DEPARTMENT OF PUBLIC HEALTH

NOTICE OF PROPOSED AMENDMENTS

1) Heading of the Part: Control of Tuberculosis Code

2) Code Citation: 77 Ill. Adm. Code 696

3) Section Numbers: Proposed Action:

696.100	Amendment
696.110	Amendment
696.130	Amendment
696.140	Amendment
696.150	Amendment
696.160	Amendment
696.170	Amendment
696.200	Amendment
696.APPENDIX A	Amendment
696.APPENDIX B	Amendment

4) Statutory Authority:

Implementing the Communicable Disease Report Act [745 ILCS 45] and implementing and authorized by the Department of Public Health Act [20 ILCS 2305].

5) A Complete Description of the Subjects and Issues Involved:

The current rules on tuberculosis (TB) cover the screening, treatment, testing, management and reporting requirements for persons with active or suspected of TB, having TB disease or latent TB infection (LTBI). The current rules require the use of the Mantoux tuberculin skin test (TST) as the only test approved for screening for LTBI. The proposed amendment will allow the use of a newly developed FDA-approved blood test for the detection of patients with active TB disease or LTBI. The proposed amendment only adds the use of the new FDA approved blood test as an approved test for screening patients and does not remove the TST as an approved test for screening.

The proposed rulemaking is needed because of the availability of the first test in over 100 years for persons with LTBI. This test can also be used as part of an evaluation for individuals with active or suspected of tuberculosis (TB) disease. In some testing situations, the FDA-approved blood test provides more specific, efficient and effective means of screening for LTBI or active TB disease. In particular, the current Mantoux skin test has false positive reactions because it cannot distinguish between persons who are infected with *M. tuberculosis* complex (MTB) and those either infected with other non-tuberculosis Mycobacterium (e.g., *M. avium* complex) or persons recently vaccinated

with the TB vaccine Bacillus of Calmette and Guerin (BCG), which is used in many countries where TB is an endemic disease (e.g., the new FDA blood test, Quantiferon® Gold test, does not cross react with *M. avium* or BCG).

6) Will this proposed amendment replace an emergency rule currently in effect? No

7) Does this rulemaking contain an automatic repeal date? No

8) Does this proposed amendment contain incorporations by reference? Yes

9) Are there any other proposed amendments pending on this Part? No

10) Statement of Statewide Policy Objectives:

This rulemaking does not create or expand any state mandates on units of local government.

11) Time, Place, and Manner in which interested persons may comment on this proposed rulemaking:

Written or e-mail comments may be submitted within 45 days after this issue of the Illinois Register to:

Susan Meister
Division of Legal Services
Illinois Department of Public Health
535 West Jefferson, Fifth Floor
Springfield, Illinois 62761
217-782-2043
(E-mail: rules@idph.state.il.us)

12) Initial Regulatory Flexibility Analysis:

A) Types of small businesses, small municipalities and not for profit corporations affected:

Hospitals, alcohol and drug treatment centers

B) Reporting, bookkeeping or other procedures required for compliance:

There are no new requirements for reporting, bookkeeping or other procedures required for compliance.

C) Types of Professional skills necessary for compliance:

None

13) Regulatory Agenda on which this rulemaking was summarized: July 2006

The full text of the Proposed Amendment(s) begins on the next page:

DEPARTMENT OF PUBLIC HEALTH

NOTICE OF PROPOSED AMENDMENTS

TITLE 77: PUBLIC HEALTH
CHAPTER I: DEPARTMENT OF PUBLIC HEALTH
SUBCHAPTER k: COMMUNICABLE DISEASE CONTROL AND IMMUNIZATIONS

PART 696
CONTROL OF TUBERCULOSIS CODE

SUBPART A: GENERAL PROVISIONS

Section
696.100 Definition of Terms
696.110 Incorporated Materials

SUBPART B: TUBERCULOSIS PREVENTION AND CONTROL MEASURES

Section
696.130 Responsibilities of High-Risk Congregate Settings and Programs Providing Alcohol and Drug Treatment
696.140 Screening for Tuberculosis Infection and Disease
696.150 Management of Persons with Tuberculosis Infection
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SUBPART C: ENFORCEMENT OF TUBERCULOSIS PREVENTION AND CONTROL MEASURES

Section
696.180 Role of the Department in Enforcement
696.190 Role of the Local Tuberculosis Control Authority in Enforcement
696.200 Types of Directives
696.210 Potential Recipients of Directives

696.APPENDIX A Mantoux Skin Testing Procedures
696.APPENDIX B Waivers for TB Screening Tests~~Mantoux Skin Testing Requirements~~
696.APPENDIX C Summary of the Interpretation of Tuberculin Skin Test Results

DEPARTMENT OF PUBLIC HEALTH

NOTICE OF PROPOSED AMENDMENTS

AUTHORITY: Implementing the Communicable Disease Report Act [745 ILCS 45] and implementing and authorized by the Department of Public Health Act [20 ILCS 2305].

SOURCE: Adopted at 22 Ill. Reg. 10870, effective June 5, 1998; amended at 30 Ill. Reg. _____, effective _____.

SUBPART A: GENERAL PROVISIONS

Section 696.100 Definition of Terms

For the purpose of this Part, the following shall be the accepted definitions of the terms used herein:

"Anergy" means the absence of a reaction to skin test antigens, such as tuberculin (when the person is infected with the organism tested) because of immunosuppression. The absence of a reaction to the tuberculin skin test does not rule out the diagnosis of tuberculosis (TB) infection or disease. Anergy may be caused by many factors, such as HIV infection, overwhelming miliary or pulmonary TB, severe or febrile illness, measles or other viral infections, Hodgkin's disease, sarcoidosis, live virus vaccination, and the administration of corticosteroids or immunosuppressive drugs.

"Bacteriologic Examinations" means tests done in a mycobacteriology laboratory to diagnose TB disease, including smears for acid-fast bacilli (AFB), cultures and other tests for Mycobacterium (M.) tuberculosis, and drug susceptibility tests.

