

INSPECTIONS AND APPEALS DEPARTMENT[481]

Notice of Intended Action

Twenty-five interested persons, a governmental subdivision, an agency or association of 25 or more persons may demand an oral presentation hereon as provided in Iowa Code section 17A.4(1)“b.”

Notice is also given to the public that the Administrative Rules Review Committee may, on its own motion or on written request by any individual or group, review this proposed action under section 17A.8(6) at a regular or special meeting where the public or interested persons may be heard.

Pursuant to the authority of Iowa Code sections 10A.104(5) and 135B.7, the Department of Inspections and Appeals hereby gives Notice of Intended Action to amend Chapter 51, “Hospitals,” and to adopt new Chapter 59, “Tuberculosis (TB) Screening,” Iowa Administrative Code.

Proposed new Chapter 59 outlines requirements and procedures to conduct tuberculosis screenings for health care workers of Iowa licensed hospitals and health care workers and residents of Iowa licensed health care facilities, including the screening process to be used, the risk classification, and who may conduct TB screenings. Additionally, corresponding technical changes are proposed in subrule 51.24(3) to reference new Chapter 59.

The proposed language in Chapter 59 was substantially written by the Iowa Department of Public Health and provides uniformity in the requirements and procedures to conduct TB screening (see **ARC 0365B** herein for rules regarding tuberculosis screening adopted by the Department of Public Health).

The Department does not believe that the proposed amendments impose any financial hardship on any regulated entity, body, or individual. Rather, the proposed amendments provide uniformity in the requirements and procedures to conduct TB screening for health care workers and residents.

The Hospital Licensing Board reviewed and approved the proposed amendments at its August 7, 2012, meeting. The Board of Health also reviewed the proposed amendments at its September 12, 2012, meeting.

Any interested person may make written suggestions or comments on the proposed amendments on or before October 23, 2012. Such written materials should be addressed to the Director, Department of Inspections and Appeals, Lucas State Office Building, 321 East 12th Street, Des Moines, Iowa 50319-0083; faxed to (515)242-6863; or e-mailed to david.werning@dia.iowa.gov.

After analysis and review of this rule making, no impact on jobs has been found.

These amendments are intended to implement Iowa Code section 135B.7.

The following amendments are proposed.

ITEM 1. Amend subrule 51.24(3) as follows:

51.24(3) Health examinations. Health examinations for all personnel shall be required at the commencement of employment and thereafter at least every four years. The examination shall include, at a minimum, the health ~~and tuberculosis~~ status of the employee. Consideration shall be given to requiring health examinations at shorter intervals for those employees working in high-risk areas. Screening and testing for tuberculosis shall be conducted pursuant to 481—Chapter 59.

ITEM 2. Adopt the following **new** 481—Chapter 59:

CHAPTER 59

TUBERCULOSIS (TB) SCREENING

481—59.1(135B) Purpose. The intent of this chapter is to outline requirements and procedures to conduct tuberculosis screening for health care workers in health care facilities and hospitals and for residents of health care facilities regulated by the department.

481—59.2(135B) Definitions. For purposes of this chapter, the following definitions apply:

“*Bacille Calmette-Guérin (BCG) vaccination*” means a vaccine for TB. BCG is used in many countries with a high prevalence of TB to prevent childhood tuberculosis meningitis and military

disease. BCG is not generally recommended for use in the United States because of the low risk of infection with *Mycobacterium tuberculosis*, the variable effectiveness of the vaccine against adult pulmonary TB, and the vaccine's potential interference with tuberculin skin test reactivity.

“*Baseline TB screening*” means the screening of health care workers (HCWs) of health care facilities or hospitals and residents of health care facilities for latent tuberculosis infection (LTBI) and TB disease at the beginning of employment in a facility or hospital, or upon admission to a facility. Baseline TB screening includes a symptom screen for all HCWs and residents, and tuberculin skin tests (TSTs) or interferon-gamma release assay (IGRA) for *Mycobacterium tuberculosis* for those persons with previous negative test results for *M. tuberculosis* infection.

