CABINET FOR HEALTH AND FAMILY SERVICES

Office of Inspector General

Division of Health Care

(Amendment)

 902 KAR 20:200. Tuberculosis (TB) testing for residents in long-term care settings [~~facilities~~].

RELATES TO: KRS 215.520-215.600, 216B.010-216B.131, 216B.990

STATUTORY AUTHORITY: KRS 216B.042(1)[~~, 216B.105~~]

 NECESSITY, FUNCTION, AND CONFORMITY: KRS 216B.042(1) requires the Cabinet for Health and Family Services to establish licensure standards and procedures to ensure safe, adequate, and efficient health facilities and health services. KRS 215.590 requires a health service or health facility licensed pursuant to KRS Chapter 216B or KRS Chapter 333 to report knowledge of a person who has active tuberculosis to the local health department. The purpose of this administrative regulation is to establish requirements for tuberculosis (TB) testing of residents in the following long-term care settings: nursing facilities, intermediate care facilities, nursing homes, Alzheimer’s nursing homes, personal care homes, and Intermediate Care Facilities for Individuals with an Intellectual Disability (ICF/IID). These procedures are necessary to minimize the transmission of infectious tuberculosis among the staff and residents in long-term care settings.

Section 1. Definitions.

(1) “Air Changes per Hour” (ACH) means the air change rate expressed as the

number of air exchange units per hour.

(2) “Airborne Infection Isolation (AII) precautions” means the isolation of patients

infected with organisms spread through airborne droplet nuclei 1--5 *µ*m in diameter. This isolation area receives substantial ACH (≥12 ACH for new construction since 2001 and ≥6 ACH for construction before 2001) and is under negative pressure (i.e., the direction of the air flow is from the outside adjacent space [e.g., the corridor] into the room). The air in an AII room is preferably exhausted to the outside, but may be recirculated if the return air is filtered through a high efficiency particulate respirator (HEPA) filter.

(3) “AII room” means a room designed to maintain AII. Formerly called negative pressure isolation room, an AII room is a single-occupancy patient-care room used to isolate persons with suspected or confirmed infectious TB disease. Environmental factors shall be controlled in AII rooms to minimize the transmission of infectious agents that are usually spread from person-to-person by droplet nuclei associated with coughing or aerosolization of contaminated fluids. AII rooms shall provide negative pressure in the room (so that air flows under the door gap into the room), an air flow rate of 6--12 ACH, and direct exhaust of air from the room to the outside of the building or recirculation of air through a HEPA filter.

(4) “BAMT” or “Blood Assay for *Mycobacterium tuberculosis*” means a diagnostic blood test that assesses for the presence of infection with *M. tuberculosis,* and its results are reported as positive, negative, indeterminate, or borderline. This test includes interferon-gamma (IFN- ɣ) release assays (IGRA).

(5) “BAMT conversion” means a change in the BAMT test result, on serial testing, from negative to positive over a two (2) year period.

(6) “Boosting” or the “booster phenomenon” means if nonspecific or remote sensitivity to tuberculin purified protein derivative (PPD) in the skin test wanes or disappears over time, subsequent tuberculin skin tests (TSTs) may restore the sensitivity. An initially small TST reaction size is followed by a substantial reaction size on a later test, and this increase in millimeters of induration may be confused with a conversion or a recent *M. tuberculosis* infection. Two-step testing shall be used to distinguish new infections from boosted reactions in infection-control surveillance programs.

(7) “Directly Observed Therapy” (DOT) means an adherence-enhancing strategy:

(a) In which a health care worker or other trained person watches a patient swallow each dose of medication; and

(b) Which is the standard care for all patients with TB disease and is a preferred option for patients treated for latent TB infection (LTBI).

(8) “DOPT” means Directly Observed Preventive Therapy, which is the DOT for treatment of LTBI.

(9) “Extrapulmonary tuberculosis” means TB disease in any part of the body other than the lungs (e.g., kidney, spine, or lymph nodes). The presence of extrapulmonary disease does not exclude pulmonary TB or other infectious TB diseases. Laryngeal and tracheal TB are infectious respiratory forms of TB but are also extrapulmonary.

(10) “Health care workers” (HCWs) means all paid and unpaid persons working in health care settings who have the potential for exposure to infectious materials, including body substances, contaminated medical supplies and equipment, contaminated environmental surfaces, or contaminated air, and may include physicians, physician assistants, nurses, medical assistants, nursing assistants, therapists, technicians, emergency medical service personnel, dental personnel, pharmacists, laboratory personnel, autopsy personnel, students and trainees, contractual staff not employed by the health care facility, and persons (e.g., clerical, dietary, housekeeping, laundry, security, maintenance, billing, and volunteers) not directly involved in patient care but potentially exposed to infectious agents that may be transmitted to and from health care workers and patients or residents.

(11) "Induration" means a firm area in the skin which develops as a reaction to injected tuberculin antigen if a person has tuberculosis infection and which is measured in accordance with Section 2 of this administrative regulation.

(12) “Infectious tuberculosis” means pulmonary, laryngeal, endobroncheal, or tracheal TB disease or a draining TB skin lesion that has the potential to cause transmission of tuberculosis to other persons.

(13) “Latent TB infection” or “LTBI” means infection with *M. tuberculosis* without symptoms or signs of disease have manifested.

(14) “Long-term care setting” means a nursing facility, intermediate care facility, nursing home, Alzheimer’s nursing home, personal care home, or Intermediate Care Facility for Individuals with an Intellectual Disability.

(15) “Multidrug-resistant tuberculosis (MDR TB)” means TB disease caused by *M. tuberculosis* organisms that are resistant to at least isoniazid (INH) and rifampin.