"BCG Vaccine" means a TB vaccine used in many parts of the world.

"Checklist of Signs and Symptoms of TB Disease" means a list that includes the following signs and symptoms: pulmonary – productive prolonged cough, chest pain, hemoptysis; generalized – fever, chills, night sweats, easy fatigability, loss of appetite and weight loss.

"Close Contacts" means those sharing the same household or other enclosed environments of persons known or suspected to have TB.

"Confirmed Case" means an occurrence of TB disease that is laboratory confirmed or, in the absence of laboratory confirmation, an occurrence that meets the clinical case definition.

Laboratory confirmation – Laboratory criteria for diagnosis includes isolation of M. tuberculosis from a clinical specimen; demonstration of M. tuberculosis from a clinical specimen by DNA probe or mycolic acid pattern on high-pressure liquid chromatography; or demonstration of acid-fast bacilli in a clinical specimen when a culture has not been or cannot be obtained.

Clinical case definition – A clinical case meets all the following criteria: a positive TB screening test ~~Mantoux tuberculin skin test (Mantoux skin test)~~; other signs and symptoms compatible with TB, such as an abnormal, unstable (worsening or improving) chest radiograph, or clinical evidence of current disease; treatment with two or more anti-tuberculosis medications; and completed diagnostic evaluation.

"Department" means the Illinois Department of Public Health.

"Diagnostic Evaluation" means a process used to diagnose TB disease, which includes a physical examination, medical history, TB screening test~~Mantoux skin test~~, chest radiograph and bacteriologic examinations.

"Directly Observed Therapy (DOT)" means a process by which a trained healthcare worker or other designated trained person watches the patient swallow each dose of TB medication. Family members are generally not recommended to provide DOT.

"Directly Observed Preventive Therapy (DOPT)" means a process by which a trained healthcare worker or other designated trained person watches the patient swallow each dose of preventive TB medication. Family members are generally not recommended to provide DOPT.

"Employee" means a full-time, part-time or temporary worker who receives compensation. (See definition of "Volunteer".)

"Facility" means any organization or unit of an organization.

"Healthcare Facility" means a hospital, medical ward in a correctional facility, nursing home or hospice. (See definition of "Other Healthcare Setting".)

"Healthcare Worker" means an employee or volunteer in a healthcare facility who has the potential for exposure to M. tuberculosis. Healthcare workers may include, but are not limited to, physicians, nurses, aides, dental workers, technicians, workers in laboratories and morgues, emergency medical service personnel, part-time personnel, temporary staff (such as students) not employed by the healthcare facility, and persons who are not involved directly in patient care but who are potentially at risk for occupational exposure to M. tuberculosis (e.g., volunteers, or dietary, housekeeping, maintenance, clerical, and janitorial staff).

"High-Risk Congregate Setting" means, but is not limited to, detention centers, in-patient healthcare facilities, nursing homes and other long-term care facilities for the elderly, mental health facilities, licensed supportive residences for HIV-infected persons, shelters for the homeless, other long-term residential facilities and programs that treat persons who inject non-prescribed drugs or other substance users in locally identified high-risk groups (e.g., crack cocaine users).

> Other long-term care facilities include facilities that care for the developmentally disabled, are designed for retirees, or others, and that are considered high-risk congregate settings according to a risk assessment performed in cooperation with the local TB control authority.

"High-Risk for Nonadherence to a Prescribed Treatment Regimen" means any person who has a history of treatment nonadherence; whose treatment has failed or disease has relapsed; who uses alcohol or controlled substances; who has mental, emotional, or physical impairments that interfere with the ability to self-administer medications; or who is a child or adolescent.

"High-Risk Groups" means the following categories of people who should be screened for TB infection because of an increased probability of becoming infected with TB, and/or who, once infected, have increased probability of

progressing to TB disease:

close contacts;

persons who inject non-prescribed drugs or other substance users in locally identified high-risk groups (e.g., crack cocaine users);

persons who have medical risk factors known to increase the risk for disease if infection occurs. Medical risk factors means the following conditions: infection with HIV/AIDS; diabetes mellitus; conditions requiring prolonged high-dose corticosteroid therapy and other immunosuppressive therapy (including bone marrow and organ transplantation); chronic renal failure; some hematologic disorders (e.g., leukemias and lymphomas); other specific malignancies (carcinoma of the head or neck); body weight of 10% or more below ideal body weight; silicosis; gastrectomy; jejunoileal bypass; abnormal chest radiographs showing fibrotic lesions consistent with healed TB; and abnormal chest radiographs showing parenchymal lung scarring in persons with a positive TB screening test ~~skin test~~ who have not previously received TB treatment or preventive therapy;

clients, employees and volunteers of high-risk congregate settings;

healthcare workers who serve clients in high-risk groups;

foreign-born persons, including children, who have arrived within the past five ~~5~~ years from countries that have a high TB incidence or prevalence;

groups defined locally as high-risk (e.g., some medically underserved low-income populations and some racial or ethnic minority populations);

Infants, children and adolescents exposed to adults in high-risk categories.

"Infection" means the condition in which organisms (e.g., M. tuberculosis) capable of causing disease enter the body and elicit a response from the host's immune defenses. TB infection may or may not progress to clinical disease.

"Infectious" means a person who has, or is suspected of having, pulmonary or laryngeal TB and who:

coughs, is undergoing cough-inducing or aerosol-generating procedures, or has sputum smears that contain acid-fast bacilli (AFB) ~~AFB~~; and

is not receiving treatment, has just begun treatment, or has a poor clinical or bacteriologic response to treatment. A person on treatment for one month or less is considered to have just begun treatment. A poor clinical response to treatment can be suggested by a failure of signs and symptoms to improve after two months of treatment. A poor bacteriologic response to treatment can be suggested by a failure of AFB on smear to decrease after two weeks of treatment.

