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

Do Not Mark In This Box

FILED

2009 JUN -5 AM 10: 00

OFFICE WEST VIRGINIA
SECRETARY OF STATE

Form #6

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

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

AMENDMENT TO AN EXISTING RULE: YES X NO ____

IF YES, SERIES NUMBER OF RULE BEING AMENDED: 76

TITLE OF RULE BEING AMENDED: TUBERCULOSIS TESTING, CONTROL, TREATMENT AND COMMITTMENT

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 195

SECTION 1(c), PASSED ON April 9, 2009

THIS RULE IS FILED WITH THE SECRETARY OF STATE. THIS RULE BECOMES EFFECTIVE ON THE FOLLOWING DATE: June 5, 2009

Martha Yeager Walker
Authorized Signature

TITLE 64
LEGISLATIVE RULE
BUREAU FOR PUBLIC HEALTH
DEPARTMENT OF HEALTH AND HUMAN RESOURCES

SERIES 76
TUBERCULOSIS TESTING, CONTROL, TREATMENT AND COMMITTMENT

§64-76-1. General.

1.1. Scope. -- This legislative rule establishes specific standards and procedures concerning compulsory testing for tuberculosis of school children and school personnel; tuberculosis (TB) control in state institutions including reporting of admissions, forms for committing patients, maintenance of patients; standards concerning registration of cases by the Department of Health and Human Resources; Bureau for Public Health procedures when a patient is a health menace to others; and procedures for immediate involuntary commitment. This rule should be read in conjunction with WV Code §16-3D-1, et seq.

1.2. Authority. -- WV Code §16-3D-9.

1.3. Filing Date. -

1.4. Effective Date. --

§64-76-2. Application and Enforcement.

2.1. Application - This rule applies to public health officers, health care providers and facilities, mental health officials and facilities and magistrate and circuit court officials.

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

§64-76-3. Definitions.

3.1. Case – An occurrence of disease in human or animal which meets a specific case definition listed in the West Virginia Reportable Diseases Protocol Manual or a case definition approved by the Commissioner.

3.2. Commit or commitment - Official consignment, as to a prison, mental hospital or institution.

3.3. Confirmed (when used in relation to the diagnosis of tuberculosis) - A specimen from the patient grows mycobacterium tuberculosis in a culture.

3.4. Contact – A person who has been exposed to *M. tuberculosis* infection by sharing air space with a person with infectious TB.

3.5. Contact Investigation – Procedures that occur when a case of infectious TB is identified, including finding contacts exposed to the case, testing and evaluation of contacts to identify Latent Tuberculosis Infection (LTBI) or TB disease and treatment of these contacts, as indicated.

3.6. Department – The Department of Health and Human Resources.

3.7. Diagnosis of tuberculosis - A determination of tuberculosis based on:

3.7.a. Laboratory criteria for diagnosis:

3.7.a.1. Isolation of M.tuberculosis from a clinical specimen;

3.7.a.2. Demonstration of M.tuberculosis from a clinical specimen by nucleic acid amplification test; or

3.7.a.3. Demonstration of acid-fast bacilli in a clinical specimen when a culture has not been or cannot be obtained.

3.7.b. Clinical case definition:

3.7.b.1. A positive tuberculin skin or another recognized test for tuberculosis infection;

3.7.b.2. Other signs and symptoms compatible with TB (e.g. an abnormal, unstable [i.e. worsening or improving] chest radiograph, or clinical evidence of current disease);

3.7.b.3. Treatment with two or more anti-tuberculosis drugs; and

3.7.b.4. A completed diagnostic evaluation.

3.8. Directly Observed Therapy (DOT) – An adherence-enhancing strategy in which a health-care worker or other trained person watches a patient swallow each dose of medication and is accountable to the public health system. DOT is the standard method of care for all patients with TB disease and is an option for patients under treatment for latent infection.

3.9. Health care provider - Any physician, dentist, nurse, paramedic, psychologist or other person providing medical, dental, nursing, psychological or other health care services of any kind.

3.10. Health menace - A patient who has tuberculosis in an infectious state, is at risk of becoming infectious, or is at risk for drug-resistant tuberculosis as determined by the Commissioner or his or her designee, and is unable or unwilling to conduct himself or herself in such a manner as not to expose others to his or her disease or fails to cooperate in his or her standard TB treatment.

3.11. Institution - A hospital, nursing home, clinic or correctional facility responsible for the care and treatment of a patient with tuberculosis.

3.12. Isolation – The separation of infected persons or animals from other persons or animals, under the necessary time frame and conditions to prevent the direct or indirect transmission of the infectious agent from the infected persons or animals to other persons or animals who are susceptible or who may spread the disease to others.