(16) “NAA” or “Nucleic Acid Amplification” means a laboratory method used to target and amplify a single deoxyribonucleic acid (DNA) or ribonucleic acid (RNA) sequence usually for detecting and identifying a microorganism. The NAA tests for *M. tuberculosis* complex are sensitive and specific and can accelerate the confirmation of pulmonary TB disease or other infectious tuberculosis diseases.

(17) “PCR” or “Polymerase chain reaction” means a system for in vitro amplification of DNA or RNA that can be used for diagnosis of infections.

(18) “Staggered tuberculosis testing” means the testing of residents in the same month as the anniversary date of the resident’s admission, or testing in the birth month so that all residents do not have tuberculosis testing in the same month. Staggered tuberculosis screening increases opportunities for early recognition of infection control problems that may lead to conversions in test results for *M. tuberculosis* infection.

(19) “Tuberculosis Risk Assessment” means an initial and ongoing evaluation of the risk for LTBI or active TB disease in a particular resident, and is performed in accordance with the provisions established in Sections 3, 7, 8, and 11 of this administrative regulation.

(20) "Tuberculin Skin Test” (TST) means a diagnostic aid for finding *M. tuberculosis* infection that:

(a) Is performed by using the intradermal (Mantoux) technique using five (5) tuberculin units of purified protein derivative (PPD); and

(b) Has its results read forty-eight (48) to seventy-two (72) hours after injection and recorded in millimeters of induration.

(21) “Tuberculosis (TB) disease” means a condition caused by infection with a member of the *M. tuberculosis* complex that meets the descriptions established in Section 2(2) of this administrative regulation.

(22) “TST conversion” means a change in the result of a test for *M. tuberculosis* infection in which the condition is interpreted as having progressed from uninfected to infected in accordance with Section 2(3) of this administrative regulation.

(23) "Two (2) step TST" or “two-step testing” means a series of two (2) TSTs administered seven (7) to twenty-one (21) days apart and used for the baseline skin testing of persons who will receive serial TSTs, including health care workers and residents of long-term care settings to reduce the likelihood of mistaking a boosted reaction for a new infection.

Section 2. Tuberculosis Testing Requirements for TSTs.

(1) Induration Measurements. The diameter of the firm area shall be measured transversely (i.e., perpendicularly) to the long axis of the forearm to the nearest millimeter to gauge the degree of reaction, and the result shall be recorded in millimeters. The diameter of the firm area shall not be measured along the long axis of the forearm.

(a) A reaction of ten (10) millimeters or more of induration, if the TST result is interpreted as positive, shall be considered highly indicative of tuberculosis infection in a health care setting.

(b) A reaction of five (5) millimeters to nine (9) millimeters of induration may be significant in certain individuals with risk factors, as described in Section 3(3) of this administrative regulation, for rapid progression to active tuberculosis disease if infected.

(2) Tuberculosis (TB) disease.

(a) A person shall be diagnosed as having tuberculosis (TB) disease if the infection has progressed to causing clinical (manifesting signs or symptoms) or subclinical (early stage of disease in which signs or symptoms are not present, but other indications of disease activity are present, including radiographic abnormalities) illness.

1. Tuberculosis that is found in the lungs is called pulmonary TB and may be infectious.

2. Extrapulmonary disease (occurring at a body site outside the lungs) may be infectious in rare circumstances.

(b) If the only clinical finding is specific chest radiographic abnormalities, the condition is termed "inactive TB" and may be differentiated from active TB disease, which is accompanied by symptoms or other indications of disease activity, including the ability to culture reproducing TB organisms from respiratory secretions or specific chest radiographic finding.

(3)(a) A TST conversion shall have occurred if the size of the measured TST induration increases by ten (10) millimeters or more during a two (2) year period in a resident with a:

1. Documented baseline two (2) step TST result; or

2. Previous follow-up screening TST result with induration measured as zero (0) millimeters to nine (9) millimeters and interpreted as negative during serial testing.

(b) A TST conversion shall be presumptive evidence of new *M. tuberculosis* infection and poses an increased risk for progression to TB disease.

Section 3. TB Risk Assessment and Tuberculin Skin Tests or BAMTs for Residents.

(1) Risk Assessment.

(a) To perform a risk assessment, a standardized questionnaire shall be used and the following factors shall be assessed:

 1. The clinical symptoms of active TB disease;

 2. Events and behaviors that increase the risk for exposure to *M. tuberculosis* and the risk of acquiring LTBI; and

 3. Medical risk factors that increase the risk for a resident with LTBI to develop active TB disease.

 (b) A TB Risk Assessment questionnaire may be obtained from the Kentucky Department for Public Health (published online at: <http://chfs.ky.gov/dph/epi/tb.htm>) or from a national medical or public health organization, including the American Academy of Pediatrics or the Centers for Disease Control and Prevention.

(c) TB Risk Assessment questions may be incorporated into the long-term care setting’s medical forms or into forms or other features of the long-term care setting’s electronic medical record systems.

(2) Exclusion of Residents from Tuberculin Skin Tests or BAMTs on Admission. A TST or BAMT shall not be required on admission if the resident, resident’s guardian, resident’s health care surrogate, or resident’s responsible party provided medical documentation for one (1) of the following as part of a TB Risk Assessment:

(a) A prior TST of ten (10) or more millimeters of induration if the TST result was interpreted as positive;

(b) A prior TST of five (5) millimeters to nine (9) millimeters of induration if the resident has a medical reason as described in subsection (3) of this section for his or her TST result to be interpreted as positive;

(c) A positive BAMT;

(d) A TST conversion;

(e) A BAMT conversion;

(f) The resident is currently receiving or has completed treatment for LTBI with one (1) of the treatment regimens recommended by the Centers for Disease Control and Prevention;

(g) The resident has completed a course of multiple-drug therapy for active TB disease recommended by the Centers for Disease Control and Prevention; or

(h) The resident has had a TST or BAMT within three (3) months prior to admission and has previously been in a serial testing program at another medical facility, long-term care setting, or other health care setting.