“*Baseline TST*” or “*baseline IGRA*” means the TST or IGRA, respectively, that is administered at the beginning of employment to newly hired HCWs or upon admission to residents of health care facilities.

“*Boosting*” means a phenomenon in which a person has a negative TST (i.e., false-negative) result years after infection with *M. tuberculosis* and then a positive subsequent TST result. The positive TST result is caused by a boosted immune response of previous sensitivity rather than by a new infection (false-positive TST conversion). Two-step testing reduces the likelihood of mistaking a boosted reaction for a new infection.

“*Department*” means the department of inspections and appeals.

“*Employment*” or “*employed*” means hired or retained for paid or unpaid work in a facility or hospital.

“*Extrapulmonary TB*” means TB disease in any part of the body other than the lungs (e.g., kidney, spine, or lymph nodes).

“*Health care facility*” or “*facility*” means a health care facility as defined in Iowa Code section 135C.1 or a long-term care service of a hospital as defined in rule 481—51.38(135B).

“*Health care worker*” or “*HCW*” means any paid or unpaid person working in a health care facility or hospital, including any volunteer or person who is paid either by the health care facility or hospital, or paid by any other entity (i.e., temporary agency, private duty, Medicaid/Medicare or independent contractors).

“*Hospital*” means a hospital as defined in Iowa Code section 135B.1.

“*Interferon-gamma release assay*” or “*IGRA*” means whole-blood tests that can aid in diagnosing *Mycobacterium tuberculosis* infection.

“*Laryngeal TB*” means a form of TB disease that involves the larynx and may be highly infectious.

“*Latent TB infection*” or “*LTBI*” means infection with *M. tuberculosis* without symptoms or signs of disease having manifested.

“*Mantoux method*” means a skin test performed by intradermally injecting 0.1 mL of purified protein derivative (PPD) tuberculin solution into the volar or dorsal surface of the forearm.

“*Patient*” means a person admitted to a hospital.

“*Pulmonary TB*” means TB disease that occurs in the lung parenchyma, usually producing a cough that lasts greater than three weeks. Pulmonary TB is usually infectious.

“*Purified protein derivative (PPD) tuberculin*” means a material used in diagnostic tests for detecting infection with *M. tuberculosis*.

“*Resident*” means a person admitted to a health care facility or a long-term care service of a hospital as defined in rule 481—51.38(135B). For purposes of this chapter, “resident” does not include a patient admitted to a hospital.

“*Risk classification*” means the category the infection control team, or designated other staff, determines is appropriate for the facility or hospital as a result of the TB risk assessment.

“*Serial screening*” refers to TB screening performed at regular intervals following baseline TB screening. Serial TB screening, also called annual or ongoing TB testing, consists of two components: (1) assessing for current symptoms of active TB disease, and (2) testing for the presence of infection with *M. tuberculosis* by administering either a TST or single IGRA.

“*Symptom screen*” means a procedure used during a clinical evaluation in which persons are asked if they have experienced any departure from normal in function, appearance, or sensation related to TB disease (e.g., cough).

“*TB patient*” means a person who had undiagnosed infectious pulmonary or laryngeal TB while in a health care facility or hospital during the preceding year. “TB patient” does not include persons with LTBI (treated or untreated), extrapulmonary TB disease, pulmonary, or laryngeal TB that have met criteria for noninfectiousness.

“*TB risk assessment*” means an initial and ongoing evaluation of the risk for transmission of *M. tuberculosis* in a particular health care setting.

“*TB screening*” means an administrative control measure in which evaluation for LTBI and TB disease is performed through baseline and serial screening of HCWs in hospitals and health care facilities and residents of health care facilities.

“*TB screening plan*” means a plan that health care facilities and hospitals develop and implement that comprises four major components: (1) baseline testing for *M. tuberculosis* infection, (2) serial testing for *M. tuberculosis* infection, (3) serial screening for signs or symptoms of TB disease, and (4) TB training and education.

