

## 105 CMR: DEPARTMENT OF PUBLIC HEALTH

### 105 CMR 140.000: LICENSURE OF CLINICS

#### Section

- 140.001: Purpose
- 140.010: Scope
- 140.020: Definitions
- 140.025: Special Projects
- 140.099: Waiver of Requirements Imposed on Clinics

#### Application for License

- 140.101: Requirement of License
- 140.102: Application for a License
- 140.103: Other Licensing Requirements
- 140.104: Timing of Application
- 140.105: Transfer of Ownership and Change in Location
- 140.106: Acceptance of Application
- 140.107: Updating of Information
- 140.108: Evaluation of Application
- 140.109: Evidence of Responsibility and Suitability

#### Inspection

- 140.110: Right to Visit and Inspect
- 140.111: Frequency of Inspection
- 140.112: Deficiency Statements
- 140.113: Plan of Correction

#### Licensing

- 140.120: Issuance of License
- 140.121: Period of License
- 140.122: Coverage of License
- 140.123: Posting of Clinic License

#### License Denial, Refusal to Renew, Revocation, and Suspension

- 140.130: Grounds for Suspension of License or Part of License
- 140.131: Grounds for Denial, Refusal to Renew or Revocation of a License or Part of License
- 140.132: Hearings: Procedures
- 140.133: Hearings: Scope of Review
- 140.134: Judicial Review of Agency Decision
- 140.140: Closing of a Clinic
- 140.141: Temporary Interruption of Service
- 140.150: Requirement for Personnel to Be Vaccinated against Influenza Virus and Coronavirus Disease 2019 (COVID-19) Caused by the Virus SARS-CoV-2

#### Physical Plant

- 140.201: General Physical Environment
- 140.202: Reception and Office Areas
- 140.203: Consultation, Examination and Treatment Areas
- 140.204: Clean Storage and Soiled Holding Areas
- 140.205: Handwashing and Toilet Facilities
- 140.206: Utility Closet
- 140.208: Ventilation
- 140.209: Accessibility to Individuals with Disabilities

#### Supplies and Equipment

- 140.210: Supplies and Equipment
- 140.211: Maintenance and Sanitation of Supplies and Equipment
- 140.212: Linen and Laundry

#### Fire Protection

- 140.220: Emergency Plan
- 140.221: Fire Drills

Section: continued

Administration

- 140.301: Administrative Records
- 140.302: Patient Records
- 140.303: Posting of Notice of Patients' Rights
- 140.304: Off-hour Coverage
- 140.305: Emergency Transfer
- 140.306: Serious Complaint Procedure
- 140.307: Serious Incident Reports
- 140.308: Ambulatory Surgery Center Reporting of Serious Reportable Events and Serious Adverse Drug Events
- 140.309: Ambulatory Surgery Center Healthcare-associated Infection Data Collection, Submission and Reporting

Staff

- 140.310: Clinic Administrator
- 140.311: Professional Services Director
- 140.312: Dual Appointment
- 140.313: Physician Staff and Responsibility for Practice of Medicine
- 140.314: Nursing Staff
- 140.315: Health Care Staff
- 140.316: Nutrition Services
- 140.317: Social Services
- 140.318: In-service Training for Health Care Staff
- 140.330: Satellite Clinics

Clinic Pharmacy Services

- 140.340: Limitation on Dispensing and Administration of Controlled Substances
- 140.341: Compliance with Applicable Laws and Regulations
- 140.342: Clinic Pharmacy Staffing
- 140.343: Clinic Pharmacy Policies
- 140.344: Pharmacy and Therapeutics Committee
- 140.345: Drug Handling and Administration
- 140.346: Facilities and Equipment
- 140.347: Pharmacy Services by Clinics without Clinic Pharmacies

Clinical Laboratory Services

- 140.350: Approval of In-house Clinical Laboratory Services
- 140.351: Contracting for outside Clinical Laboratory Services

Diagnostic Radiology

- 140.360: Compliance with Applicable Laws and Regulations
- 140.361: Radiologist
- 140.362: Radiologic Technologist
- 140.363: Diagnostic Radiology Facilities
- 140.364: Mammography Facility – Licensure
- 140.370: Evaluation of Quality
- 140.380: Procurement, Storage and Administration of Blood
- 140.381: Autologous Hematopoietic Progenitor/Stem Cell Transplantation

- 140.400: Applicability of 105 CMR 140.401 through 140.405
- 140.401: Minimum Dental Services
- 140.402: Dental Services Staff
- 140.403: Dental Policies and Procedures
- 140.404: Anesthesia
- 140.405: Dental Surgery
- 140.450: Applicability of 105 CMR 140.451 through 140.453
- 140.451: Host Sites for Mobile Services

105 CMR: DEPARTMENT OF PUBLIC HEALTH

Section: continued

140.452: Medications for Mobile Services

140.453: Signage for Mobile Services

140.500: Applicability of 105 CMR 140.510 through 140.560

140.510: Mental Health Services

140.520: Adequate Mental Health Services

140.530: Staffing

140.540: Case Review

140.550: Additional Recordkeeping Requirements

140.560: Mental Health Outreach Programs

140.600: Applicability of 105 CMR 140.601 through 140.614

140.601: Incorporation of Medicare Conditions of Participation for Ambulatory Surgical Services

140.602: Surgical and Anesthesia Privileges

140.603: Surgery Director

140.604: Procedures

140.605: Preoperative Evaluation

140.606: Anesthesia Director

140.607: Adequate Assistance

140.608: Surgical Area

140.609: Specimens

140.610: Recovery Procedures

140.612: Physical Environment and Safety Provisions

140.613: Evaluation of Quality

140.614: Limitation on Transfusions

140.620: Surgical Technology Definitions

140.621: Surgical Technology

140.700: Applicability of 105 CMR 140.701 through 140.702

140.701: Physician's Direction and Plan of Care

140.702: Rehabilitation Staff

140.801: Substance Use Disorder Treatment Services

140.901: Birth Center Written Policies and Procedures

140.902: Staffing

140.903: Equipment and Supplies

140.904: Patient Records

140.905: Care and Services

140.906: Prohibited Practices

140.907: Off-hour Coverage

140.908: System for Referral

140.909: Reporting Requirements

140.911: Lithotripsy

140.1000: Applicability of 105 CMR 140.1001 and 140.1002

140.1001: Policies and Procedures for Limited Services Clinics

140.1002: Physical Plant Environment Requirements in Limited Services Clinics

140.1100: Electronic Health Records in Community Health Centers

140.1200: Definitions Applicable to 105 CMR 140.1201

140.1201: Provision of Information on Palliative Care and End-of-life Options

140.1300: Severability

LICENSURE OF CLINICS

140.001: Purpose

105 CMR 140.000 sets forth standards for the maintenance and operation of clinics.

140.010: Scope

105 CMR 140.000 applies to every clinic subject to licensure under M.G.L. c. 111, §§ 51 through 56, including any satellites of a licensed clinic that are not independently licensed.

140.020: Definitions

The following terms as used in 105 CMR 140.000 shall be interpreted as follows, unless the context or subject matter clearly requires a different interpretation:

Ambulatory Surgery Center (ASC). An entity subject to licensure or licensed under M.G.L. c. 111, § 51 and 105 CMR 140.000 to provide surgical services.

Birth Center. A home-like facility where births expected to be low risk are planned to occur following uncomplicated pregnancy.

Birth Center Services. Professional midwifery services provided to low risk pregnant persons during pregnancy, birth, and post-partum, and to the infant during the immediate newborn period by nurse-midwives or by obstetricians or family practitioners. Birth center services are provided in a free standing facility.

Certified Nurse Midwife. An individual authorized by the Board of Registration in Nursing under M.G.L. c. 112, § 80C and authorized to practice as a nurse-midwife pursuant to 244 CMR 4.00: *Advanced Practice Registered Nursing*.

CLIA. Clinical Laboratories Improvements Amendments and its implementing regulations set forth in 42 CFR 493.

Clinic. Any entity, however organized, whether conducted for profit or not for profit, is advertised, announced, established, or maintained for the purpose of providing ambulatory medical, surgical, dental, physical rehabilitation, or mental health services. In addition, clinic shall include any entity, however organized, whether conducted for profit or not for profit, advertised, announced, established, or maintained under a name includes the word clinic, "dispensary", or "institute", and suggests that ambulatory medical, surgical, dental, physical rehabilitation, or mental health services are rendered. With respect to any entity is not advertised, announced, established, or maintained under one of the names in the preceding sentence, Clinic shall not include a medical office building, or one or more practitioners engaged in a solo or group practice, whether conducted for profit or not for profit, and however organized, so long as such practice is wholly owned and controlled by one or more of the practitioners so associated, or, in the case of a not for profit organization, its only members are one or more of the practitioners so associated or a clinic established solely to provide service to employees or students of such corporation or institution. Notwithstanding the foregoing, Clinic shall include any entity certified or has applied for certification as an ambulatory surgery center by the Centers for Medicare and Medicaid Services for participation in the Medicare program. No matter how the clinic is named, clinic shall not include a clinic conducted by a hospital licensed under M.G.L. c. 111, § 51 or by the federal government, or the commonwealth. Clinic shall not include dental clinics operated by local schools and health departments for the sole purpose of providing education and dental hygiene services, including routine examinations, cleaning and topical fluoride applications. Clinic shall not include ad hoc health promotion and screening programs.

Clinic Pharmacy. A pharmacy not registered as a retail drug business pursuant to M.G.L. c. 112, § 39 and which is maintained and operated by a clinic.

140.020: continued

Clinical Laboratory Services. The biological, serological, chemical, immunohematological, cytological, pathological, or other examinations of materials derived from a human body.

Commissioner. The Commissioner of the Massachusetts Department of Public Health or his or her designee.

Dentist. An individual registered by the Board of Registration in Dentistry under M.G.L. c. 112, § 45.

Department. The Massachusetts Department of Public Health.

Diagnostic Radiology. The use of ionizing radiation or ultrasonic procedures for diagnostic purposes only.

Host Site. The location off the premises of the clinic where a clinic provides mobile services.

Licensee. Any person holding a license to operate a clinic. In the case of a licensee that is not a natural person, Licensee shall also mean any shareholder owning 5% or more of any class of the outstanding stock of a privately-held corporation; any limited partner owning 5% or more of the partnership interests and any general partner of a partnership licensee; any trustee of any trust licensee; any sole proprietor of any licensee that is a sole proprietorship; any mortgagee in possession; and any executor or administrator of an estate of a licensee.

Mental Health. Any condition pertaining to mental health as defined by the 5<sup>th</sup> edition of the Diagnostic and Statistical Manual of Mental Disorders.

Mental Health Outreach Program. A mental health program, which may include treatment of co-occurring substance use disorder treatment, delivered off the premises of a clinic or any of its satellite clinics that provides services in patients' homes or other community environments, including practitioners' offices or community health centers defined as free-standing or hospital licensed community health centers licensed by the Department pursuant to M.G.L. c. 111, § 51.

For the purposes of 105 CMR 140.000, outreach services do not include patient visits to a practitioner's home or office.

Mobile Unit. A specially equipped, self-contained vehicle that may be driven, moved, towed or transported from one location to another, such as a van or trailer.

Mobile/Portable Unit. A mobile unit from which, from time to time, equipment and supplies may be removed to offer services at a location outside the mobile unit at which the clinic will provide licensed services. A Mobile/Portable Unit shall not mean a satellite of the clinic.

Notice of Intent Form. A form prescribed by the Department through which an applicant notifies the Department of its intent to acquire a clinic and/or to apply for a license to operate a clinic.

Nurse Practitioner. A registered nurse who holds authorization in advanced nursing practice as a nurse practitioner under M.G.L. c. 112, § 80B.

Nutritionist. A person who has an M.S. in public health nutrition, community nutrition, or human nutrition, from an accredited institution or who has a B.S. and is registered by the American Dietetic Association.

Physician. An individual registered by the Board of Registration in Medicine under M.G.L. c. 112, § 2 as a qualified physician.

Physician Assistant. A person who meets the requirements for registration set forth in M.G.L. c. 112, § 9I and who may provide medical services appropriate to his or her training, experience and skills under the supervision of a registered physician.

140.020: continued

Podiatrist. An individual registered by the Board of Registration in Podiatry under M.G.L. c. 112, § 16.

Point-of-care Testing. The analysis of clinical specimens at the site of patient care, in order to provide immediate results to the health care provider. Examples of point-of-care tests include blood glucose tests, urine strip tests and other tests that do not require submission of the specimens to an outside laboratory.

Portable Unit. A vehicle that only transports equipment, supplies and/or personnel to a host site location at which the clinic will provide licensed services. A Portable Unit may be an extension/addition of services provided by a clinic with an existing licensed physical site, an addition/extension of services provided by a mobile unit, or a clinic that is exclusively portable, with no licensed physical site or mobile unit in which services are provided.

Practice. An enterprise involving the diagnosis or treatment of medical, surgical, dental, physical rehabilitation, or mental health problems. The supervision and direction of clinical staff, the assignment of patients to practitioners or other clinical staff, and the maintenance of patient records shall be deemed to be part of a practice. Billing and collection services, rental of space and rental of equipment shall also be considered part of a practice; however, the provision by a nonpractitioner of any one of these services to practitioner(s) shall not by itself mean such nonpractitioner shares in the control of the practice.

Practitioner. Any individual who holds a license, registration or authorization pursuant to M.G.L. c. 112 that authorizes the individual to diagnose and treat medical, surgical, dental, physical rehabilitation, or mental health problems within the scope of practice for his or her profession.

Primary Care Provider. A health care professional qualified to provide general medical care for common health care problems, who supervises, coordinates, prescribes or otherwise provides or proposes health care services, initiates referrals for specialist care and maintains continuity of care within the scope of practice.

Psychiatric Day Treatment Program. A specialized mental health program providing a planned combination of diagnostic, treatment, and rehabilitative services to individuals seeking treatment for mental health conditions, which may include co-occurring substance use disorder, who need more active or inclusive treatment than is typically available through a weekly visit to a mental health center or hospital outpatient department, but who do not need full-time hospitalization or institutionalization. Such a program utilizes multiple, intensive, and focused activities in a supportive environment to enable such persons to acquire more realistic, skillful, and effective behavior patterns, attitudes, and skills to support sustained independent functioning in the community. A clinic may provide psychiatric day treatment services only if it is licensed to provide mental health services.

Registered Nurse. An individual registered under M.G.L. c. 112, § 74.

Registered Pharmacist. An individual registered by the Board of Registration in Pharmacy pursuant to M.G.L. c. 112, § 24.

Satellite Clinic. A clinic operation off the premises of a clinic at which health services are provided, other than a mobile service. A Mental Health Outreach Program as defined in 105 CMR 140.020 shall not be considered a satellite clinic.

Social Worker. An individual who is currently licensed to practice social work in Massachusetts pursuant to M.G.L. c. 112, § 131 under the licensure categories of Licensed Independent Practitioner of Clinical Social Work, or Licensed Certified Social Worker.

Solo or Group Practice. The primary enterprise of the practitioner(s) as identified with the practitioner's licensing authority.

140.020: continued

Specific Service. Any one of the following:

- (1) Surgical Service. A service providing diagnosis or care through endoscopic procedures, or operative procedures requiring regional or general anesthesia.
- (2) Dental Service. A service providing oral diagnostic, maintenance, preventive and restorative care and treatment to relieve dental pain and infection.
- (3) Physical Rehabilitation Service. A service that provides physical restoration to physically handicapped and disabled persons through such therapies as physical therapy, occupational therapy and speech therapy.
- (4) Mental Health Service. A separate, identifiable service providing diagnosis and treatment to individuals seeking treatment for mental health conditions, which may integrate treatment for co-occurring substance use disorder, and their families.
- (5) Medical Service. A service providing diagnosis or treatment of illness or other medical services that are distinct from the services provided under 105 CMR 140.020: Specific Service(1) through (9).
- (6) Mobile Service. A service providing diagnostic or treatment services through a mobile unit, a portable unit or a mobile/portable unit.
- (7) Substance Use Disorder Treatment Service. A separate, identifiable service for individuals seeking treatment for substance use disorders which may integrate treatment for co-occurring mental health conditions.
- (8) Birth Center Service. A service providing professional midwifery services to low risk pregnant persons during pregnancy, birth, and post-partum, and to the infant during the immediate newborn period by nurse-midwives or by obstetricians or family practitioners.
- (9) Limited Services. Diagnosis, treatment, management and monitoring of acute and chronic disease, wellness and preventive services of a nature that may be provided within the scope of practice of a nurse practitioner using available facilities and equipment, including shared toilet facilities for point-of-care testing. Limited Services shall not mean surgical services, dental services, physical rehabilitation services, mental health services, substance use disorder services, or birth center services as defined in 105 CMR 140.020: Specific Service(1) through (8), which require a separate licensure designation.