(3) A medical reason for a resident’s TST result of five (5) millimeters to nine (9) millimeters of induration to be interpreted as positive may include:

(a) HIV-infection;

(b) Immunosuppression;

(c) Fibrotic changes on chest radiograph consistent with previous TB disease: or

(d) Recent contact with a person who has active TB disease.

(4) TB Risk Assessments and Tuberculin Skin Tests or BAMTs on Admission.

(a) A baseline TB Risk Assessment and a TST or BAMT, if not excluded pursuant to subsection (2) of this section, shall be initiated on each new resident before or during the first week of admission. The results shall be documented in the resident’s medical record or electronic medical record within the first two (2) weeks of admission.

(b)1. A TB Risk Assessment required by paragraph (a) of this subsection shall be performed by a physician, advanced practice registered nurse, physician assistant, or registered nurse.

2. A licensed practical nurse under the supervision of a registered nurse may perform the TB Risk Assessment.

(c) An initial or first-step TST result of ten (10) millimeters or more of induration may be interpreted as positive for a new resident.

(d) An initial or first-step TST result on admission of five (5) to nine (9) millimeters of induration may be interpreted as positive for a resident who has a medical reason as described in subsection (3) of this section for the TST result to be interpreted as positive.

(5)(a) A two-step baseline TST shall be required on admission for each resident aged fourteen (14) years and older whose initial or first-step TST on admission is interpreted as negative.

(b) The second step test shall be initiated seven (7) to twenty-one (21) days after the first test.

1. A TST result of five (5) millimeters to nine (9) millimeters of induration may be interpreted as positive on the second step TST for a resident who has a medical reason as described in subsection (3) of this section for the TST result to be interpreted as positive.

2. If a resident aged fourteen (14) years and older does not have a medical reason as identified in subsection (3) of this section and the resident’s initial or first-step TST (initiated before or during the first week of admission) shows less than ten (10) millimeters of induration and a second step TST shows more than ten (10) millimeters of induration, the TST shall be interpreted as positive.

3. The initial TST, initiated before or during the first week of admission, shall count as the second step TST if the resident aged fourteen (14) years and older provided medical documentation that he or she has had a one (1) step TST interpreted as negative within one (1) year prior to initial testing upon admission to the long-term care setting.

(6) BAMT. A BAMT may be used in place of, but not in addition to, a TST.

(a) If a BAMT is performed before or during the first week of admission and the result is positive or negative, only a one (1) step BAMT test result shall be required.

(b) A second BAMT shall be performed if the BAMT result is borderline, indeterminate, or invalid.

Section 4. Admission of Patients under Treatment for Pulmonary Tuberculosis Disease or Other Infectious Tuberculosis Diseases.

(1)(a) A long-term care setting as described in Section 1(14) of this administrative regulation shall not admit a person under medical treatment for suspected or confirmed pulmonary tuberculosis disease or other suspected or confirmed infectious tuberculosis diseases caused by non-MDR TB unless the person is declared noninfectious by a licensed physician or other licensed medical provider in conjunction with the local and state health department.

(b) Documentation of noninfectious status shall include:

1. Documented TB disease treatment with multi-drug therapy for at least two (2) weeks; and

2. Documentation of clinical improvement on therapy; and

3.a. Three (3) consecutive acid-fast bacilli (AFB) negative sputum smear results for specimens collected in eight (8) to twenty-four (24) hours apart, with at least one (1) being an early morning specimen; or

b. Two (2) consecutive negative sputum cultures for TB.

(2)(a) A long-term care setting as described in Section 1(14) of this administrative regulation shall not admit a person under medical treatment for suspected or confirmed pulmonary tuberculosis disease or other suspected or confirmed infectious tuberculosis diseases, caused by MDR TB unless the person is declared noninfectious by a licensed physician or other licensed medical provider in conjunction with the local and state health department.

(b) Documentation of noninfectious status if a patient is diagnosed or suspected with MDR TB shall include:

1. Documented TB disease treatment with multi-drug therapy for at least two (2) weeks;

2. Documentation of clinical improvement on therapy;

3. Three (3) consecutive negative AFB sputum smear results for specimens collected eight (8) to twenty-four (24) hours apart, with at least one (1) being an early morning specimen; and

4. Two (2) consecutive negative sputum cultures for TB with specimens collected at least two (2) weeks apart.

(3)(a) A long-term care setting as described in Section 1(14) of this administrative regulation shall not admit a person under medical treatment for suspected or confirmed extrapulmonary tuberculosis disease, caused by non-MDR TB or MDR TB, unless the person is declared noninfectious by a licensed physician or other licensed medical provider in conjunction with the local and state health department.

(b) Documentation of noninfectious status shall include clinical, radiographic, and laboratory evidence that concurrent pulmonary TB disease or other infectious TB disease has been excluded.

Section 5. Medical Record or Electronic Medical Record Documentation for Residents.

(1) The TB Risk Assessment shall be documented in the resident's medical record or electronic medical record by recording the date of the assessment and the results.

(2) The TST result of each resident shall be documented in the resident’s medical record or electronic medical record by recording the date of measurement and millimeters of induration of all TSTs.

(3) The medical record shall be labeled inside or the electronic medical record shall be labeled with the notation "TST Positive" for each resident with a reaction of:

(a) Ten (10) millimeters or more of induration if the TST result was interpreted as positive; or

(b) Five (5) millimeters to nine (9) millimeters of induration if the resident has a medical reason as described in Section 3(3) of this administrative regulation for the TST result to be interpreted as positive.