“*Treatment for LTBI*” means treatment that prevents the progression of *M. tuberculosis* infection into TB disease.

“*Tuberculin skin test*” or “*TST*” means a diagnostic aid for finding *M. tuberculosis* infection. The Mantoux method is the recommended method to be used for TST.

“*Tuberculosis*” or “*TB*” means the namesake member organism of *M. tuberculosis* complex and the most common causative infectious agent of TB disease in humans. In certain instances, the species name refers to the entire *M. tuberculosis* complex, which includes *M. bovis* and *M. african*, *M. microti*, *M. canetti*, *M. caprae*, and *M. pinnipedii*.

“*Tuberculosis disease*” or “*TB disease*” means a condition caused by infection with a member of the *M. tuberculosis* complex that has progressed to causing clinical (manifesting symptoms or signs) or subclinical (early stage of disease in which signs or symptoms are not present, but other indications of disease activity are present) illness.

“*Two-step tuberculin skin test*” or “*two-step TST*” means the procedure used for the baseline skin testing of persons who will receive serial TSTs to reduce the likelihood of mistaking a boosted reaction for a new infection.

481—59.3(135B) TB risk assessment.

59.3(1) Annually, a health care facility or hospital shall conduct a TB risk assessment to evaluate the risk for transmission of *M. tuberculosis*, regardless of whether a person with suspected or confirmed TB disease is expected to be encountered in the facility or hospital. The TB risk assessment shall be utilized to determine the types of administrative, environmental, and respiratory protection controls needed and serves as an ongoing evaluation tool of the quality of TB infection control and for the identification of needed improvements in infection control measures.

59.3(2) The TB risk assessment shall include:

- a. The community rate of TB,
- b. The number of persons with infectious TB encountered in the facility or hospital, and
- c. The speed with which persons with infectious TB disease are suspected, isolated, and evaluated to determine if persons with infectious TB exposed staff or others in the facility or hospital. TB cases include persons who had undiagnosed infectious pulmonary or laryngeal TB while in the facility or hospital during the preceding year. This does not include persons with LTBI (treated or untreated), persons with extrapulmonary TB disease, or persons with pulmonary and laryngeal TB that have met criteria for noninfectiousness.

481—59.4(135B) Health care facility or hospital risk classification. The infection control team or designated staff in a health care facility or hospital is responsible for determining the type of risk classification. The facility or hospital risk classification is used to determine frequency of TB

screening. The facility or hospital risk classification may change due to an increase or decrease in the number of TB cases during the preceding year. The following criteria are consistent with those of the Centers for Disease Control and Prevention (CDC), TB Elimination Division, as outlined in the MMWR December 30, 2005/Vol. 54/No. RR-17, “Guidelines for Preventing the Transmission of *Mycobacterium tuberculosis* in Health-Care Settings, 2005.”

59.4(1) Types of risk classifications.

a. “Low risk” means that a facility or hospital is one in which persons with active TB disease are not expected to be encountered and in which exposure to TB is unlikely.

b. “Medium risk” means that a facility or hospital is one in which health care workers will or might be exposed to persons with active TB disease or to clinical specimens that might contain *M. tuberculosis*.

c. “Potential ongoing transmission” means that a facility or hospital is one in which there is evidence of person-to-person transmission of *M. tuberculosis*. This classification is a temporary classification. If it is determined that this classification applies to a facility or hospital, the facility or hospital shall consult with the department of public health’s TB control program.

59.4(2) Classification criteria—low risk.

a. Inpatient settings with 200 beds or more: If a facility or hospital has fewer than six TB patients for the preceding year, the facility or hospital shall be classified as low risk.

b. Inpatient settings with fewer than 200 beds: If a facility or hospital has fewer than three TB patients for the preceding year, the facility or hospital shall be classified as low risk.

