

DEPARTMENT OF PUBLIC HEALTH

NOTICE OF PROPOSED AMENDMENTS

- a) Heading of the Part: Control of Tuberculosis Code
- b) Code Citation: 77 Ill. Adm. Code 696
- c)

<u>Section Numbers:</u>	<u>Proposed Action:</u>
696.100	Amend
696.110	Amend
696.130	Amend
696.140	Amend
696.150	Amend
696.160	Amend
696.170	Amend
696.180	Amend
696.190	Repeal
696.200	Repeal
696.210	Repeal
696.APPENDIX A	Repeal
696.APPENDIX B	Repeal
696.APPENDIX C	Repeal
- d) 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]
- e) 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 TB disease or latent TB infection (LTBI). The current rules are based on the Department of Public Health Act and on the U.S. Centers for Disease Control and Prevention (CDC) guidelines, which have been updated or replaced since prior rule revisions, and do not include the established web-based reporting system. The proposed rulemaking updates the rules to be consistent with current regulations and guidelines and removes all language that refers to non-mandated TB prevention and control activities or is solely descriptive of procedures or practices.

The proposed rulemaking provides updated definitions to be consistent with current CDC guidelines; updates incorporated and referenced materials to include current federal regulations and guidelines; updates reporting requirements to include electronic submission of reports through the Illinois-National Electronic Disease Surveillance System (I-NEDSS) or other authorized web-based system by providers to the local TB

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control authority, and by local TB control authorities to the Department; and updates the roles of the Department and the local TB control authority to be consistent with the current Department of Public Health Act for enforcement purposes.

The proposed rulemaking is needed because the current rule is not consistent with current federal guidelines, the current Department of Public Health Act, current communicable disease reporting practices and current professional standards. New CDC guidelines related to TB screening, diagnosis and management of LTBI, diagnosis and management of active TB, TB infection control, TB contact investigation, and TB control in correctional settings have all been issued since the current rule was enacted.

The economic effect of this proposed rulemaking is unknown. Therefore, the Department requests any information that would assist in calculating this effect.

The Department anticipates adoption of this rulemaking approximately six to nine months after publication of the Notice in the *Illinois Register*.

- 6) Published studies or reports, and sources of underlying data used to compose this rulemaking: Guidelines for Preventing the Transmission of Mycobacterium Tuberculosis in Health-Care Settings, 2005, 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) December 30, 2005; 54 (No. RR17):1-141)

Treatment of Tuberculosis, U.S. Department of Health and Human Services, Centers for Disease Control and Prevention, Atlanta, GA 30333, (Morbidity and Mortality Weekly Report (MMWR) June 20, 2003; 52 (No. RR-11)

Guidelines for the Investigation of Contacts of Persons with Infectious Tuberculosis: Recommendations from the National Tuberculosis Association and 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) December 16, 2005; 54 (No. RR15):1-47))

Targeted Tuberculin Testing and Treatment of Latent Tuberculosis Infection, U.S. Department of Health and Human Services, Centers for Disease Control and Prevention, Atlanta, GA 30333 (Morbidity and Mortality Report (MMWR) June 9, 2000; 49 (No. RR-6))

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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) July 7, 2006; 55 (No. RR9):1-44)

- 7) Will this rulemaking replace any emergency rulemaking currently in effect? No
- 8) Does this rulemaking contain an automatic repeal date? No
- 9) Does this rulemaking contain incorporations by reference? Yes
- 10) Are there any other proposed rulemakings pending on this Part? No
- 11) Statement of Statewide Policy Objectives: This rulemaking does not create or expand any State mandates on units of local government.
- 12) 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: dph.rules@illinois.gov
- 13) Initial Regulatory Flexibility Analysis:
 - A) Types of small businesses, small municipalities and not for profit corporations affected: Hospitals, long-term care facilities, residential facilities, alcohol and drug treatment centers, laboratories and other health care settings.
 - B) Reporting, bookkeeping or other procedures required for compliance: A new reporting requirement includes submission of reports electronically through the Illinois-National Electronic Disease Surveillance System (I-NEDSS) or other

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web-based system. Reporting by mail or facsimile followed by telephone call is still permitted. There are no new requirements for bookkeeping or other procedures required for compliance.