(4)(a) If performed, the BAMT result of each resident shall be documented in the resident’s medical record or electronic medical record by recording of the date and result as positive, negative, borderline, or indeterminate.

(b) If a resident has a positive BAMT, his or her medical record shall be labeled inside or electronic medical record shall be labeled with the notation “BAMT Positive.”

Section 6. Medical Evaluations, Chest X-rays, and Monitoring of Residents with a Positive TST, a Positive BAMT, a TST Conversion, or a BAMT Conversion.

(1) At the time of admission or annual testing, a resident shall have a medical evaluation, including an HIV test unless the resident, resident’s guardian, resident’s health care surrogate, or resident’s responsible party opts out of HIV testing, if the resident is found to have a:

(a) TST result of ten (10) millimeters or more induration if the TST result is interpreted as positive;

(b) TST result of five (5) millimeters to nine (9) millimeters of induration if the resident has a medical reason as described in Section 3(3) of this administrative regulation for the TST result to be interpreted as positive;

(c) Positive BAMT:

(d) TST conversion: or

(e) BAMT conversion.

(2) A chest x-ray shall be performed as part of the medical evaluation required by subsection (1) of this section unless a chest x-ray within the previous two (2) months showed no evidence of tuberculosis disease.

(3)(a) A resident with no clinical evidence of active TB disease upon evaluation by a licensed physician or other licensed medical provider, and a negative chest x-ray shall be offered treatment for LTBI unless there is a medical contraindication.

(b) A resident who refuses or whose guardian, health care surrogate, or responsible party refuses on behalf of the resident treatment for LTBI, or a resident who has a medical contraindication shall be monitored according to the requirements in Section 7 of this administrative regulation.

(4) A resident with symptoms or an abnormal chest x-ray consistent with TB disease shall be:

(a) Isolated in an AII room or transferred within eight (8) hours of notification to a facility with an AII room; and

(b) Evaluated for active tuberculosis disease;

1. Three (3) sputum samples, collected eight (8) to twenty-four (24) hours apart with at least one(1) being an early morning specimen shall be submitted to a hospital laboratory or a state or national reference laboratory for tuberculosis culture and smear for acid-fast bacilli (AFB), and NAA tests or PCR tests.

2. Multi-drug antituberculosis treatment shall be administered by DOT for suspected or active tuberculosis disease.

3. Individuals under treatment for suspected or confirmed pulmonary tuberculosis disease or other suspected or confirmed infectious tuberculosis diseases may be readmitted to the long-term care setting in accordance with the requirements of Section 4 of this administrative regulation.

Section 7. Monitoring of Residents with a Positive TST, a Positive BAMT, a TST Conversion, or a BAMT Conversion.

(1) A resident shall be monitored for development of pulmonary symptoms, including cough, sputum production, and chest pain, if the resident has:

(a) A TST result with ten (10) or more millimeters of induration;

(b) A TST result of five (5) millimeters to nine (9) millimeters of induration if the resident has a medical reason as described in Section 3(3) of this administrative regulation for his or her TST result to be interpreted as positive;

(c) A positive BAMT;

(d) A TST conversion; or

(e) A BAMT conversion.

(2)(a) If pulmonary symptoms, including cough, sputum production, and chest pain, develop and persist for three (3) weeks or longer:

 1. The resident shall have a medical evaluation; and

 2. A chest x-ray shall be taken.

 (b) A resident with symptoms or an abnormal chest x-ray, consistent with TB disease shall:

1. Be isolated in an AII room; or

2. Transferred within eight (8) hours of notification to a facility with an AII room.

a. Three (3) sputum samples, collected eight (8) to twenty-four (24) hours apart with at least one (1) being an early morning specimen, shall be submitted to a hospital laboratory or national reference laboratory for tuberculosis culture and smear for acid-fast bacilli (AFB), and NAA tests.

b. Multi-drug antituberculosis treatment shall be administered by DOT for suspected or active tuberculosis disease.

c. Individuals under treatment for suspected or confirmed pulmonary tuberculosis disease or other suspected or confirmed infectious tuberculosis diseases may be readmitted to the long-term setting in accordance with the requirements of Section 3 of this administrative regulation.

(3)(a) A resident with a positive TST or a positive BAMT on admission who stays eleven (11) months or longer in the long-term care setting shall have an annual TB Risk Assessment in the same month as the anniversary date of his or her last TB Risk Assessment.

(b) The resident shall not be required to submit to an annual TST or BAMT.

(4)(a) A resident with a TST conversion or a BAMT conversion shall:

1. Be educated about and advised of the clinical symptoms of active TB disease;

2. Have an interval medical history for clinical symptoms of active TB disease every six (6) months during the first two (2) years following TST conversion or BAMT conversion followed thereafter by an annual TB Risk Assessment in the same month as the anniversary of his or her last TB Risk Assessment.

(b) The resident shall not be required to submit to an annual TST or BAMT.

Section 8. Monitoring of Residents with a Negative TST or a Negative BAMT who are Residents for Eleven (11) Months or Longer.

(1) A long-term care setting shall use staggered tuberculosis testing to assure that all residents are not tested in the same month. Staggered testing shall be performed monthly, quarterly, or semiannually.

(2) An annual TB Risk Assessment and a TST or BAMT shall be required in the same month as the anniversary date of the resident’s last TB Risk Assessment and TST or BAMT.