"Intermittent Therapy" means therapy administered either two ~~2~~ or three ~~3~~ times per week, rather than each day.

"Isolation" means the separation of a person with suspected or confirmed tuberculosis disease from other persons using universally ~~-~~accepted techniques that effectively prevent transmission of M. tuberculosis during that person's period of communicability.

"Isolation Rooms" means rooms with special characteristics, including negative-pressure ventilation, to prevent the spread of droplet nuclei expelled by a TB patient.

"Likely to Become Infectious" means a person whose treatment has failed; whose disease has relapsed; who does not consistently adhere to or complete a prescribed treatment regimen; who has received inadequate treatment; or who has drug-resistant disease.

"Local TB Control Authority" means the agency at the local level recognized by the Department as having jurisdiction over the prevention and control of tuberculosis. The local TB control authority may be an autonomous TB board or a TB program within a local health department.

"Long-Term Inmate" means an inmate who will remain in custody for a period of

14 days or longer.

"Mantoux Tuberculin Skin Test or Mantoux Skin Test" means a method of skin testing that is performed by injecting 0.1 mL of purified protein derivative (PPD) tuberculin containing five tuberculin units into the dermis of the forearm with a needle and syringe.

"Negative Cultures" means cultures that contain no detectable tubercle bacilli.

"Nonadherence" means not following the recommended course of treatment or therapy by not taking all the medications in the manner prescribed for the entire length of time.

"Not Infectious" means a person previously determined to be infectious who now meets the following criteria:

received a treatment regimen for two or more weeks composed of multiple drugs to which the organisms are susceptible in accordance with the incorporated publication, Treatment of TB and TB Infection;

has favorable clinical response to treatment; and

has three ~~3~~ consecutive negative sputum smear results from sputum collected on different days.

"OSHA" means the U.S. Department of Labor, Occupational Safety and Health Administration.

"Other Healthcare Setting" means an ambulatory care facility, emergency department, home healthcare setting, emergency medical services, medical and dental office or any location where medical care is provided. (See definition of "Healthcare Facility".)

"Past or Present Behavior that Indicates a Substantial Likelihood of Not Cooperating with Prevention and Control Measures" means, but is not limited to:

refusal or failure to keep appointments for diagnosis or treatment;

refusal or failure to consistently adhere to and complete a prescribed preventive therapy or disease treatment regimen;

refusal or failure to participate in DOPT or DOT;

disregard for isolation procedures;

leaving the hospital against medical advice; or

inability or unwillingness to voluntarily use prevention and control measures.

"Preventive Therapy" means treatment of TB infection to prevent the progression to clinically active disease.

"Relapse" means the return of TB disease after a partial recovery from disease.

"Short-Term Inmate" means an inmate who remains in custody for less than 14 days, especially pretrial detainees likely to be released without supervision or placed in the community under court supervision.

"Suspected Case" means an occurrence that is being considered as TB disease while diagnostic procedures are being completed, whether or not treatment has been started.

"TB Screening Test" means a federal Food and Drug Administration (FDA) approved screening test to detect latent TB Infection. Examples of screening tests include, but are not limited to, the Mantoux tuberculin skin test and whole blood interferon-gamma release assays.

"Treatment Failure" means TB disease in patients who do not respond to chemotherapy and whose disease worsens after having improved initially.

"Volunteer" means a person who, for a period of time, provides services of his or her own free will with no promise of compensation. (See definition of "employee".)

(Source: Amended at 30 Ill. Reg. _____, effective _____)

Section 696.110 Incorporated Materials

a) The following materials are incorporated by reference in this Part:

1) "Prevention and Control of Tuberculosis in Correctional and Detention Facilities: Recommendations from CDC - U.S. Department of Health and Human Services, Coordinating Center for Health Information and Service, Centers for Disease Control and Prevention, Atlanta, GA 30333 (Morbidity and Mortality Weekly Report (MMWR) 2006; 55 (No. RR-09, 1-44)~~"Controlling TB in Correctional Facilities", U.S. Department of Health and Human Services, Public Health Service, Centers for Disease Control and Prevention, Atlanta, Georgia 30333 (1995).~~

2) "Core Curriculum on Tuberculosis, What the Clinician Should Know" (Core Curriculum), U.S. Department of Health and Human Services, Public Health Service, Centers for Disease Control and Prevention, Atlanta, Georgia 30333, (1994).

3) "Guidelines for Preventing the Transmission of Mycobacterium tuberculosis in Health-Care Settings, 2005" (Guidelines for Health-Care Settings), U.S. Department of Health and Human Services, Coordinating Center for Health Information and Service, Centers for Disease Control and Prevention, Atlanta, GA 30333 (Morbidity and Mortality Weekly Report (MMWR) 2005;54(No. RR-17)). ~~"Guidelines for Preventing the Transmission of *Mycobacterium tuberculosis* in Health-Care Facilities, 1994" (Guidelines for Healthcare Facilities), U.S. Department of Health and Human Services, Public Health Service, Centers for Disease Control and Prevention, Atlanta, Georgia 30333 (Morbidity and Mortality Weekly Report (MMWR) 1994;43(No. RR-13)).~~

4) ”OSHA Instruction CPL.106, February 9, 1996" (OSHA Instruction).

5) "Prevention and Control of Tuberculosis in Correctional Facilities", U.S. Department of Health and Human Services, Public Health Service, Centers for Disease Control and Prevention, Atlanta, Georgia 30333 (Morbidity and Mortality Weekly Report (MMWR) 1996;45(No. RR-8)).

6) ”The Role of BCG Vaccine in the Prevention and Control of Tuberculosis in the United States@ (The Role of BCG Vaccine), U.S. Department of Health and Human Services, Public Health Service, Centers for Disease Control and Prevention, Atlanta, Georgia 30333 (Morbidity and Mortality Weekly Report (MMWR) 1996;45(No. RR-4)).

