CABINET FOR HEALTH AND FAMILY SERVICES

Office of Inspector General

Division of Health Care

(New Administrative Regulation)

 902 KAR 20:205. Tuberculosis (TB) testing for health care workers.

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

STATUTORY AUTHORITY: KRS 216B.042(1)

 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 health care workers in health facilities or settings licensed under KRS Chapter 216B or KRS Chapter 333. These procedures are necessary to minimize the transmission of infectious tuberculosis disease among staff and patients or residents of health facilities.

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) “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.

 (8) “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.

(9) “Health care setting” or “health facility” means an abortion facility, adult day health program, Alzheimer’s nursing home, ambulatory care clinic, ambulatory surgical center, blood establishment, chemical dependency treatment service, community mental health center, comprehensive physical rehabilitation hospital, critical access hospital, family care home, freestanding birth center, group home, home health agency, hospice program, hospital, intermediate care facility, Intermediate Care Facility for Individuals with an Intellectual Disability (ICF/IID), limited services clinic, medical laboratory, mobile health service, network, nursing facility, nursing home, nursing pool, outpatient health care center, pain management facility, personal care home, prescribed pediatric extended care facility, psychiatric hospital, primary care center, private duty nursing agency, Level I or Level II psychiatric residential treatment facility, rehabilitation agency, renal dialysis facility, residential hospice facility, rural health clinic, special health clinic, specialty intermediate care clinic, and specialized medical technology service.

(10) "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 3(1) of this administrative regulation.

(11) “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.

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

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

(14) “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.

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

(16) “Staggered tuberculosis testing” means the testing of health care workers in the same month as the anniversary date of his or her date of initial employment, or testing in the birth month so that all health care workers 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.

(17) “Tuberculosis Risk Assessment” means an initial and ongoing evaluation of the risk for LTBI or active TB disease in a particular health care worker and is performed in accordance with the provisions established in Sections 4, 5, 7, and 11 of this administrative regulation.

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

(19) “Tuberculosis (TB) disease” means a condition caused by infection with a member of the *M. tuberculosis* complex that meets the descriptions established in Section 3(2) of this administrative regulation.

(20) “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 4(3) of this administrative regulation.

(21) "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. TB Infection Control Program

(1) Each health facility shall have a written TB infection control plan that is part of an overall infection control program.

(2) The TB infection control plan shall be designed to control *M. tuberculosis* transmission through early detection, isolation, diagnosis, and treatment of persons with active TB.

(3) A hierarchy of control measures shall be used, including:

(a) Administrative controls, and

(b) Environmental controls, and

(c) Respiratory protection.

(4) A TB infection control plan shall include a listing of the job series of healthcare workers or another standardized method to describe which healthcare workers shall be included in the facility TB screening program.

(a) At a minimum, health care workers shall be included in the TB screening program if they have:

1. Duties that involve face‑to-face contact with patients with suspected or confirmed active TB disease (including transport staff), or

2. The potential for exposure to *M. tuberculosis* through air space shared with persons with suspected or confirmed active TB disease of the respiratory system, or

3. Duties that involve the processing of laboratory specimens for TB testing or TB cultures, or

4. Duties that have the potential for exposure to the environment of care of persons with suspected or confirmed active TB disease, or

5. Perform other tasks or procedures which may generate infectious aerosol droplet nuclei where they have or may have exposure to TB.

(b) A facility may voluntarily include additional or even all health care workers in the TB screening program based upon TB incidence (local or regional), patient safety strategies, or risk management strategies.

Section 3. 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 4(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 health care worker 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 4. TB Risk Assessment and Tuberculin Skin Tests or BAMTs for Health Care Workers on Initial Employment.

(1) Risk Assessment.

(a) To perform a TB 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 health care worker 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 facility’s medical history forms or into forms or other features of the facility’s electronic medical record systems.

(2) Exclusion of Health Care Workers from Tuberculin Skin Tests or BAMTs Upon Initial Employment in a Health Facility. A TST or BAMT shall not be required at the time of initial employment if the health care worker provided medical documentation for one (1) of the following as part of a TB Risk Assessment:

(a) A prior TST of ten (10) millimeters or more 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 health care worker 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 health care worker 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 health care worker has completed a course of multiple-drug therapy for active TB disease recommended by the Centers for Disease Control and Prevention; or

(h) The health care worker provided medical documentation that he or she has had a TST or BAMT within three (3) months prior to initial employment at the facility and has previously been in a serial testing program at another medical facility or health care setting.

(3) A medical reason for a health care worker’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 for health care workers upon initial employment in a health facility.