C) Types of Professional skills necessary for compliance: None

14) Regulatory Agenda on which this rulemaking was summarized: January 2011

The full text of the Proposed Amendments begins on the next page:

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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 ~~Definitions~~Definition of Terms
 696.110 Incorporated and Referenced Materials

SUBPART B: TUBERCULOSIS PREVENTION AND CONTROL MEASURES

Section

- 696.130 ~~Responsibilities of Health Care Settings~~Responsibilities of High Risk Congregate Settings and Programs Providing Alcohol and Drug Treatment
 696.140 ~~Screening for Latent Tuberculosis Infection (LTBI) and Active Tuberculosis (TB) Disease~~Screening for Tuberculosis Infection and Disease
 696.150 ~~Management of Persons with Latent Tuberculosis Infection (LTBI)~~Management of Persons with Tuberculosis Infection
 696.160 Diagnosis and Management of Persons with Suspected and Confirmed Active Tuberculosis Disease
 696.170 Reporting

SUBPART C: ENFORCEMENT OF TUBERCULOSIS PREVENTION AND CONTROL MEASURES

Section

- 696.180 Role of the Department or Local TB Control Authority in Enforcement and Control
 696.190 Role of the Local Tuberculosis Control Authority in Enforcement (Repealed)
 696.200 Types of Directives (Repealed)
 696.210 Potential Recipients of Directives (Repealed)
 696.APPENDIX A Mantoux Skin Testing Procedures (Repealed)
 696.APPENDIX B Waivers for Initial TB Screening Tests (Repealed)
 696.APPENDIX C Summary of the Interpretation of Tuberculin Skin Test Results (Repealed)

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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 32 Ill. Reg. 4010, effective February 29, 2008; amended at 36 Ill. Reg. _____, effective _____..

SUBPART A: GENERAL PROVISIONS

Section 696.100 ~~Definitions~~ Definition of Terms

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

~~"Active Tuberculosis Disease" or "Active TB Disease" means a diagnosis demonstrated by clinical, bacteriologic or diagnostic imaging evidence, or a combination thereof. Persons who have been diagnosed as having active TB and have not completed a course of TB treatment are still considered to have active tuberculosis and may be infectious.~~

~~"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 active 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~~

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~~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 active 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 ~~include~~includes isolation of M. tuberculosis from a clinical specimen; demonstration of M. tuberculosis by other laboratory technique~~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; other signs and symptoms compatible with active TB disease, 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.

~~"Contact" means a person who has been exposed to M. tuberculosis by sharing air space with a person with infectious TB.~~

"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, chest radiograph and bacteriologic examinations.~~

"Directly Observed Therapy" or "DOT" means a process by which a trained health care~~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" or "DOPT" means a process by which a trained healthcare worker or other designated trained person watches the patient~~

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~~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".)~~

~~"Health Care Setting" means any relationship (physical or organizational) in which a health care worker might share air space with a person with active TB disease or in which a health care worker might be in contact with clinical specimens.~~

~~"Health CareHealthcare Worker" means a paid or unpaid person working in a health care settingan employee or volunteer in a healthcare facility who has the potential for exposure to M. tuberculosis through air space shared with persons with infectious TB disease, or contact with clinical specimens. 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.~~

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~~"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 ~~with 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 active 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; jejunioileal 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 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 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);~~

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~~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 that a person ~~who~~ has, or is suspected of having, active TB disease of the respiratory tract capable of producing infection or disease in others as demonstrated by the presence of AFB in the sputum or bronchial secretions or by chest radiograph and clinical findings. ~~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); 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 or three times per week, rather than each day.~~

~~"Isolation" means the physical separation and confinement of a person with suspected or confirmed active TBtuberculosis disease in a place and under conditions that prevent the transmission of the infection. ~~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.~~

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

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~~"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.~~

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

~~has received a minimum of two weeks of standard multidrug anti-tuberculosis treatment~~a treatment regimen for two or more weeks composed of multiple drugs to which the organisms are susceptible in accordance with Treatment of Tuberculosis, incorporated by reference in Section 696.110(a)~~the incorporated publication, Treatment of TB and TB Infection;~~

has ~~demonstrated~~favorable clinical response to ~~therapy~~treatment; and

has three consecutive negative AFB sputum smear results from sputum collected in eight-hour or greater intervals, with at least one being an early

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~~morning specimen 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 a tentative diagnosis, an occurrence that is being considered as TB disease while diagnostic procedures are being completed, of active TB disease, whether or not treatment has been started, or a person with an~~

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illness marked by signs, symptoms and/or laboratory tests that may be indicative of tuberculosis.

"TB Screening Test" means a federal Food and Drug Administration (FDA) approved screening test to detect ~~latent-TB~~ infection~~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 36 Ill. Reg. _____, effective _____)

Section 696.110 Incorporated and Referenced 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), July 7, 2006; 55 (No. RR9):1-44).~~
- 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).~~
- 2)3) ~~"Guidelines for Preventing the Transmission of Mycobacterium Tuberculosis~~tuberculosis in Health-Care Settings, 2005" (referred to as "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), December 30, 2005; 54 (No.

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RR17):1-141).

