105 CMR 365.000: Standards for Management of Tuberculosis Outside Hospitals

Section

365.001: Purpose

The purpose of 105 CMR 365.000 is to protect the public health through standards for outpatient management of tuberculosis. The objectives are to enhance treatment adherence, to provide clinical monitoring, to insure completion of therapy through public health case management and to describe the responsibilities and requirements for case reporting.

365.002: Authority

105 CMR 365.000 is adopted under the authority of M.G.L. c. 111, §§ 3, 5, 6, 7, 18, 81, 94H, 95 and c. 111D, § 6.

365.003: Citation

105 CMR 365.000 shall be known, and may be cited, as 105 CMR 365.000: *Standards for the Management of Tuberculosis (TB) Outside Hospitals.*

365.004: Definitions

Acid Fast Bacilli: Organisms that retain certain stains even after being washed with acid alcohol. Most are mycobacteria. When seen as stained smear of sputum or other clinical specimen, a diagnosis of tuberculosis should be considered.

Adherence: The willingness and/or ability of patients to maintain their share of the responsibility for their therapy by taking their anti-tuberculosis medications as prescribed and by keeping the necessary health care appointments.

Case Assessment: The investigation conducted by the local board of health nurse to determine the potential the patient has to transmit disease to others, the risk of infection for contacts based on level and duration of exposure, and the medical, environmental, economic and social factors which may influence adherence to the prescribed treatment plan.

Clinically Suspected Tuberculosis: A condition in which the individual has acid fast bacilli in the sputum or other bodily fluid or tissue as evidenced by a laboratory smear; or has chest x-ray findings interpreted as probable tuberculosis by a qualified medical authority.

Communicable: The ability to transmit disease from one person or animal to another.

Confirmed Case of Tuberculosis: "Confirmed Case" refers to meeting the criteria as set forth by the federal Centers for Disease Control and Prevention (CDC) to verify a case as tuberculosis disease.

Contact: An individual that has shared the same airspace with a person with communicable tuberculosis for a sufficient amount of time so that there is a probability that transmission of tuberculosis has occurred.

Contact Investigation: The procedure of tracing, testing and evaluating persons who have been in contact with a patient with potentially infectious tuberculosis.

Division of Tuberculosis Control or Division: The program within the Department of Public Health which administers the provisions of 105 CMR 360.000.

Droplet Nuclei: The microscopic airborne particles of aerosolized sputum which can carry tubercle bacilli to the lungs of susceptible individuals.

Drug Resistant Tuberculosis: Tuberculosis caused by tubercle bacilli that are unresponsive to one or more anti-tuberculosis drugs.

Enablers: A term used to describe anything that helps the patient to more readily access the treatment delivery system. These include: providing transportation, bus fares, helping to obtain a driving license, etc.

Incentives: "Motivators": or something which motivates a patient to take his or her medication, keep clinic appointments or do anything else that is necessary to ensure completion of therapy. Incentives include food coupons, cash or any individualized gift or reward for adhering to the treatment plan.

Nurse Case Manager: A registered nurse, designated by the local board of health, who has the overall responsibility of monitoring and coordinating the implementation of the patient's treatment plan until the completion of therapy. The nurse case manager also assists the patient in obtaining other community resources, such as social services, that will assist him or her with adherence to therapy.

Tubercle Bacillus/Bacilli: A bacillus (bacteria) causing tuberculosis; usually refers to *Mycobacterium tuberculosis.*

Tuberculosis Infection: Condition in which living tubercle bacilli are present in an individual, without producing clinically active disease. The infected individuals usually have a positive tuberculin skin test but are not infectious.

Tuberculosis Surveillance Area (TSA) Nurse: A Public Health Nursing Advisor who works for the Division of Tuberculosis Control and is responsible for all tuberculosis activities in a designated regional geographic area of the state.

365.100: Public Health Precautions

A) The period of infectivity for tuberculosis is defined in 105 CMR 300.200: *Isolation and Quarantine Regulations.* 105 CMR 300.200 determines when health care providers may discontinue isolation precautions and when individuals with confirmed or clinically suspected tuberculosis may resume community activities and community living. This includes, but is not limited to, resuming employment, school attendance, shelter living or other residential living arrangements.

B) Outpatient facilities (including but not limited to, hospital outpatient departments, clinics and medical office buildings

where active tuberculosis cases are seen for treatment) shall follow current national and local infection control guidelines for the isolation of individuals who are excreting tubercle bacilli into the room air and who may be infectious to others.

365.200: Case Management

A) Case management for tuberculosis is defined as the coordination of the necessary medical, nursing, outreach and social service systems which ensure that all persons with confirmed and clinically suspected tuberculosis complete an appropriate and effective course of treatment.

B) The Division of Tuberculosis Control shall assign regional Tuberculosis Surveillance Area (TSA) Nurses, as necessary, to work cooperatively and in consultation with local board of health authorities and the nurse case manager, designated by the local board of health, to ensure that a case management system is in place for every confirmed or clinically suspected case of tuberculosis.

C) The following measures are a requirement of the case management system:

1) The case shall be reported to the Massachusetts Department of Public Health, Division of Tuberculosis Control, as required by 105 CMR 365.500.

2) All persons with confirmed or clinically suspected tuberculosis shall have a nurse case manager designated by the local board of health who will work in consultation and cooperation with the regional TSA nurse, as necessary, to manage persons with confirmed or clinically suspected tuberculosis. This case management is required regardless of the source of health care (public or private) and the ability to pay for the services or medications.