Substance Use Disorder. Any condition pertaining to substance use disorder as defined by the 5<sup>th</sup> edition of the Diagnostic and Statistical Manual of Mental Disorders.

Transfer of Ownership. Includes, but not be limited to, the following transfers:

- (1) a transfer of a majority interest in the ownership of a clinic;
- (2) in the case of a privately-held for-profit corporation, transfer of a majority of any class of the stock thereof;
- (3) in the case of a partnership, transfer of a majority of the partnership interest;
- (4) in the case of a trust, change of the trustee or a majority of trustees; or
- (5) in the case of a nonprofit corporation, such changes in the corporate membership and/or trustees as the Department determines to constitute a shift in control of the clinic.

Transfer of Ownership also means any change in the ownership interest or structure of the clinic or the clinic's organization or parent organization(s) that the Commissioner determines to effect a change in control of the operation of the clinic. A transfer of ownership shall also be deemed to have occurred where foreclosure proceedings have been instituted by a mortgagee in possession. The Commissioner may, in his or her discretion, determine a proposed transaction does not rise to the level of a transfer of ownership.

Urgent Care. Delivery of episodic care for the diagnosis, treatment, management or monitoring of acute and chronic disease or injury that is:

- (1) for the treatment of illness or injury that is immediate in nature, but does not require emergency services;
- (2) generally provided on a walk-in basis without prior appointment; and
- (3) available to the general public; and not intended as the patient's primary care provider.

Urgent Care shall not mean surgical services, dental services, physical rehabilitation services, mental health services, substance use disorder services, birth center services or limited services as defined in 105 CMR 140.020: Specific Service(1) through (9), which require a separate licensure designation; or Emergency Service or Satellite Emergency Facility as defined in 105 CMR 130.020: *Hospital Licensure*.

140.025: Special Projects

The Department will consider proposals for special projects for the innovative delivery of clinic services. No such proposal shall be implemented without prior written approval of the Department. The Department may impose conditions on special projects as necessary.

140.099: Waiver of Requirements Imposed on Clinics

The Department may waive the applicability to a particular clinic of one or more of the requirements imposed on clinics by 105 CMR 140.000 if:

- (A) the Department finds:
  - (1) compliance would cause undue hardship to the clinic;
  - (2) the clinic is in substantial compliance with the spirit of the requirement; and
  - (3) the clinic's noncompliance does not jeopardize the health or safety of its patients and does not limit the clinic's capacity to give adequate care.
- (B) the clinic provides to the Department written documentation supporting its request for a waiver.

140.101: Requirement of License

Every entity within the definition of "clinic" in M.G.L. c. 111, § 52 is required by M.G.L. c. 111, §§ 51 and 56 to obtain a clinic license from the Department covering all locations at which the clinic provides services.

140.102: Application for a License

- (A) Applications for licensure shall be made on forms prescribed by the Department. The term "application" as used in 105 CMR 140.102 shall include initial and renewal applications.
- (B) In support of an application for an original or renewal license, each applicant shall submit the following information, updated as required by 105 CMR 140.107:
  - (1) Information concerning ownership or control that identifies:
    - (a) If owned by an individual, partnership or trust, the names and ownership percentages of such individual, partners or trustees, except, in the case of a limited partnership, such information shall be provided only for those limited partners owning 5% or more of the partnership interest and the general partner.
    - (b) If owned by a privately held for-profit corporation, the names of all stockholders who hold 5% or more of any class of the outstanding stock, specifying the percentage owned.
    - (c) If owned by a not-for-profit corporation, the names of the members and directors of the corporation.
    - (d) The name and ownership percentage of each individual who directly or indirectly has any ownership interest of 5% or more, unless otherwise provided pursuant to 105 CMR 104.102(B)(1)(a), (b) or (c).
  - (2) If ownership of the clinic has been transferred, satisfactory documentary evidence (such as a contract or a deed) showing ownership of the clinic has been transferred to the applicant.
  - (3) Any information required by the Commissioner as part of the application, including such additional information concerning ownership or control as the Commissioner may require.
- (C) Deemed-by-accreditation Licensure for Ambulatory Surgery Centers. The Department may deem the conditions of original or renewal licensure in 105 CMR 140.000 satisfied for an ambulatory surgery center (ASC) meeting the requirements of 105 CMR 140.102(C).
  - (1) Deemed-by-accreditation Original License. An ASC meeting the following criteria shall be eligible to apply for a deemed-by-accreditation original license from the Department.



140.102: continued

- (a) on the date of application, the entity is accredited to provide ambulatory surgery services by the Accreditation Association for Ambulatory Health Care, Inc. (AAAHC), the Joint Commission, the American Association for Accreditation of Ambulatory Surgery Facilities (AAAASF) or any other national accrediting body as determined by the Department; and
  - (b) on the date of application, the entity is certified or has applied for certification as an ASC by the Centers for Medicare and Medicaid Services for participation in the Medicare program;
- (2) Deemed-by-accreditation Renewal License. An ASC meeting the following criteria shall be eligible to apply for a deemed-by-accreditation renewal license from the Department:
  - (a) on the date of application, the entity is accredited to provide ambulatory surgery services by the Accreditation Association for Ambulatory Health Care, Inc. (AAAHC), the Joint Commission, the American Association for Accreditation of Ambulatory Surgery Facilities (AAAASF) or any other national accrediting body as determined by the Department; and
  - (b) on the date of application, the entity is certified as an ASC by the Centers for Medicare and Medicaid Services for participation in the Medicare program;
- (3) Application for Deemed-by-accreditation License. An application for a deemed-by-accreditation original or renewal license shall be made on forms prescribed by the Department. The applicant or licensee shall:
  - (a) submit the information required by 105 CMR 104.102(B);
  - (b) release to the Commissioner a copy of the applicant or licensee's current accreditation letter and the accrediting agency's explanation of its survey findings; and
  - (c) for a deemed-by-accreditation original license, comply with the requirements of 105 CMR 140.103(A), (B), (C)(2), and (D).
- (4) Evaluation of Deemed-by-accreditation License Application. The Department shall not approve an application for deemed-by-accreditation original or renewal license, unless it determines:
  - (a) the requirements of 105 CMR 140.108(B) and 105 CMR 140.109 relating to responsibility and suitability are met; and
  - (b) for a deemed-by-accreditation original license, the requirements of 105 CMR 140.108(C) relating to determination of need or exemption there from are met.
- (5) Obligations of Deemed-by-accreditation Licensee. Upon issuance of a deemed-by-accreditation original or renewal license, a licensee is subject to all of the requirements of 105 CMR 140.000, unless otherwise specified. In addition, a deemed-by-accreditation licensee shall:
  - (a) permit Department staff to participate in any summation conference(s) scheduled at the completion or renewal of accreditation; and
  - (b) release to the Commissioner any other accreditation information requested or specified in guidelines of the Department.
- (6) Suspension, Denial, Refusal to Renew, or Revocation of Deemed-by-accreditation License.
  - (a) Following the procedures in 105 CMR 140.132 through 140.134, the Commissioner may suspend, deny, refuse to renew, or revoke a deemed-by-accreditation license on any of the grounds specified in 105 CMR 140.130 or 105 CMR 140.131.
  - (b) In addition the Commissioner may suspend, deny, refuse to renew, or revoke a deemed-by-accreditation license under the following circumstances:
    - 1. the licensee loses its accreditation status;
    - 2. the Commissioner finds the licensee is out of compliance with one or more conditions of accreditation or determines a significant deficiency exists;
    - 3. the licensee's application for Medicare certification is denied; or
    - 4. the Commissioner finds the licensee is out of compliance with one or more Medicare Conditions of Participation or determines a significant deficiency exists.

140.103: Other Licensing Requirements

- (A) Ownership Interest. An applicant or licensee must be the owner of the premises on which the facility is operated or lessee of the premises for at least one year.

140.103: continued

(B) Name. Each clinic applying for a license shall be designated by a permanent and distinctive name, which shall appear on the application for a license. The Department may disapprove any name that misrepresents or may otherwise mislead the public regarding the ownership of the clinic or the services provided. A clinic may not change its name without prior approval by the Department.

(C) Prior Approvals. As a prerequisite for a license, all applicants must obtain and submit the following documents in support of the application for licensure:

- (1) a copy of the certificate of inspection issued by a building inspector of the Department of Public Safety or appropriate local jurisdiction stating the clinic and any satellite clinic premises comply with the Department's requirements governing egresses, fire prevention, and fire extinguishing apparatus; and
- (2) a copy of the certificate of inspection issued by the head of the local fire department stating the clinic and any satellite clinic premises comply with local ordinances.

(D) Fees. The clinic license fee shall accompany every application submitted. Payment of the fee shall be by check or money order payable to the Commonwealth of Massachusetts. The fee shall be subject to refund only in the event the application is withdrawn.

(E) Submission and Approval of Plans. In the case of new construction of a clinic or any satellite clinic, or in the case of alterations or additions to an existing clinic or any satellite clinic, preliminary architectural plans and final architectural plans and specifications shall be submitted to the Commissioner.

- (1) No clinic may begin construction without prior written approval of the Commissioner.
- (2) The Commissioner shall establish standards for review and approval of plans, based on the *Facility Guidelines Institute's Guidelines for Design and Construction of Health Care Facilities*. Those provisions of the *Facility Guidelines Institute's Guidelines for Design and Construction of Health Care Facilities* which pertain to services a particular clinic does not provide shall not apply to the clinic.
- (3) In the case of a clinic providing mobile services, the clinic may be required to submit plans for siting at each host location, including contracts and/or lease arrangements for the use of space at the host location.
- (4) The Commissioner shall establish standards for review and approval of plans for clinics providing only birth center services, based on the facility requirements in the Commission for the Accreditation of Birth Centers Indicators of Compliance. Clinics providing only birth center services shall be exempt from 105 CMR 140.103(E)(2).

(F) Each applicant shall include a description of the specific service as defined in 105 CMR 140.020 for which it is seeking licensure. An applicant for a limited services clinic license shall include on the licensure application a description of the limited services it proposes to provide.

(G) An applicant seeking licensure for a mobile service license shall include on the licensure application the following information:

- (1) a description of the services to be provided by each mobile, portable, or mobile/portable unit; and
- (2) the proposed schedule for the provision of services by each unit or at each host site.

(H) Each clinic shall comply with all applicable state and federal statutes and regulations pertaining to health care facilities, including any applicable statutes and regulations of the Division of Medical Assistance.

140.104: Timing of Application

(A) In the case of a transfer of ownership, the application shall be submitted no later than two business days following the transfer; provided, however, the Department will not accept an application from any owner who was not found suitable pursuant to 105 CMR 140.109.

(B) Clinics shall submit applications for renewals at least 60 days prior to expiration of the license.

140.105: Transfer of Ownership and Change in Location

- (A) A licensed clinic must notify the Department in writing of any proposed change in name or location of a facility at least 30 days prior to the change. A license shall not be transferred from one person or entity to another or from one location to another.
- (B) The proposed licensee shall submit a Notice of Intent form to acquire a clinic to the Department at least 30 calendar days in advance of any transfer of ownership.
- (C) Any person applying for a license as a result of any transfer of ownership shall file an application for licensure within two business days of the transfer. If the Notice of Intent form was not timely filed, at the discretion of the Commissioner, an application received as a result of a transfer of ownership will not be considered as filed for 30 calendar days, or such longer period as the Commissioner shall designate in order to conduct a suitability review, after such application is received.
- (D) An application filed as a result of a transfer of ownership, if timely filed, shall have the effect of a license for a period of three months from the date of filing or until such time as the Department takes action on the application. If not timely filed, such an application shall not have such effect.
- (E) Any notice of hearing, order or decision the Department or the Commissioner issues for a clinic prior to a transfer of ownership shall be effective against the former owner prior to such transfer and, where appropriate, the new owner, following such transfer, unless said notice, order or decision is modified or dismissed by the Department or by the Commissioner.
- (F) A transfer of ownership shall not be recognized and the new owner shall not be considered suitable for licensure when the transfer is proposed or made to circumvent the effect and purposes of 105 CMR 140.000. The Department shall consider the following factors in determining whether a transfer has been proposed or made to circumvent 105 CMR 140.000:
- (1) the transferor's record of compliance with Department licensure laws and 105 CMR 140.000;
  - (2) the transferor's current licensure status;
  - (3) the transferor's familial, business and/or financial relation to the transferee;
  - (4) the terms of the transfer; and
  - (5) the consequences of the transfer.
- (G) To transfer ownership, an ambulatory surgery center must comply with any additional procedures set forth in 105 CMR 100.000 *Determination of Need*.

140.106: Acceptance of Application

- (A) The Department shall not accept an application for an original or renewal license unless:
- (1) the application includes all information required by the Department;
  - (2) the application and all required attachments and statements submitted by the applicant meet the requirements of 105 CMR 140.000; and
  - (3) the applicant has paid all required fees.
- (B) In the case of the transfer of ownership of a clinic, the application of the new owner for a license shall not have the effect of a license for a period of three months (or until such time as the Department takes action on the application) when the application is not filed in accordance with 105 CMR 140.106(A).

140.107: Updating of Information

Each licensee shall keep current all ownership or control information submitted under the requirements of 105 CMR 140.000 or otherwise required by the Commissioner. Each licensee shall file any document that amends, supplements, updates or otherwise alters any ownership or control document with the Department within 30 calendar days of the execution thereof. Each licensee shall file any changes in, or additions to, the content of the information contained in any ownership or control document required to be filed to the Department within 30 calendar days of such change or addition.

140.108: Evaluation of Application

The Department shall not approve an application for original or renewal license, unless:

- (A) the Department has conducted an inspection or other investigation of the facility and has determined the applicant complies with all applicable provisions in 105 CMR 140.000;
- (B) the Commissioner has conducted an investigation of the proposed licensee(s) and determined each proposed licensee is suitable and responsible to establish or maintain a clinic; and
- (C) in the case of original licensure or addition of a satellite unit, the Department has determined there is need for the facility at the designated location if the facility is subject to determination of need pursuant to M.G.L. c. 111, § 51.

140.109: Evidence of Responsibility and Suitability

(A) In determining whether an applicant is responsible and suitable to be granted a clinic license, the Department shall consider all relevant information including, but not limited to, the following:

- (1) the proposed licensee's history of prior compliance with Massachusetts state laws and regulations governing health facility operation. Assessment of this factor shall include the ability and willingness of the proposed licensee to take corrective action when notified by the Department of any regulatory violations;
- (2) the proposed licensee's financial capacity to provide services in compliance with state law and 105 CMR 140.000 as evidenced by sufficiency of present resources and assessment of past history, including financial involvement with health care facilities that have filed petitions for bankruptcy;
- (3) the history of criminal conduct of the proposed licensee and clinic administrator, officers and directors as evidenced by criminal proceedings against those individuals resulting in convictions, or guilty pleas, or pleas of *nolo contendere*, or admission of sufficient facts; and
- (4) the proposed licensee's history of suspension, revocation, or refusal to grant or renew a health care facility license in other jurisdictions, or suspension, revocation or refusal of certification for Medicaid or Medicare to the proposed licensee.

(B) The Commissioner will consider the evidence produced and make licensure recommendations accordingly.

140.110: Right to Visit and Inspect

The Department or its agents may visit and inspect a clinic, satellite, or mobile or portable unit subject to licensure under M.G.L. c. 111, § 51 at any time without prior notice in order to determine the clinic's compliance with state law and 105 CMR 140.000. All parts of the clinic, satellite, or mobile or portable unit (including the site of any mental health outreach program), all staff and activities, and all records are subject to such visit and inspection.