- ~~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. RR8)).~~
- ~~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. RR4)).~~
- ~~3)7) Targeted Tuberculin Testing and Treatment of Latent Tuberculosis Infection, U.S. Department of Health and Human Services, Centers for Disease Control and Prevention, Atlanta GA 30333 (Morbidity and Mortality Weekly Report (MMWR), June 9, 2000; 49 (No. RR-6))."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).~~
- ~~4)8) Treatment of Tuberculosis, U.S. Department of Health and Human Services, Centers for Disease Control and Prevention, Atlanta GA 30333 (Morbidity and Mortality Weekly Report (MMWR), June 20, 2003; 52 (No. RR-11))."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. RR15):49-55).~~

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- 5) Guidelines for the Investigation of Contacts of Persons with Infectious Tuberculosis: Recommendations from the National Tuberculosis Association and CDC (referred to as "Guidelines for Investigation of Contacts"), 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), December 16, 2005; 54 (No. RR15):1-47).
 - 6) Privacy Rule (Standards for Privacy of Individually Identifiable Health Information) of the Health Insurance Portability and Accountability Act of 1996 and 45 CFR 164.512(a) and (k)(6) (October 1, 2007).
- b) All incorporations by reference of federal regulations and guidelines of federal agencies and the standards of nationally recognized organizations refer to the regulations, guidelines and standards on the date specified and do not include any amendments or editions subsequent to the date specified.
- c) The following materials are referenced in this Part:
- 1) Medical Studies Act [735 ILCS 5/8-2101]
 - 2) Illinois Health Statistics Act [410 ILCS 520]
 - 3) Control of Communicable Diseases Code (77 Ill. Adm. Code 690)

(Source: Amended at 36 Ill. Reg. _____, effective _____)

SUBPART B: TUBERCULOSIS PREVENTION AND CONTROL MEASURES

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

- a) TB Risk Assessment. Every health care setting shall conduct initial and ongoing evaluation of the risk for transmission of M. tuberculosis, regardless of whether patients with suspected or confirmed active TB disease are expected to be encountered in the setting. The TB risk assessment shall address administrative,

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environmental and respiratory-protection controls needed for the health care setting and shall be reviewed at least annually.

- b)a) Written Plans. A written TB infection control plan shall be developed that includes protocols for the screening and management of latent TB infection among health care workeremployees, volunteers and clients; protocols for the screening, diagnosis and management of active TB disease among health care workeremployees, volunteers and clients; data collection; evaluation of data; reporting of persons with suspected or confirmed activesigns or symptoms of TB disease to the local TB control authority; and a health care workeran 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 health care settingfacility; procedures to protect health care workersfor the purpose of protecting employees, volunteers and clients from contracting tuberculosis; and a referral mechanism to ensure that transmission of TB is prevented and treatment is completedprevention of transmission and completion of treatment for clients with TB who leave the health care settingsfacility. The written plan shall be updated at least annually. (See the incorporated publications, Guidelines for Health-Care Settingsand the OSHA Instruction.)
- c)b) TB Prevention and Control Program. A program shall be executed in accordance with the written TB infection control plan.
- d)e) Health Care WorkerEmployee and Volunteer Education. Training about TB shall be provided or arranged. All health care workeremployees and volunteers shall be trained upon hiring and periodically thereafter to ensure employee knowledge relevantequivalent to the employee's work responsibilities and the level of risk in the health care settingfacility. OSHA-regulated settings and programs shall comply with the incorporated publications, OSHA Instruction. (See the Guidelines for Health-Care Settings.)incorporated publications, Core Curriculum and Controlling TB in Correctional Facilities.)
- e)d) Collaboration. Health care settingsThe 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 latent TB infection and active TB disease, reporting of active TB disease, and the education of health care workeremployees and volunteers.

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- ~~f)e)~~ Records. Records shall be maintained on TB screening 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 ~~(b)(a)~~ of this Section. Individual and aggregate data ~~shall~~should be analyzed periodically to identify the health care setting's 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 control authority upon request.

(Source: Amended at 36 Ill. Reg. _____, effective _____)

Section 696.140 Screening for Latent Tuberculosis Infection (LTBI) and Active Tuberculosis (TB) Disease~~Screening for Tuberculosis Infection and Disease~~

~~A~~The TB screening test shall be used when screening persons for latent TB infection (LTBI). ~~(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 active TB disease or a positive TB screening test ~~result~~results shall ~~complete~~have additional diagnostic evaluation for active TB disease tests as recommended in the Centers for Disease Control and Prevention (CDC) guidelines~~incorporated publications Targeted Tuberculin Testing and Treatment of Latent Tuberculosis Infection and Guidelines for Health-Care Settings~~Treatment of TB and TB Infection and Guidelines for Health-Care Settings.

