

105 CMR: DEPARTMENT OF PUBLIC HEALTH

105 CMR345.000: THE ESTABLISHMENT OF STATE CERTIFIED CLINICS FOR THE DIAGNOSIS,  
TREATMENT AND CONTROL OF SEXUALLY TRANSMITTED DISEASES

Section

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345.001: Purpose

The purpose of 105 CMR 345.000 is to regulate the procedures for designation of state cooperating and certified STD clinics and for reimbursement for treatment of STDs.

345.002: Authority

105 CMR 345.000 is adopted under the authority of M.G.L. c. 111, §§ 3, 5, 6 and 117.

345.003: Citation

105 CMR 345.000 shall be known and may be cited as The Establishment of State Certified Clinics for the Diagnosis, Treatment and Control of Sexually Transmitted Diseases.

345.004: Application

105 CMR 345.000 is applicable to any clinic for the treatment of STDs which seeks designation by the Department as a Certified STD clinic, and to any health care provider who is required by law to report STDs to the Department.

345.010: Definitions

Certified STD Clinic is a facility for treatment of STDs that has been designated by the Department, via an application process, to provide clinical services according to Department Clinical Guidelines to persons infected or suspected of being infected with an STD.

Clinic Guidelines means the policies and procedures established by the Department for the management and treatment of STDs in certified STD clinics.

Commissioner means the Commissioner of the Massachusetts Department of Public Health.

Contact means a person who had sexual exposure to a person infected or suspected of being infected with an STD or, in the case of a newborn infant, exposure during the pregnancy of the infant's mother if the mother is infected or suspected of being infected with an STD.

Department means the Massachusetts Department of Public Health.

Health Care Provider means a physician, physician's assistant or nurse, who is registered in accordance with the provisions of M.G.L. c. 112. 105 CMR: DEPARTMENT OF PUBLIC HEALTH

Prophylactic Treatment means treatment of contacts or persons suspected of being infected with an STD.

Sexually Transmitted Diseases (STDs) are those diseases listed in 105 CMR 300.140(A) and, in addition, other such non-reportable STDs as defined from time to time by the Department including but not limited to, the following: Nongonococcal urethritis, mucopurulent cervicitis (chlamydial), bacterial vaginosis, HIV, herpes genitalis, hepatitis B, scabies, pediculosis pubis, and molluscum contagiosum. Sexually Transmitted Disease shall be abbreviated in 105 CMR 345.000 by "STD".

Sexually Transmitted Disease Control Division or Division refers to that program within the Department which administers the provisions of 105 CMR 345.000.

Suspect is any person with positive physical and/or laboratory findings strongly suggesting an STD infection.

#### 345.099: Waiver of Requirements Imposed on Certified STD Clinics

The Commissioner or his/her designee may waive the applicability to a particular certified STD clinic of one or more of the requirements imposed by 105 CMR 345.000 if:

(A) The Commissioner finds that:

- (1) compliance would cause undue hardship to the STD clinic; and
- (2) the STD clinic's noncompliance does not jeopardize the health or safety of its patients and does not limit the STD clinic's capacity to give adequate care; and

(B) STD clinic provides to the Commissioner or his designee written documentation supporting its request for a waiver.

#### 345.100: Application for Designation as a Certified STD Clinic

(A) Application for designation as a certified STD clinic shall be made in writing as follows:

- (1) in response to a request for proposals (RFP) issued by the Massachusetts Department of Public Health, or

(2) directly to the Director of the Division of Sexually Transmitted Disease Control if not in response to an RFP. Applicants will provide information regarding accessibility, physical facilities, clinical diagnostic and treatment protocols, quality assurance, disease reporting protocols, staffing patterns and proposed hours of operation on a form provided by the Division.

(B) The term application shall include initial and renewal applications.

(C) With respect to a renewal designation, the application shall be submitted in accordance with the RFP, or, in the case of an application not in response to an RFP, such application shall be submitted three months prior to the expiration of the designation.

#### 345.200: Designation as a Certified STD Clinic

The Division will base its decision to accept or reject an application for designation as a certified STD clinic based on the extent to which the applicant satisfies the conditions of the RFP as indicated by the award of a contract, or, upon a review of the information provided pursuant to 105 CMR 345.100(A)(2) and a site visit, based on a determination that the clinic is in compliance with the Clinic Guidelines and the provisions of 105 CMR 345.000. 105 CMR: DEPARTMENT OF PUBLIC HEALTH

#### 345.300: Duties of a Certified Clinic

(A) A certified clinic shall report to the Department, on forms provided for that purpose, every patient with a sexually transmitted disease, every contact, and every suspect who visits the clinic subsequent to its designation as a certified clinic.

(B) Any person found to be infected with an STD shall be referred to a Disease Intervention Specialist (DIS) for assistance with partner notification.

(C) A certified clinic, if designated via a contract, shall submit a monthly bill compiled for all visits of every patient, contact, and suspect, and for pharmacy charges, on forms provided by the Department for that purpose.

(D) A certified clinic shall permit authorized representatives of the Department to examine the clinic record of any patient, contact, or suspect at any reasonable time.

(E) A certified clinic shall dispense without charge any ordinary drugs or appliances necessary or ordinarily used to treat an STD of any patient who cannot afford to purchase the prescribed drugs or appliances.

(F) A certified clinic shall ensure that each patient, contact or suspect receives information on how to reduce the risk of subsequent infections and transmissions to others.

(G) A certified clinic shall conduct its activities in conformance with the Clinic Guidelines.

#### 345.400: Reimbursement

(A) Only clinics operating under a contract via an RFP will be reimbursed by the Department for the examination for and/or treatment of a sexually transmitted disease among cases, contacts, and suspects.

(B) Reimbursement for services rendered in the operation of an STD clinic will be in accordance with agreements made by this Department, and subject to the qualification: that if any patient, contact or suspect can pay any part of the clinic's established fee or has insurance that can do so, he or she shall be required to

do so, and the total amount so collected from such patients, contacts and suspects shall be deducted from the clinic bill submitted to the Department.

#### 345.500: Period of Designation

Each designation as a certified STD clinic shall be for the duration and under the conditions of the operative RFP or, in the case of a clinic that is not operating under a contract with the Department, for a period of one year.

#### 345.501: Visits and Audits

Division staff will visit each certified clinic at least once each year and audit any and all aspects of clinic operations. Follow-up visits, coordinated with clinic officials, may be made as often as is deemed necessary to review audit findings. Results of the audit will be used to renegotiate contracts and to renew certification. Visits may also be made when specific operational issues are brought to the attention of the Department, such as when complaints are filed.

#### 345.502: Deficiency Correction Orders

Each certified clinic will be informed in writing of all audit findings and deficiencies requiring correction. Any clinic that receives a deficiency statement shall submit a plan of correction to the Division within 14 days of the date the statement is sent. If the Division notifies the clinic that the plan of correction is not acceptable, the clinic shall submit an acceptable plan within ten days of the date of such notice.

#### 345.600: Revocation of Designation

(A) Revocation of designation as a certified clinic shall be carried out in accordance with the provisions of the applicable RFP or contract.

(B) In the case of a clinic that is certified other than through the RFP process, the Division may revoke such certification if the clinic has been cited for deficiencies and has either failed to submit an acceptable plan of correction or failed to comply with an acceptable plan of correction. The Division shall provide such clinic with an opportunity for a hearing prior to revocation of certification.

REGULATORY AUTHORITY 105 CMR 345.000: M.G.L. c. 111, §§ 3 and 112.