3.13. Laboratory – Any licensed facility or place, however named, for the biologic, microbiologic, serologic, virologic, chemical, hematologic, immuno-hematologic, biophysical, cytologic, pathologic, genetic, molecular or other examination of materials for the purpose of providing medical or epidemiologic assessment of the health of human beings. The term "laboratory" includes both public and private laboratories, free-standing laboratories and hospital laboratories.

3.14. Medical Evaluation – An examination to diagnose TB disease or Latent Tuberculosis Infection (LTBI), to select treatment, and to assess the patient's response to therapy. A medical evaluation may include a medical history and TB symptom screen, a clinical or physical examination, screening and diagnostic tests (for example: Tuberculin Skin Tests, chest radiographs, bacteriologic examination, and HIV testing), counseling, and treatment referrals.

3.15. Medical Information – Data or other information regarding the history, examination, radiologic or laboratory findings, diagnosis, treatment, or other clinical care for a person examined or treated for a suspected or actual disease.

3.16. Non-adherent - A patient afflicted with tuberculosis who has demonstrated an inability or an unwillingness to adhere to a prescribed treatment regimen, or fails to cooperate in his or her treatment regimen.

3.17. OLS – The Office of Laboratory Services in the Bureau.

3.18. Patient - Any individual confirmed or suspected of having tuberculosis.

3.19. Physician – An individual licensed to practice medicine by either the Board of Medicine or the Board of Osteopathy.

3.20. Reporting source - An institution or

provider which diagnoses or provides treatment for tuberculosis.

3.21. School children or student - All children under the age of 25 who attend schools in West Virginia including colleges and universities.

3.22. Tuberculin skin test – A medically valid and recognized procedure for testing an individual for the presence of a tuberculosis infection.

3.23. WVEDSS – West Virginia Electronic Disease Surveillance System – an electronic data system for reporting and tracking cases and outbreaks of infectious diseases with simultaneous reporting of the disease to the Bureau and local health departments.

§64-76-4. Report of Admissions, Registration by Bureau for Public Health.

4.1. Any institution admitting a patient diagnosed with tuberculosis, shall report that admission within ten days to the Bureau's tuberculosis control program.

4.2. The institution shall make available to the Bureau any patient-related records, reports, and other data pertaining to confirmed and suspected tuberculosis patients, required to: confirm the diagnosis; monitor treatment; follow up on contacts; provide tuberculosis surveillance in the community; or to initiate actions to protect others in the community from risk of disease.

4.3. The institution shall report the death, discharge, and transfer of any patient with tuberculosis to the Bureau.

4.4. The Bureau shall maintain a current registry of all verified cases of tuberculosis.

4.5. The Bureau or its designee may release tuberculosis related information regarding a patient for the following purposes:

4.5.a. To allow for the diagnosis, treatment and monitoring care by the original reporting source and other health providers in charge of the patient's care or in charge of the patient's contact's care;

4.5.b. To identify a specific patient to the HIV/AIDS/STD program in the Bureau to compare registries to assist in case finding, and patient care; and

4.5.c. To allow for the diagnosis, treatment and monitoring care by tuberculosis control programs in other states for the patient who has relocated to another state and for the patient's contacts who live in another state who are under a health care provider's care.

§64-76-5. Compulsory Testing of School Children and School Personnel.

5.1. Each student transferring from a school located outside this state or enrolling for the first time from outside the state shall furnish proof of a tuberculin skin test done, read and evaluated within four months prior to the beginning of the school year.

5.1.a. The date that a transfer student enrolls in a West Virginia school is the beginning of the school year for that student.

5.2. Proof of a tuberculin skin test shall be made by a certification from a physician on the physician's letterhead or prescription pad stating the following information:

5.2.a. the student's full name;

5.2.b. the date the skin test was given;

5.2.c. the date the skin test was read;

5.2.d. the skin test reaction in millimeters (mm) of induration (hardness), with 0mm being no induration felt; and

5.2.e. the physician's signature.

5.3. Positive reactors shall immediately submit to an evaluation including:

5.3.a. a chest x-ray;

5.3.b. physical examination;

5.3.c. medical history; and

5.3.d. bacteriologic or histologic examination, when medically indicated.

5.4. Students found to have tuberculosis disease shall obtain written approval from the local health officer indicating that it is safe and appropriate for them to return to school and this document shall be presented to the school principal, or his or her designee, before the student is permitted to reenter school.

5.5. All school personnel shall have one tuberculin skin test at the time of employment performed by the local health department or the person's physician.

5.5.a. The time of employment for school personnel means the first time that they are employed in a West Virginia school. Employees do not need to have a tuberculin skin test when transferring between schools within the state, unless medically indicated.

5.6. Local health officers are responsible for arranging proper follow-up for school students and personnel who are unable to obtain a physician's evaluation for a positive tuberculin skin test.