- a) Screening for Latent TB Infection~~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 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 active TB disease shall be evaluated in accordance with the CDC Guidelines for the Investigation of Contact~~tested with a TB screening test to identify infection.~~ ~~Close contacts shall be retested three months after the last exposure if their reaction to the first TB screening test was negative. A high priority should be given to evaluating contacts who are children or contacts infected with HIV/AIDS.~~

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- 2) ~~Workers and clients at health care settings and other residential settings serving high-risk groups shall be screened~~~~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 ~~(a)(2), Appendices A, B, and C,~~ and the following ~~CDC guidelines~~~~incorporated publications:~~ Targeted Tuberculin Testing and Treatment of Latent Tuberculosis Infection, Guidelines for Health-Care Settings, Prevention and Control of Tuberculosis in Correctional and Detention Facilities: Recommendations from CDC~~Screening High-Risk Populations; Guidelines for Health-Care Settings; Prevention and Control of Tuberculosis in Correctional Facilities; and the OSHA Instruction.~~
- A) ~~Health care workers and workers in other residential care settings serving high-risk groups~~~~All employees and volunteers in high-risk congregate settings and programs providing alcohol and drug treatment~~ shall obtain a TB screening test within seven days after being employed. ~~If Mantoux skin testing is used, two-step testing shall be done, with the first test placed within seven days after employment. However, a second skin test is not needed if the worker has a documented skin test result from any time during the previous 12 months. The need for routine periodic screening shall be determined by a risk assessment.~~~~should be done.~~ ~~Employees and volunteers who are part of a routine, periodic screening program shall initially be screened by TB screening tests.~~
- B) All clients in ~~non-acute-care residential health care settings~~~~high-risk congregate settings and clients in high-risk groups in programs providing alcohol and drug treatment~~ shall obtain a TB screening test within seven days after admission. If Mantoux skin testing is used ~~for clients with an anticipated stay longer than 30 days,~~ two-step testing ~~shall~~~~should~~ be done, ~~with the first test placed within seven days after admission. Routine periodic screening shall be determined by a risk assessment performed in cooperation with the local TB control authority.~~ ~~In addition:~~
- C) TB screening shall be instituted in other residential care settings serving high-risk groups as directed by the local TB control authority or the Department when a community or residential care

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setting has a higher than expected incidence of active TB disease or prevalence of LTBI.

D) Inmates and employees in correctional and detention facilities shall be screened in accordance with the CDC guideline Prevention and Control of Tuberculosis in Correctional and Detention Facilities: Recommendations from CDC.

~~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 within seven 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 within seven days after admission. If Mantoux skin testing is used, 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 days after admission, when feasible. Regardless of TB screening 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 publications incorporated in this Part.~~

~~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~~

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~~incorporated publications: Guidelines for Health Care Settings and Screening High-Risk Populations.~~

- 4) ~~Employees, Volunteers and Students in a School (Pupil Attendance Center) or School District.~~
- A) ~~Initial screening of employees and volunteers in a school or a school district shall be performed using a TB screening test within seven 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.~~
- 3)5) ~~Workers in child day care and pre-school settings~~Day-Care Center Employees and Volunteers. ~~Day care center employees and volunteers shall obtain a TB screening test within seven days after being employed. If Mantoux skin testing is used, two-step testing shall be done, with the first test administered seven days after employment. Routine, periodic screening of ~~workers shall~~employees and volunteers should be determined by the child day care or pre-school facility's TB risk assessment ~~performed in cooperation with the local TB control authority.~~~~
- b) Screening for Active TB Disease. The following persons shall be screened for active TB disease:
- 1) ~~Checklist of Signs and Symptoms.~~ A checklist that includes but is not limited to pulmonary symptoms (productive prolonged cough, chest pain,

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~~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:~~

- ~~1)A) Persons with a documented positive TB screening test result who are required to receive TB screening tests, regularly and periodically shall, instead of receiving such screening tests, complete a signs and symptoms checklist. A checklist takes the place of a TB screening test for these persons. Repeat screening tests are not needed or required. Routine, periodic chest radiographs should not be done. Chest radiographs do not take the place of a TB screening test or checklist.~~
- ~~2)B) Clients admitted to health care settings and residential care settings serving high-risk groups, 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.~~
- ~~3) Inmates in correctional and detention facilities, who shall be screened for active TB disease in accordance with Prevention and Control of Tuberculosis in Correctional and Detention Facilities: Recommendations from CDC.~~
- ~~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 test results.~~
 - ~~B) Screening for disease among the homeless may also include sputum smears and cultures.~~~~

(Source: Amended at 36 Ill. Reg. _____, effective _____)