140.111: Frequency of Inspection

The Department shall make an inspection or other investigation prior to the issuance of every license. Additional inspections may be made, consistent with the availability of staff, whenever the Commissioner deems it necessary for the enforcement of 105 CMR 140.000.

140.112: Deficiency Statements

After every inspection in which any violation of 105 CMR 140.000 is observed, the Commissioner shall prepare a deficiency statement citing every violation observed, a copy of which shall be sent to the clinic.

140.113: Plan of Correction

(A) A clinic shall submit to the Commissioner a written plan of correction of violations cited in a deficiency statement prepared pursuant to 105 CMR 140.112 within ten calendar days after receipt of the deficiency statement.

(B) Every plan of correction shall set forth, with respect to each deficiency, the specific corrective step(s) to be taken, a timetable for such steps, and the date by which compliance with 105 CMR 140.000 will be achieved. The timetable and the compliance dates shall be consistent with achievement of compliance in the most expeditious manner possible.

(C) The Department shall review the plan of correction for compliance with the requirements of 105 CMR 140.113(B) and will notify the licensee of either the acceptance or rejection of the plan. An unacceptable plan must be amended and resubmitted within five calendar days of the date of notice.

140.120: Issuance of License

Upon the approval of the application for a license, the Department shall issue a clinic license to the applicant. Every license shall state the name and address of the clinic if either differs from that of the licensee; the period of licensure; the specific service(s) the clinic is licensed to deliver; and the name and address of any satellite clinic. In the case of a clinic providing mobile medical services, the license shall state the name and address of the clinic, including address of the administrative offices, if separate from the site(s) of service, and the name and address of the host locations.

140.121: Period of License

(A) The Department shall issue a clinic license for a period of two years.

(B) Provided a licensed clinic submits a timely application for a renewal license, its previous license shall be valid until the Department acts on its renewal application.

140.122: Coverage of License

A license is valid only for the premises and the specific services authorized by the Department.

140.123: Posting of Clinic License

The current license from the Department, or a copy thereof, shall be posted in a conspicuous place in the clinic, and in any of its satellites or mobile services sites.

140.130: Grounds for Suspension of License or Part of License

The Commissioner may summarily suspend a clinic's license or a part of its license covering a specific service or specific services, if he or she decides the continuation in operation of the clinic or the specific service(s) poses an imminent risk to the safety or proper health care of the clinic's patients.

140.131: Grounds for Denial, Refusal to Renew or Revocation of a License or Part of License

Each of the following, in and of itself, shall constitute full and adequate grounds on which to deny, revoke, or refuse to renew a license to operate a clinic in whole or in part with respect to a specific service or specific services or a part or parts thereof:

(A) Lack of legal capacity to provide the service(s) to be covered by a license.

(B) Lack of responsibility and suitability to operate a clinic.

(C) Failure to submit the required license fee.

140.131: continued

- (D) Violation of any state or federal statute or regulation pertaining to operation of the clinic.
- (E) Violation of any applicable provision of 105 CMR 140.000 and:
  - (1) Failure to submit an acceptable plan of correction pursuant to 105 CMR 140.113; or
  - (2) Failure to remedy or correct a cited violation by the date specified in the plan of correction as accepted or modified by the Department.
- (F) Willful misrepresentation of information or data submitted to the Department or any other agency of the Commonwealth.
- (G) Denial of the right of agents of the Department to visit and inspect.
- (H) Provision of services as defined in 105 CMR 140.020 for which the clinic is not licensed.

140.132: Hearings: Procedure

- (A) Suspension of a License.
  - (1) Upon suspension of a license or any part thereof, the Commissioner shall give the licensee written notice thereof, stating the reason(s) for the suspension. The suspension shall take effect immediately upon issuance of the notice.
  - (2) The Department shall initiate a hearing pursuant to 801 CMR 1.00: *Standard Adjudicatory Rules of Practice and Procedure* no later than 21 calendar days after the effective date of the suspension.
  - (3) In cases of suspension of a license, the hearing officer shall determine whether the Department has proved by a preponderance of the evidence there existed, immediately prior to or at the time of the suspension, an imminent risk to the safety or proper health care of the clinic's patients.
- (B) Revocation of or Refusal to Renew License.
  - (1) A license may be revoked or refused renewal in whole or in part only after a hearing as required by M.G.L. c. 111, § 51.
  - (2) If the Commissioner determines a licensee is not suitable or responsible or a license should be revoked or refused renewal pursuant to 105 CMR 140.000, the Commissioner shall initiate a hearing pursuant to 801 CMR 1.00: *Standard Adjudicatory Rules of Practice and Procedure*.
  - (3) In cases of revocation of or refusal to renew a license, the hearing officer shall determine whether the Department has proved by a preponderance of the evidence the licensee is not suitable or responsible and/or the license should be revoked or refused renewal, based on relevant facts as they existed at or prior to the time the Commissioner initiated the hearing procedure.
- (C) License Denial.
  - (1) Upon receipt of notice that an application for original licensure has been denied, a proposed licensee may appeal to a hearing officer pursuant to 801 CMR 1.00: *Standard Adjudicatory Rules of Practice and Procedure*.
  - (2) In cases of denial of an original license, the hearing officer shall determine whether the the applicant has proved by a preponderance of the evidence the proposed licensee is suitable and responsible for licensure under M.G.L. c. 111, § 51, and 105 CMR 140.000.
- (D) Denial, Revocation or Refusal to Renew Based on Lack of Certificate of Inspection. If the Department is notified the local jurisdiction or the head of the local fire department has denied any applicant or licensee a certificate of inspection, and that an appeal, if requested, has been duly denied by the local jurisdiction or the head of the local fire department, the Commissioner may:
  - (1) inform the applicant or licensee the Department has been notified a certificate of inspection has been denied;
  - (2) offer the applicant or licensee an opportunity to submit a current certificate of inspection within two weeks, or within such other time period as the Commissioner shall designate; or

140.132: continued

(3) deny, revoke or refuse to renew the license of the applicant or licensee without further hearing, unless the applicant or licensee submits a current certificate of inspection within the time allowed.

140.133: Hearings: Scope of Review

(A) Any hearing officer conducting a hearing shall determine the suitability or responsibility of any licensee or proposed licensee on request of the Department, whether or not the applicant or licensee is licensed at the time the determination is made.

(B) If a hearing officer finds the licensee or proposed licensee is unsuitable or not responsible under any single provision of 105 CMR 140.109, the hearing officer shall uphold the decision of the Commissioner and finds the proposed licensee or licensee is not suitable or responsible.

(C) If the hearing officer finds any single ground for denial of, revocation of or refusal to renew a license pursuant to 105 CMR 140.131 the hearing officer shall uphold the decision of the Commissioner to deny, revoke or refuse to renew the license.

140.134: Judicial Review of Agency Decision

(A) The decision of a hearing officer in any adjudicatory proceeding conducted pursuant to 105 CMR 140.132 shall be reviewed by the Commissioner. His or her decision upon this review shall constitute a final agency decision in an adjudicatory proceeding subject to judicial review pursuant to M.G.L. c. 30A, § 14.

(B) Any licensee or proposed licensee that fails to exercise its right to an adjudicatory proceeding pursuant to 105 CMR 140.132 waives both its right to administrative review by the Commissioner and its right to judicial review pursuant to M.G.L. c. 30A, § 14.

140.140: Closing of a Clinic

If a clinic intends to cease operation for a period greater than seven consecutive days, it shall obtain written approval for a specified period from the Commissioner at least 30 calendar days in advance of the proposed closing. If circumstances are such that it is not possible to obtain approval from the Commissioner prior to closing, such approval shall be obtained within three business days of closing. Failure to obtain approval and closure of the clinic for more than seven days shall constitute abandonment of license.

140.141: Temporary Interruption of Service

If a clinic finds any of the services required under 105 CMR 140.000 cannot be provided to patients for a temporary period of time, the clinic shall report such a temporary interruption of service to the Department as soon as the interruption of service is known to the clinic.

140.150: Requirement for Personnel to Be Vaccinated against Influenza Virus and Coronavirus Disease 2019 (COVID-19) Caused by the Virus SARS-CoV-2

(A) Requirement for Personnel to Be Vaccinated against Influenza Virus.

(1) Definitions.

(a) For purposes of 105 CMR 140.150(A), personnel means an individual or individuals who either work at or come to the licensed clinic site and who are employed by or affiliated with the clinic, whether directly, by contract with another entity, or as an independent contractor, paid or unpaid including, but not limited to, employees, members of the clinical staff, contract employees or staff, students, and volunteers whether or not such individual(s) provides direct patient care.

140.150: continued

- (b) For purposes of 105 CMR 140.150(A), the requirement for influenza vaccine or vaccination means immunization by either influenza vaccine, inactivated or live; attenuated influenza vaccine including seasonal influenza vaccine pursuant to 105 CMR 140.150(A)(2); and/or other influenza vaccine pursuant to 105 CMR 140.150(A)(3).
- (c) For purposes of 105 CMR 140.150(A), mitigation measures mean measures that personnel who are exempt from vaccination take to prevent viral infection and transmission.
- (2) Each clinic shall ensure all personnel are vaccinated annually with seasonal influenza vaccine, consistent with any guidelines of the Commissioner, unless an individual is exempt from vaccination in accordance with 105 CMR 140.150(A)(6).
- (3) Each clinic shall also ensure all personnel are vaccinated against other pandemic or novel influenza virus(es) as specified in guidelines of the Commissioner, unless an individual is exempt from vaccination in accordance with 105 CMR 140.150(A)(6). Such guidelines may specify:
  - (a) the categories of personnel to be vaccinated and the order of priority of vaccination of personnel, with priority for personnel with responsibility for direct patient care;
  - (b) the influenza vaccine(s) to be administered;
  - (c) the dates by which personnel must be vaccinated; and
  - (d) any required reporting and data collection relating to the personnel vaccination requirement of 105 CMR 140.150(A)(3).
- (4) Each clinic shall provide all personnel with information about the risks and benefits of influenza vaccine.
- (5) Each clinic shall notify all personnel of the influenza vaccination requirements of 105 CMR 140.150(A) and shall, at no cost to any personnel, provide or arrange for vaccination of all employees who cannot provide proof of current immunization against influenza, as required pursuant to 105 CMR 140.150(A)(2) and (3), unless an individual is exempt from vaccination in accordance with 105 CMR 140.150(A)(6).
- (6) Exemptions.
  - (a) Subject to the provisions set forth in 105 CMR 140.150 (A)(6)(b), a clinic shall not require an individual to receive an influenza vaccine pursuant to 105 CMR 140.150(A)(2) or (3) if the individual declines the vaccine.
  - (b) For any individual subject to the exemption, a clinic may require such individual take mitigation measures, consistent with guidance from the Department.
  - (c) An individual who is exempt from vaccination shall sign a statement certifying they are exempt from vaccination and they received information about the risks and benefits of the influenza vaccine.
- (7) Unavailability of Vaccine. A clinic shall not be required to provide or arrange for influenza vaccination during such times that the vaccine is unavailable for purchase, shipment, distribution or administration by a third-party, or when complying with an order of the Commissioner restricts the use of the vaccine. A clinic shall obtain and administer influenza vaccine in accordance with 105 CMR 140.150(A) as soon as vaccine becomes available.
- (8) Documentation.
  - (a) A clinic shall require and maintain for each individual proof of current vaccination against influenza virus pursuant to 105 CMR 140.150(A) or the individual's exemption statement pursuant to 105 CMR 140.150(A)(6).
  - (b) Each clinic shall maintain a central system to track the vaccination status of all personnel.
  - (c) If a clinic is unable to provide or arrange for influenza vaccination for any individual, it shall document the reasons such vaccination could not be provided or arranged for.
- (9) Reporting and Data Collection. Each clinic shall report information to the Department documenting the clinic's compliance with the personnel vaccination requirements of 105 CMR 140.150(A), in accordance with reporting and data collection guidelines of the Commissioner.
- (10) 105 CMR 140.150 establishes requirements for influenza vaccination of clinic personnel. Nothing in 105 CMR 140.000 shall be read to prohibit clinics from establishing policies and procedures for influenza vaccination of personnel that exceed the requirements set forth in 105 CMR 140.150.



140.150: continued

(B) Requirement for Personnel to Be Vaccinated against Coronavirus Disease 2019 (COVID-19) Caused by the Virus SARS-CoV-2.

(1) Definitions.

(a) For purposes of 105 CMR 140.150(B), personnel means an individual or individuals who either work at or come to the licensed clinic site and who are employed by or affiliated with the clinic, whether directly, by contract with another entity, or as an independent contractor, paid or unpaid including, but not limited to, employees, members of the medical staff, contract employees or staff, students, and volunteers, whether or not such individual(s) provide direct care.

(b) For purposes of 105 CMR 140.150(B), COVID-19 vaccination means being up to date with COVID-19 vaccines as recommended by the Centers for Disease Control and Prevention (CDC).

(c) For purposes of 105 CMR 140.150(B), mitigation measures mean measures that personnel who are exempt from vaccination take to prevent viral infection and transmission.

(2) Each clinic shall ensure all personnel have received COVID-19 vaccination in the timeframe specified in Department guidelines, unless an individual is exempt from vaccination in accordance with 105 CMR 140.150(B)(5).

(3) Each clinic shall provide all personnel with information about the risks and benefits of COVID-19 vaccination.

(4) Each clinic shall notify all personnel of the COVID-19 vaccination requirements of 105 CMR 140.150(B) and shall, at no cost to any personnel, provide or arrange for vaccination of all personnel who cannot provide proof of current vaccination against COVID-19 unless an individual is exempt from vaccination in accordance with 105 CMR 140.150(B)(5).

(5) Exemptions.

(a) Subject to the provisions set forth in 105 CMR 140.150(B)(5)(b), a clinic shall not require an individual to receive a COVID-19 vaccine pursuant to 105 CMR 140.150(B)(2) if the individual declines the vaccine.

(b) For any individual subject to the exemption, a clinic may require such individual take mitigation measures, consistent with guidance from the Department.

(c) An individual who is exempt from vaccination shall sign a statement certifying that they are exempt from vaccination and they received information about the risks and benefits of COVID-19 vaccine.

(6) Unavailability of Vaccine. A clinic shall not be required to provide or arrange for COVID-19 vaccination during such times the vaccine is unavailable for purchase, shipment, distribution, or administration by a third-party or when complying with an order of the Commissioner restricting the use of the vaccine. A clinic shall obtain and administer COVID-19 vaccine in accordance with 105 CMR 140.150(B) as soon as vaccine becomes available.

(7) Documentation.

(a) A clinic shall require and maintain for each individual proof of current vaccination against COVID-19 virus pursuant to 105 CMR 140.150(B), or the individual's exemption statement pursuant to 105 CMR 140.150(B)(5).

(b) Each clinic shall maintain a central system to track the vaccination status of all personnel.

(c) If a clinic is unable to provide or arrange for COVID-19 vaccination for any individual, it shall document the reasons such vaccination could not be provided or arranged for.

(8) Reporting and Data Collection. Each clinic shall report information to the Department documenting the clinic's compliance with the personnel vaccination requirements of 105 CMR 140.150(B), in accordance with reporting and data collection guidelines of the Commissioner.

(9) 105 CMR 140.150 establishes requirements for COVID-19 vaccination of clinic personnel. Nothing in 105 CMR 140.000 shall be read to prohibit clinics from establishing policies and procedures for COVID-19 vaccination of personnel that exceed the requirements set forth in 105 CMR 140.150.

140.201: General Physical Environment

Each clinic shall maintain its physical facilities in good repair in a safe, comfortable and sanitary state, free from dirt, rubbish, vermin, solid wastes, and objectionable odors.

140.202: Reception and Office Areas

Each clinic shall provide adequate space and equipment for reception and waiting areas, for administrative and staff offices, and appropriate storage for patient records whether paper or electronic.

140.203: Consultation, Examination and Treatment Areas

Each clinic shall provide consultation, examination, treatment and dressing areas appropriate to the services provided by the clinic. Each clinic shall furnish and arrange such areas in a manner consistent with their use and that safeguards the personal dignity and privacy (in terms of both sight and sound) of the patient during interview, examination and treatment. If separate consultation or interview rooms are not provided, the treatment area shall have floor to ceiling partitions to ensure minimum sound transmission.

