.c. The Commissioner shall request access to all convicted sex offenders who test HIV positive for the purposes of contact notification consultation under the direction of the Commissioner. Contact notification information obtained from the convicted sex offender is protected information and shall be used by the Commissioner solely for referring individuals with a potential HIV exposure to HIV counseling and testing sources.

4.3.d. The Commissioner shall set the level of reimbursement the Bureau shall pay for the mandated HIV testing and pre- and post-conviction HIV-related testing and counseling for which it is responsible pursuant to the provisions of WV Code §16-3C-2(f).

§64-64-5. Cease and Desist Orders.

5.1. A cease and desist order issued under the authority of WV Code §16-3C-2(f)(4) shall be in writing, and shall set forth the name of the person to be restricted, and the initial period of time during which the order remains effective, the terms of the restrictions and other conditions that are warranted to protect the public health.

5.2. If any person violates a cease and desist order issued pursuant to this rule and WV Code §16-3C-2(f)(5) and the person is a danger to the health of others, the Commissioner shall apply to the circuit court of Kanawha County to enforce the cease and desist order by imposing any restrictions upon the person that are necessary to prevent the specific conduct which endangers the health of others.

§64-64-6. Charting Information.

A health care provider shall enter the confirmed positive results of an HIV-related test in each patient's chart or in the patient's electronic health record through the Health Information Exchange (HIE).

§64-64-7. Post-Exposure Care and Treatment.

7.1. A health facility shall have access to a knowledgeable trained health care provider to assess the HIV exposure risk of health care providers, emergency responders or other persons during all working hours, including nights and weekends. The assessment of HIV exposure risk and initiation of basic post-exposure care regimen requires knowledge or experience in clinical epidemiology, infection control, occupational health, or the clinical treatment of HIV. Consultation with subject matter experts on the facility's currently accepted practice, when prescribing post-exposure prophylaxis, is strongly encouraged.

7.2. A health facility shall have a written post-exposure HIV management plan patterned after current recommendations of the United States Centers for Disease Control and Prevention (CDC).

7.3. A laboratory shall not determine a test result to be positive, and a health care provider shall not reveal a positive test result to any person, without conducting corroborating or confirmatory testing.

However, a laboratory may release preliminary test results to the health care provider assessing the significant exposure for the purposes of determining post-exposure management of the health care provider, emergency responder or other person.

7.4. Health care providers shall report all confirmed positive test results to the Bureau in compliance with Section 12 of this rule.

7.5. The employer of a health care provider or emergency responder who was exposed while performing a duty of his or her employment shall bear the costs of HIV tests of blood or oral samples of the source patient and the health care provider or emergency responder, unless a workers' compensation or other benefit program affords coverage for the testing. For a health care provider or emergency responder who tested negative for HIV antibodies immediately following the exposure, the employer shall also bear the costs of the CDC's recommended initial prophylactic treatment and additional HIV testing at three and six months after exposure, unless a workers' compensation or other job-related employee benefit program affords coverage for the treatment and testing.

7.6. Relative to the management of source patient medical information, the health care provider or emergency responder reporting a significant exposure is subject to the requirements of the disclosure statement contained in WV Code §16-3C-3(c) and to the remedies and penalties specified in WV Code §16-3C-5.

§64-64-8. Confidentiality and Disclosure.

8.1. The victims or alleged victims of sexual crimes are eligible for HIV counseling and testing at public health HIV testing sites in West Virginia. The provisions of this rule and WV Code §16-3C-1 et seq. regarding voluntary testing apply to testing and counseling of these persons. All victim testing information is subject to the confidentiality requirements of this rule and WV Code §16-3C-1 et seq. for voluntary testing.

8.2. An agent or employee of a health facility or health care provider has a need to know HIV test results under the provisions of WV Code §16-3C-3(a)(4) when the information is medically necessary to protect the individual from a significant risk of transmission or will have an impact on the treatment modality.