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**Section 696.150 Management of Persons with Latent Tuberculosis Infection (LTBI)
~~Management of Persons with Tuberculosis Infection~~**

- a) ~~Treatment for LTBI~~Preventive Therapy. Persons~~Before therapy is started,~~
~~persons~~ with a positive TB screening test result shall ~~complete~~receive a diagnostic
evaluation for active TB disease. ~~See Appendix C for information on how to~~
~~interpret skin test results.~~ If there is no evidence of active TB disease, persons
with LTBI ~~shall~~TB infection should be considered for ~~treatment~~preventive
therapy. Treatment for LTBI~~Preventive therapy~~ shall be conducted in accordance
with the CDC guidelines~~incorporated publication, Targeted Tuberculin Testing~~
and Treatment of Latent TB Infection~~Treatment of TB and TB Infection.~~
- 1) ~~The following persons with positive TB screening test results 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 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) ~~Adults with positive results from a TB screening test with~~

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~~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) of this Section, the following persons younger than 35 years of age with a positive TB screening test result 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 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 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) ~~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.)~~

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- 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. (See the incorporated publication, The Role of BCG Vaccine.)~~
- e) ~~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.~~
- b)d) Monitoring for Adverse Reactions. At a minimum, patients ~~shall~~should be ~~monitored~~seen monthly during therapy and evaluated for adverse drug reactions.

(Source: Amended at 36 Ill. Reg. _____, effective _____)

Section 696.160 Diagnosis and Management of Persons with Suspected or Confirmed Active 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~~History;
 - 2) Physical ~~examination~~Examination;
 - 3) TB ~~screening test~~Screening Test;
 - 4) Chest ~~radiograph~~Radiograph; ~~and~~
 - 5) Bacteriologic ~~examinations on available specimens; and~~Examinations on Available Specimens (e.g., smears, cultures and other tests for M. tuberculosis, and drug-susceptibility tests).
 - 6) Assessment of risk for HIV infection and testing, and counseling as indicated.

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

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- b) Clinical Management of Persons with Suspected or Confirmed Active 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 ~~and OSHA Instruction.~~
- A) In settings that serve infectious TB patients, precautions that shall be implemented include early identification and airborne infection isolation of patients with suspected or confirmed active TB disease. Infection control measures shall be maintained until the patient is determined to be non-infectious~~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.~~

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~~B)C)~~ Once determined to be infectious, a ~~patient~~person is considered infectious until medically determined to be ~~non-infectious~~not infectious and not 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 ~~non-infectious~~not infectious status of a patient with a suspected or confirmed case of TB, the Department will make a final decision of infectiousness ~~will be made only by the Department.~~ Determination of infectiousness for patients with positive AFB sputum smear results with pending or negative AFB sputum cultures, and for patients with multi-drug resistant (MDR) TB, shall be made in consultation with the Department.

- 2) Treatment of Suspected or Confirmed Active TB Disease. Patients with suspected~~Suspected~~ or confirmed active TB disease shall be treated ~~with multiple drugs~~ in accordance with ~~the incorporated publication, Treatment of Tuberculosis~~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) Treatment Regimen. Persons with suspected or confirmed active TB disease shall be treated with a multi-drug regimen in accordance with Treatment of Tuberculosis.

B)A) Adherence to Treatment. Health care providers shall use strategies such as directly observed therapy (DOT) and patient-centered case management to assure successful completion of treatment. Directly Observed Therapy (DOT). Treatment of all patients with TB should be conducted by DOT.

C)B) Monitoring for Response to ~~Therapy~~Antituberculosis Chemotherapy. Patients shall be monitored for response to treatment in accordance with Treatment of Tuberculosis. Persons with M. tuberculosis identified in sputum shall be monitored by

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~~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 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.~~

~~D) Monitoring for Adverse Reactions. Patients shall be monitored for adverse drug reactions in accordance with Treatment of Tuberculosis. 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) The Department of Public Health shall investigate the causes of contagious, or dangerously contagious, or infectious diseases, especially when existing in epidemic form, and take means to restrict and suppress the same, and whenever such disease becomes, or threatens to become, epidemic in any locality and the local board of health or local authorities neglect or refuse to enforce efficient measures for its restriction or suppression or to act with sufficient promptness or~~

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efficiency, or whenever the local board of health or local authorities neglect or refuse to promptly enforce efficient measures for the restriction or suppression of dangerously contagious or infectious diseases, the Department of Public Health may enforce such measures as it deems necessary to protect the public health, and all necessary expenses so incurred shall be paid by the locality for which services are rendered. (Section 2(a) of the Act)