7) "Screening for Tuberculosis and Tuberculosis Infection in High-risk Populations" (Screening High-risk Populations), U.S. Department of Health and Human Services, Public Health Service, Centers for Disease Control and Prevention, Atlanta, Georgia 30333, HHS Publication No. (CDC) 95-8017 (1995).

8) "Treatment of Tuberculosis and Tuberculosis Infection in Adults and Children" (Treatment of TB and TB Infection), American Thoracic Society, Medical Section of the American Lung Association, New York, New York 10006, U.S. G.P.O.:1994-533-001:501.

9) "Guidelines for Using the QuantiFERON®-TB Gold Test for Detecting Mycobacterium tuberculosis Infection, United States" (Guidelines for QuantiFERON®-TB Gold), U.S. Department of Health and Human Services, Coordinating Center for Health Information and Service, Centers for Disease Control and Prevention, Atlanta, GA 30333 (Morbidity and Mortality Weekly Report (MMWR) 2005;54(No. RR-15):49-55).

b) All incorporations by reference of guidelines of federal agencies and the standards of nationally recognized organizations refer to the guidelines and standards on the date specified and do not include any amendments or editions ~~additions or deletions~~ subsequent to the date specified.

(Source: Amended at 30 Ill. Reg. _____, effective _____)

SUBPART B: TUBERCULOSIS PREVENTION AND CONTROL MEASURES

Section 696.130 Responsibilities of High-Risk Congregate Settings and Programs Providing Alcohol and Drug Treatment

a) Written Plans. A written plan shall be developed that includes protocols for the screening and management of infection among employees, volunteers and clients; protocols for the screening, diagnosis and management of TB disease among employees, volunteers and clients; data collection; evaluation of data; reporting of persons with signs or symptoms of TB to the local TB control authority; and an employee and volunteer education program. All components of the plan shall reflect compliance with this Part. The plan shall include the: name of the person or persons responsible for the TB prevention and control program at each facility; procedures for the purpose of protecting employees, volunteers and clients from contracting tuberculosis; and a referral mechanism to ensure prevention of transmission and completion of treatment for clients with TB who leave the facility. The written plan shall be updated at least annually. (See the incorporated publications, Guidelines for Health-Care Settings ~~Healthcare Facilities~~ and the OSHA Instruction.)

b) TB Prevention and Control Program. A program shall be executed in accordance with the written plan.

c) Employee and Volunteer Education. Training about TB shall be provided or arranged. All employees and volunteers shall be trained upon hiring and periodically thereafter to ensure employee knowledge equivalent to the employee's work responsibilities and the level of risk in the facility. OSHA-regulated settings and programs shall comply with the incorporated publications, OSHA Instruction. (See the incorporated publications, Core Curriculum and Controlling TB in Correctional Facilities.)

d) Collaboration. The settings and programs listed above shall consult with the local TB control authority, as necessary, to determine their respective responsibilities in the screening, diagnosis and management of TB infection and disease, reporting of disease, and the education of employees and volunteers.

e) Records. Records shall be maintained on TB screening test results~~Mantoux skin~~

~~test results~~; TB diagnostic evaluation results (including whether the tuberculosis was drug-resistant); other information about any persons exposed to tuberculosis; and the current written plan as required in subsection (a) of this Section. Individual and aggregate data should be analyzed periodically to identify the facility's level of risk and changes in the risk of TB transmission. Correctional facilities should maintain a retrievable aggregate record system in accordance with the incorporated publication, Prevention and Control of Tuberculosis in Correctional Facilities. All records required in this subsection shall be made available for inspection by the Department or the local TB authority upon request.

(Source: Amended at 30 Ill. Reg. _____, effective _____)

Section 696.140 Screening for Tuberculosis Infection and Disease

The TB screening test ~~Mantoux skin test~~ shall be used when screening persons for infection. (See Appendices A, B, and C of this Part.) Chest radiographs and bacteriologic examinations can be used when screening certain persons for disease. (See subsection (b)(2) of this Section.) Persons who have signs and symptoms of disease, a positive TB screening test results ~~skin test or other positive screening test results~~ shall have additional diagnostic tests as recommended in the incorporated publications Treatment of TB and TB Infection and Guidelines for Health-Care Settings ~~Healthcare Facilities~~.

a) Screening for TB Infection. Persons in high-risk groups should be screened for tuberculosis. Local health department clients who are in high-risk groups should be screened and records maintained of TB screening~~Mantoux skin~~ test results. These screening requirements can be modified or waived in accordance with Appendix B of this Part. In addition:

1) Close Contacts. Persons who are close contacts to suspected or confirmed cases of TB disease shall be tested with a TB screening~~the Mantoux skin~~ test to identify infection. Close contacts shall be retested three ~~3~~ months after the last exposure if their reaction to the first TB screening ~~skin~~ test was negative. A high priority should be given to evaluating contacts who are children or contacts infected with HIV/AIDS.

2) Employees, Volunteers and Clients of High-Risk Congregate Settings and Programs Providing Alcohol and Drug Treatment. Screening shall be

done in accordance with this subsection, Appendices A, B, and C, and the following incorporated publications: Screening High-Risk Populations; Guidelines for Health-Care Settings~~Healthcare Facilities~~; Prevention and Control of Tuberculosis in Correctional Facilities; and the OSHA Instruction.

A) All employees and volunteers in high-risk congregate settings and programs providing alcohol and drug treatment shall obtain a TB screening~~Mantoux skin~~ test within seven ~~7~~ days after being employed. If Mantoux skin testing is used, two-step testing should be done. Employees and volunteers who are part of a routine, periodic screening program shall initially be screened by TB screening tests.~~two-step testing. Routine, periodic screening of employees and volunteers should be determined by a risk assessment performed in cooperation with the local TB control authority. Persons who are not part of a routine, periodic screening program may be screened by a single Mantoux skin~~ test.