140.204: Clean Storage and Soiled Holding Areas

Each clinic, except clinics providing only mental health services or small clinics that do not have more than two examination rooms, shall provide a clean supply storage room and a soiled workroom or soiled holding room, that are apart from any examination, treatment or dressing area as necessary for the services provided by the clinic to meet accepted standards of practice. The clean storage room shall accommodate storage for clean supplies. The soiled workroom area shall contain a work counter, a clinical service sink, and if physically separate from the clean work area, a handwashing sink with hot and cold water. If patient care does not involve disposal of fluid waste, a soiled holding room equipped with a handwashing sink with hot and cold water may be provided in *lieu* of a soiled workroom.

140.205: Handwashing and Toilet Facilities

- (A) Each clinic shall provide conveniently located handwashing and toilet facilities adequate for patients and personnel, as appropriate to the services provided by the clinic.
- (B) A soap dispenser, disposable towels or electronic hand dryers, and a waste receptacle shall be provided at each handwashing sink. Surgical scrub sink faucets shall be provided with blade type operating handles, knee or foot controls.
- (C) The clinic shall provide a handwashing facility with hot and cold water and blade type operating handles or knee or foot controls in each examination and treatment area.
- (D) A limited service clinic or mobile/portable unit located on or at the premises of another entity may share toilet facilities with that entity.

140.206: Utility Closet

Each clinic shall provide one or more suitably located utility closets equipped with a service sink or floor receptacle with hot and cold water for emptying and cleaning housekeeping equipment. A limited services clinic located on the premises of another entity may store supplies in a utility closet or other designated space provided by entity provided that the utility closet or other designated space is suitably located. Each utility closet must have a door that locks. Each clinic shall label cleaning compounds properly and clearly and store them in a utility closet or other locked closet.

140.208: Ventilation

Each clinic shall provide all rooms that do not have direct access to the outside, including toilets and soiled holding rooms, with satisfactory mechanical ventilation.

140.209: Accessibility to Individuals with Disabilities

Clinic space, including satellites, mobile/portable units and mental health outreach sites used for patients shall be accessible to individuals with disabilities and shall comply with all federal, state and local requirements for accessibility.

140.209: continued

(A) Mobile Medical Services. A mobile medical service shall meet the requirements set forth in 105 CMR 140.209, either directly or through written arrangements for shared service areas with the host locations.

(B) Any clinic located on the premises of another entity shall be accessible through well marked corridors or aisles that constitute an accessible route for individuals with disabilities. The clinic shall be responsible for establishing a formal agreement with that entity for the purpose of maintaining the accessible route free of obstructions at all times.

140.210: Supplies and Equipment

Each clinic shall have supplies and equipment appropriate in quantity and type to the specific service(s) the clinic renders its patients and adequate storage space for such supplies and equipment.

140.211: Maintenance and Sanitation of Supplies and Equipment

Each clinic shall keep supplies and equipment safe, sanitary and in good working condition as necessary for the services offered by the clinic.

(A) Shelf Life. The clinic shall discard supplies used for examination or treatment of patients when beyond their shelf life.

(B) Disinfection. The clinic shall disinfect diagnostic and therapeutic equipment after each use in accordance with recognized standards of practice.

(C) Sterilization. Each clinic shall sterilize after each use nondisposable equipment and supplies requiring sterilization. Single use items shall not be reused. Sterilized materials shall be packaged and labeled in a manner assuring sterility and shall indicate the sterility dates.

(D) Sterilization Equipment. Each clinic shall maintain sterilization equipment adequate to the needs of the clinic, for the purpose of sterilizing equipment and supplies as required or shall have an arrangement to obtain such services from a source approved by the Commissioner. The clinic shall have a recognized method of checking clinic sterilizer performance.

(E) Safety of Equipment. The clinic shall establish and enforce a preventive maintenance program to ensure all equipment is in safe working order. A maintenance check shall be regularly performed on all mechanical and electronic medical equipment. Electrified equipment shall be properly grounded and calibrated consistent with manufacturer's recommendations.

(F) Disposal of Waste. Each clinic shall ensure the safe disposal of hazardous and infectious waste.

140.212: Linen and Laundry

If a clinic requires linen in its operation, it shall at all times maintain a quantity of clean washable or disposable linen sufficient for the needs of the clinic.

(A) The clinic shall provide and maintain separate, suitable space and equipment for the handling and storage of clean linen and soiled linen.

(B) The clinic shall store clean linen in a closed closet, cabinet, or cart away from soiled areas.

140.220: Emergency Plan

Each clinic shall develop and maintain a written plan for dealing with fire or other emergency. The clinic shall make a copy of the plan available to all staff members. Each emergency plan shall specify persons to be notified, locations of alarm signals and fire extinguisher, evacuation routes, procedures for evacuating individuals with disabilities and nonambulatory patients, and assignments of specific tasks and responsibilities. A copy of the plan shall be posted in a conspicuous area of each separate clinic premises.

140.221: Fire Drills

Each separate clinic premises shall conduct a fire drill at least twice a year in each work shift, and such drills shall include the entire staff. Documentation of such drills shall be available to the Commissioner for review.

140.301: Administrative Records

(A) Each clinic shall maintain current, complete, and accurate administrative records in a safe location. The clinic shall make all administrative records available promptly to any agent of the Department seeking to determine compliance with 105 CMR 140.000.

(B) Administrative records shall include:

- (1) Updated articles of organization and bylaws, partnership agreement or trust instrument, as appropriate. The documents shall specify the organizational structure of the governing body and the methods of the selection of its members.
- (2) Updated lists of the names and addresses of the persons set forth in 105 CMR 104.102(B)(1)(a) through (d).
- (3) Minutes of meetings of the governing body and of the members.
- (4) An organizational chart for the entire organization.
- (5) Written policies and procedures designed to safeguard the health and safety of patients and staff. These policies and procedures shall be reviewed and updated annually. At a minimum the policies shall address:
  - (a) Selection of personnel and the qualifications for each position. A job description for each position must be included in the administrative records.
  - (b) Employee health policies ensuring employees are free of communicable disease.
  - (c) Patient treatment criteria.
  - (d) The provision of emergency care and the retention of emergency equipment appropriate to the clinic's patient population.
  - (e) Obtaining informed consent for surgical procedures and other treatment where required by law.
  - (f) A policy for off-hour coverage posted conspicuously in the clinic and any of its satellite clinics. The policy must ensure compliance with 105 CMR 140.315(B).
  - (g) The disposal of hazardous and infectious waste.
  - (h) Infection control.
  - (i) Services that the clinic provides.
  - (j) Smoking on the premises.
  - (k) Procedures for complying with laws and regulations relating to reportable diseases and conditions.
  - (l) Procedures for ensuring all patients of a clinic providing mobile services at host locations are provided with written information clearly identifying the clinic, and not the host location, as the licensed health care facility responsible for the service provided.
  - (m) Policies and procedures for documenting clinical supervision of health care staff by licensed staff members.
- (6) Personnel records for each employee, including evidence of any required license or registration number; documentation of any specialty certification, education and job experience.

140.302: Patient Records

(A) Each clinic shall maintain centralized records documenting all the services rendered to clinic patients. Records shall contain sufficient information to justify the diagnosis(es) and treatment, and to document the results accurately. A mobile medical service or mental health outreach program shall maintain patient records as records of the clinic and not of the host locations or outreach location(s).

(B) Each patient shall have a single integrated record, except mental health, dental, substance use disorder, and, upon approval of the Commissioner, other records, may be filed separately, provided there is an effective cross-referencing system. Each entry into each patient record shall be dated and authenticated by the staff member making the entry, including the staff's name and title. Each page or each entry of each patient's record shall have two unique forms of identification. The record with respect to each patient shall include the following:

140.302: continued

- (1) Patient's name, date of birth, sex, home address and telephone number, and sponsor or responsible party if any.
- (2) Date of each patient visit with clinic staff at the clinic, satellite clinic or at mental health outreach sites.
- (3) Medical or dental history, as appropriate.
- (4) Diagnostic observations, evaluations, and therapeutic plans.
- (5) Orders for any medication, test, or treatment.
- (6) Records of any administration of medications, treatment, or therapy.
- (7) Laboratory, radiology, and other diagnostic reports.
- (8) Progress notes.
- (9) Reports of any consultations, special examinations, or procedures.
- (10) Operative and anesthesia records for surgical patients.
- (11) Social service reports.
- (12) Referrals to other agencies.
- (13) Documentation that informed consent has been obtained for surgical procedures and other treatment where required by law and in accordance with 105 CMR 140.301(B)(5)(e).
- (14) Discharge summary, when appropriate.
- (15) Documentation of patient consent to release information to the receiving provider prior to or upon patient transfer.

(C) Retention of Medical Records. The purpose of 105 CMR 140.302(C) is to establish a minimum retention period and does not preclude clinics from maintaining records for a longer period of time.

- (1) In accordance with M.G.L. c. 111, § 70, each clinic shall maintain records of the diagnosis and treatment of patients under its care for a minimum of 20 years after the discharge or the final treatment of the patient to whom the record relates. Medical records may be handwritten, printed, typed or in electronic digital format, or converted to electronic digital format or an alternative archival method. Handwritten, printed or typed medical records converted to electronic digital format or an alternative archival format may be destroyed before the expiration of the 20-year retention period. The manner of destruction must ensure the confidentiality of patient information. For purposes of 105 CMR 140.302, medical records in electronic digital format shall have the same force and effect as the original records from which they were made.
- (2) For the purpose of 105 CMR 140.302, a clinic shall not be required to consider the following as part of the medical record subject to the retention requirements in M.G.L. c. 111, § 70: radiological films, scans, other image records, raw psychological testing data, electronic fetal monitoring tracings, electroencephalograph, electrocardiography tracings and the like, provided that any signed narrative reports, interpretations or sample tracings reporting the results of such tests and procedures shall be maintained as part of the record. Such records as described in 105 CMR 140.302(C)(2) shall be retained for a period of at least five years following the date of service.
- (3) Medical records retained by the facility in accordance with 105 CMR 140.302(C) shall be made available, for inspection and copying, upon written request of the patient or his or her authorized representative. The clinic may charge a reasonable fee for copying, not to exceed the rate of copying expenses, as specified in M.G.L. c. 111, § 70.

(D) Each clinic shall maintain and use patient records in a manner that protects the confidentiality of the information contained therein. Printed copies of electronically stored records shall be disposed of in a manner that ensures the confidentiality of patient information.

(E) Each clinic shall make all patient records available promptly to any agent of the Department.

(F) At the expiration of 20 years after the discharge or the final treatment of the patient to whom a retained medical record relates, a clinic may destroy the medical record. The manner of destruction must ensure the confidentiality of patient information. At least 30 calendar days prior to the proposed date of destruction of a medical record(s), a clinic shall provide written notification to the Department generally indicating the type of records to be destroyed and the dates of service exceeding the applicable retention period, as specified in guidelines of the Department, of the clinic's intent to destroy medical record(s) exceeding the 20-year retention period. A clinic may, but is not required to, notify a patient before destroying the patient's medical record pursuant to 105 CMR 140.302.

140.302: continued

(G) A clinic shall provide written notice to a patient of the patient's right to inspect and to receive a copy of the patient's medical records and the clinic's medical record retention policy, as specified in M.G.L., c. 111, § 70.

(H) Each urgent care clinic shall provide a copy of the medical record of each visit to the patient at the end of the visit or as soon as available and, with the patient's consent, provide a facsimile or electronically transmitted copy of the medical record of the visit to the patient's primary care provider, if any. Such copies or transmission shall be provided at no charge to the patient.

140.303: Posting of Notice of Patients' Rights

Each clinic shall have visibly posted a notice, the mandatory heading "NOTICE OF PATIENTS' RIGHTS" in block letters at least one inch high and containing all the rights provided by M.G.L. c. 111, § 70E. The notice shall be posted in at least one central area where all patients are likely to see it. In addition, the clinic shall provide a written document containing all the rights provided by M.G.L. c. 111, § 70E, in understandable language and translated into the major languages spoken by the clinic's patients, to each patient at his or her first visit to the clinic.

140.304: Off-hour Coverage

Each clinic shall make arrangements for the delivery of the services it provides during the hours when it is not open, at least through an answering service or, with the exception of clinics providing mental health services, a recorded message referring patients to another provider of the same services as geographically close as possible and open at those hours.

(1) Mental Health clinics must provide an answering service after hours, in accordance with 105 CMR 140.520(E).

(2) A limited services clinic may provide a taped message directing patients to a toll-free number that will enable the patient to speak directly with a practitioner. These arrangements shall be reflected in a written policy provided to all the clinic's patients.

140.305: Emergency Transfer

(A) Each clinic shall have a written policy addressing the procedures for calling 911 for patients who need emergency treatment. A clinic is not precluded from entering into agreements for inter-facility transport in nonemergency situations.

(B) Each clinic providing obstetrical services shall, prior to each patient's expected delivery date, arrange for the patient to be admitted for delivery to a facility licensed to perform deliveries. Unless the patient objects, the clinic shall send a copy of the record of its obstetrical care of the patient to this facility at the beginning of the patient's third trimester of pregnancy, and update it as necessary.

(C) Whenever a clinic refers a patient to another facility, agency, or health care provider, unless the patient objects (except in the case of involuntary commitment to a psychiatric hospital) it shall send a copy of relevant portions of the clinic patient's record to such facility, agency, or provider.

140.306: Serious Complaint Procedure

Each clinic shall develop a written procedure that ensuring prompt and complete investigations of all serious complaints filed against the clinic, employees of the clinic or members of its professional staff. The procedure shall include, at a minimum, the following provisions:

(A) Designation of a senior member of the clinic administration as the person responsible for overseeing the investigation of serious complaints lodged against the clinic, an employee or member of the professional staff;

140.306: continued

(B) Establishment of a reporting procedure ensuring the designated administrator will receive from clinical staff written reports of serious complaints within one day of the clinic's receipt of the serious complaint;

(C) Development by the designated administrator of a written process of investigation, which shall include the following:

- (1) A process of fact-gathering, including provision for interviewing of the complainant, patient, and relevant witnesses;
- (2) Creation of a complaint file that includes the original report of complaint, progress reports as investigation is carried out and outcome of investigation including action taken, if any;
- (3) Notification of the complainant of the outcome of the investigation.

(D) The complaint files shall be available for inspection by agents of the Department.

140.307: Serious Incident Reports

(A) A clinic shall immediately report to the Department, pursuant to Department guidelines, any of the following incidents occurring on premises covered by its license:

- (1) death that is unanticipated, not related to the natural course of the patient's illness or underlying condition, or that is the result of an error or other incident as specified in guidelines of the Department;
- (2) full or partial evacuation of the facility for any reason;
- (3) fire;
- (4) suicide;
- (5) serious criminal acts;
- (6) pending or actual strike action by its employees, and contingency plans for operation of the clinic;
- (7) reports on surgery-related and anesthesia-related complications that result in serious morbidity or death of a patient; or
- (8) any other serious incident or accident as specified in guidelines of the Department.

(B) A clinic shall immediately report to the Department, for any patient treated at the clinic, any suspected instance(s) of abuse, neglect, mistreatment of that patient, or misappropriation of that patient's property, at or by a nursing home, rest home, home health, home maker or hospice.

(C) A clinic shall report to the Department any other serious incident occurring on premises covered by the clinic's license that seriously affects the health and safety of a patient(s) or that causes serious physical injury to a patient(s) within seven calendar days of the date of occurrence of the event.

(D) If an ambulatory surgery center makes a report of any incident pursuant to 105 CMR 140.307(A), (B) or (C), and the incident meets the definition of Serious Reportable Event in 105 CMR 140.308(A) or a medication error within the definition of a Serious Adverse Drug Event (SADE) pursuant to 105 CMR 140.308(A), the ambulatory surgery center also shall comply with the requirements of 105 CMR 140.308.

140.308: Ambulatory Surgery Center Reporting of Serious Reportable Events and Serious Adverse Drug Events

(A) Definitions. For the purposes of 105 CMR 140.308.

