



Proposed Amendments to 105 CMR 365.000: STANDARDS FOR MANAGEMENT OF TUBERCULOSIS OUTSIDE HOSPITALS

Public Health Council
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Background

- Tuberculosis (TB) is a disease caused by a bacterium called *Mycobacterium tuberculosis*, the bacteria usually attack the lungs, but can attack any part of the body.
- It is estimated that tuberculosis has been present on Earth for over 20,000 years, but not discovered and named until 1882 by Dr. Robert Koch.
- Once the leading cause of death in the US, today, TB does not make the list of the top ten causes of death.
- A total of 9,421 TB cases were reported in the US in 2014 - over half of these cases were among foreign born persons.
- Cases of TB have been on the decline since 1992, but there is still a need for regulatory framework to inform treatment and care.
- In 2014, 199 cases (incidence rate 3.0 per 100,000 population) of active tuberculosis were reported to the Department of Public Health.
- This case rate is the same rate as in 2013, and the same case rate as the reported across the United States.

<http://www.cdc.gov/tb/>

<http://www.news-medical.net/health/History-of-Tuberculosis.aspx>

<http://www.medicalnewstoday.com/articles/282929.php>

<http://www.cdc.gov/tb/publications/factsheets/statistics/tbtrends.htm>

-Massachusetts Department of Public Health, Bureau of Infectious Disease, Division of Global Populations and Infectious Disease Prevention - Summary Tuberculosis Statistics for the Year 2014. <http://www.mass.gov/eohhs/docs/dph/cdc/tb/summary-data-2014.pdf>

Reasons to Amend

- 105 CMR 365 sets forth the standards for outpatient management of tuberculosis.
- 105 CMR 365 is intended to enhance treatment adherence, provide clinical monitoring, and insure completion of therapy through public health case management.
- This regulation was promulgated in 1956, and has not been updated in over 20 years.
- During that time, terminology and service systems have evolved.

Proposed Amendments

- 105 CMR 365.001: Purpose, 105 CMR 365.002: Authority, 105 CMR 365.003: Citation
 - Sections are proposed for deletion to conform to formatting policy from the Office of the Secretary of State.
- 105 CMR 365.004: Definitions:
 - Removal of the terms Acid Fast Bacilli, Droplet Nuclei
 - Differentiation of the terms Active and Latent Tuberculosis
 - Updated definition of Adherence focused on agreement to follow a treatment plan
 - Description of Adherence Support
 - Update to terminology concerning the terms Clinically Suspected Tuberculosis, Contact, Enablers, Incentives
 - Formalizing the current name of the Tuberculosis Program within the Bureau of Infectious Disease that administers the provisions of 105 CMR 360.000 (formerly named the Division of Tuberculosis Control)
 - Formalizing the current term Tuberculosis Surveillance Nurse within the Bureau of Infectious Disease as a public health nurse who works for the Tuberculosis Program (formerly named Tuberculosis Surveillance Area (TSA) Nurse).

Proposed Amendments cont.

- 105 CMR 365.200: Case management, 105 CMR 365.300: Medical Care and Follow-up
 - Proposed amendments represent mainly practical language changes.
 - Proposed amendments do not fundamentally alter the case management or contact investigation responsibilities of the Tuberculosis Program, identified physician or the local board of health.
 - References to current treatment standards are updated to include the Infectious Disease Society of America (IDSA).
- 105 CMR 365.500: Notification:
 - Proposed removal of the entire section - based on reporting of tuberculosis being covered in 2013 amendments to 105 CMR 300.000 Reportable Diseases, Surveillance, and Isolation and Quarantine Requirements.
- 105 CMR 365.000: Discharge of an Inpatient Tuberculosis Patient to Outpatient Treatment:
 - Proposed amendments represent mainly practical language changes. These proposed amendments do not fundamentally alter the responsibilities of the Tuberculosis Program, identified acute or chronic hospital or the local board of health.

Recommendation/Next Steps

- Bureau of Infectious Disease and Laboratory Sciences has conducted a comprehensive review of 105 CMR 365.000 – Standards for Management of Tuberculosis Outside Hospitals and recommends these proposed amendments.
- Following this presentation to the Public Health Council, a public hearing and comment period will be held.
- A summary of public comments and any changes to the proposed amendments will be presented at a subsequent meeting of the Public Health Council.