B) All clients in high-risk congregate settings and clients in high-risk groups in programs providing alcohol and drug treatment shall obtain a TB screening~~Mantoux skin~~ test within seven ~~7~~ days after admission. If Mantoux skin testing is used, two-step testing should be done. ~~All clients who are part of a routine, periodic screening program should be initially screened by two-step testing. Routine, periodic screening of clients should be determined by a risk assessment performed in cooperation with the local TB control authority. Persons who are not part of a routine, periodic screening program may be screened by a single Mantoux skin test.~~ In addition:

i) Nursing home residents, persons who inject non-prescribed drugs and other substance users in locally identified high-risk groups (e.g., crack cocaine users) in treatment programs, and clients of programs providing methadone maintenance therapy shall obtain a TB screening test ~~be screened with the first Mantoux skin test of a two-step test~~ within seven ~~7~~ days after admission. If Mantoux skin

testing is used, two-step testing shall be done.

ii) Routine, periodic screening of the homeless should be done when feasible. (See subsection (b) of this Section.)

iii) Long-term inmates in detention centers shall obtain a TB screening test ~~Mantoux skin test~~ within seven ~~7~~ days after admission. If Mantoux skin testing is used, two~~Two~~-step testing should be done when feasible. Routine, periodic screening of long-term inmates should be done. Short-term inmates in detention centers should obtain a Mantoux skin test or another TB screening test within seven ~~7~~ days after admission, when feasible. Regardless of TB screening ~~skin~~ test results, inmates who have HIV infection and those at risk for HIV infection but whose HIV status is unknown should have a chest radiograph as part of the initial screening. (See subsection (b) of this Section for requirements for screening short-term and long-term inmates for disease.) Inmates of detention centers shall be screened in accordance with the ~~following incorporated~~ publications incorporated herein. ~~: Prevention and Control of Tuberculosis in Correctional Facilities and Screening High-Risk Populations.~~

3) Employees, Volunteers and Clients of Other Healthcare Settings. Other healthcare settings should conduct screening programs based upon a risk assessment performed in cooperation with the local TB control authority. Screening programs should be conducted in accordance with the following incorporated publications: Guidelines for Health-Care Settings~~Healthcare Facilities~~ and Screening High-Risk Populations.

4) Employees, Volunteers and Students in a School (Pupil Attendance Center) or School District.

A) Initial screening ~~skin testing~~ of employees and volunteers in a school or a school district shall be performed using~~by~~ a TB screening ~~Mantoux skin~~ test within seven ~~7~~ days after beginning

employment. This requirement can be modified or waived in accordance with Appendix B of this Part.

B) When a community, school, or school district has a higher than expected prevalence of TB infection, the local TB control authority or the Department may institute routine, periodic skin testing of school employees, volunteers and students. Any such testing program should take into consideration:

i) epidemiologic factors and currently accepted public health standards pertaining to the prevention and control of TB; and

ii) the identification and availability of necessary school, school district and local TB control authority resources and facilities.

5) Day Care Center Employees and Volunteers. Day care center employees and volunteers shall obtain a TB screening test ~~the first Mantoux skin test of a two-step test~~ within seven ~~7~~ days after being employed. If Mantoux skin testing is used, two-step testing shall be done. Routine, periodic screening of employees and volunteers should be determined by a risk assessment performed in cooperation with the local TB control authority.

b) Screening for TB Disease.

1) Checklist of Signs and Symptoms. A checklist that includes but is not limited to pulmonary symptoms (productive prolonged cough, chest pain, hemoptysis) and generalized signs and symptoms (fever, chills, night sweats, easy fatigability, loss of appetite and weight loss) shall be used to screen for TB disease in the following circumstances:

A) Persons with a documented ~~prior~~ positive TB screening test result, ~~Mantoux skin test~~ who are required to receive ~~a skin test or skin~~ TB screening tests routinely and periodically shall, instead of receiving such screening tests~~a skin test~~, complete a signs and symptoms checklist. A checklist takes the place of a TB screening

~~skin~~ test for these persons. Repeat screening tests~~skin testing~~ are ~~is~~ not needed or required. Routine, periodic chest radiographs should not be done. Chest radiographs do not take the place of a TB screening ~~skin~~ test or checklist.

B) Clients admitted to high-risk congregate settings and programs providing alcohol and drug treatment shall be screened for current disease status with a signs and symptoms checklist in addition to meeting other screening requirements for infection.

2) Chest Radiography or Bacteriologic Examinations. The use of chest radiography or bacteriologic examinations should be considered in certain instances in addition to a signs and symptoms checklist.

A) Chest radiography may be the best screening method in jails, homeless shelters, and single-room-occupancy facilities that house the homeless for more than one night. Also, inmates who either have HIV infection or are at risk for HIV infection, but whose HIV status is unknown, should receive a chest radiograph as part of the initial screening, regardless of TB screening ~~skin~~ test results.

B) Screening for disease among the homeless may also include sputum smears and cultures.

(Source: Amended at 30 Ill. Reg. _____, effective _____)

Section 696.150 Management of Persons with Tuberculosis Infection

a) Preventive Therapy. Before therapy is started, persons with a positive TB screening test result ~~skin test reaction~~ shall receive a diagnostic evaluation for TB disease. See Appendix C for information on how to interpret skin test results. If there is no evidence of disease, persons with TB infection should be considered for preventive therapy. Preventive therapy shall be conducted in accordance with the incorporated publication, Treatment of TB and TB Infection.