National Quality Forum (NQF). The not-for-profit membership organization created to lead national collaboration to improve health and healthcare through measurement.

Preventable. An event that could have been anticipated and prepared for, but that occurs because of an error or other system failure including, but not limited to, lack of adherence to best practices, patient safety guidelines or established policies and procedures.



140.308: continued

Serious Adverse Drug Event (SADE). Any untoward, preventable medical occurrence associated with the use of a controlled substance, as defined in M.G.L. c. 94C, § 1, in humans that results in any of the following outcomes:

- (1) death;
- (2) a life-threatening outcome;
- (3) inpatient hospitalization or prolongation of existing hospitalization;
- (4) a persistent or significant incapacity or substantial disruption of the ability to conduct normal life functions; or
- (5) a congenital anomaly or birth defect; provided, however, that adverse medical occurrences directly associated with the use of a controlled substance in humans that may not immediately result in one of the outcomes listed in 105 CMR 140.308: Serious Adverse Drug Event (SADE)(1) through (5), may be considered a serious adverse drug event when they develop into or result in any of the outcomes listed in 105 CMR 140.308: Serious Adverse Drug Event (SADE)(1) through (5).

Serious Reportable Event (SRE). An event that occurs on premises covered by an ASC's license that results in an adverse patient outcome, is clearly identifiable and measurable, has been identified to be in a class of events that are largely preventable and harmful. The Department will issue and maintain a list of SREs based on those events included on the NQF's table of reportable events to which 105 CMR 140.308 applies.

Unambiguously the Result of a System Failure. Events determined by the ASC to result from:

- (1) a failure to follow the ASC's policies and procedures;
- (2) inadequate or nonexistent ASC policies and procedures; or
- (3) inadequate system design.

(B) Reporting of SREs.

- (1) Within seven calendar days of the date of discovery of an SRE, an ASC shall:
  - (a) file a written report with the Department of an SRE ("SRE report") as specified in guidelines of the Department;
  - (b) inform the patient or the patient's representative orally or in writing or both about:
    1. the occurrence of the SRE including unanticipated outcomes of care, treatment and services provided as the result of an SRE;
    2. the ASC's policies and procedures and documented review process for making a preventability determination as required by 105 CMR 140.308(C); and
    3. the option to receive a copy of the SRE report filed with the Department; and
  - (c) affirm on the SRE report that the ASC has complied with the patient notification requirements of 105 CMR 140.308(B)(1)(b).
- (2) An ASC that provides services resulting from an SRE which did not occur on its premises shall file a written report with the Department within seven calendar days of the date of discovery of the SRE. The reporting ASC shall comply with the requirements of 105 CMR 140.308(B)(1), but need not make a preventability determination for the SRE.

(C) Preventability Determination.

- (1) An ASC shall establish policies and procedures for a documented review process to determine whether an SRE was:
  - (a) preventable;
  - (b) within the ASC's control; and
  - (c) unambiguously the result of a system failure.

An ASC shall make a preventability determination for all SREs occurring on premises covered by its license.
- (2) No later than 30 days after the date of reporting of the SRE to the Department the ASC shall:
  - (a) make the preventability determination required by 105 CMR 140.308(C)(1);
  - (b) file an updated SRE report with the Department describing the ASC's preventability determination including, at a minimum, the following:
    1. narrative description of the SRE;
    2. analysis and identification of the root cause of the SRE;
    3. analysis of the preventability criteria required by 105 CMR 140.308(C)(1);

140.308: continued

4. description of the corrective actions developed, implemented and to be monitored by the ASC following discovery of the SRE; and
  5. whether the ASC intends to charge or seek reimbursement for services provided by the ASC as a result of the SRE; and
  - (c) provide a copy of the updated SRE report to the Department, the patient and any responsible third-party payer.
  - (3) For services to MassHealth members, the ASC shall perform the documented review process solely for purposes of reporting, not for purposes of determining reimbursement.
- (D) Reimbursement for SREs.
- (1) An ASC may not charge or seek reimbursement from a patient or responsible third-party payer for services provided as a result of an SRE occurring on premises covered by the ASC's license if the ASC determines that the SRE was:
    - (a) preventable; and
    - (b) unambiguously the result of a system failure, as required by 105 CMR 140.308(B) and (C).
  - (2) An ASC shall immediately suspend or rescind any claims to any patient or responsible third-party payer pending the preventability determination and notification requirements of 105 CMR 140.308(C).
  - (3) An ASC may charge or seek reimbursement for services it provides that result from an SRE that did not occur on its premises; however an ASC that provides services (treating facility) resulting from an SRE occurring on premises of a hospital licensed pursuant to 105 CMR 130.000: *Hospital Licensure* or a separately licensed ASC (responsible facility), may not charge or seek reimbursement for those services, if the treating facility and the responsible facility have common ownership or a common corporate parent.
  - (4) Any dispute(s) arising between the ASC and any responsible third-party payer resulting from a charge or claim for reimbursement for services provided by the ASC as a result of an SRE shall be addressed through the third-party payer's provider claims appeals process.
  - (5) The provisions of 105 CMR 140.308(D) shall not be construed to prohibit a Medicare provider from submitting a claim for reimbursement to the Medicare program.
  - (6) For services to MassHealth members, the ASC shall perform the documented review process solely for the purposes of reporting, not for purposes of determining reimbursement.
- (E) Serious Adverse Drug Events.
- (1) Within seven days of the date of discovery of a medication error that occurs or occurred on the premises of the ASC and that meets the definition of a SADE, an ASC shall report the SADE to the Department as specified in guidelines of the Department.
  - (2) If a SADE also is an SRE, the ASC shall also comply with the requirements of 105 CMR 140.308(B), (C) and (D).
  - (3) Upon first discovering, through diagnostic evaluation and assessment of an individual patient, that a SADE has resulted from a patient's use, consumption or interaction with any pharmaceutical or drug preparation, an ASC must report the event to the federal MedWatch Program, as well as the pharmacy from which the drug was produced or compounded in addition to all other reporting requirements.
  - (4) Any facility failing to comply with 105 CMR 140.308(E) may:
    - (a) be fined up to \$1,000 per day per violation;
    - (b) have its license revoked or suspended by the Department; or
    - (c) be fined up to \$1,000 per day per violation and have its license revoked or suspended by the Department.

140.309: Ambulatory Surgery Center Healthcare-associated Infection Data Collection, Submission and Reporting

(A) Definitions.

Healthcare-associated Infection (HAI). A localized or systemic condition that results from an adverse reaction to the presence of an infectious agent or its toxins that:

140.309: continued

- (1) occurs in a patient in an ambulatory surgery center (ASC); and
- (2) was not present or incubating at the time of the admission during which the reaction occurs;
- (3) meets the criteria for a specific infection as defined by the federal Centers for Disease Control and Prevention and its National Healthcare Safety Network; and
- (4) any additional elements as set forth in administrative guidelines of the Department based on the National Healthcare Safety Network.

National Healthcare Safety Network (NHSN). The HAI tracking system operated by the federal Centers for Disease Control and Prevention.

(B) HAI Reporting by Ambulatory Surgery Centers.

- (1) Each ASC shall:
  - (a) register with the NHSN; and
  - (b) grant access to the Department, in accordance with guidelines of the Department, to healthcare-associated infection data elements reportable to the NHSN.
- (2) Each ASC shall collect and submit to the NHSN, and then grant access as provided under 105 CMR 140.309(B) to the Department to healthcare-associated infection data elements.
- (3) Each ASC shall collect and submit to the Department other data related to infection control, including process measures, in accordance with guidelines of the Department.

140.310: Clinic Administrator

Each clinic shall designate a person to administer the clinic and ensure that it complies with applicable statutes and regulations. The clinic administrator must be physically present in the clinic as necessary to perform the duties of his or her position. In his or her absence, a professional staff person with the appropriate skills and training shall be designated to act in his or her place.

140.311: Professional Services Director

Each clinic shall designate a professional services director, who shall be responsible for the clinical services provided at the clinic. The professional services director must be a health care professional possessing academic training and experience in direct patient care and shall be qualified to direct the services provided by the clinic. The professional services director must be physically present in the clinic as necessary to oversee the professional services provided by the clinic. In his or her absence, a professional staff person with the appropriate skills and training shall be designated to act in his or her place.

If the clinic provides only surgical services, the professional services director must be a surgeon.

140.312: Dual Appointment

One person may serve as both clinic administrator and professional services director if he or she meets the requirements for both positions and can properly perform the duties of both positions.

140.313: Physician Staff and Responsibility for Practice of Medicine

(A) One or more physicians, as necessary, shall provide, or supervise the provision of, all services involving the practice of medicine.

(B) At least one physician shall be present at the clinic whenever medical services are provided, unless these services are provided pursuant to written protocols or guidelines by a physician assistant or a nurse practicing in an expanded role in accordance with the regulations of the appropriate registration board.

140.314: Nursing Staff

Each clinic shall retain a sufficient number of nurses qualified to provide the nursing services necessary to the type of care the clinic provides. These services shall be under the direction of a registered nurse.

140.315: Health Care Staff

(A) Each clinic shall retain sufficient qualified professional health care staff to render adequately and appropriately to each patient's needs the health services the clinic is licensed to provide. The clinic shall ensure the qualifications of its practitioners extend to appropriate training for the age range of patients treated at the clinic. Professional health care staff shall be registered or licensed as required by law. They shall comply with the regulations of their registration or licensing boards, including all applicable supervision requirements.

(B) At least one professional health care staff member shall be present when patient health care services are being provided in the clinic.

140.316: Nutrition Services

If a clinic provides nutrition educational and counseling services, a nutritionist must be retained on at least a part-time basis to provide or supervise the service.

140.317: Social Services

If a clinic provides social services, the clinic shall retain on at least a part-time basis a social worker to provide or supervise the service.

140.318: In-service Training for Health Care Staff

There shall be a program of evidence-based, ongoing in-service training that pertains to the service type(s) the clinic is licensed to provide for all staff providing health care services. Such training may include case studies and staff presentations provided within the facility or may be obtained through participation in continuing education courses offered outside the clinic.

140.330: Satellite Clinics

No clinic licensed pursuant to 105 CMR 140.000 may provide services at a satellite, unless the satellite meets, independently of its parent clinic, all the requirements imposed on clinics by 105 CMR 140.000, except that a satellite clinic, as part of the legal entity operating its parent clinic, shall have no separate articles of organization, or bylaws or other charter of its own, and no separate governing body, shareholders, members, or officers.

140.340: Limitation on Dispensing and Administration of Controlled Substances

A clinic pharmacy shall dispense or administer controlled substances as defined by M.G.L. c. 94C, § 1 only to patients currently under treatment at the clinic and employees of the clinic in accordance with employee health policies, pursuant to the prescription of a clinic practitioner legally authorized to issue prescriptions.

140.341: Compliance with Applicable Laws and Regulations

A clinic that maintains prescription medications on its premises must register annually under the Controlled Substances Act with the Drug Control Program pursuant to M.G.L. c. 94C, § 7 and operate in accordance with all applicable federal, state, and local laws and regulations.

140.342: Clinic Pharmacy Staffing

(A) Pharmacy Director. The clinic shall employ a registered pharmacist to direct and manage the clinic pharmacy.

(B) Registered Pharmacist. A registered pharmacist shall be on duty whenever the clinic pharmacy is open.

140.343: Clinic Pharmacy Policies

(A) Each clinic that operates a clinic pharmacy shall maintain a pharmacy policy manual describing in writing the organization of the clinic pharmacy and the specific services it provides.

(B) The policy manual shall be reviewed annually by the pharmacy and therapeutics committee and include at least those policies required under 105 CMR 140.344(B).

140.344: Pharmacy and Therapeutics Committee

Each clinic that maintains and operates a clinic pharmacy shall establish a pharmacy and therapeutics committee composed of members of the medical staff, the pharmacy director, the clinic administrator or his or her representative, members of the nursing staff and other personnel as appropriate to the services the clinic provides.

(A) The committee shall serve as an advisory group to the medical staff and pharmacy director on matters concerning drugs used in the clinic. The committee shall review all reports of medication errors and adverse drug reactions. The committee shall meet at least quarterly and shall keep minutes of its meetings.

(B) The committee shall develop written policies for safe and effective drug therapy, distribution, control and use. The clinic shall adopt policies developed and recommended by the committee, including at least:

- (1) a therapeutic guide and recommended drug list for use in the clinic, which shall be reviewed not less than once a year;
- (2) standards concerning the use and control of investigational drugs and drug research programs;
- (3) procedures for access to drugs for use by the clinic when the pharmacy is closed, and a list of persons who are allowed such access;
- (4) methods to ensure appropriateness of continuing drug therapy;
- (5) procedures for reporting and preventing medication errors and reporting adverse drug reactions;
- (6) methods to ensure compliance with M.G.L. c. 112, § 12D, and 105 CMR 720.000: *List of Interchangeable Drug Products*, 105 CMR 721.000: *Standards for Prescription Format and Security in Massachusetts* and 105 CMR 722.000: *Dispensing Procedures for Clinic and Hospital Pharmacies*;
- (7) a drug recall procedure that can be readily implemented; and
- (8) systems for the control and accountability of all drugs including, but not limited to, procedures for reporting theft, loss or suspected tampering of any controlled substance, in accordance with 105 CMR 700.005(D). Such policies must ensure compliance with up to date standards for product quality, security and record keeping systems.

140.345: Drug Handling and Administration

A clinic with a pharmacy shall comply with the requirements of 105 CMR 140.345 and 105 CMR 722.000: *Dispensing Procedures for Clinic and Hospital Pharmacies*, which shall be included in the clinic pharmacy policy manual.

(A) Administration. All drugs administered to patients in the clinic shall be administered by appropriately licensed personnel.

(B) Access to Emergency Drugs. The clinic shall maintain an emergency medication kit. The emergency medication kit shall be kept in a separate sealed container when not in use. Drugs requiring refrigeration shall be kept in a separate sealed container under proper refrigeration when not in use. Each emergency medication kit shall be prepared, packaged and sealed by a registered pharmacist or pharmacy intern under the direct supervision of a registered pharmacist, and shall contain a list of contents on the outside cover and within the box. After an emergency medication kit has been opened, it shall be inspected, restocked and resealed by a registered pharmacist or a pharmacy intern under the direct supervision of a registered pharmacist the next day the clinic pharmacy is open.

140.345: continued

- (C) Drugs for External Use; Poisons. The clinic pharmacy shall label drugs for external use and poisons as such, and shall keep such drugs separate from other medications.
- (D) Labeling. All drugs shall be labeled adequately, including cautionary statements as appropriate. Clinic staff shall return drug containers with illegible, incomplete, damaged, worn, soiled, or missing labels to the clinic pharmacy, and the pharmacy staff shall dispose of such containers and drugs appropriately.
- (E) Outdated Drugs. As drugs become outdated, the clinic pharmacy shall eliminate them from its stock in accordance with clinic policy. All drugs shall be destroyed in accordance with applicable state and federal laws.
- (F) Prescriptions. All prescriptions shall be issued to patients and transmitted to a pharmacy on an Electronic Prescribing System, as defined in 105 CMR 721.000: *Standards for Prescription Format and Security in Massachusetts*, unless an ePrescribing exception, listed in 105 CMR 721.070: *ePrescribing Exceptions*, is applicable.

140.346: Facilities and Equipment

- (A) Drug Preparation Areas. The clinic pharmacy shall have adequate and properly controlled drug preparation areas, wherever drugs are prepared for administration or dispensing. The areas shall have adequate lighting, ventilation and temperature controls, and be located such that personnel will not be interrupted when handling drugs.
- (B) Storage of Drugs. Drugs shall be stored under proper conditions to ensure product stability and security. Drug storage facilities shall be locked. Schedule II drugs shall be kept double locked.
- (C) Reference Materials. The clinic pharmacy shall maintain and make available up-to-date pharmaceutical reference materials to furnish the clinic pharmacy and other staff with adequate information concerning drugs.
- (D) Antidote Information; Poison Control Center. The clinic pharmacy shall maintain authoritative and current antidote information, readily available in the pharmacy for emergency reference, along with the telephone number of the regional poison control center.