(3)(a) If pulmonary symptoms, including cough, sputum production, and chest pain, develop and persist for three (3) weeks or longer:

 1. The resident shall have a medical evaluation;

 2. The TST or BAMT shall be repeated; and

 3. A chest x-ray shall be taken.

 (b) A resident with symptoms or an abnormal chest x-ray, consistent with TB disease shall:

1. Be isolated in an AII room; or

2. Transferred within eight (8) hours of notification to a facility with an AII room.

(c) Three (3) sputum samples, collected eight (8) to twenty-four (24) hours apart with at least one (1) being an early morning specimen, shall be submitted to a hospital laboratory or a state or national reference laboratory for tuberculosis culture, smear for acid-fast bacilli (AFB), and NAA tests.

(d) Multi-drug antituberculosis treatment shall be administered by DOT for suspected or active tuberculosis disease.

(e) Persons under treatment for suspected or confirmed pulmonary tuberculosis disease or other suspected or confirmed infectious tuberculosis diseases may be readmitted to the long-term care setting in accordance with the requirements of Section 4 of this administrative regulation.

Section 9. Responsibility for Screening and Monitoring Requirements: Residents.

(1) A long-term care setting’s administrator or administrator’s designee shall be responsible for ensuring that all TB Risk Assessments, TSTs, BAMTs, chest x-rays and sputum sample submissions for residents comply with Section 2 through Section 8 of this administrative regulation.

(2) If a long-term care setting does not employ licensed professional staff with the technical training to carry out the screening and monitoring requirements for residents, the administrator shall arrange for training or professional assistance from the local health department or from a licensed medical provider.

(3) All TSTs with the date of measurement and millimeters of induration and the date performed and reported results of all BAMTs, all chest x-rays, and all sputum sample smears for AFB and TB cultures, all TB-related NAA tests, and all TB-related PCR tests for a resident shall be:

(a) Recorded as a permanent part of the resident's medical record or electronic medical record; and

(b) Summarized on the resident’s transfer form if an inter-facility transfer occurs.

Section 10. Reporting to Local Health Departments. (1) A long-term care setting’s administrator or the administrator’s designee shall report a resident identified with one (1) of the following to the local health department having jurisdiction within one (1) business day upon becoming known:

(a) TST conversions or BAMT conversions on serial testing or identified in a contact investigation;

(b) Chest x-rays which are suspicious for TB disease;

(c) Sputum smears positive for acid-fast bacilli;

(d) Rapid laboratory tests positive for *Mycobacterium tuberculosis* DNA or RNA, such as *Mycobacterium tuberculosis* positive NAA tests or PCR tests;

(e) Sputum cultures positive for *Mycobacterium tuberculosis*; or

(f) The initiation of multi-drug antituberculosis treatment for a resident.

(2) A long-term care setting’s administrator or the administrator’s designee shall report a resident identified with one (1) of the following to the local health department having jurisdiction within five (5) business days upon becoming known:

(a) A TST of ten (10) millimeters or more induration at the time of admission, if the TST result was interpreted as positive;

(b) A TST result of five (5) millimeters to nine (9) millimeters of induration at the time of admission for a resident who has a medical reason as described in Section 3(3) of this administrative regulation for his or her TST result to be interpreted as positive;

(c) A positive BAMT at the time of admission;

Section 11. Treatment for LTBI in Residents.

(1) A resident with a TST conversion or a BAMT conversion with no clinical evidence of active TB disease upon evaluation by a licensed physician or other licensed medical provider and a negative chest x-ray shall be considered to be recently infected with *Mycobacterium tuberculosis*.

(2) Recently infected persons as described in subsection (1) of this section shall have a medical evaluation, an HIV test unless the resident , resident’s guardian, resident’s health care surrogate, or resident’s responsible party opts out of HIV testing, and a chest x-ray.

(3)(a) Individuals who meet the criteria of subsection (1) of this section and have no signs or symptoms of tuberculosis disease by medical evaluation or on chest x-ray shall be offered treatment for LTBI, in collaboration with the local health department, unless medically contraindicated as determined by a licensed physician or other licensed medical provider.

(b) Medications shall be:

1. Administered to residents upon the written order of a physician or other licensed medical provider acting within his or her statutory scope of practice; and

2. Given by DOPT.

(4) If a resident, resident’s guardian, resident’s health care surrogate, or resident’s responsible party refuses treatment of the resident for LTBI after a TST conversion or a BAMT conversion or has a medical contraindication, the individual shall:

(a) Be educated about and advised of the clinical symptoms of active TB disease; and

(b) Have a TB Risk Assessment which includes an interval medical history for clinical symptoms of active TB disease every six (6) months during the first two (2) years following TST conversion or BAMT conversion, followed thereafter by an annual TB Risk Assessment in the same month as the anniversary of the resident’s last TB Risk Assessment.

(c) The resident shall not be required to submit to an annual TST or BAMT.

(d) Documentation that the resident, resident’s guardian, resident’s heath care surrogate, or resident’s responsible party was educated and advised of the clinical symptoms of active TB shall be documented in the resident’s medical record or electronic medical record.

(5)(a) A resident who has a TST result of ten (10) millimeters or more induration, if the TST result is interpreted as positive, or a positive BAMT at the time of admission shall be offered treatment for LTBI, unless medically contraindicated.

(b) A resident who has a TST result of five (5) millimeters to nine (9) millimeters of induration at the time of admission and who has a medical reason as described in Section 3(3) in this administrative regulation for his or her TST result to be interpreted as positive shall be offered treatment for LTBI, unless medically contraindicated.

(c) If a resident refuses, or the resident’s guardian, resident’s health care surrogate, or resident’s responsible party refuses treatment on behalf of the resident for LTBI detected upon admission, the individual shall:

1. Be educated about and advised of the clinical symptoms of active TB disease;

2. Have a TB Risk Assessment which includes an interval medical history for clinical symptoms of active TB disease every six (6) months during the first two (2) years following admission, followed thereafter by an annual TB Risk Assessment in the same month as the anniversary of his or her last TB Risk Assessment.