1) The following persons with positive TB screening test results ~~skin tests~~ should be considered for preventive therapy regardless of age:

A) Persons with HIV/AIDS and persons with risk factors for HIV/AIDS whose HIV infection status is unknown;

B) Close contacts of persons with newly diagnosed infectious tuberculosis;

C) Recent tuberculin skin test converters (equal to or greater than a 10 mm increase within a two-year period for persons younger than 35 years of age; equal to or greater than a 15 mm increase for persons 35 years of age or older);

D) All infants and children younger than four ~~4~~ years of age with a skin test reaction equal to or greater than 10 mm;

E) Persons with medical risk factors that may increase the risk of tuberculosis (e.g., diabetes mellitus, prolonged therapy with adrenocorticosteroids, immunosuppressive therapy, some hematologic and reticuloendothelial diseases such as leukemia or Hodgkin's disease), injection drug users known to be HIV-seronegative, end-stage renal disease, and clinical situations associated with substantial rapid weight loss or chronic undernutrition;

F) ~~Tuberculin-positive~~ Adults ~~adults~~ with positive results from a TB screening test with abnormal chest radiographs that show fibrotic lesions likely representative of old healed tuberculosis and adults diagnosed with silicosis. These persons should usually receive 4-month multiple-drug chemotherapy. Alternatively, such persons may receive 12 months of isoniazid preventive therapy.

G) Persons converting from a negative to a positive TB screening test result, other than a Mantoux skin test.

2) In the absence of risk factors listed in subsections (a)(1)(A) through (G) ~~(E)~~ of this Section, the following persons younger than 35 years of age with a positive TB screening test result ~~skin tests~~ should be considered for

preventive therapy:

A) Foreign-born persons from high-prevalence countries including those in Latin America, Asia, and Africa;

B) Medically underserved low-income populations, including high-risk racial or ethnic minority populations, especially blacks, Hispanics and Native Americans;

C) Residents of high-risk congregate settings; and

D) Persons with no risk factors.

3) The following persons with a negative TB screening test result ~~skin tests~~ should be considered for preventive therapy:

A) Children who have been close contacts to infectious cases within the last three months. If the TB screening test ~~skin test~~ remains negative after 12 weeks and there has been no continued exposure, preventive therapy need not be continued; and

B) Anergic HIV-infected adults.

4) ~~Positive Skin Test Reaction in Persons in High-Risk Groups.~~ All persons in high-risk groups, with a positive TB screening test result, should be considered for preventive therapy. (See Appendix C and the incorporated publications, Screening High-Risk Populations and Treatment of TB and TB Infection.)

b) BCG Vaccine and Preventive Therapy. A diagnosis of TB infection and the use of preventive therapy should be considered for any BCG-vaccinated person with a positive TB screening test result~~Mantoux skin test reaction~~. (See the incorporated publication, The Role of BCG Vaccine.)

c) Directly Observed Preventive Therapy (DOPT). In settings where DOPT can be given by a responsible and trained employee or volunteer, twice-a-week DOPT should be considered. DOPT should especially be considered for persons who are

at high-risk for TB disease, or at high-risk of nonadherence to preventive therapy.

d) Monitoring for Adverse Reactions. At a minimum, patients should be seen monthly during therapy and evaluated for adverse drug reactions.

(Source: Amended at 30 Ill. Reg. _____, effective _____)

Section 696.160 Diagnosis and Management of Persons with Suspected or Confirmed Tuberculosis Disease

a) Diagnostic Evaluation. The evaluation of persons with suspected or confirmed TB disease shall include but not be limited to:

1) Medical History;

2) Physical Examination;

3) TB Screening Test~~Mantoux Skin Test~~;

4) Chest Radiograph; and

5) Bacteriologic Examinations on Available Specimens (e.g., smears, cultures and other tests for M. tuberculosis, and drug susceptibility tests).

Agency note: TB is sometimes overlooked in the differential diagnosis of pulmonary conditions (e.g., pneumonia), especially in the elderly.

b) Clinical Management of Persons with Suspected or Confirmed TB Disease.

1) Infection Control Measures. If infectious TB disease is suspected, precautions shall be taken to prevent transmission in accordance with the incorporated publications: Guidelines for Health-Care Settings ~~Healthcare Facilities~~ and OSHA Instruction.

A) In settings that serve infectious TB patients, precautions that shall be implemented include early identification and isolation of patients with suspected or confirmed TB disease. Infection control

measures shall be maintained until it is determined that the patient is not infectious.

i) Precautions shall include the use of ventilation systems in TB isolation rooms to maintain negative pressure and to exhaust air in such a manner to prevent transmission of M. tuberculosis.

ii) Personal respirators that meet the requirements in the incorporated publication, OSHA Instruction, shall be used by workers in areas (e.g., TB isolation rooms, rooms where cough--inducing procedures are done) where exposure cannot be avoided or there is an increased risk of exposure. Patients may be masked with a surgical mask if they must leave the isolation room while they are infectious and coughing.

iii) In in-patient settings, continuous isolation should be considered for patients with multiple drug-resistant TB.

B) Infectious TB patients may be confined to their homes in order to prevent transmission of disease. Personal respirators that meet the requirements in the incorporated publication, OSHA Instruction, shall be used by workers when in the homes of patients with infectious TB and when transporting infectious patients.

C) Once determined to be infectious, a person is considered infectious until medically determined to be not infectious and likely not to become infectious again, as evidenced by compliance with a multiple-drug treatment regimen to which the organisms are susceptible. When a consensus cannot be reached concerning the infectious or not infectious status of a suspected or confirmed case of TB, a final decision of infectiousness will be made only by the Department.

2) Treatment of Suspected or Confirmed TB Disease. Suspected or confirmed TB disease shall be treated with multiple drugs in accordance

with the incorporated publication, Treatment of TB and TB Infection. Agency Note: TB disease in infants and children younger than four years of age and in immunosuppressed individuals (such as HIV/AIDS patients) is more likely to spread throughout the body and progress rapidly with severe consequences; prompt and vigorous treatment is appropriate as soon as TB is suspected.

A) Directly Observed Therapy (DOT). Treatment of all patients with TB should be conducted by DOT.