- 1)e) Contact Investigation. The local TB control authority is responsible for assuring that a contact investigation, including identification, prioritization and evaluation of contacts, is completed for each case of active TB disease of the respiratory tract. ~~Contacts Close contacts to suspected or confirmed cases of TB disease~~ shall obtain an evaluation, including screening for signs and symptoms of active TB disease and a TB screening test, to identify latent TB infection. ~~Contacts Close contacts~~ shall be retested eight to 10 weeks~~three months~~ after the last exposure if their reaction to the first TB screening test was negative. (See Guidelines for the Investigation of Contacts. Contacts who have signs and symptoms of active TB disease or a positive TB screening test result shall complete a diagnostic evaluation for active TB disease as recommended in the Targeted Tuberculin Testing and Treatment of Latent Tuberculosis Infection, and Guidelines for Health-Care Settings. 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.)
- 2) When cases of active TB disease occur in any business, organization, institution or private home, the business owner, the person in charge of the establishment or the homeowner shall cooperate with local TB control authorities in the investigation, including, but not limited to, release of name and other pertinent information about employees, customers, passengers, travelers, transportation crews and/or guests as the information relates to the investigation.
- 3) Entering a place of employment for the purpose of conducting investigations of those processes, conditions, structures, machines, apparatus, devices, equipment, records, and materials within the place of employment that are relevant, pertinent, and necessary to the investigation. Investigations shall be conducted during regular business hours, if possible, and with such notice as is possible under the circumstances.

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- 4) School, child care facility, and college/university authorities shall handle contacts of infectious disease cases in the manner prescribed in this Part, or as recommended by the local health authority.

(Source: Amended at 36 Ill. Reg. _____, effective _____)

Section 696.170 Reporting

Health care professionals listed in subsection (a)(1) shall report suspected and confirmed cases of active TB disease 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 reports shall be submitted electronically through the Illinois National Electronic Disease Surveillance System (I-NEDSS) or other authorized web-based system, or by mail or facsimile, and followed up with a telephone call to the local TB control authority in whose jurisdiction the reporter is located. Reports by mail or facsimile shall be made on forms available from the local TB control authority or the Department. The local TB control authority shall report to the Department.

a) Reports to the Local TB Control Authority.

- 1) Health Care Professionals Required to Report. Health care professionals such as ~~Reports shall be made by~~ physicians, physician assistants, nurses, dentists, coroners, medical examiners, laboratory personnel and the health ~~coordinator~~seordinator of health care settings shall report 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.
- 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.~~
- 2)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 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

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suspected or confirmed case of TB, including the dates and results of TB screening tests (Mantoux skin test results shall be recorded in millimeters) 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 ~~non-infectious~~not infectious status, isolation precautions taken, treatment regimen and severe adverse reactions to medication; ~~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 ~~shall~~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. ~~The~~Such information may include hospital discharge plans for out-patient follow-up and the names, locating information, test results and treatment information of all persons considered during a contact investigation 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

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and surveillance of suspected and confirmed cases of TB and the investigation of contacts, as follows. The local TB control authority shall make ~~its~~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 calendar days after a local TB control authority's receipt of a report of a suspected or confirmed case of TB, ~~the local TB control authority shall report available information to~~ the Department ~~electronically through the I-NEDSS or other authorized web-based system. If the local TB control authority is unable to report electronically, reports shall be made by telephone, facsimile or mail on forms available from the Department~~shall receive available information on an RVCT form.
- 2) Reports ~~of Follow-up Information 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. ~~The information shall be reported electronically through the I-NEDSS or other authorized web-based system. If the local TB control authority is unable to report electronically, reports shall be made by telephone, facsimile or mail.~~
- 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~~M. tuberculosis, ~~any culture result associated with an AFB-positive smear (even if negative for M. tuberculosis complex (MTB complex)), and drug susceptibility test results as follows: by telephone followed by mail, facsimile or approved electronic reporting format to the person who requested the test; to the local TB control authority; and by mail, facsimile or approved electronic format to the Department.~~and drug susceptibility test results.
- d) ~~Isolates to State Public Health Laboratory. Laboratories shall send one isolate for each person to the State Public Health Laboratory within seven days after culture results are positive for MTB complex. If specimens are submitted to an out-of-~~

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state reference laboratory, the submitter shall ensure that the isolate is sent to the State Public Health Laboratory.