8.3. HIV test results may be disclosed to health care providers, emergency responders or others who have been subject to a significant exposure during the course of medical practice or in the performance of professional duties. The health care provider or emergency responder is subject to the requirements of the disclosure statement contained in WV Code §16-3C-3(c) and to the remedies and penalties provided in WV Code §16-5C-5.

8.4. Solely for the purpose of prompt and accurate evaluation and payment of medical or related claims HIV test results may be disclosed to claims management personnel employed by or associated with an insurer, health care service contractor, health maintenance organization, self-funded health plan, state-administered health care claims payer or any other payer of health care claims. Information released under this subsection is confidential and shall not be released or made available to persons who are not involved in handling or determining medial claims payment.

8.5. HIV test results may be disclosed to facilitate health information exchanges and to legally authorized public health authorities.

8.6. HIV test results may be disclosed to persons allowed access to the record by a court order issued in accordance with the provisions of WV Code §16-3C-3(11).

§64-64-9. Contact and Partner Notification.

9.1. Notification made by the Commissioner under WV Code §16-3C-3(d) shall include an explanation of exposure to HIV, HIV prevention messages and information on accessibility to HIV counseling and testing services to the contact with a reported HIV exposure. The confidentiality rules that apply to the names of HIV-infected persons shall apply to the names of their contacts.

9.2. In contact notification situations, the Bureau recommends that a private health care provider refer contact notification activities to the Bureau rather than attempt notification itself. The Bureau has an established program for notifying partners of persons with infectious conditions; including but not limited to the Internet Partner Services Protocol available at:

<http://www.dhhr.wv.gov/oeps/std-hiv-hep>.

§64-64-10. Consent by Legal Representative.

10.1. Substituted consent for HIV-related testing or for the authorization of the release of test results shall be obtained in accordance with WV Code §16-3C-4 and this rule.

10.2. Minors shall be treated as established under WV Code §16-4-10.

§64-64-11. School Exclusion.

School exclusions shall be in accordance with WV Code §16-3C-6. If the student is under the jurisdiction of a protection or advocacy agency, a representative from that agency may be included in consultation. The provisions of this rule and of WV Code §16-3C-1, et seq. regarding the confidentiality and the release of information are applicable in the school setting.

§64-64-12. Requirement for All Health Care Providers to Report Positive Tests for the Human Immunodeficiency Virus.

12.1. In accordance with the Bureau for Public Health's rule, Reportable Diseases, Events and Conditions, 64CSR7, all health care providers in West Virginia who perform, or cause to have performed, serologic or other tests for HIV shall report all HIV infection associated with laboratory tests that are positive or results that are either indicative of or a progression toward the HIV infection to the Commissioner on forms provided by the Commissioner or via electronic reporting to include:

12.1.1. All positive (reactive) laboratory test results; and

12.1.2. All clinical status data.

12.2. A health care provider report shall include:

12.2.1. The name and full address of the laboratory;

12.2.2. The name of the tests performed, the date each test was performed and the results of the tests;

12.2.3. The legibly printed or typed name and location of the health care provider reporting the positive HIV laboratory results;

12.2.4. The name of the confidentially-tested individual;

12.2.5. The patient's demographic information including the patient's age, sex, race and address, unless the patient requests anonymous reporting;

12.2.6. Social and risk factor information of the patient relative to HIV infection; and

12.2.7. Other information concerning HIV infection judged necessary by the Commissioner.

12.3. A confirmed positive report of HIV shall be submitted within thirty days of the receipt of the test results.

12.4. Health care providers performing anonymous HIV testing on patients shall use confidential reporting of HIV infection for patients revealing his or her identity in HIV infection consultation. If a patient who has been tested anonymously, either makes his or her identity known to the health care provider or rescinds the request for anonymity, the health care provider shall report the name to the Commissioner.