140.347: Pharmacy Services by Clinics without Clinic Pharmacies

If the clinic does not maintain a clinic pharmacy, but drugs are stored and administered at the clinic directly to patients, the clinic shall comply with the requirements of 105 CMR 140.347 and 105 CMR 700.000: *Implementation of M.G.L. c. 94C*.

- (A) Compliance with Federal and State Law. The clinic must register annually under the Controlled Substances Act with the Department pursuant to M.G.L. c. 94C, § 7 and shall comply with all applicable federal, state, and local drug laws and regulations.
- (B) Record System. The clinic professional services director or his or her designee shall be responsible for ensuring a record system that maintains control over the requisitioning and administration of controlled substances. The recordkeeping system shall comply with all federal and state laws and regulations.
- (C) Storage of Drugs. Drugs shall be stored under proper conditions to ensure product stability and security. Drug storage facilities shall be locked. Schedule II drugs shall be kept double locked.
- (D) Medications for External Use. The clinic shall accurately label each medication for external use as such, and shall store such medications separately from medications for internal use.
- (E) Outdated Drugs. Outdated drugs shall be eliminated from the clinic's stock in accordance with clinic policies. All drugs shall be destroyed in accordance with applicable state and federal laws.

140.347: continued

(F) Administration of Medications. All drugs administered directly to patients in the clinic shall be administered by appropriately licensed personnel. Prescriptions shall be issued for all drugs not administered within the clinic. However, drugs may be dispensed by a prescribing practitioner for immediate treatment until such time as a prescription can be filled at a pharmacy.

(G) Labeling. All drugs shall be adequately and distinctly labeled.

(H) Reference Source. The clinic shall maintain and make available up-to-date pharmaceutical reference materials for reference by clinic staff.

140.350: Approval of In-house Clinical Laboratory Services

In-house clinical laboratory services offered by a clinic are subject to clinical laboratory approval as set forth in 105 CMR 180.000: *The Operation and Licensing of Clinical Laboratories*, and 42 CFR 493, except that laboratory director qualifications must, at a minimum, meet CLIA requirements and any Department administrative guidelines.

140.351: Contracting for Outside Clinical Laboratory Services

(A) A clinic may enter into a written contract for the provision of all or part of its clinical laboratory services with a laboratory independent of the clinic that is licensed, approved or certified by the appropriate federal or state agencies.

(B) The clinic must have detailed written statements of policy on procedures for the collection, transport, and handling of specimens referred to such an outside laboratory. These written statements shall be available for review by the Commissioner.

140.360: Compliance with Applicable Laws and Regulations

Each clinic that provides diagnostic radiology shall comply with M.G.L. c. 111, § 5B, and 105 CMR 120.000: *The Control of Radiation*. Clinics providing such service must register with the Department's Division of Radiation Control pursuant to 105 CMR 120.100. The provisions of 105 CMR 140.361 through 140.362 do not apply to a clinic that is licensed to provide dental services only.

140.361: Radiologist

Each clinic that provides diagnostic radiology shall retain, at least on a consulting basis, a board certified or board qualified radiologist to meet the needs of the clinic. The radiologist shall be responsible for the proper performance of the radiological services.

140.362: Radiologic Technologist

Diagnostic radiology procedures that are not performed or directly supervised at all times by a board certified or board qualified radiologist shall be performed only by radiologic technologists licensed pursuant to M.G.L. c. 111, § 5L, and 105 CMR 125.000: *Licensing of Radiologic Technologists*.

140.363: Diagnostic Radiology Facilities

Each clinic providing diagnostic radiology services shall provide the following, in adequate and suitable form for the services provided:

- (1) X-ray equipment appropriate to the diagnostic services offered by the clinic;
- (2) at least one radiographic room of adequate size for the equipment provided;
- (3) space for preparation of barium mixtures, if applicable; and
- (4) adequate storage space for files of X-ray films.

140.364: Mammography Facility – Licensure

Each clinic operating a mammography facility, as defined in M.G.L. c. 111, § 5Q, and 105 CMR 127.000: *Licensing of Mammography Facilities*, shall obtain and maintain a license issued pursuant to 105 CMR 127.000.

140.370: Evaluation of Quality

(A) Each clinic shall establish an organized, comprehensive program adequate to regularly review and evaluate the quality of care provided. The program shall:

- (1) be defined in writing and approved by its governing body;
- (2) identify an individual to be responsible for the implementation and continuity of the program;
- (3) be reevaluated at least annually; and
- (4) describe the mechanisms in effect to identify and resolve problems.

(B) The findings of the program shall, as appropriate, be utilized in the revision of clinic policies and procedures.

(C) Clinics licensed for surgical services shall meet the additional requirements set forth in 105 CMR 140.613.

140.380: Procurement, Storage and Administration of Blood

Each clinic that administers human whole blood and/or its components and/or derivatives in transfusion shall meet the following requirements:

(A) The clinic shall have a current, effective agreement with a blood bank licensed by the Department that meets the requirements of 105 CMR 135.000: *Use of Blood, Blood Components, and Derivatives for the Purpose of Transfusion*.

(B) The clinic shall obtain blood from a licensed blood bank immediately prior to its administration. All blood so obtained shall be identified, stored, handled, and administered in accordance with the requirements of 105 CMR 135.000: *Use of Blood, Blood Components, and Derivatives for the Purpose of Transfusion*.

(C) The clinic shall develop policies and procedures specific to all aspects of the procurement, storage and administration of blood. These policies and procedures at a minimum shall address patient selection and consent, the requirements for explicit written order(s) from a physician, nurse practitioner, or physician assistant the prompt availability of physicians in the event of an emergency, the proper identification of the patient, the qualifications and training of the registered nurse administering the blood, the monitoring of patients undergoing transfusion, including the required observation time following administration, procedures to follow in the event of a transfusion reaction and recordkeeping requirements.

(D) Prior to the initiation of a program to procure, store and administer blood for transfusion, each clinic shall inform the Department in writing and receive Department approval. Department approval shall be based on compliance with 105 CMR 140.380(A), (B) and (C) and other relevant clinic licensure regulations.

(E) Except as provided for in 105 CMR 140.614, transfusion of blood shall not be permitted as part of the surgical service of a clinic.

140.381: Autologous Hematopoietic Progenitor/Stem Cell Transplantation

Autologous hematopoietic progenitor/stem cell transplantation may be performed in a separately licensed freestanding clinic if the clinic transplantation services are a formal part of a hospital-based hematopoietic progenitor/ stem cell transplantation program. The clinic must have a written, current collaboration agreement with the hospital-based hematopoietic progenitor/stem cell transplantation program. The collaboration agreement shall, at a minimum:

- (1) Describe the services to be provided at the clinic site;



140.381: continued

- (2) Describe the support services available at the hospital site, with particular attention to availability for patient care consultation by all members of the multidisciplinary team including, but not limited to, physicians, nurses, nutritionists, social workers, physical therapists and psychologists;
- (3) Describe the oversight responsibilities of the hospital;
- (4) Identify a physician or nurse coordinator on-site at the clinic;
- (5) Describe the quality assessment and assurance programs for transplantation at the clinic site, with particular attention to how the assessment data is used to improve services and how the data is integrated in both the clinic's and the hospital's quality assurance programs; and
- (6) Be signed and dated by the Hospital Administrator, Hospital Vice President of Nursing or Clinical Services, Hospital Hematopoietic Progenitor/Stem Cell Transplantation Program Director, Clinic Medical Director and Clinic Physician or Nurse Coordinator.

140.400: Applicability of 105 CMR 140.401 through 140.405

The requirements of 105 CMR 140.401 through 140.404 are applicable to clinics subject to Department licensure to provide dental services.

140.401: Minimum Dental Services

A clinic offering dental services shall at a minimum provide oral diagnostic services; services to maintain oral health and prevent oral disease; basic restorative dental care; and services to relieve dental pain and infection.

140.402: Dental Services Staff

- (A) Each clinic shall be staffed with one or more dentists as necessary to provide or supervise the provision of dental services.
- (B) Dental hygienists employed by the clinic shall be registered by the Board under M.G.L. c. 112, § 51.
- (C) Dental assistants employed shall be licensed pursuant to M.G.L. c. 112, § 51½ and shall meet the requirements of 234 CMR 4.11: *Initial Dental Assistant Licensure for EFDA-, CA- and FTDA-qualified Individuals* and 234 CMR 4.12: *Initial Licensure for Dental Assistants Trained on the Job*.

140.403: Dental Policies and Procedures

- (A) Each clinic offering dental services shall have a written policy providing for the referral of patients to other health care providers as necessary for services that are not part of the clinic's services.
- (B) Each clinic shall have policies and procedures for recalling patients on a periodic basis as appropriate for the patient's needs for dental care maintenance procedures.

140.404: Anesthesia

- (A) Each clinic licensed for dental services may administer local anesthesia, nitrous oxide sedation and conscious intravenous sedation. General anesthesia may not be administered, unless the clinic is licensed under 105 CMR 140.600 through 140.614 to provide surgical services.
- (B) Conscious intravenous sedation may only be performed by individuals with appropriate training as established separately by the Commissioner as administrative guidelines.

140.405: Dental Surgery

A clinic that performs dental surgical procedures including, but not limited to, procedures requiring general anesthesia, advanced oral maxillofacial surgery, removal of a large tumor, or major surgery to the mandible or maxilla such as reduction of a fractured jaw must be licensed to provide surgical services pursuant to 105 CMR 140.600(B).

140.450: Applicability of 105 CMR 140.451 through 140.453

The requirements of 105 CMR 140.451 through 140.453 are applicable to clinics subject to Department licensure to provide mobile health services.

140.451: Host Sites for Mobile Services

(A) Host sites for mobile services may include community environments including, but not limited to, long-term care facilities licensed pursuant to M.G.L. c. 111, § 71, assisted living facilities, corporate or business locations, community centers, social service agencies, or churches.

(B) Host sites shall not include commercial office space rented by the licensed clinic.

(C) If the site is leased, rented or otherwise under the control of the clinic, the clinic must obtain approval for the site as a satellite.

140.452: Medications for Mobile Services

(A) The clinic may not store medications at any host site.

(B) The clinic may not store medications overnight in a mobile, portable or mobile/portable unit.

140.453: Signage for Mobile Services

The clinic shall appropriately identify the mobile, portable or mobile/portable unit, including, if applicable, signage identifying any affiliation with the host site. All signage must clearly state that the unit provides mobile services, and, if applicable, state that the service is sponsored by a parent or host facility.

140.500: Applicability of 105 CMR 140.510 through 140.560

To provide Mental Health Services, as that term is defined in 105 CMR 140.020, clinics must meet the requirements of 105 CMR 140.510 through 140.560.

140.510: Mental Health Services

For purposes of 105 CMR 140.500 through 140.560, each clinic licensed to provide mental health services shall operate a mental health program that provides, internally or by contract, in accordance with the requirements of 105 CMR 140.520, the following services, as appropriate to the patient's chief complaint or problem:

- (1) intake services including, but not limited to, a substance use disorder screening;
- (2) evaluation and diagnostic services;
- (3) treatment planning services;
- (4) treatment services that include:
  - (a) case consultation, psychotherapy and counseling; and
  - (b) pharmacotherapy;
- (5) emergency services; and
- (6) referral services including for, but not limited to, any co-occurring substance use disorder.

Emergency services may be provided by arrangement. If emergency services are provided by arrangement, there must be a written agreement between the clinic and the provider to meet the requirements set forth in 105 CMR 140.520(E)(1) and (2).

140.520: Adequate Mental Health Services

(A) Intake Services. During intake, the clinic licensed to provide mental health services must accumulate and record at least the minimally required patient information necessary to facilitate evaluation and diagnostic services and/or for referral to an appropriate professional person or agency. This intake must include screening for any co-occurring substance use disorder.

140.520: continued

(B) Evaluation and Diagnostic Services.

(1) Evaluation and diagnostic services must be documented and shall include:

- (a) Identification of the patients presenting complaint or problem at the time of evaluation;
- (b) An assessment of the current status and history of the patient's physical and psychological health;
- (c) Current and former substance use disorder treatment, or any other related treatment, including pharmacotherapy; and
- (d) Current and former social, economic, developmental, and educational functioning, describing both strengths and needs.

The above assessment shall be conducted by health care providers trained in completing such an evaluation, which includes evidence-based, specialized training in the assessment of substance used disorders, as appropriate to the patient's needs.

(2) After initiating a patient's evaluation, but prior to completion, patient treatment may begin, provided that sufficient information to initiate treatment for the presenting complaint or problem on that day of services is obtained and that the evaluation is completed in a reasonable timeframe. When appropriate, a diagnostic evaluation shall include the finding of a formal mental status examination and a diagnosis.

(3) When the initial evaluation indicates further assessment beyond the scope of the clinic's capabilities, the clinic program must refer the patient to the appropriate health care provider, pursuant to 105 CMR 140.520(F).

(C) Treatment Planning Services.

(1) The patient's written treatment plan shall be appropriate to the patient's presenting complaint or problem and based on information gathered during the intake, evaluation and diagnostic process, including any substance use disorder screening results.

The treatment plan must reflect the services delivered to address the chief complaint or problem on the date of first presentation as well as services rendered during subsequent encounters. As treatment progresses, further assessment and diagnostic information must be gathered and documented so as to inform longitudinal treatment planning.

(2) The treatment plan must include at least the following information, as appropriate to the patient's presenting complaint or problem:

- (a) identified problems and needs relevant to treatment and discharge expressed in behavioral, descriptive terms;
- (b) the patient's strengths and needs;
- (c) measurable treatment goals addressing identified problems with time guidelines for accomplishing goals;
- (d) identified clinical interventions, including pharmacotherapy, to obtain treatment goals;
- (e) evidence of patient involvement in formulation of the treatment plan;
- (f) clearly defined staff responsibilities and assignments for implementing the plan;
- (g) the date the plan was last reviewed and/or revised; and
- (h) the signatures and licenses and/or degrees of staff involved in the review and/or revision.

(3) The treatment plan must be revised as necessary to reflect current problems, specific and concrete goals, and treatments.

(D) Treatment Services.

(1) Case Consultation, Psychotherapy, and Counseling Services. These services must include case consultation, individual, group, couple, and family therapies provided by and/or supervised by the mental health professionals identified in 105 CMR 140.530(C). There must be documentation of progress towards defined treatment plan goals as a result of the clinical intervention(s).

140.520: continued

(2) Pharmacotherapy Services. These services must include, but are not limited to, an assessment of the patient's psychiatric symptoms and disorders, health status including medical conditions and medications, use or misuse of alcohol or other substances and prior experience with psychiatric medications. Services also include medication prescribing, reviewing, and monitoring by a prescriber working within the scope of their training and license. The services may also include administration of medications in accordance with a prescribing practitioner's order or prescription. The clinic may contract with appropriately licensed individuals with the authority to prescribe medications.

(3) When necessary treatment services for a patient are beyond the scope of the clinic's capabilities, the clinic program must refer the patient to the appropriate health care provider, pursuant to 105 CMR 140.520(F).

(E) Emergency Services. Each clinic licensed to provide mental health services must provide clinic coverage 24 hours a day, seven days per week that includes evaluation, diagnosis, and disposition services for an existing patient's presenting crisis, including short-term intervention and/or referral, and must have a written policy addressing emergency treatment referral for patients and individuals pursuant to 105 CMR 140.305(A). Such coverage must include telephone coverage that provides qualified professionals who are available to talk with patients over the telephone during nonbusiness hours and, if indicated, arrange for further care and assistance directly or through referrals in real time.

(a) During nonbusiness hours, a prerecorded message will not fulfill 105 CMR 140.520(E) requirement for access to a qualified professional by phone.

(b) Clinics are expected to keep a current on call roster of clinicians available to speak with patients at all times, as well as information on available regional services.

(F) Referral Services. Each clinic licensed to provide mental health services must have written policies and procedures that address the referral of patients to the appropriate health care providers including, but not limited to, substance use disorder providers, should the patient's identified health needs exceed the scope of services provided by the clinic's mental health service. Such policies and procedures must also address emergency referral, including for voluntary and involuntary commitments to psychiatric hospitals.

(G) Other services not specifically listed in 105 CMR 140.520 that enhance and augment the required or adequate mental health services, such as case management or community rehabilitation support, may be but are not required to be provided by the licensed clinic.