(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 health care worker before or during the first week of employment. The results shall be documented in the health care worker's medical record or electronic medical record within the first month of employment.

(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 health care worker.

(d) An initial or first-step TST result of five (5) millimeters to nine (9) millimeters of induration may be interpreted as positive for a new health care worker 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 for a health care worker aged fourteen (14) years and older whose initial or first-step TST, initiated before or during the first week of employment, 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 health care worker 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 health care worker aged fourteen (14) years and older does not have a medical reason as identified in subsection (3) of this section and the worker’s initial or first-step TST (initiated before or during the first week of employment) shows less than ten (10) millimeters of induration and a second-step TST shows ten (10) millimeters or more of induration, the TST shall be interpreted as positive.

3. The initial TST, initiated before or during the first week of employment, shall count as the second step TST if the health care worker 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 at the time of initial employment.

(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 employment 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 5. Annual TB Risk Assessments and Annual Tuberculin Skin Tests or BAMTs for Health Care Workers.

(1) All health care workers shall have an annual TB risk assessment and annual education about the signs and symptoms of active TB disease.

(2) All health care workers included in the TB screening program, as determined by the health facility TB infection control plan, shall also have annual TB testing.

(3) When performing annual TB testing:

(a) Health care settings shall use staggered tuberculosis testing to assure that all health care workers are not tested in the same month. Staggered testing shall be performed monthly, quarterly, or semiannually.

(b) A health care worker who has worked eleven (11) months or more in the facility and who has never had a TST interpreted as positive or has never had a positive BAMT shall have a TB Risk Assessment and a TST or BAMT annually in the same month as the anniversary date of his or her last TB Risk Assessment and TST or BAMT.

(c) A health care worker who has worked eleven (11) months or more in the facility and who has had a previous TST interpreted as positive or a previously positive BAMT shall only have an annual TB Risk Assessment in the same month as the anniversary date of his or her last TB Risk Assessment and shall not be required to submit to an annual TST or BAMT.

Section 6. Medical Record or Electronic Medical Record Documentation for Health Care Workers.

(1) The TB Risk Assessment shall be documented in each health care worker’s medical record or electronic medical record by recording the date of the assessment and the results.

(2) The TST result of each health care worker shall be documented in the worker’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 health care worker 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 health care worker has a medical reason as described in Section 4(3) of this administrative regulation for the TST result to be interpreted as positive.

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

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

Section 7. Medical Evaluations, Chest X-rays, and Monitoring of Health Care Workers with a Positive TST, a Positive BAMT, a TST Conversion, or a BAMT Conversion.

(1) At the time of initial employment testing or annual testing, a health care worker shall have a medical evaluation, including an HIV test unless the health care worker opts out of HIV testing, if the health care worker 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 health care worker has a medical reason as described in Section 4(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 health care worker 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 medically contraindicated.

(b) A health care worker who refuses treatment for LTBI or who has a medical contraindication shall be monitored according to the following requirements:

1. A health care worker who has a positive TST or a positive BAMT at the time of initial employment and works eleven (11) months or longer in the health facility shall:

a. Have an annual TB Risk Assessment in the same month as the anniversary date of his or her last TB Risk Assessment; and

b. Shall not be subject to an annual TST or BAMT.

2. A health care worker with a documented TST conversion or a BAMT conversion shall:

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

b. Have an interval medical history for clinical symptoms of active TB disease every six (6) months during the first two (2) years after conversion, followed by an annual TB Risk Assessment in the same month as the anniversary date of the worker’s last TB Risk Assessment; and

c. Not be subject to an annual TST or BAMT.

3. A health care worker with a positive TST, a positive BAMT, a TST conversion, or a BAMT Conversion shall be:

a. Educated about and advised of the clinical symptoms of active TB disease; and

b. Instructed to report to his or her facility supervisor and seek medical attention promptly, if symptoms persist for three (3) weeks or longer.

c. Documentation that the health care worker was educated and advised of the clinical symptoms of active TB disease shall be included in the health care worker’s medical record or electronic medical record.

Section 8. Medical Evaluations, Chest X-rays, Laboratory Tests, Treatment, and Monitoring of Health Care Workers with Suspected TB Disease or Active TB Disease.

(1) A health care worker with symptoms or an abnormal chest x-ray, consistent with TB disease shall be:

(a) Immediately excluded from work;

(b) Isolated in an AII room, referred to a facility with an AII room, or placed in home isolation in collaboration with the local health department;

(c) Evaluated for active tuberculosis disease and if needed, treated with multi-drug TB therapy as recommended by the Centers for Disease Control and Prevention; and

(d) Remain off work until cleared as being noninfectious for TB by a licensed physician or other licensed medical provider in conjunction with the local and state health department.