B) Monitoring for Response to Antituberculosis Chemotherapy. Persons with M. tuberculosis identified in sputum shall be monitored by sputum smears and cultures until conversion is documented. Drug susceptibility testing shall be done initially on culture positive specimens.

i) Sputum smears should be repeated until three ~~3~~ consecutive negative sputum smear results are obtained from sputum collected on different days.

ii) Sputum cultures should be monitored at least monthly until negative cultures are obtained. Patients whose cultures have not become negative or whose symptoms do not resolve after two months of therapy shall be reevaluated for drug-resistant disease, as well as for failure to adhere to the regimen. For patients receiving self-administered therapy, the remainder of treatment should be directly observed.

iii) In patients with multiple drug-resistant disease, sputum cultures should be monitored monthly for the entire course of treatment.

C) Monitoring for Adverse Reactions. Adults treated for TB disease should have baseline tests to detect any abnormality that would complicate treatment or require a modified regimen. Baseline tests, except visual acuity, are unnecessary in children unless a complicating condition is known or clinically suspected. At a

minimum, patients should be seen monthly during treatment and evaluated for adverse reactions. If symptoms suggesting drug toxicity occur, then appropriate laboratory testing should be performed to confirm or exclude such toxicity. (See the incorporated publication, Treatment of TB and TB Infection.)

c) Contact Investigation. Close contacts to suspected or confirmed cases of TB disease shall obtain a TB screening test ~~be tested with a Mantoux skin test~~ to identify infection. Close contacts shall be retested three ~~3~~ months after the last exposure if their reaction to the first TB screening test ~~skin test~~ was negative. A high priority should be given to evaluating contacts who are children or contacts infected with HIV/AIDS. (See Section 696.150(a)(3) for information regarding preventive therapy.)

(Source: Amended at 30 Ill. Reg. _____, effective _____)

Section 696.170 Reporting

Health professionals listed in subsection (a)(1) shall report suspected and confirmed cases of TB to the local TB control authority or, in the absence of a local TB control authority, to the TB Control Section of the Department. The local TB control authority shall report to the Department.

a) Reports to the Local TB Control Authority.

1) Health Professionals Required to Report. Reports shall be made by physicians, physician assistants, nurses, dentists, laboratory personnel and the health coordinator of settings serving high-risk groups to the local TB control authority or, in the absence of a local TB control authority, to the TB Control Section of the Department.

~~3)~~2) Report Forms and Transmission of Reports. Reports of suspected and confirmed cases of TB shall be made on forms available from the local TB control authority or the Department. To facilitate prompt reporting, telephone or facsimile reports are acceptable if followed by a written report sent through the mail.

3) Reports of Suspected and Confirmed Cases of TB. Persons required to report under subsection (a)(1) of this Section (except for laboratory personnel) shall, within seven ~~7~~ calendar days after the diagnosis of a suspected or confirmed case of TB, notify the local TB control authority of the following:

A) Diagnosis. Information shall be provided about the diagnosis of a suspected or confirmed case of TB, including the dates and results of TB screening tests (Mantoux skin test results shall be recorded in millimeters) ~~in millimeters of Mantoux skin~~ and the results of bacteriologic examinations and chest radiographs. When an apparent occurrence of TB does not have laboratory confirmation or meet the clinical case definition, the local TB control authority should consult with the Department.

B) Clinical Management Information. Information shall be provided about the clinical management of a suspected or confirmed case of TB, including the determination of the infectious or not infectious status, isolation precautions taken, treatment regimen, whether the client is at high-risk for nonadherence to a prescribed treatment regimen, and past or present behavior that indicates a substantial likelihood of not cooperating with prevention and control measures.

C) Surveillance Information. Reportable demographic and locating information regarding the suspected or confirmed case of TB should include the name, address, date of birth, gender, race, ethnic origin, country of origin, month and year the person arrived in the United States (if applicable), non-prescribed drug use and excess alcohol use within the year before the date of submission, occupation, address changes, names and addresses of close contacts, and other information required to complete the tuberculosis reporting form of the Department and the Centers for Disease Control and Prevention, the Report of Verified Case of TB (RVCT) form.

D) Other Information. Any other relevant information requested by the local TB control authority or the Department should be provided. Such information may include hospital discharge plans for out-patient follow-up and locating information for persons with TB infection.

b) Reports to the Department from Local TB Control Authorities. Local TB control authorities shall report to the Department on the diagnosis, clinical management and surveillance of suspected and confirmed cases of TB and the investigation of contacts, as follows. The local TB control authority shall make their records available for inspection by the Department when requested in order to carry out the provisions of this Part.

1) Reports of Suspected or Confirmed Cases of TB. Within seven ~~7~~ calendar days after a local TB control authority's receipt of a report of a suspected or confirmed case of TB, the Department shall receive available information on a RVCT form.

2) Reports Due Within 30 Calendar Days After the Department's Request for Information. The Department shall be notified of the status of drug susceptibility test results, contact investigation information, case completion of therapy and other relevant information within 30 calendar days after the Department's request for information.

c) Reports from Laboratories. Within one calendar day after obtaining results, laboratories shall report to the person who requested the test, to the local TB control authority and to the Department smears positive for acid-fast bacilli, cultures or other tests positive for *M. tuberculosis*, and drug susceptibility test results.

d) Confidentiality

1) It is the policy of the Department to maintain the confidentiality of information that would identify individual patients.

2) *Whenever any statute of this state of any ordinance or resolution of a municipal corporation or political subdivision enacted pursuant to statute*

or any rule of an administrative agency adopted pursuant to statute requires medical practitioners or other persons to report cases of tuberculosis to any governmental agency or officer, such reports shall be confidential and any medical practitioner or other person making such report in good faith shall be immune from suit or slander or libel based upon any statements contained in such report. The identity of any individual contained in the report of tuberculosis or an investigation conducted pursuant to a report of tuberculosis shall be confidential and such identity shall not be disclosed publicly in an action of any kind in court or before any tribunal, board or agency, (Communicable Disease Report Act [745 ILCS 45]).