3. The resident shall not be required to submit to an annual TST or BAMT

4. Documentation that the resident, resident’s guardian, resident’s health care surrogate, or resident’s responsible party was educated about and advised of the clinical symptoms of active TB shall be documented in the resident’s medical record or electronic medical record.

(6) A resident who stays eleven (11) months or longer in the long-term care setting and who provided medical documentation for completion of treatment for LTBI with one (1) of the treatment regimens recommended by the Centers for Disease Control and Prevention shall:

(a) Not be required to submit to an annual TST or BAMT; and

(b) The resident, resident’s guardian, resident’s health care surrogate, or resident’s responsible party shall receive education on the clinical symptoms of active TB disease during a TB Risk Assessment annually in the same month as the anniversary date of the resident’s last TB Risk Assessment and any other monitoring in accordance with Section 6 through Section 9 of this administrative regulation.

 Section 12. Supersede. If any requirement stated in another administrative regulation within 902 KAR Chapter 20 contradicts a requirement stated in this administrative regulation, the requirement stated in this administrative regulation shall supersede the requirement stated elsewhere within 902 KAR Chapter 20.

 Section 13. Incorporation by Reference. (1) The TB-4, "Kentucky Department for Public Health Tuberculosis (TB) Risk Assessment", March 2013 edition is incorporated by reference.

(2) This material may be inspected, copied, or obtained, subject to applicable copyright law, at the Office of Inspector General, 275 East Main Street, Frankfort, Kentucky 40621, Monday through Friday, 8 a.m. to 4:30 p.m. [~~KRS 216B.042 and 216B.105 mandate that the Kentucky Cabinet for Human Resources regulate health facilities and health services. KRS 215.520 to 215.590 mandates that nursing homes report cases of tuberculosis. The purpose of this administrative regulation is to establish licensure requirements concerning uniform procedures for the identification and control of tuberculosis in nursing facilities, skilled nursing facilities, intermediate care facilities, nursing homes, and personal care homes. These procedures are necessary to minimize the transmission of tuberculosis infection among the staff and residents of such facilities.~~

~~Section 1. Definitions. (1) "Induration" means a firm area in the skin which develops as a reaction to injection tuberculosis proteins when a person has tuberculosis infection. The diameter of the firm area is measured to the nearest millimeter to gauge the degree of reaction. A reaction of ten (10) millimeters or more of induration is considered highly indicative of tuberculosis infection.~~

~~(2) "Skin test" means a tuberculin skin test utilizing the intradermal (Mantoux) technique using five (5) tuberculin units of purified protein derivative (PPD). The results of the test must be read forty-eight (48) to seventy-two (72) hours after injection and recorded in terms of millimeters of induration.~~

~~(3) "Two (2) step skin testing" means a series of two (2) tuberculin skin tests administered seven (7) to fourteen (14) days apart.~~

~~Section 2. Admission of Patients under Treatment for Pulmonary Tuberculosis Disease. No licensee shall admit a person under medical treatment for pulmonary tuberculosis disease unless there is documentation of three (3) consecutive sputum smears negative for acid-fast bacilli within the month prior to admission and the patient is considered noninfectious by a licensed physician.~~

~~Section 3. Tuberculin Skin Testing of Residents. (1) For residents entering a facility, no skin testing is required if one of the following can be documented:~~

~~(a) A previous documented skin test has shown ten (10) or more millimeters of induration; or~~

~~(b) The resident is currently receiving or has completed six (6) months of prophylactic therapy or a course of multiple-drug chemotherapy for tuberculosis; or~~

~~(c) The resident can document that he/she has had a tuberculin skin test within three (3) months prior to admission.~~

~~(2) For all other residents, however, skin testing is required upon admission to the facility. For such residents whose initial skin test shows less than ten (10) millimeters of induration, two (2) step skin testing is required, unless they can document that they have had a tuberculosis skin test within one (1) year prior to their initial testing upon admission to the facility. The skin test status of all residents must be documented through recording of the date and millimeters of induration of the most recent skin test in the medical record. The front cover of the medical record shall be labeled in a conspicuous manner with the notation "PPD+" for all residents with a reaction of ten (10) or more millimeters of induration.~~

~~Section 4. X-raying of Residents. All residents found on admission testing to have a skin test of ten (10) or more millimeters of induration shall receive a chest x-ray, unless a chest x-ray done within two (2) months prior to admission showed no evidence of tuberculosis disease or the resident can document the previous completion of a course of prophylactic treatment with isoniazid.~~

~~Section 5. Monitoring of Residents with a Skin Test of Ten (10) or More Millimeters of Induration. Residents with a skin test of ten (10) or more millimeters of induration shall be monitored for development of pulmonary symptoms such as cough, sputum production or chest pain. If such symptoms develop and persist of three (3) weeks or longer, a chest x-ray shall be taken and three (3) sputum samples shall be submitted to the Division of Laboratory Services, Department for Health Services, Frankfort, Kentucky, for tuberculosis culture and smear.~~

~~Section 6. Monitoring of Residents with a Skin Test of Less than Ten (10) Millimeters of Induration. Annual skin testing is required. In addition, if pulmonary symptoms develop and persist for three (3) weeks or more, the tuberculin skin test shall be repeated, three (3) sputum samples shall be submitted to the Division of Laboratory Services, Department for Health Services, Frankfort, Kentucky for tuberculosis culture and smear, and a chest x-ray shall be taken.~~