5.7. The Commissioner may require selective testing of students and school personnel for tuberculosis:

5.7.a. when the student or personnel have traveled to a TB endemic country;

5.7.b. when the student or personnel have signs and symptoms indicative of TB;

5.7.c. as part of a contact investigation; or

5.7.d. at any time there is reason to suspect an exposure to TB has occurred.

§64-76-6. Forms for Admitting and Committing Patients; Other Records.

6.1. Protocols for appropriate state institution admissions are available from the Bureau's tuberculosis control program at:

TB Program
WVDHHR/BPH/SDC
350 Capitol St. Room 125,
Charleston, WV 25301
or online at: www.wvtb.gov.

6.2. Application forms for the voluntary admission of a patient to an institution for the care and treatment of tuberculosis are available from the Bureau and the institution. The patient's attending physician shall submit the forms and any medical reports, such as X-ray and sputum reports to the local health department. The local health department shall then submit forms to the TB control program for review and approval.

6.3. For involuntary and immediate involuntary commitment of a patient to an institution equipped for the care and treatment of tuberculosis, the Commissioner of the Bureau for Public Health, or the local health officer as the Commissioner's designee, or another designee of the Commissioner shall sign a completed form, and submit the form to the prosecuting attorney for petition to the circuit court, or magistrate court in the circuit judge's absence.

6.4. The institution shall keep a case record for each patient. If the patient is transferred, the institution shall forward a copy of the patient's record to the institution to which the patient is being transferred. If the patient is discharged, the institution shall forward a copy of the patient's record to the local health department.

§64-76-7. Active Disease and Latent TB Infection Reporting.

7.1. Every health care provider, public health officer and every chief medical officer having charge of any hospital, clinic or other similar public or private institution in the State, shall immediately telephone the local health department

and report the name, age, sex, race, home address and type of disease of any person with a diagnosis of, or who is suspected of having, tuberculosis.

7.1.a. Reporting forms for persons with latent tuberculosis infection and for persons with active tuberculosis disease are available from the Bureau's tuberculosis control program at: TB Program, WVDHHR/BPH, 350 Capitol Street, Room 125, Charleston, WV 25301 or online at: www.wvtb.gov.

7.2. The health care provider reporting under subsection 7.1. of this section shall also submit a written report on forms made available by the Bureau to the local health department in the patient's county of residence within twenty four (24) hours of a diagnosis of tuberculosis or upon suspicion that a person has tuberculosis.

7.3. The health care provider shall submit updates of patients' progress or lack of progress, including, but not limited to, the latest bacteriology results of cultures, any development of drug resistance, the most recent chest x-ray results, clinical symptoms and treatment to the local health department.

7.4. The health care provider shall report any screening of contacts, with the names and addresses and results of the screening tests of the contacts, to the local health department. Also, the health care provider shall report to the local health department the names of contacts of cases that did not return for follow up for necessary interventions.

7.4.a. The local health officer in the patient's county of residence shall meet with the contact to determine why the contact has not returned for follow up.

7.4.b. The local health officer may request an opportunity to perform a medical evaluation on the contact.

7.5. The local health department shall report all information received under this section to the Bureau.

§64-76-8. Procedure When Patient Is a Health Menace to Others.

8.1. A health care provider shall consider a patient non-adherent if the patient is unable or unwilling to report for medical examinations or is unable or unwilling to adhere to prescribed treatment, such as refusing to take medications or showing other evidence of not taking medications as prescribed, e.g., incorrect pill count or a urine test showing no evidence of drug metabolites.

8.2. Any health care provider who is aware of a non-adherent tuberculosis patient shall contact the local health officer for necessary interventions. The local health officer:

8.2.a. In the patient's county of residence shall meet with the patient to determine why the patient is non-adherent to therapy;

8.2.b. May request an opportunity to examine the non-adherent patient;

8.2.c. May offer the non-adherent patient a course of treatment;

8.2.d. May prescribe DOT for the non-adherent patient; and

8.2.e. May institute proceedings for involuntary commitment or emergency involuntary commitment of the non-adherent patient, if, in the judgment of the health officer, the measures are necessary to protect the public health and safety.

8.3. A patient with tuberculosis shall be isolated while he or she is in a communicable stage. The patient shall be restricted to his or her isolation room or primary residence until he or she is no longer infectious. The health care provider shall advise immunocompromised individuals and guardians of children of the need for them to be removed from the household, if the patient stays there while infectious.

8.4. Patients unable to adhere to therapy or isolate themselves from others, may voluntarily admit themselves to an institution equipped for the

care and treatment of tuberculosis. The local health department shall assist with the admission by following protocols available at the Bureau's TB control program.