- e) Reports Between Jurisdictions. Reports, such as laboratory reports and other pertinent reports, shall be made by one local TB control authority to another local TB control authority when more than one jurisdiction is involved with a case or their contacts, i.e., when the party submitting a specimen for diagnosis is in a different jurisdiction from that in which the patient resides or when a patient or contact resides, works or attends school in, or moves to, a different jurisdiction. Local TB control authorities receiving reports of persons with suspected or active TB being discharged or transferred to another jurisdiction shall notify the receiving jurisdiction by telephone, followed by facsimile or mail, prior to the planned discharge or transfer.
- f) Reports of Discharge or Transfer. Institutional settings, such as hospitals, long-term care facilities and correctional settings, shall report by telephone to the local TB control authority in whose jurisdiction the reporter is located its plans to discharge or transfer persons with suspected or active TB prior to discharge or transfer.
- g)d) Confidentiality. Confidentiality of information shall be maintained in accordance with 77 Ill. Adm. Code 690.200(d).
- 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 or 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 a 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 any action of any kind in any court or before any tribunal, board or agency. (Communicable Disease Report Act [745 ILCS 45])~~

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- h) Identifiable data may be released to the extent necessary for the treatment, control, investigation and prevention of diseases and conditions dangerous to the public health. Identifiable data can be shared in special circumstances, e.g., as permitted by the Privacy Rule, the Medical Studies Act, and the Illinois Health Statistics Act. As described in the Illinois Health Statistics Act, a Department-approved Institutional Review Board or its equivalent on the protection of human subjects in research shall review and approve requests from researchers for individually identifiable data.

(Source: Amended at 36 Ill. Reg. _____, effective _____)

SUBPART C: ENFORCEMENT OF TUBERCULOSIS PREVENTION
AND CONTROL MEASURES

Section 696.180 Role of the Department or Local TB Control Authority in Enforcement and Control

~~The~~After providing an opportunity for a patient to present information to support his or her position at a hearing, the Department or local TB control authority may issue directives, ~~and~~ seek court orders or issue emergency orders, as necessary to protect the public health, safety and welfare.

- a) ~~Opportunity to be Heard. Prior to issuance of any directive, the Department shall notify the prospective recipient of the directive of the intent to issue a directive and shall offer the recipient an opportunity to be heard before the Director or a designee, provided that within 7 days after receipt of the notice the recipient makes written request for hearing. The notice shall be in writing, shall be served in person or by certified mail, and shall include a brief description of the reasons for issuance of a directive and of the type of directive that may be issued. Any hearing under this Section shall be promptly scheduled and determined.~~
- a)b) Directives. When ~~it is~~ necessary to protect the public health, safety and welfare, the Department or local TB control authority may ensure prevention and control measures by issuing Department or local TB control authority directives. A directive is a letter that informs recipients what is required of them ~~in order~~ to be in compliance with this Part and the consequences of noncompliance. ~~A directive may include one or more types of directives, as appropriate to the case. (See Sections 696.200 and 696.210.)~~

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- b) The Department or local TB control authority shall implement matters of quarantine, isolation and closure in accordance with 77 Ill. Adm. Code 690. Subpart H.
- e) ~~Court Orders. The Department may seek court orders for diagnostic evaluation, preventive therapy, DOPT, disease treatment, DOT and isolation.~~

(Source: Amended at 36 Ill. Reg. _____, effective _____)

Section 696.190 Role of the Local Tuberculosis Control Authority in Enforcement
(Repealed)

~~After providing an opportunity for a patient to present information to support his or her position at a hearing, the local TB control authority may issue directives and seek court orders, as necessary to protect the public health, safety and welfare.~~

- a) ~~Opportunity to be Heard. Prior to issuance of any directive, the local TB control authority shall notify the prospective recipient of the directive of the intent to issue a directive and shall offer the recipient an opportunity to be heard before the administrator of the local TB control authority or a designee, provided that within 7 days after receipt of the notice the recipient makes written request for hearing. The notice shall be in writing, shall be served in person or by certified mail, and shall include a brief description of the reasons for issuance of a directive and of the type of directive which may be issued. Any hearing under this Section shall be promptly scheduled and determined.~~
- b) ~~Directives. When it is necessary to protect the public health, safety and welfare, the local TB control authority may ensure prevention and control measures by issuing directives. A directive is a letter that informs recipients what is required of them in order to be in compliance with this Part and the consequences of noncompliance. A directive may include one or more types of directives, as appropriate to the case. (See Sections 696.200 and 696.210.)~~
- e) ~~Court Orders. The local TB control authority may seek court orders for diagnostic evaluation, preventive therapy, DOPT, disease treatment, DOT and isolation.~~
- d) ~~Notification. The local TB control authority shall inform the Department~~

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~~regarding persons in their jurisdiction meeting the description of potential recipients of directives, as specified in Section 696.210.~~

- e) ~~Documentation. The local TB control authority shall document evidence (e.g., appointment logs, patient records) concerning the circumstances, as specified in Section 696.210, that make it necessary to seek directives or court orders. Upon the request of the Department, the local TB control authority shall provide such evidence to the Department.~~

(Source: Repealed at 36 Ill. Reg. _____, effective _____)