~~Section 7. Tuberculin Skin Testing of Staff. The skin test status of all staff members shall be documented in the employee's personnel record. A skin test shall be initiated on all new staff members before or during the first week of employment and the results shall be documented in the employee's personnel record within the first month of employment. No skin testing is required at the time of initial employment if the employee documents a prior skin test of ten (10) or more millimeters of induration or if the employee is currently receiving or has completed six (6) months of prophylactic therapy or a course of multiple-drug chemotherapy for tuberculosis. Two (2) step skin testing is required for new employees over age forty-five (45) whose initial test shows less than ten (10) millimeters of induration, unless they can document that they have had a tuberculosis skin test within one (1) year prior to their current employment. All staff who have never had a skin test of ten (10) or more millimeters induration must be skin tested annually on or before the anniversary of their last skin test.~~

~~Section 8. X-raying and Monitoring of Staff with a Skin Test of Ten (10) or more Millimeters of Induration. All staff who are found to have a skin test of ten (10) or more millimeters induration, on initial employment testing or annual testing, must receive a chest x-ray unless a chest x-ray within the previous two (2) months showed no evidence of tuberculosis or, the individual can document the previous completion of a course of prophylactic treatment with isoniazid. They shall be advised of the symptoms of the disease and instructed to report to their employer and seek medical attention promptly, if symptoms persist.~~

~~Section 9. Responsibility for Screening and Monitoring Requirements. The administrator of each long-term care facility is responsible for ensuring that all skin-tests, chest x-rays and sputum sample submissions are done in accordance with Sections 1 through 8 of this administrative regulation. In those facilities not employing professional staff with the technical training to carry out the screening and monitoring requirements, the administrator shall arrange for professional assistance from either the local health department or private medical practitioners. Irrespective of who carries out the screening and monitoring requirements, all skin testing dates and results, all chest x-ray reports and all sputum sample culture and smear results shall be recorded as a permanent part of the medical record and be summarized on the individual's transfer form when an interfacility transfer occurs.~~

~~Section 10. Reporting to Local Health Departments. The following shall be reported to the local health department having jurisdiction by the administrator of the long-term care facility immediately upon becoming known: chest x-rays which are suspicious for tuberculosis; sputum smears positive for acid-fast bacilli; sputum cultures positive for mycobacterium tuberculosis; residents or staff who converts from a skin test of less than ten (10) to a skin test of ten (10) or more millimeters of induration; and all residents and staff who have a skin test of ten (10) millimeters or more induration at the time of admission or employment, respectively.~~

~~Section 11. Prophylaxis of Persons with Recent Infection but no Disease. Any resident or staff whose skin test status changes on annual testing from less than ten (10) to ten (10) or more millimeters of induration shall be considered to be recently infected with Mycobacterium tuberculosis. Such recently infected persons who have no signs or symptoms of tuberculosis disease on chest x-ray or medical history should be given preventive therapy with isoniazid for six (6) months unless medically contraindicated as determined by a licensed physician. Medications shall be administered to patients only upon the written order of a physician. If such individual is unable to take isoniazid therapy, the individual shall be advised of the clinical symptoms of the disease, and have an interval medical history and a chest x-ray taken and evaluated for tuberculosis infection every six (6) months during the two (2) years following conversion.~~

~~Section 12. Any staff or resident who can document completion of preventive treatment with isoniazid shall be exempt from further screening requirements except in accordance with Section 5 of this administrative regulation.~~]

902 KAR 20:200

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Maryellen Buxton Mynear Date

 Executive Director

 Office of Inspector General

APPROVED:

 \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

 Audrey Tayse Haynes Date

 Secretary

902 KAR 20:200

PUBLIC HEARING AND PUBLIC COMMENT PERIOD:

A public hearing on this administrative regulation shall, if requested, be held on \_\_ (Date TBD)\_\_\_ at 9:00 a.m. in Conference Room A, Health Services Building, First Floor, 275 East Main Street, Frankfort, Kentucky. Individuals interested in attending this hearing shall notify this agency in writing by \_\_\_(Date TBD)\_\_\_\_, five (5) workdays prior to the hearing, of their intent to attend. If no notification of intent to attend the hearing is received by that date, the hearing may be canceled. The hearing is open to the public. Any person who attends will be given an opportunity to comment on the proposed administrative regulation. A transcript of the public hearing will not be made unless a written request for a transcript is made. If you do not wish to attend the public hearing, you may submit written comments on the proposed administrative regulation. You may submit written comments regarding this proposed administrative regulation until close of business \_\_\_(Date TBD)\_\_\_\_\_. Send written notification of intent to attend the public hearing or written comments on the proposed administrative regulation to:

CONTACT PERSON: Tricia Orme, Office of Legal Services, 275 East Main Street 5 W-B, Frankfort, KY 40621, Phone: 502-564-7905, Fax: 502-564-7573

**NOTE: Dates for the public hearing and public comment period will be announced in 2015.**

**DO NOT SUBMIT COMMENTS NOW**

REGULATORY IMPACT ANALYSIS AND TIERING STATEMENT

Regulation: 902 KAR 20:200

Contact Person:

Maryellen Buxton Mynear, Executive Director, Office of Inspector General;

 Robert L. Brawley, MD, MPH, FSHEA, Chief, Infectious Disease Branch,

Division of Epidemiology and Health Planning, 502-564-3261;

Stephanie Brammer-Barnes, Internal Policy Analyst,

 Office of Inspector General, 502-564-2888

 (1) Provide a brief summary of:

 (a) What this administrative regulation does: This administrative regulation establishes requirements for tuberculosis (TB) testing of residents in the following long-term care settings: nursing facilities, intermediate care facilities, nursing homes, Alzheimer’s nursing homes, personal care homes, and Intermediate Care Facilities for Individuals with an Intellectual Disability.

(b) The necessity of this administrative regulation: This administrative regulation is necessary to establish procedures to minimize the transmission of infectious tuberculosis disease among the staff and residents in long-term care settings.