12.5. The Commissioner shall work with a patient's health care provider in any follow-up of reported positive laboratory tests or HIV infection.

12.6. A Health care provider who provides HIV care to patients on the basis of a medical or a self-referral shall submit an HIV infection report form to the Bureau.

12.7. The reports of all HIV infection submitted in compliance with this rule are protected and are exempt from public disclosure under the exemption for medical records contained in WV Code §29B-1-1 et seq., the Freedom of Information Act: Provided, That the reports are subject to the provisions of WV Code §16-3C-1 et seq. This information in the reports shall not be used, except as necessary, to enforce State public health laws and rules and to analyze the magnitude of HIV infection in this State for assisting in the development of adequate safeguards against its spread.

§64-64-13. Requirement for Laboratories to Report Positive Tests for the Human Immunodeficiency Virus.

13.1. All laboratories conducting HIV testing in West Virginia or providing HIV testing results for use in this State shall make a report on the first and fifteenth days of each month of all laboratory tests that are positive or results that are indicative of the HIV infection to the Commissioner on forms provided by the Commissioner or by electronic transmittal for that purpose to include:

13.1.1. All CLIA certified tests that are intended to diagnose or document HIV infection, including, but not limited to, viral load, P24 antigen and western blot tests and;

13.1.2. All positive (reactive) laboratory tests for known positive patients, all CD4+ test results on peripheral blood with counts less than 200/mm³ or less than fourteen percent (14%).

13.2. These reports shall include:

13.2.1. The name and full address of the laboratory;

13.2.2. The name of the test, the date performed, and the result;

13.2.3. The name and location of the health care provider who submitted the specimen;

13.2.4. The name of the patient;

13.2.5. Other information concerning HIV infection management and control judged necessary by the Commissioner; and

13.2.6. The signature of the supervisor of the laboratory.

13.3. The laboratory shall submit the results of the laboratory reports related to subsections 13.1.1 and 13.1.2. of this rule on the first and fifteenth days of each month.

13.4. If no reportable tests are performed during a reporting period, a statement to this effect shall be submitted by the supervisor of the laboratory.

13.5. The Commissioner shall work with a patient's health care provider in any follow-up of the reports of confirmed positive laboratory tests.

13.6. The reports of all positive tests submitted in compliance with this rule are protected and are exempt from public disclosure under the exemption for medical records contained in WV Code §29B-1-1 et seq., the Freedom of Information Act: Provided, That the reports are subject to the provisions of WV Code §16-3C-1 et seq. The information in the reports shall not be used except as is necessary to enforce State public health laws and rules and to analyze the magnitude of HIV infection in the State for assisting in the development of adequate safeguards against its spread.

§64-64-14. Quality Assessment of Laboratories Conducting HIV Tests.

14.1. Laboratories Required to be Approved.

14.1.1. All laboratories conducting HIV testing in this State or providing HIV testing results for use in this State shall be approved by the Bureau.

14.1.2. A laboratory located in West Virginia and seeking approval shall:

14.1.2.a. Show that it complies with the applicable requirements of WV Code §16-3C-1 et seq. and this rule;

14.1.2.b. Complete application forms when seeking initial approval or when there is a change in director, owner, location or testing method; and

14.1.2.c. Be certified to perform waived or non-waived (moderate or high) complexity HIV testing following at a minimum the test categorization requirements in accordance with the provisions of the federal regulations promulgated pursuant to the Clinical Laboratory Improvement Amendment (CLIA-1988) 42 CFR Part 493, as revised October 1, 2006.

14.1.3. A laboratory located outside of West Virginia conducting HIV related testing on West Virginia patients is eligible for approval only if it is approved for non-waived (moderate or high complexity) laboratory testing by the federal government regulations promulgated pursuant to CLIA-88 as revised October 1, 2006 and/or a Centers for Medicare and Medicaid Services (CMS) approved accreditation agency. The laboratory shall complete an application when seeking initial approval or when there is a change in director, owner, location or test method.