140.530: Staffing

(A) A clinic providing mental health services must provide a multidisciplinary staff who meets the requirements set forth at 105 CMR 140.530(B), and shall ensure an adequate number of staff are available to fulfill the program's objectives, including substance use disorder screening, as appropriate.

The staff may also include other related mental health professionals necessary for the provision of intake, evaluation, diagnostic and treatment services. The staff must be appropriately trained to assess and treat mental health conditions, which may include co-occurring substance use disorders.

(B) Personnel Qualifications.

(1) The clinic must have on staff or contract with a psychiatrist who is a physician, as defined in 105 CMR 140.020, and who is board certified by the American Board of Psychiatry and Neurology or the American Osteopathic Board of Neurology and Psychiatry, or eligible for such certification. Such psychiatrist shall be responsible for prescribing, or monitoring and supervising, the prescription of all medications.

(2) In addition to the requirements of 105 CMR 140.530(B)(1), the multidisciplinary staff must include at least two of the following types of mental health professionals:

(a) Psychologist. A psychologist licensed by the Massachusetts Board of Registration of Psychologists pursuant to M.G.L. c. 112, §§ 118 through 127, and 251 CMR 3.00: *Registration of Psychologists*.

## 140.530: continued

- (b) Social Worker. A licensed independent clinical social worker.
  - (c) Psychiatric Nurse. A registered nurse with a master's degree in psychiatric nursing licensed by the Board of Registration in Nursing pursuant to M.G.L. c. 112, § 80B, and 244 CMR 3.00: *Registered Nurse and Licensed Practical Nurse*.
  - (d) Psychiatric Nurse Mental Health Clinical Specialist. A psychiatric nurse mental health clinical specialist licensed by the Board of Registration in Nursing pursuant to M.G.L. c. 112, § 80B, and 244 CMR 4.00: *Advanced Practice Registered Nursing*.
  - (e) Licensed Mental Health Counselor. A licensed mental health counselor licensed by the Board of Registration of Allied Mental Health and Human Service Professions pursuant to M.G.L. c. 112, § 165, and 262 CMR 2.00: *Requirements for Licensure as a Mental Health Counselor*.
  - (f) Licensed Alcohol and Drug Counselor. An alcohol and drug counselor licensed by the Department pursuant to 105 CMR 168.000: *Licensure of Alcohol and Drug Counselors*.
  - (g) Other Licensed Mental Health and Substance Use Disorder Practitioners. Other mental health and substance use disorder practitioners licensed by the Division of Professional Licensure, the Department or any Board of Registration and deemed by the Department to be mental health and substance use disorder professionals.
- (3) A clinic whose mental health service consists solely of a psychiatric day treatment program as defined in 105 CMR 140.020 may substitute a rehabilitation counselor or occupational therapist as defined in 105 CMR 140.530(B)(3)(a) and (b) for one of the professionals listed in 105 CMR 140.530(B)(2)(b) through (g):
- (a) Rehabilitation Counselor. An individual who has at least a master's degree in rehabilitation or vocational counseling and one year's full-time supervised experience in a mental health setting, or its equivalent.
  - (b) Occupational Therapist. An individual licensed by the Massachusetts Board of Registration of Allied Health Professions and currently certified or eligible for certification by the American Occupational Therapy Association. The occupational therapist must have at least one year of experience in a mental health setting.

(C) Mental Health Clinic Leadership Responsibilities. In addition to the requirements at 105 CMR 140.310 through 140.312, clinics with a licensed mental health service must designate a lead for the mental health service who meets the qualifications outlined in 105 CMR 140.530(B)(1) or 140.530(B)(2)(a) through (e) and who is responsible for establishing all administrative policies and protocols for the mental health service; provided that standards informing medical policies and protocols must be approved by medical personnel. The professional services director, as required by 105 CMR 140.311, may be designated the mental health clinic lead if such director is a mental health professional listed in 105 CMR 140.530(B).

(D) Supervision. All staff members other than those meeting the qualifications set forth in 105 CMR 140.530(B) must be clinically supervised on a regular basis by licensed professional staff members as defined in 105 CMR 140.530(B). The documentation of supervision must be available for review.

140.540: Case Review

- (A) The clinic must establish a case review process that includes a review of each patient's treatment plan and progress including, but not limited to, a patient's prescribed medication.
- (B) Case review shall be conducted by one or more members of the multidisciplinary staff as defined in 105 CMR 140.530(B).
- (C) Case review shall not be completed by the mental health professional(s) responsible for implementing the patient's treatment plan.
- (D) Case reviews must be conducted as necessary, but at least once a year or at discharge. The frequency of case reviews shall be based upon the patient's current problems, specific and concrete goals and treatment.

140.550: Additional Recordkeeping Requirements

In addition to the requirements at 105 CMR 140.302, clinics with a licensed mental health service must comply with the following:

- (A) Documentation of the delivery of mental health services, which may include substance use disorder treatment, including progress notes or statements recorded by the mental health professionals who are responsible for implementing the patient's treatment plan. In the case of unlicensed clinicians recording progress notes or implementing treatment plans, a licensed clinician is responsible for clinical oversight of all clinical activities.
- (B) Patient records must be created and maintained in accordance with all federal and state laws, regulations, and requirements applicable to the services provided.

140.560: Mental Health Outreach Programs

- (A) A mental health outreach program must be operated by a clinic licensed to provide mental health services.
- (B) Outreach programs shall be operated in conformance with the standards for mental health services contained in 105 CMR 140.500 through 140.550.
- (C) Outreach services may include diagnostic services and treatment services, including emergency services provided to patients in their homes or other community environments.
- (D) Documentation of services delivered in settings other than the clinic must describe the place of service in which the care was delivered.
- (E) When outreach services must be provided in buildings with community health or social service uses, the site will be maintained in a safe and sanitary manner.
- (F) If the mental health outreach program site is leased, rented or otherwise under the control of the clinic, the clinic must obtain approval for the mental health outreach program as a satellite.

140.600: Applicability of 105 CMR 140.600 through 140.614

- (A) The requirements of 105 CMR 140.600 through 140.614 are applicable to clinics subject to Department licensure to provide surgical services.
- (B) A clinic may perform surgery, including those dental surgical procedures set forth in 105 CMR 140.600(C), only if specifically licensed to do so by the Department, unless it performs only simple surgical procedures such as incision and drainage or suturing of simple lacerations.
- (C) Dental surgical procedures for which a clinic must be licensed pursuant to 105 CMR 140.600(B) include procedures requiring general anesthesia; advanced oral maxillofacial surgery; removal of a large tumor; or major surgery to the mandible or maxilla such as reduction of a fractured jaw.
- (D) A clinic may perform surgical procedures under regional or general anesthesia only if licensed to provide surgical services.
- (E) No clinic may perform cardiac catheterization services.

140.601: Incorporation of Medicare Conditions of Participation for Ambulatory Surgical Services

A clinic licensed to perform surgery must comply with the standards of the Medicare Conditions of Participation for Ambulatory Surgical Services set forth in 42 CFR 416.42(a)(I) relating to anesthesia risk and evaluation; 42 CFR 416.44(a)(1) and (2) relating to physical environment; 42 CFR 416.44(c) relating to emergency equipment; and 42 CFR 416.44(d) relating to emergency personnel. Clinics administering general anesthesia shall also comply with 42 CFR 416.44(b) of the Medicare Conditions of Participation relating to safety from fire.

140.602: Surgical and Anesthesia Privileges

- (A) Surgical staff shall be granted privileges to perform only those surgical procedures that they are legally and professionally qualified to perform.
- (B) Anesthesia staff shall be granted privileges to administer anesthesia, including conscious intravenous sedation, only in accordance with their legal and professional qualifications.
- (C) Surgical and anesthesia privileges shall be granted by the governing body based on the recommendation of the Surgery Director or Anesthesia Director.
- (D) The clinic shall maintain a list of individuals granted surgical and/or anesthesia privileges including each individual's name, profession, specialty and the surgical procedures he or she is permitted to perform or the type of anesthesia he or she is permitted to administer.

140.603: Surgery Director

- (A) Each clinic licensed to perform surgery shall designate, as appropriate for the services offered, a physician, podiatrist or dentist with surgical privileges and certification by an appropriate specialty board, as the Surgery Director.
- (B) The Surgery Director shall direct and observe surgical staff and is responsible for maintaining the quality of surgery.
- (C) Clinics performing only dental surgery shall designate a dentist who is board certified by the American Board of Oral and Maxillofacial Surgery as the Surgery Director.

140.604: Procedures

Each clinic licensed to perform surgery shall determine, with the advice of its surgery director, the types of surgical procedures it may perform. The clinic shall maintain a current list of these procedures.

140.605: Preoperative Evaluation

- (A) A physician shall perform a physical examination, review the patient's medical history, and review the results of pertinent preoperative diagnostic studies prior to surgery.
- (B) Prior to the performance of a dental surgical procedure where there is no known medical problem, a dentist may perform a physical examination, review the patient medical history, and review the results of pertinent preoperative diagnostic studies prior to surgery in *lieu* of a physician upon:
  - (1) successful completion of a physical evaluation program or course at an accredited hospital or teaching institution, and
  - (2) board certification or eligibility by the American Board of Oral and Maxillofacial Surgery or by the American Board of Pedodontics.
- (C) Each patient undergoing regional or general anesthesia shall have a preoperative evaluation performed by a physician or in the case of patients without medical problems admitted for dental procedures, dentist with anesthesia privileges.

140.606: Anesthesia Director

- (A) Each clinic administering regional or general anesthesia shall designate an anesthesiologist to be responsible for the anesthesia services. For the purposes of 105 CMR 140.600 through 140.614, an anesthesiologist is a physician who is certified by the American Board in Anesthesiology.
- (B) The Anesthesia Director is responsible for the supervision of all persons administering anesthesia in the clinic, the review of all anesthesia complications and the development of policies and procedures related to preoperative and postoperative anesthesia care.

140.607: Adequate Assistance

No surgical procedure shall be initiated without adequate assistance present in the operating room:

- (A) The operating room circulator shall meet the definition and functions set out in 105 CMR 140.620 and 105 CMR 140.621; and
- (B) The person administering general anesthesia, functioning within his or her scope of practice, shall be someone other than the primary operating surgeon.

140.608: Surgical Area

- (A) Acceptable aseptic techniques shall be used by all persons in the surgical area.
- (B) Each clinic licensed to perform surgery shall designate a receiving area appropriately designed and equipped for preoperative preparation, examination, holding and observation of patients.
- (C) Each clinic licensed to perform surgery shall have at least one operating room.

140.609: Specimens

- (A) Except as provided in 105 CMR 140.609(B), all specimens of tissue removed during a surgical procedure shall be submitted to a pathologist for microscopic examination.
- (B) An exception to the requirements of 105 CMR 140.609(A) may be made in the case of dental surgery involving tooth removal where no soft tooth tissue pathology is suspected. The number of teeth, including fragments, shall be recorded in the patient's record.
- (C) Each clinic licensed to perform surgery shall have written policies and procedures governing microscopic examination of tissue and the verification of removal of non-tissue specimens, such as foreign bodies.
- (D) The results of all tissue examinations shall be entered in the patient's medical record. Each clinic shall provide treatment, or referral for treatment of any diagnosed pathological condition.

140.610: Recovery Procedures

- (A) Each postoperative patient shall be supervised constantly while recovering from surgery and anesthesia by a registered nurse trained to recognize complications until released from the recovery area.
- (B) Patients shall be sufficiently recovered from surgery and anesthesia prior to discharge. The individual who performed the surgical procedure shall be responsible for a postoperative evaluation and shall enter his or her report and discharge order into the patient's record prior to the patient's discharge. Patients recovering from general or regional anesthesia shall have a post anesthesia evaluation performed by a physician or, in the case of a patient without medical problems admitted for dental procedures, a dentist with anesthesia privileges.
- (C) The clinic shall provide each patient with written instructions including possible complications arising from the surgery, how to recognize these complications, whom to contact for follow-up care with questions if the clinic is closed and in the event of an emergency.

140.612: Physical Environment and Safety Provisions

In addition to the physical environment requirements set forth in 105 CMR 140.201 through 140.208 and 105 CMR 140.601, each clinic licensed to perform surgery shall meet the physical environment and safety requirements of 105 CMR 140.612.



140.612: continued

(A) Each clinic licensed to perform surgery using regional or general anesthesia shall inspect the condition of electrical and mechanical medical equipment used in each operating room when such equipment is obtained and regularly thereafter. A licensed electrician or biomedical technician shall routinely test and maintain electrical equipment. Written records must be kept of such inspections.

(B) Each clinic must have an adequate sterilizing area, instrument storage area, change area, scrub area, pack area, and clean-up area. Clean work areas shall be physically separate from soiled work areas.

(C) Emergency power shall be available in the surgical and recovery areas.

140.613: Evaluation of Quality

(A) In addition to the requirements set forth in 105 CMR 140.370, the quality assurance program established by each clinic licensed to perform surgery shall include reviews of at least the following:

- (1) medical necessity of procedures performed, including the review of tissue removed at surgery to determine agreement or disagreement among the preoperative, postoperative and pathological diagnoses;
- (2) whether adequate pre and postoperative services and procedures met patient needs; and
- (3) all complications.

(B) Each clinic shall use the findings of the assessments required by 105 CMR 140.613(A) in the revision of clinic policies and consideration of clinical privileges.

(C) Each clinic shall document all such reviews conducted and their findings and shall make such documentation available to the Department upon request.

140.614: Limitation on Transfusions

(A) Surgical services shall not do procedures that generally result in extensive blood loss or for which the need for blood replacement is anticipated.

(B) Transfusions shall be permitted as part of the clinic's surgical services in accordance with 105 CMR 135.410: *Transfusion Outside of a Licensed Hospital* that allow such transfusions outside a transfusion service in rare and unusual circumstances as deemed necessary by the blood bank director, provided that blood or blood product is released to the requesting physician and that physician is responsible for the transfusion.

(C) Surgical services that administer whole blood and/or its components and/or derivatives in transfusion as authorized by 105 CMR 140.614(B) shall meet the requirements set forth in 105 CMR 140.380(A) through (C).

140.620: Surgical Technology Definitions

For the purposes of 105 CMR 140.621, the following terms have the following meanings:

Operating Room Circulator. A licensed registered nurse who is educated, trained and experienced in perioperative nursing, who is immediately available to physically intervene in providing care to a surgical patient.

Surgical Technologist. Any person who provides surgical technology services who is not licensed or registered under M.G.L. c. 112, §§ 2, 16, 74 or 74A, or who is not an intern, resident, fellow or medical officer who conducts or assists with the performance of surgery.

Surgical Technology. Surgical patient care including, but not limited to, one or more of the following:

140.620: continued

- (1) collaboration with an operating room circulator prior to a surgical procedure to carry out the plan of care by preparing the operating room, gathering and preparing sterile supplies, instruments and equipment, preparing and maintaining the sterile field using sterile and aseptic technique and ensuring surgical equipment is functioning properly and safely;
- (2) intraoperative anticipation and response to the needs of a surgeon and other team members by monitoring the sterile field and providing the required instruments or supplies;
- (3) performance of tasks at the sterile field, as directed in an operating room setting, including:
  - (a) passing supplies, equipment or instruments;
  - (b) sponging or suctioning an operative site;
  - (c) preparing and cutting suture material;
  - (d) transferring and irrigating with fluids;
  - (e) transferring, but not administering, drugs within the sterile field;
  - (f) handling specimens;
  - (g) holding retractors; and
  - (h) assisting in counting sponges, needles, supplies and instruments with an operating room circulator.

140.621: Surgical Technology

(A) Each clinic licensed to provide surgical services shall adopt policies and procedures addressing the following requirements set forth in M.G.L. c. 111, § 229.