59.4(3) Classification criteria—medium risk.

a. Inpatient settings with 200 beds or more: If a facility or hospital has six or more TB patients for the preceding year, the facility or hospital shall be classified as medium risk.

b. Inpatient settings with fewer than 200 beds: If a facility or hospital has three or more TB patients for the preceding year, the facility or hospital shall be classified as medium risk.

59.4(4) Classification criteria—potential ongoing transmission. If evidence of ongoing *M. tuberculosis* transmission exists at a facility or hospital, the facility or hospital shall be classified as potential ongoing transmission, regardless of the facility’s or hospital’s previous classification.

481—59.5(135B) Baseline TB screening procedures for health care facilities and hospitals.

59.5(1) All HCWs shall receive baseline TB screening upon hire. Baseline TB screening consists of two components: (1) assessing for current symptoms of active TB disease and (2) using a two-step TST or a single IGRA to test for infection with *M. tuberculosis*.

59.5(2) An HCW may begin working with patients or residents after a negative TB symptom screen (i.e., no symptoms of active TB disease) and a negative TST (i.e., first step) or negative IGRA. The second TST may be performed after the HCW starts working with patients or residents.

59.5(3) An HCW with a new positive test result for *M. tuberculosis* infection (i.e., TST or IGRA) shall receive one chest radiograph result to exclude TB disease. Repeat radiographs are not needed unless symptoms or signs of TB disease develop or unless recommended by a clinician. Treatment for LTBI should be considered in accordance with CDC guidelines.

59.5(4) An HCW with documentation of past positive test results (i.e., TST or IGRA) and documentation of the results of a chest radiograph indicating no active disease, dated after the date of the positive TST or IGRA test result, does not need another chest radiograph at the time of hire.

59.5(5) TB, TST or IGRA tests for *M. tuberculosis* infection do not need to be performed for HCWs with a documented history of TB disease, documented previously positive test result for *M. tuberculosis* infection, or documented completion of treatment for LTBI or TB disease. Documentation of a previously positive test result for *M. tuberculosis* infection can be substituted for a baseline test result if the documentation includes a recorded TST result in millimeters or IGRA result, including the concentration of cytokine measured (e.g., interferon-gamma (IFN-g)). All other HCWs should undergo baseline testing for *M. tuberculosis* infection to ensure that the test result on record in the setting has been performed and measured using the recommended diagnostic procedures.

59.5(6) A second TST is not needed if the HCW has a documented TST result from any time during the previous 12 months. If a newly employed HCW has had a documented negative TST result within the

previous 12 months, a single TST can be administered in the new setting. This additional TST represents the second stage of two-step testing. The second test decreases the possibility that boosting on later testing will lead to incorrect suspicion of transmission of *M. tuberculosis* in the setting.

59.5(7) Previous BCG vaccination is not a contraindication to having an IGRA, a TST or two-step skin testing administered. HCWs with previous BCG vaccination should receive baseline and serial testing in the same manner as those without BCG vaccination. Evaluation of TST reactions in persons vaccinated with BCG should be interpreted using the same criteria for those not BCG-vaccinated. An HCW's history of BCG vaccination should be disregarded when administering and interpreting TST results. Prior BCG vaccination does not cause a false-positive IGRA test result.

481—59.6(135B) Serial TB screening procedures for health care facilities and hospitals.

59.6(1) *Health care facilities or hospitals classified as low risk.* After baseline testing of HCWs for infection with *M. tuberculosis*, additional TB screening of HCWs is not necessary unless an exposure to *M. tuberculosis* occurs.

59.6(2) *Health care facilities or hospitals classified as medium risk.*

a. After undergoing baseline testing for infection with *M. tuberculosis*, HCWs should receive TB screening annually (i.e., symptom screen for all HCWs and testing for infection with *M. tuberculosis* for HCWs with baseline negative test results).

b. HCWs with a baseline positive or new positive test result for *M. tuberculosis* infection or documentation of previous treatment for LTBI or TB disease shall receive one chest radiograph result to exclude TB disease. Instead of participating in serial testing, HCWs should receive a symptom screen annually. This screen should be accomplished by educating HCWs about symptoms of TB disease and instructing HCWs to report any such symptoms immediately to the occupational health unit. Treatment for LTBI should be considered in accordance with CDC guidelines.