14.2. Laboratory Director and Personnel Qualifications.

14.2.1. The laboratory director and personnel shall at a minimum meet the qualifications set forth by the federal government pursuant to CLIA for certification of laboratories 42 CFR Part 493, Laboratory Requirements, as amended in the October 1, 2006, edition of the Federal Register (60 FR 20035), are hereby incorporated by reference.

14.2.2. The person specified as the laboratory director on the CMS issued CLIA certificate is ultimately responsible for the reliability of HIV testing. The laboratory director shall be a licensed medical professional acting within the scope of his or her license.

14.2.3. For waived HIV testing methods only, while there are no formal educational requirements for testing personnel, the director shall assure the testing personnel are properly trained and competent.

14.3. Quality Assessment Standards.

A laboratory requesting approval shall demonstrate that a quality assessment program acceptable to the Bureau is in effect for verification and assessment of accuracy, measurement, precision, and detection of laboratory errors. This demonstration shall be evidenced, when applicable, in part by:

14.3.1. The selection of test methods appropriate to the needs of persons served by the laboratory;

14.3.2. The use of quality controls and calibrating standards;

14.3.3. The recording of the acceptable limits and the results of controls and calibrating standards;

14.3.4. The recording of quality assessment activities; including, but not limited to, calibration, quality control, corrective action, preventative maintenance and patient test management;

14.3.5. The labeling and dating of all reagents, solutions, standards, and quality control materials;

14.3.6. Following HIV test method manufacturer requirements approved by the Federal Food and Drug Administration (FDA).

14.3.7. Maintaining a site specific manual containing all procedures and policies currently in use, which shall include action to be taken when control results are outside the acceptable limits and the procedure for reporting positive HIV test results to the Bureau along with protocols for reporting HIV testing to the Bureau.

14.4. Proficiency Testing, Personnel Competency Assessment. Laboratories shall participate in a CLIA approved HIV proficiency testing survey or an alternative HIV testing personnel competency assessment program approved by the Bureau and in accordance with CLIA-88 Proficiency testing requirement by test complexity. The assessment shall be conducted biannually and satisfactory performance by the laboratory is mandatory. The laboratory shall forward proficiency testing survey results to the Bureau.

14.5. On-site Inspection. The Commissioner or his or her designee may conduct an on-site inspection or a paper or electronic survey to determine compliance with this rule initially prior to approval, and thereafter as frequently as the Commissioner considers necessary to insure compliance with this

subsection. The Bureau has the right of entry upon proper identification at times judged necessary during operating hours in order to conduct the inspections.

14.6. Certificate of Approval; Revocation.

14.6.1. The Commissioner shall issue certificates of approval for a laboratory to perform HIV testing upon initial approval and on an annual basis thereafter pursuant to the conditions listed in this rule. Certificates issued shall contain the name and location of the laboratory, a laboratory code number, the name of the laboratory director and the date of expiration of the certificate.

14.6.2. Laboratories shall notify the Bureau when there is a change in ownership, laboratory director, testing method or location of the testing laboratory. In the case of mobile laboratory programs, the certificate shall be issued to the mobile laboratory's home-based address.

14.6.3. The Commissioner may revoke or suspend a laboratory's approval if the laboratory:

14.6.3.a. Performs unsatisfactorily in on-site inspections;

14.6.3.b. Fails to comply with this rule and all applicable provisions of WV Code §16-3C-1, et seq.;

14.6.3.c. Fails to report positive test results to the Bureau in accordance with WV Code §16-3C-8B and this rule; or

14.6.3.d. Closes.

§64-64-15. Administrative Due Process.

Those persons adversely affected by the enforcement of this rule desiring a contested case hearing to determine any rights, duties, interests or privileges shall do so in a manner prescribed in the Bureau for Public Health rule, Rules of Procedure for Contested Case Hearings and Declaratory Rulings, 64CSR1.