(Source: Amended at 30 Ill. Reg. _____, effective _____)

Section 696.200 Types of Directives

a) Initiation or Completion of the Diagnostic Evaluation. This directive requires the initiation or completion of the diagnostic evaluation for TB infection or disease in accordance with the following incorporated publication: Guidelines for Healthcare Facilities. The diagnostic evaluation may include, but is not limited to, a medical history, physical examination, TB screening test ~~Mantoux skin test~~, chest radiograph and bacteriologic examinations.

b) Preventive Therapy or Disease Treatment. This directive requires completion of a prescribed course of preventive therapy for TB infection or a prescribed course of treatment for TB disease, and bacteriologic or other tests needed to monitor response to treatment or adverse reactions in accordance with the following incorporated publication: Treatment of TB and TB Infection.

c) DOPT or DOT. This directive requires completion of a course of preventive therapy by DOPT for infection or treatment by DOT for disease, in accordance with the following incorporated publications: Guidelines for Healthcare Facilities and Treatment of TB and TB Infection.

d) Isolation. This directive requires isolation, in accordance with Section 696.160 (b)(1) and the incorporated publications: Guidelines for Health-Care Settings ~~Healthcare Facilities~~, and the OSHA Instruction, for any person with suspected or

confirmed TB disease who is considered to be infectious or likely to become infectious, according to the definitions in this Part.

(Source: Amended at 30 Ill. Reg. _____, effective _____)

Section 696.APPENDIX A Mantoux Skin Testing Procedures

Mantoux Skin Test. The Mantoux skin test or other TB screening test shall be used when identifying persons with infection, regardless of whether a BCG vaccination was received in the past. (See the incorporated publication, The Role of BCG Vaccine.) Multiple puncture tuberculin tests should not be used to determine whether a person has TB infection.

The following applies to Mantoux skin testing only:

a) Administration. A trained person shall administer the Mantoux skin test in accordance with the incorporated publication, Core Curriculum.

b) Reading Reactions. Mantoux skin test reactions should be read 48 to 72 hours after administration in accordance with Appendix C and the incorporated publication Core Curriculum, and recorded in millimeters of induration. A positive reaction can be documented up to seven ~~7~~ days after the skin test was performed. A negative reaction shall not be documented beyond 72 hours after the skin test was performed. A trained person shall read the test. The recipient of a skin test should not read his or her own skin test, even if the recipient is a trained health care worker.

c) Interpreting Reactions. The millimeter reading for defining a positive reaction shall depend on a person's risk factors for TB. (See Appendix C and the incorporated publications, Screening for High-Risk Populations and Treatment of TB and TB Infection, for further information about interpreting reactions in specific groups.)
Agency Note: Anergy. The absence of a reaction to the tuberculin skin test does not rule out the diagnosis of TB infection or disease. Anergy should be considered in immunosuppressed persons who have no reaction to the skin test.

d) Two-Step Testing. Testing of persons who will be retested periodically (such as persons at high risk of exposure to TB) and who do not have a documented

negative skin test reaction during the preceding 12 months shall be done by two-step testing, except as provided for in Section 696.140(a)(2)(B). The first Mantoux skin test in two-step testing can be read from 48 hours to seven ~~7~~ days after the test is administered. If the reaction to the first test is positive, a person shall be considered infected. If the reaction to the first skin test is negative, a second test shall be administered seven ~~7~~ to 21 days after the first test was administered. The second test shall be read 48 to 72 hours after administration. (See Appendix B.)

(Source: Amended at 30 Ill. Reg. _____, effective _____)

Section 696.APPENDIX B Waivers for TB Screening Tests ~~Mantoux Skin Testing Requirements~~

a) Persons Who are Not Part of a Routine, Periodic Screening Program. TB screening test ~~Mantoux skin testing~~ requirements can be waived when documentation is available of a ~~Mantoux skin~~ TB screening test result read within 90 days before employment.

b) Persons Who are Part of a Routine, Periodic Screening Program. TB screening test ~~Mantoux skin testing~~ requirements can be waived with documentation of:

1) Two or more negative Mantoux skin test results read within one year before employment/admission, with the most recent Mantoux skin test read within 90 days before employment/admission; or

2) A negative TB screening test ~~Mantoux skin test~~ result read within one year before employment/admission, provided that the employee shall then receive an additional TB screening test ~~Mantoux skin test~~ within 7 days after employment/admission; or

3) Negative Mantoux two-step testing or other TB screening test results read within 90 days before employment/admission; or

4) Negative Mantoux two-step testing or other TB screening test results read within one year before employment/admission, followed by a negative Mantoux skin test result read within 90 days before

employment/admission; or

5) Negative two-step testing results read within one year before employment/admission, provided that the employee shall then receive an additional Mantoux skin test within seven ~~7~~ days after employment/admission.

c) Employees Re-hired or Clients Re-admitted Within a 12-Month Period. Employees and clients sometimes leave a facility for a period of time and later return to that facility. These employees and clients, who have previously met TB screening test ~~skin testing~~ requirements, may have such ~~the skin test~~ requirements for new hires or new admissions waived if indicated by a risk assessment and, in the judgement of the facility's medical director, these persons were at low risk of exposure to tuberculosis during their absence from the facility. Consultation should be obtained from the local TB control authority as necessary. A waiver signed by the facility's medical director shall be included in the employees' files.

d) Persons with Documentation of a Previous Positive TB Screening Test Result. ~~Reaction.~~ Repeat skin testing is not needed or required for persons with documentation of a previous positive test result ~~reaction to a Mantoux skin test~~. (See Section 696.140(b) for screening procedures for persons with documentation of a previous positive result~~reaction~~.)

e) Volunteers. At workplaces, screening requirements for volunteers may be waived based on the results of a risk assessment performed by the local TB control authority. Documentation of such waiver shall be kept on file at the facility.

(Source: Amended at 30 Ill. Reg. _____, effective _____)