(2) A health care worker under treatment for suspected or confirmed pulmonary tuberculosis disease, suspected or confirmed extrapulmonary tuberculosis disease, or other suspected or confirmed infectious tuberculosis diseases caused by non-MDR TB may return to work in the facility after being declared noninfectious, per the Centers for Disease Control and Prevention’s “Guidelines for Preventing the Transmission of *Mycobacterium tuberculosis* in Health-Care Settings, 2005”, by a licensed physician or other licensed medical provider in conjunction with the local and state health department.

(3) A health care worker under treatment for suspected or confirmed pulmonary tuberculosis disease, suspected or confirmed extrapulmonary tuberculosis disease, or other suspected or confirmed infectious tuberculosis diseases caused by MDR TB may return to work in the facility after being declared noninfectious, per the Centers for Disease Control and Prevention’s “Guidelines for Preventing the Transmission of *Mycobacterium tuberculosis* in Health-Care Settings, 2005” or other CDC TB guidelines, by a licensed physician or other licensed medical provider in conjunction with the local and state health department.

Section 9. Responsibility for Screening and Monitoring Requirements: Health Care Workers.

(1) A facility’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 health care workers comply with the requirement of Section 3 through Section 8 of this administrative regulation and the Centers for Disease Control and Prevention’s “Guidelines for Preventing the Transmission of *Mycobacterium tuberculosis* in Health-Care Settings, 2005”.

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

(3)(a) 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 health care worker shall be recorded as a permanent part of the worker's medical record or electronic medical record.

(b) Copies of the health care worker’s medical record or electronic medical record shall be provided to the worker upon request by the worker if he or she transfers to another health facility.

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

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

(b) A chest x-ray which is 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 active TB in a health care worker.

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

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

(b) A TST result of five (5) or more millimeters of induration for a health care worker at the time of initial employment who has a medical reason as described in Section 4(3) of this administrative regulation for the TST result to be interpreted as positive;

(c) A positive BAMT at the time of initial employment;

Section 11. Treatment for LTBI.

(1) A health care worker 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 individual opts out of HIV testing, and a chest x-ray.

(3) Individuals who meet the criteria listed in 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.

(4) If a health care worker refuses treatment 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 his or her last TB Risk Assessment.

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

(d) Documentation that the health care worker was educated and advised of the clinical symptoms of active TB disease shall be included in the health care worker’s medical record or electronic medical record.

(5)(a) A health care worker 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 initial employment shall be offered treatment for LTBI, unless medically contraindicated.

(b) A health care worker who has a TST result of five (5) millimeters to nine (9) millimeters of induration upon initial employment and who has a medical reason as described in Section 4(3) of this administrative regulation for the TST result to be interpreted as positive shall be offered treatment for LTBI, unless medically contraindicated.

(c) If a health care worker refuses treatment for LTBI detected at the time of initial employment in the facility or has a medical contraindication, 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 after the date of initial employment in the facility, 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 health care worker shall not be required to submit to an annual TST or BAMT.

4. Documentation that the health care worker was educated about and advised of the clinical symptoms of active TB disease shall be included in the health care worker’s medical record or electronic medical record.

(6) A health care worker who works eleven (11) months or longer in the facility and who provided medical documentation that he or she has completed 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) 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 his or her last TB Risk Assessment.

 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 following material is incorporated by reference:

      (a) TB-4, "Kentucky Department for Public Health Tuberculosis (TB) Risk Assessment", March 2013 edition; and

      (b) "Centers for Disease Control and Prevention. Guidelines for Preventing the Transmission of *Mycobacterium tuberculosis* in Health-Care Settings, 2005. MMWR 2005;54 (No. RR-17): 1-141”.

      (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.

902 KAR 20:205

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

Maryellen Buxton Mynear Date

 Executive Director

 Office of Inspector General

APPROVED:

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

 Audrey Tayse Haynes Date

 Secretary

902 KAR 20:205

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 Auditorium 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 \_\_\_\_\_\_\_(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 20:205

Contact Person:

Maryellen Buxton Mynear, Executive Director of the 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 health care workers in health facilities or settings licensed and regulated by the Office of Inspector General (OIG) under KRS Chapter 216B or KRS Chapter 333.

(b) The necessity of this administrative regulation: This administrative regulation is necessary to establish procedures to minimize the transmission of infectious tuberculosis disease among staff and patients or residents of health facilities or settings licensed and regulated by the OIG under KRS Chapter 216B or KRS Chapter 333.