(c) How this administrative regulation conforms to the content of the authorizing statutes: This administrative regulation conforms to the content of the authorizing statutes by establishing standards and procedures to ensure safe, adequate, and efficient health facilities and health services.

(d) How this administrative regulation currently assists or will assist in the effective administration of the statutes: This administrative regulation assists in the effective administration of the statutes by establishing procedures to minimize the transmission of infectious tuberculosis disease among the staff and residents in long-term care settings.

 (2) If this is an amendment to an existing administrative regulation, provide a brief summary of:

(a) How the amendment will change this existing administrative regulation: This amendment updates existing TB screening requirements to help ensure compliance with the Centers for Disease Control and Prevention’s (CDC) guidelines for preventing the transmission of TB in health care facilities, including long-term care settings.

(b) The necessity of the amendment to this administrative regulation: This amendment is necessary to update existing requirements to ensure compliance with the CDC’s guidelines for preventing the transmission of infectious TB disease in health care facilities, including long-term care settings.

(c) How the amendment conforms to the content of the authorizing statutes: This amendment conforms to the content of the authorizing statutes by updating standards intended to prevent the transmission of infectious TB disease in long-term care settings.

(d) How the amendment will assist in the effective administration of the statutes: This amendment will assist in the effective administration of the statutes by updating existing standards intended to prevent the transmission of infectious TB disease in long-term care settings.

 (3) List the type and number of individuals, businesses, organizations, or state and local governments affected by this administrative regulation: This administrative regulation impacts residents of the following long-term care settings (the number of currently licensed facilities appears in parenthesis next to the facility type): nursing facilities (281), intermediate care facilities (9), nursing homes (6), Alzheimer’s nursing homes (1), personal care homes (157), and Intermediate Care Facilities for Individuals with an Intellectual Disability (14).

 (4) Provide an analysis of how the entities identified in question (3) will be impacted by either the implementation of this administrative regulation, if new, or by the change, if it is an amendment, including:

 (a) List the actions that each of the regulated entities identified in question (3) will have to take to comply with this administrative regulation or amendment: The entities identified in question (3) will be required to comply with TB testing requirements that are consistent with the Centers for Disease Control and Prevention’s guidelines.

 (b) In complying with this administrative regulation or amendment, how much will it cost each of the entities identified in question (3): No additional costs will be incurred by the entities affected.

 (c) As a result of compliance, what benefits will accrue to the entities identified in question (3): Staff and residents in long-term care settings will benefit from revised standards intended to prevent the transmission of TB.

 (5) Provide an estimate of how much it will cost the administrative body to implement this administrative regulation:

 (a) Initially: This administrative regulation imposes no costs on the administrative body.

 (b) On a continuing basis: This administrative regulation imposes no costs on the administrative body.

 (6) What is the source of the funding to be used for the implementation and enforcement of this administrative regulation: No additional funding is necessary to implement the administrative regulation.

 (7) Provide an assessment of whether an increase in fees or funding will be necessary to implement this administrative regulation, if new, or by the change if it is an amendment: No fee or funding increase is necessary to implement the administrative regulation.

(8) State whether or not this administrative regulation established any fees or directly or indirectly increased any fees: The administrative regulation does not establish or increase any fees.

 (9) TIERING: Is tiering applied? (explain why or why not) Tiering is not applicable as compliance with this administrative regulation applies equally to all individuals or entities regulated by it.

FISCAL NOTE ON STATE OR LOCAL GOVERNMENT

 1. Does this administrative regulation relate to any program, service, or requirements of a state or local government (including cities, counties, fire departments, or school districts)?

 Yes \_X\_\_\_ No \_\_\_\_\_

 If yes, complete questions 2-4.

 2. What units, parts or divisions of state or local government (including cities, counties, fire departments, or school districts) will be impacted by this administrative regulation? This administrative regulation impacts residents of the following long-term care settings (the number of currently licensed facilities appears in parenthesis next to the facility type): nursing facilities (281), intermediate care facilities (9), nursing homes (6), Alzheimer’s nursing homes (1), personal care homes (157), and Intermediate Care Facilities for Individuals with an Intellectual Disability (14).

 3. Identify each state or federal statute or federal regulation that requires or authorizes the action taken by the administrative regulation. KRS 215.520-215.600, 216B.010-216B.131

 4. Estimate the effect of this administrative regulation on the expenditures and revenues of a state or local government agency (including cities, counties, fire departments, or school districts) for the first full year the administrative regulation is to be in effect.

 (a) How much revenue will this administrative regulation generate for the state or local government (including cities, counties, fire departments, or school districts) for the first year? This administrative regulation will not generate revenue for state or local government.

 (b) How much revenue will this administrative regulation generate for the state or local government (including cities, counties, fire departments, or school districts) for subsequent years? This administrative regulation will not generate revenue for state or local government.

 (c) How much will it cost to administer this program for the first year? This administrative regulation imposes no costs on the administrative body.

 (d) How much will it cost to administer this program for subsequent years? This administrative regulation imposes no costs on the administrative body.

Note: If specific dollar estimates cannot be determined, provide a brief narrative to explain the fiscal impact of the administrative regulation.

 Revenues (+/-):

 Expenditures (+/-):

 Other Explanation:

COMMONWEALTH OF KENTUCKY

CABINET FOR HEALTH AND FAMILY SERVICES

Office of Inspector General

902 KAR 20:200, Tuberculosis (TB) testing for residents in long-term care settings.

Summary of Material Incorporated by Reference

The TB-4, "Kentucky Department for Public Health Tuberculosis (TB) Risk Assessment", March 2013 edition is the form used by health care settings to assess and document a health care worker’s TB symptoms or risk factors. This form contains one (1) page.

The total number of pages incorporated by reference is one (1) page.