Section 696.200 Types of Directives (Repealed)

- 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, 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.~~
- e) ~~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, 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: Repealed at 36 Ill. Reg. _____, effective _____)

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Section 696.210 Potential Recipients of Directives (Repealed)

~~The local TB control authority shall document information used to identify potential recipients of directives. The local TB control authority or the Department may identify potential recipients of directives. The local TB control authority may seek the cooperation of the Department to identify potential recipients of directives.~~

- a) ~~Potential Recipients Based Upon Past or Present Behavior. A potential recipient shall be any person who has, or is suspected of having, TB infection or disease and who has demonstrated, in the opinion of the local TB control authority or the Department, through past or present behavior that he or she has a substantial likelihood of:~~
- ~~1) not initiating or completing a diagnostic evaluation to determine if TB infection or disease is present;~~
 - ~~2) transmitting, or being able to transmit, disease to others;~~
 - ~~3) not participating in DOPT for TB infection;~~
 - ~~4) not participating in DOT for treatment of disease; or~~
 - ~~5) not following disease isolation procedures.~~
- b) ~~Potential Recipients Based Upon Not Completing Treatment. A potential recipient shall be any person who has been reported to the local TB control authority or the Department as having TB disease and as not completing a prescribed course of treatment.~~
- e) ~~Potential Recipients Based Upon Being High-Risk for Nonadherence to a Prescribed Treatment Regimen. A potential recipient shall be any person who has a history of treatment nonadherence; whose treatment has failed (treatment failure); whose 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; who is a child or adolescent.~~

(Source: Repealed at 36 Ill. Reg. _____, effective _____)

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Section 696.APPENDIX A Mantoux Skin Testing Procedures (Repealed)

~~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 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 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 to 21 days after the first test was administered. The second test shall be read 48 to 72 hours after administration. (See Appendix B.)~~

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(Source: Repealed at 36 Ill. Reg. _____, effective _____)

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Section 696.APPENDIX B Waivers for Initial TB Screening Tests (Repealed)

- a) ~~Persons Who are Not Part of a Routine, Periodic Screening Program. TB screening test requirements can be waived when documentation is available of a TB screening test result read within 90 days before employment.~~
- b) ~~Persons Who are Part of a Routine, Periodic Screening Program. TB screening test 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 result read within one year before employment/admission, provided that the employee shall then receive an additional TB screening test within seven 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 days after employment/admission.~~
- e) ~~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 requirements, may have such 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~~

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~~the facility's medical director shall be included in the employees' files.~~

- d) ~~Persons with Documentation of a Previous Positive TB Screening Test Result. Repeat skin testing is not needed or required for persons with documentation of a previous positive test result. (See Section 696.140(b) for screening procedures for persons with documentation of a previous positive result.)~~
- 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: Repealed at 36 Ill. Reg. _____, effective _____)

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Section 696.APPENDIX C Summary of the Interpretation of Tuberculin Skin Test Results
(Repealed)

1. ~~An induration equal to or greater than 5 mm is classified as positive in the following:~~
 - ~~•Persons who have had recent close contact with persons who have active TB.~~
 - ~~☐Persons who have been diagnosed with HIV infection or who have risk factors for HIV infection but whose HIV status is unknown.~~
 - ~~•Persons who have fibrotic chest radiographs consistent with healed TB.~~

2. ~~An induration equal to or greater than 10 mm is classified as positive in all persons who do not meet any of the above criteria, but who belong to one or more of the following groups having high risk for TB:~~
 - ~~•Injecting drug users known to be HIV seronegative;~~
 - ~~☐Persons who have other medical conditions that have been reported to increase the risk for progressing from latent TB infection to active TB disease. These medical conditions include 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., leukemia and lymphomas), other specific malignancies (e.g., carcinoma of the head or neck), weight loss equal to or greater than 10% below ideal body weight, silicosis, gastrectomy, jejunioileal, bypass;~~
 - ~~☐Residents and employees of high-risk congregate settings; prisons and jails, nursing homes and other long-term residential facilities for the elderly, health-care facilities (including some residential mental health facilities), and homeless shelters;~~
 - ~~☐Foreign-born persons who have recently arrived (i.e., within the last 5 years) from countries having a high prevalence or incidence of TB;~~
 - ~~☐Some medically underserved, low-income populations, including migrant farm workers and homeless persons;~~

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- ~~•High risk racial or ethnic minority populations, as defined locally; and~~
- ~~☐Children less than 4 years of age, or infants, children, and adolescents exposed to adults in high risk categories.~~

3. ~~An induration equal to or greater than 15 mm is classified as positive in persons who do not meet any of the above criteria.~~

(Source: Repealed at 36 Ill. Reg. _____, effective _____)