(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 staff and patients or residents of health facilities or settings licensed and regulated by the OIG under KRS Chapter 216B or KRS Chapter 333.

 (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 is a new administrative regulation which establishes requirements that help ensure compliance with the Centers for Disease Control and Prevention’s (CDC) guidelines for preventing the transmission of infectious TB disease in hospitals, long-term care settings, and other health facilities or settings licensed and regulated by the OIG under KRS Chapter 216B or KRS Chapter 333.

(b) The necessity of the amendment to this administrative regulation: This is a new administrative regulation.

(c) How the amendment conforms to the content of the authorizing statutes: This is a new administrative regulation.

(d) How the amendment will assist in the effective administration of the statutes: This is a new administrative regulation.

 (3) List the type and number of individuals, businesses, organizations, or state and local governments affected by this administrative regulation: This administrative regulation impacts health care workers in the following health facilities regulated by the OIG (the number of currently licensed facilities appears in parenthesis next to the facility type): Abortion facilities (1); adult day health care (105); Alzheimer's nursing home (1); ambulatory care clinics (18); ambulatory surgical centers (39); blood establishments (135); chemical dependency treatment service (4); community mental health centers (14); family care homes (64); freestanding birth centers (no facilities currently licensed in this category); group homes (38); home health agency (109); hospice (24); hospitals, including deemed hospitals (98), nondeemed hospitals (31), deemed comprehensive physical rehabilitation hospitals (4), nondeemed comprehensive physical rehabilitation hospitals (2), critical access hospitals (29), deemed psychiatric hospitals (10), nondeemed psychiatric hospitals (3); intermediate care facilities (9); Intermediate Care Facilities for Individuals with Intellectual Disabilities (14); limited services clinics (51); medical laboratories (29); mobile health service (146); networks (5); nursing facilities (281); nursing homes (6); nursing pools (63); outpatient health care clinics (1); non-physican owned pain management facilities (4); personal care homes (157); prescribed pediatric extended care facilities (6); primary care centers (142); private duty nursing agencies (10); psychiatric residential treatment facilities (24); rehabilitation agencies (279); renal dialysis facilities (109); residential hospice facilities (8); rural health clinics (177); special health clinics (120); specialty intermediate care clinics (1); and specialized medical technology service (122).

 (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: Health care settings identified in question (3) will be required to comply with TB screening requirements which are consistent with the CDC’s "Guidelines for Preventing the Transmission of *Mycobacterium tuberculosis* in Health-Care Settings, 2005".

 (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 patients or residents in health facilities licensed and regulated by the OIG 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. 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 health care workers in the following health facilities or settings regulated by the OIG (the number of currently licensed facilities appears in parenthesis next to the facility type): Abortion facilities (1); adult day health care (105); Alzheimer's nursing home (1); ambulatory care clinics (18); ambulatory surgical centers (39); blood establishments (135); chemical dependency treatment service (4); community mental health centers (14); family care homes (64); freestanding birth centers (no facilities currently licensed in this category); group homes (38); home health agency (109); hospice (24); hospitals, including deemed hospitals (98), nondeemed hospitals (31), deemed comprehensive physical rehabilitation hospitals (4), nondeemed comprehensive physical rehabilitation hospitals (2), critical access hospitals (29), deemed psychiatric hospitals (10), nondeemed psychiatric hospitals (3); intermediate care facilities (9); Intermediate Care Facilities for Individuals with Intellectual Disabilities (14); limited services clinics (51); medical laboratories (29); mobile health service (146); networks (5); nursing facilities (281); nursing homes (6); nursing pools (63); outpatient health care clinics (1); non-physican owned pain management facilities (4); personal care homes (157); prescribed pediatric extended care facilities (6); primary care centers (142); private duty nursing agencies (10); psychiatric residential treatment facilities (24); rehabilitation agencies (279); renal dialysis facilities (109); residential hospice facilities (8); rural health clinics (177); special health clinics (120); specialty intermediate care clinics (1); and specialized medical technology service (122).

 2. 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

 3. 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 20:205, Tuberculosis (TB) testing for health care workers.

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 “Centers for Disease Control and Prevention. Guidelines for Preventing the Transmission of *Mycobacterium tuberculosis* in Health-Care Settings, 2005. MMWR 2005;54 (No. RR-17): 1-141”, contain the CDC’s current recommended TB infection-control measures. The guidelines contain 148 pages and may be downloaded at: <http://www.cdc.gov/mmwr/pdf/rr/rr5417.pdf>

The total number of pages incorporated by reference is 149 pages.