59.6(3) *Health care facilities or hospitals classified as potential ongoing transmission.* Testing for infection with *M. tuberculosis* may need to be performed every eight to ten weeks until lapses in infection control have been corrected and no additional evidence of ongoing transmission is apparent. The potential ongoing transmission classification should be used only as a temporary classification. This classification warrants immediate investigation and corrective steps. After a determination that ongoing transmission has ceased, the setting shall be reclassified as medium risk for a minimum of one year.

481—59.7(135B) Screening of HCWs who transfer to other health care facilities or hospitals.

59.7(1) *HCWs transferring from a low-risk health care facility or hospital to another low-risk health care facility or hospital.* After a baseline result for infection with *M. tuberculosis* is established and documented, serial testing for *M. tuberculosis* infection is not necessary for HCWs transferring from a low-risk health care facility or hospital to another low-risk health care facility or hospital.

59.7(2) *HCWs transferring from a low-risk health care facility or hospital to medium-risk health care facility or hospital.* After a baseline result for infection with *M. tuberculosis* is established and documented, annual TB screening, including a symptom screen and TST or IGRA for persons with previously negative test results, should be performed for HCWs transferring from a low-risk health care facility or hospital to a medium-risk health care facility or hospital.

481—59.8(135B) Baseline TB screening procedures for residents of health care facilities.

59.8(1) TB screening is a formal procedure to evaluate residents for LTBI and TB disease. Baseline TB screening consists of two components: (1) assessing for current symptoms of active TB disease and (2) using two-step TST or a single IGRA to test for infection with *M. tuberculosis*.

59.8(2) All residents shall be assessed for current symptoms of active TB disease upon admission. Within 72 hours of a resident's admission, baseline TB testing for infection shall be initiated unless baseline TB testing occurred within three months prior to the resident's admission.

59.8(3) Residents with a new positive test result for *M. tuberculosis* infection (i.e., TST or IGRA) shall receive one chest radiograph result to exclude TB disease. Repeat radiographs are not needed unless symptoms or signs of TB disease develop or unless recommended by a clinician.

59.8(4) Residents with documentation of past positive test results (i.e., TST or IGRA) and documentation of the results of a chest radiograph indicating no active disease, dated after the date of the positive TST or IGRA test result, do not need another chest radiograph at the time of admission.

59.8(5) TB, TST or IGRA tests for *M. tuberculosis* infection do not need to be performed for residents with a documented history of TB disease, documented previously positive test result for *M. tuberculosis* infection, or documented completion of treatment for LTBI or TB disease. Documentation of a previously positive test result for *M. tuberculosis* infection can be substituted for a baseline test result if the documentation includes a recorded TST result in millimeters or IGRA result, including the concentration of cytokine measured (e.g., IFN-g). All other residents should undergo baseline testing for *M. tuberculosis* infection to ensure that the test result on record in the setting has been performed and measured using the recommended diagnostic procedures.

59.8(6) A second TST is not needed if the resident has a documented TST result from any time during the previous 12 months. If a new resident has had a documented negative TST result within the previous 12 months, a single TST can be administered in the new setting. This additional TST represents the second stage of two-step testing. The second test decreases the possibility that boosting on later testing will lead to incorrect suspicion of transmission of *M. tuberculosis* in the health care facility.

481—59.9(135B) Serial TB screening procedures for residents of health care facilities. After baseline TB screening is accomplished, serial TB screening of residents is not recommended.

481—59.10(135B) Performance of screening and testing. Any nurse licensed in Iowa and properly trained to screen for TB and perform TB testing may screen for TB and perform TB testing.

These rules are intended to implement Iowa Code section 135B.7.