3) In consultation with the treating health care provider, the nurse case manager, designated by the local board of health, determines that a medical treatment plan is in place and is in accordance with the American Thoracic Society (ATS) and federal Centers for Disease Control and Prevention (CDC) standards for care.

4) The initial case assessment and contact investigation by the local board of health shall begin within three working days of notification of a potential case of tuberculosis. Contacts to the case shall be identified and categorized for their risk of tuberculosis infection as determined by their level of exposure and the person's potential for generating air-borne tubercle bacilli (droplet nuclei). Contacts shall be investigated according to the ATS/CDC standards and the policies of the MDPH, Division of Tuberculosis Control. Contact investigation reports shall be prepared and given to the TSA nurse for the region, according to the policies developed by the Division of Tuberculosis Control.

5) Starting with the first visit to a potential case by the nurse designated by the local board of health, there shall also be an assessment of whether there are factors which affect adherence with therapy. This includes, but is not limited to: poor access to health care facilities; homelessness; work schedules; poverty; language barriers; cultural beliefs; substance abuse; mental health status; recent immigration; and medical conditions which may interfere with treatment. (Complete guidelines are available from the Division of Tuberculosis Control).

6) An individualized nursing care plan shall be developed by the local board of health's designated nurse case manager and, depending upon the identified risk factors for non-adherence to therapy, the plan shall include the following:

    a) A plan to remove barriers to adherence through: enablers which increase access to care; incentives which motivate persons to remain on appropriate therapy; and referrals to community agencies and providers which can assist with identified psychosocial or medical problems.

    b) Educational services to the individual who has confirmed or clinically suspected TB. The topics include, but are not limited to, the following:

        1. how TB is spread
        2. how to prevent the spread of TB
        3. how to take medications
        4. the effects of TB if not adequately treated

5. the importance of completing the prescribed course of treatment
6. the patient's responsibility in curing his or her own disease
7. the consequences to the individual if he or she is unwilling to adhere to the treatment plan
8. causes of drug resistant TB and its effects

c) The number of nursing and outreach worker visits and the level of social support shall depend upon the assessed level of adherence to therapy and medical status.

d) Directly Observed Therapy (DOT) by medical/ nursing/ outreach care givers or other individuals identified by the local board of health shall be employed when there is an identified risk to continued adherence to therapy.

e) Voluntary hospitalization/ institutionalization in the case of person with complex medical, psycho-social, and infection control management problems.

f) Involuntary hospitalization or confinement may be necessary when there is documented non-adherence to the appropriate medical follow-up and treatment for tuberculosis, and the public health is threatened as a result of this non-adherence. Least restrictive measures shall be employed before more restrictive measures are imposed. (See M.G.L. c. 111, § 94A for involuntary commitment procedures)

365.300: Medical Care and Follow-Up

A) All persons with confirmed or clinically suspected tuberculosis shall have an identified medical doctor, qualified and licensed to practice medicine, or a nurse practitioner licensed to practice in the expanded role under the supervision of a qualified medical doctor, to provide medical supervision.

Medical treatment for tuberculosis shall be according to the current standards set forth by the federal Centers for Disease

Control and Prevention (CDC) and the American Thoracic Society (ATS), or other qualified medical authority, for chemotherapy and follow-up. The Division of Tuberculosis Control shall make these standards available and provide consultation regarding appropriate therapy when necessary.

B) Providers responsible for medical management of persons with confirmed or clinically suspected tuberculosis disease shall work in cooperation with the local board of health and the Division of Tuberculosis Control for the purposes of case management as outlined in 105 CMR 365.200.

C) Providers must also notify the local board of health in the town where the patient resides and the Division of Tuberculosis Control, of any person with confirmed or clinically suspected tuberculosis in a communicable form, who is unable or unwilling to receive proper medical care and, as such, poses a threat to the public health.

365.400: Tuberculosis Infection Management

Management and treatment of persons infected with tuberculosis, but without active disease, shall be provided in accordance with the current standards set forth by the CDC/ATS or other qualified medical authority.

365.500: Notification

Any health care provider, laboratory, board of health, office of administration of a city, state or private institution or hospital who has knowledge of a case of confirmed tuberculosis or clinically suspected tuberculosis, as defined in 105 CMR 365.004, shall notify the Division of Tuberculosis Control within 24 hours. Upon receipt of such notice, the Division of Tuberculosis Control shall notify the local board of health within 24 hours. Cases involving residents of the City of Boston having confirmed or clinically suspected tuberculosis shall be reported to both the Department and to the Boston Department of Health and Hospitals within 24 hours. This notice shall include the case name, date of birth, age, sex and address.

365.600: Discharge of Tuberculosis Patient Into Outpatient Treatment

Any acute or chronic care hospital or any other institution which provides health care to residents, including but not limited to: prisons; jails; residential treatment centers; nursing homes and rest homes, which plan to discharge a person with confirmed or clinically suspected tuberculosis into the community for outpatient tuberculosis treatment, shall do discharge planning in collaboration with the State Division of Tuberculosis Control.

The Division shall be notified of such persons with confirmed or clinically suspected tuberculosis, upon his or her admission to the hospital or institution, in order to begin the process for the development of the outpatient case management plan.

A pre-discharge conference regarding case management shall be held and shall include the designated board of health case manager, the TSA nurse from the Division of Tuberculosis Control, as necessary, as well as the discharge planner and medical providers. A plan for appropriate medical, nursing and community agency follow-up shall be made prior to discharge into the community.

Regulatory Authority

105 CMR 365.000: M.G.L. c. 111, §§ 3, 5, 6, 7, 18, 81, 94H, 95; c. 111D, § 6.