8.5. A patient who has tuberculosis demonstrated by clinical, bacteriological, radiographic or epidemiological evidence shall be considered a health menace and considered for commitment to an institution equipped for the care and treatment of tuberculosis if the patient:

8.5.a. Had previous treatment for tuberculosis but failed to complete therapy for reasons unrelated to access to treatment or medication;

8.5.b. Failed to adhere to present prescribed therapy;

8.5.c. Risks infecting others because of inadequate environmental conditions for proper isolation;

8.5.d. Has laboratory tests or a history of nonadherence to anti-tuberculosis medication which indicate possible infection with drug-resistant mycobacterium tuberculosis; or

8.5.e. Has an initial infection with multidrug resistant TB (MDRTB) or extensively drug resistant TB (XDRTB).

8.6. When the local health officer determines that commitment is necessary to protect the health of the public, the local health officer, through the prosecuting attorney, shall petition the circuit court in the county where the patient is a resident for a hearing before the circuit judge to obtain an order to commit the patient to an institution equipped for the care and treatment of persons with tuberculosis. The local health officer shall personally serve notice upon the patient seven days prior to the date of the scheduled hearing.

8.7. The patient shall be present at the hearing and shall have the right to present evidence, confront witnesses and evidence against him or her, and examine testimony offered. The patient should wear a surgical mask or cover their mouth with tissue to contain possible cough secretions and reduce the risk of transmitting the disease.

8.8. The hearing should be conducted in a well-ventilated room.

8.9. If probable cause is found, the patient shall be immediately committed to an institution equipped and maintained for the care and treatment of patients afflicted with tuberculosis.

8.10. If the patient being committed has a history of alcohol or other drug abuse, he or she shall be committed to an institution equipped for the care and treatment of emotional health for assessment and if needed for complete detoxification, prior to commitment to an institution equipped for the care and treatment of tuberculosis.

8.11. A patient with confirmed or suspected active tuberculosis should be transported with a surgical mask covering his or her nose and mouth. The windows of the vehicle should be kept open and the heating and air-conditioning system should be set on a nonrecirculating cycle. Because engineering controls cannot be ensured, personnel transporting the patient should wear respiratory protection meeting current United States Centers for Disease Control and Prevention guidelines.

8.12. Every patient committed to an institution shall observe all the rules of the institution. The patient may be placed apart from others and restrained from leaving the institution as long as he or she continues to be afflicted with tuberculosis and remains a health menace.

8.13. Nothing in this rule may be construed to prohibit any patient committed to any institution from applying to the West Virginia Supreme Court of Appeals for a review of the evidence on which the commitment was made. Nothing in this rule may be construed or operate to empower or authorize the Bureau for Public Health, the Department of Health and Human Resources or an authorized designee thereof or the chief medical officer of the institution, or their representatives, to

restrict in any manner the individual's right to select any method of tuberculosis treatment offered by the institution.

§64-76-9. Procedures for Immediate Involuntary Commitment.

9.1. When a patient has been determined by the Commissioner of the Bureau for Public Health, or by the local health officer as the Commissioner's designee, or by another designee of the Commissioner, to meet the criteria set forth in section 8 of this rule for commitment to an institution, but also has demonstrated uncooperative and irresponsible behavior with regard to isolation or safety measures and presents a health threat to others, the Commissioner should consider him or her for immediate commitment to an institution equipped for the care and treatment of tuberculosis.

9.2. The Commissioner of the Bureau for Public Health, or his or her designee, shall complete an application for hearing and deliver it to the prosecuting attorney, of the county in which the patient resides, for petitioning the circuit court, or in the judge's absence, for petitioning the magistrate court. The application shall contain facts which establish reasons for the commitment.

9.3. If in the absence of the circuit judge, the magistrate finds that immediate detention is necessary, the magistrate may issue an order for the patient to be temporarily detained in isolation for up to twenty-four hours until an application can be presented to the circuit court, or if requested by the patient or his or her counsel, temporary detention may be extended up to an additional forty-eight (48) hours.

9.4. The patient shall be detained in a room separate from others with separate ventilation, such as a hospital isolation negative air flow room, a jail where no other inmates are housed at the time or a motel room with separate air conditioning to the outside. The patient shall wear a surgical mask or cover his or her mouth with tissues to contain cough secretions to reduce any transmission. The patient should wear a surgical mask or cover their mouth with tissue at all times when out of the isolation room. Persons in contact with the patient should wear respiratory protection as stated in subsection 8.11. of this rule.

9.5. Proceedings shall then be instituted for involuntary commitment as provided in section 8 of this rule.

§64-76-10. Transportation of Persons.

Local Health Departments are responsible for coordinating the transportation of persons with tuberculosis to the appropriate hospital or institution.

§64-76-11. Administrative Due Process.

Any person 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 the manner prescribed in the Bureau procedural rule, Rules for Contested Case Hearings and Declaratory Rulings, 64CSR1.