- (1) The clinic may not employ or otherwise retain the services of any person to perform surgical technology tasks or functions, unless such person:
  - (a) has successfully completed an accredited educational program for surgical technologists and holds and maintains a certified surgical technologist credential administered by a nationally recognized surgical technologist certifying body accredited by the National Commission for Certifying Agencies and recognized by the American College of Surgeons and the Association of Surgical Technologists; or
  - (b) has successfully completed an accredited school of surgical technology, but has not, as of the date of hire, obtained the certified surgical technologist certification required in 105 CMR 140.621(A)(1)(a); provided, however, such certification shall be obtained within 12 months of the graduation date; or
  - (c) was employed as a surgical technologist in a surgical facility on or before July 1, 2013; or
  - (d) has successfully completed a training program for surgical technology in the Army, Navy, Air Force, Marine Corps or Coast Guard of the United States or in the United States Public Health Service deemed appropriate by the commissioner; or
  - (e) is performing surgical technology tasks or functions in the service of the federal government, but only to the extent the person is performing duties related to that service.
- (2) A person employed or otherwise retained to practice surgical technology in a clinic may assist in the performance of operating room circulator duties under the direct clinical supervision, limited to clinical guidance, of the operating room circulator if:
  - (a) the operating room circulator is present in the operating room for the duration of the procedure;
  - (b) any such assistance has been assigned to such person by the operating room circulator; and
  - (c) such assistance is consistent with the education, training and experience of the person providing such assistance.

(B) A clinic may employ a surgical technologist who does not meet the requirements of 105 CMR 140.621(A) if the clinic receives a waiver from the department signifying the clinic has:

- (1) made a diligent and thorough effort to employ qualified surgical technologists who meet the requirements of 105 CMR 140.621(A)(1); and
- (2) is unable to employ enough qualified surgical technologists for its needs.

(C) Nothing in 105 CMR 140.621 shall prohibit a licensed registered nurse, licensed or registered health care provider or other health care practitioner from performing surgical technology tasks or functions if such person is acting within the scope of such person's license.

140.700: Applicability of 105 CMR 140.701 through 140.702

For the purpose of 105 CMR 140.701 through 140.702, the term “physical rehabilitation services” shall mean physical therapy, occupational therapy or speech therapy services.

The requirements of 105 CMR 140.701 through 140.702 are applicable to clinics subject to Department licensure licensed to provide physical rehabilitation services.

140.701: Physician’s Direction and Plan of Care

(A) Each clinic providing physical rehabilitation services shall retain, at least on a consulting basis, one physician to, at a minimum, assist in establishing and implementing patient care policies and to provide medical consultation as needed.

(B) A clinic shall accept a patient for rehabilitation services only on the order of a clinic physician or referring physician who indicates the diagnosis and anticipated goals, and who is responsible for the general medical direction of such services as part of the total care of the patient.

(C) For each patient there shall be written plan of care approved by the physician. The plan of care must specify the type, amount, frequency and duration of the services to be provided. The plan of care and results of treatment shall be reviewed by the physician at least every 60 days or more often if required.

140.702: Rehabilitation Staff

If a clinic provides rehabilitation services, the clinic shall retain on at least a part-time basis qualified therapists to provide directly or to supervise the provision of the service.

For the purposes of 105 CMR 140.700 through 140.702, a “qualified physical therapist” shall be a physical therapist who meets the requirements of M.G.L. c. 112, § 23I. A “physical therapist assistant” shall be a person who meets the requirements of M.G.L. c. 112, § 23J.

For the purpose of 105 CMR 140.700 through 140.702, a “qualified speech pathologist” shall be a person who meets the requirements of M.G.L. c. 112, § 144.

For the purposes of 105 CMR 140.700 through 140.702, a “qualified occupational therapist” shall be a person who meets the requirements of M.G.L. c. 112, § 23G. An “occupational therapy assistant” shall be a person who meets the requirements of M.G.L. c. 112, § 23H.

140.801: Substance Use Disorder Treatment Services

To provide Substance Use Disorder Treatment Services, as that term is defined in 105 CMR 140.020, a clinic must meet the applicable programmatic and staffing requirements set forth in 105 CMR 164.000: *Licensure of Substance Abuse Treatment Programs*.

140.901: Birth Center Written Policies and Procedures

An applicant to add birth center services to its license shall develop, through an interdisciplinary team, written policies and procedures to ensure the safe operation of the birth center prior to submitting an application for approval. A birth center shall implement, review and revise, through an interdisciplinary team as needed, but not less than once a year, its written policies and procedures. A birth center shall ensure all staff, including any temporary staff and volunteers, are trained and determined to be competent as needed for their duties under the policies and procedures developed by the facility. A birth center’s policies shall include at a minimum, but not be limited to:

(A) Patient admission criteria including specific information by which a pregnant person’s risk status will be established.

(B) Off-hour coverage.

(C) Consultation and referral for obstetric and pediatric care.

(D) Specific patient transfer criteria.

140.901: continued

- (E) Emergency procedures, including adult and neonatal cardiopulmonary resuscitation.
- (F) Standards for medication procurement, storage and administration.
- (G) Protocols for screening newborns for critical congenital heart disease with pulse oximetry or another test approved by the Department in accordance with Department guidelines.

140.902: Staffing

A birth center shall have adequate, trained staff who are licensed as required and are available at all times to meet the needs of its patients including, but not limited to:

- (A) Administrative Director of the Birth Center.
  - (1) A birth center shall have an administrative director who shall be responsible for implementing and overseeing the operational policies of the birth center.
  - (2) The administrative director must have health care and business experience.
  - (3) One person may serve as both administrative director and director of medical affairs if the individual meets the requirements for both positions and can perform the duties of both positions.
  - (4) One person may serve as the administrative director and the clinic administrator if the individual meets the requirements for both positions and can perform the duties of both positions.
- (B) Director of Medical Affairs.
  - (1) A birth center shall have a Director of Medical Affairs who shall be an obstetrician, a certified nurse midwife, certified professional midwife, family practitioner or gynecologist. The Director of Medical Affairs must be licensed to practice in the Commonwealth, and their professional scope of practice must include preconception, prenatal, labor, birth and postpartum care and early care of the newborn and who may be the primary attendants during the perinatal period; and
  - (2) The Director of Medical Affairs shall be responsible for advising and consulting with the medical staff of the birth center on all matters related to medical management of pregnancy, birth, post-partum, newborn and gynecologic health care, including policies, procedures and protocols that are outside the scope of midwifery practice.
- (C) Required Staffing at Births.
  - (1) Birth Attendant. A certified nurse-midwife, certified professional midwife, or an obstetrician or family practitioner. The Birth Attendant must be licensed to practice in the Commonwealth, and their professional scope of practice must include preconception, prenatal, labor, birth and postpartum care and early care of the newborn. The Birth Attendant shall attend each pregnant person in labor from the time of admission; during labor; during the birth; and through the immediate postpartum period. Such attendance may be delegated only to another birth attendant.
  - (2) Birth Assistant. A second staff person shall also be present at each birth. The second staff person must be either a certified nurse-midwife, or a licensed nurse, or a provider licensed or certified by the Department as specified in Department guidelines. For purposes of 105 CMR 140.902(C), licensed nurses shall include registered nurses and licensed practical nurses.
  - (3) Licensed nurses functioning as a birth assistant must have experience providing direct clinical care to laboring patients, in any setting, that includes training or experience in
    - (a) adult and infant resuscitation;
    - (b) assessing the phases and stages of labor;
    - (c) psychology and physiology of labor and delivery; and
    - (d) equipment and supplies used for labor and delivery.

140.903: Equipment and Supplies

Each birth center shall have safe and adequate equipment available to meet the needs of its patients, including those with disabilities, and shall include at a minimum:

- (A) A neonatal warming device in accordance with Department guidelines.
- (B) A microscope for routine office examination of vaginal smears.
- (C) A sufficient number of sphygmomanometers and auscultation equipment, including a fetoscope or fetal doppler.

140.903: continued

- (D) Equipment and supplies for administration of intravenous fluids, and adult and infant resuscitation as required by procedures outlined in the birth center's protocols.
- (E) A supply of oxygen, including portable oxygen available for emergency use.
- (F) Portable suction available for both the birthing person and the infant.

140.904: Patient Records

A birth center shall maintain accurate and complete records on all of its patients.

- (A) At a minimum, with respect to each newborn, the following information shall be included
  - (1) The condition of the infant at birth to include APGAR Score (or its equivalent) at one minute and five minutes, time of sustained respiration, details of physical abnormalities and pathological states.
  - (2) Date and hour of birth, birth weight and period of gestation.
  - (3) Number of cord vessels and any abnormalities of the placenta.
  - (4) Verification of eye prophylaxis.
  - (5) Metabolic screening.
  - (6) Treatments, medications and special procedures.
  - (7) Condition at discharge or transfer.
- (B) At a minimum, with respect to each pregnant and birthing person, the following information shall be included:
  - (1) Birth person's medical and obstetric history including prenatal course.
  - (2) Antenatal blood serology, Rh factor, blood type, HBsAg test, rubella antibody and Group B streptococcal culture results. In addition, results of maternal HIV testing, if applicable.
  - (3) Admission examination including the condition of both the birthing person and fetus.
  - (4) Complete description of progress of labor and delivery, signed by the attending physician or certified nurse midwife.
  - (5) Names and credentials of all those present during delivery.
  - (6) Description of postpartum course, including complications and treatments, signed by the attending certified professional midwife, physician or certified nurse midwife.
  - (7) Medications, including contraceptives, prescribed at discharge.
  - (8) Assessment, diagnosis, interventions and teaching.
  - (9) Method of infant feeding and infant feeding plan of care and progress and documentation of lactation care and services provided.
  - (10) If neonatal death occurs, cause of death, assessment of the family's coping mechanisms and plans for follow-up and/or referral of the family.

140.905: Care and Services

- (A) The birth center shall provide a program of care, which includes at least the following:
  - (1) A personal and family history;
  - (2) A physical examination and appropriate laboratory tests;
  - (3) A program of prenatal care that shall include components of self-help, self-care, and fetal assessment;
  - (4) A program of prenatal education that shall include the importance of nutrition, preparation for birth and breast or chest feeding, and information on adverse effects of smoking, alcohol and other drugs;
  - (5) Intrapartum and postpartum services that foster parental control and responsibility for the birth experience and infant parental bonding;
  - (6) Labor support for the pregnant person and their family;
  - (7) Immediate postpartum care and newborn assessment;
  - (8) Required eye prophylaxis;
  - (9) Postpartum laboratory examination;
  - (10) Newborn metabolic screening and other such tests as may be required;
  - (11) A postpartum examination, including perinatal mood disorder screening, and family planning;
  - (12) A plan for routine gynecologic health care; and
  - (13) A program for prevention of Rh immunization.

140.905: continued

- (B) The birth center shall have access to diagnostic services, including clinical laboratory, sonography, radiology, and electronic monitoring.
- (C) Birthing persons and infants may be discharged or transferred within 24 hours after birth.
- (D) Maternal and newborn examinations shall be performed by the birth center professional staff or a physician or certified nurse-midwife of the family's choice within 72 hours of birth. Such examinations shall include required laboratory tests for health screening.
- (E) Each birth center shall develop and implement written policies and procedures for the prompt and safe transfer of the obstetrical patient and of the newborn for emergency treatment beyond that provided in the birth center.
- (F) Each birth center shall have written policies and procedures for the coordination of ongoing care and transfer of patients to hospitals for treatment beyond that provided by the birth center which must include, at a minimum, the process for providing the patients' medical records to the hospital at the time of transfer.
- (G) A birth center must conduct newborn infant hearing screening in accordance with the requirements regarding screening at 105 CMR 130.616(D)(2)(I): *Universal Newborn Hearing Screening Programs*. If a birth center does not have the equipment or ability to conduct such a screening, the birth center shall refer the newborn infant to a hospital or clinic able to conduct such screening. Prior to discharge, a birth center that is not able to conduct a hearing screening shall:
  - (1) make an appointment for a screening for each newborn infant at a screening site.
  - (2) provide written information in the language understood by the parent or guardian to the parent or guardian about the importance of the screening, coverage of the costs of the screening by third-party payers, the time of any screening appointment scheduled, and the location and phone number of the hearing screening site.
  - (3) within two weeks of the birth of a child, confirm the hearing screening has been completed and, if not, contact the parent or guardian of the newborn infant.
  - (4) As part of the annual report submitted to the Department pursuant to 105 CMR 130.616(D)(2)(I): *Universal Newborn Hearing Screening Programs*, the birth center shall submit information regarding the follow-up for hearing screening of newborn infants.
- (H) The administration of medications for pregnancy termination or early pregnancy loss, including but not limited to mifepristone and/or misoprostol, to birth center patients is permissible in the birth center.

140.906: Prohibited Practices

- (A) Surgical procedures shall be limited to those normally accomplished during uncomplicated childbirth, such as episiotomy and repair.
- (B) The following practices are prohibited in a birth center:
  - (1) Surgical procedures including, but not limited to, assisted vaginal delivery, tubal ligation, dilation and curettage or Cesarean section.
  - (2) Inhibition, stimulation or augmentation of the first or second stage of labor with controlled substances.
  - (3) The use of general or regional anesthesia. Local anesthesia as clinically appropriate is allowed.
  - (4) The dispensing, other than by immediate administration or in accordance with 105 CMR 700.010: *Dispensing and Labeling of Sample Medications by Practitioners*, or the provision of controlled substances for self-administration outside of the birth center, unless the clinic is licensed for pharmacy services and is staffed in accordance with 105 CMR 140.000.

140.907: Off-hour Coverage

Each birth center shall make arrangements for the provision of services 24 hours per day. These requirements can be met through on call coverage by a certified nurse-midwife or physician on the staff of the birth center. These arrangements shall be reflected in a written policy available to all the birth center's patients.

140.908: System for Referral

## 105 CMR: DEPARTMENT OF PUBLIC HEALTH

The birth center shall develop a written policy for the provision of 24-hour consultation, referral and transfer to appropriate hospital facilities for obstetric/newborn care.

### 140.909: Reporting Requirements

(A) Birth centers shall report all births to the Department, and to registrars and city or town clerks, in accordance with M.G.L c. 46.

(B) Birth centers shall report any child with low birth weight, congenital abnormalities, and other high risk infants in accordance with guidelines as may be established by the Department.

### 140.911: Lithotripsy

(A) In addition to the facilities and equipment specifically required in other applicable sections of 105 CMR 140.000, clinics offering lithotripsy shall provide at least the following in or easily accessible to the lithotripter unit:

- (1) induction/patient preparation room;
- (2) recovery area;
- (3) oxygen and suction within the unit;
- (4) emergency power within the unit;
- (5) accessibility to emergency response on-site;
- (6) accessibility to intensive care unit services on-site if host location is a licensed hospital; and
- (7) radiology services including cystoscopy facilities.

(B) A clinic providing lithotripsy under regional or general anesthesia shall meet the provisions included under 105 CMR 140.600 through 140.614.

### 140.1000: Applicability of 105 CMR 140.1001 and 140.1002

The requirements of 105 CMR 140.1001 and 140.1002 are applicable to clinics licensed to provide limited services.

### 140.1001: Policies and Procedures for Limited Services Clinics

(A) Each limited services clinic shall develop policies and procedures identifying the limited services the clinic will provide. No limited services clinic may serve as a patient's primary care provider. No limited services clinic may provide treatment to a patient younger than 18 months old.

(B) Each limited services clinic shall develop and utilize clinical practice guidelines for diagnosing and treating patients. Each limited services clinic shall utilize clinical practice guidelines for determining when patient needs are beyond the scope of the services it provides or beyond the scope of practice of its practitioners.

(C) Each limited services clinic shall develop policies and procedures specifying its staffing pattern as required by 105 CMR 140.310 through 140.315.

(D) Each limited services clinic shall develop policies and procedures for referring patients whose needs exceed the clinic's services, including those circumstances in which a telephone referral may be appropriate; each limited services clinic shall develop policies and procedures for practitioner consultation on unclear cases.

(E) Each limited services clinic shall maintain a roster of primary care practitioners, including community health centers, in the clinic's geographic area who are currently accepting new patients, and who are willing to accept a referral from the limited services clinic to serve as a primary care provider.

- (1) The limited services clinic shall provide each patient who does not have a primary care provider with a referral from the list maintained pursuant to 105 CMR 140.1001(E).

140.1001: continued

(2) If the purpose of the visit is for a childhood immunization other than the influenza vaccine, the limited services clinic shall counsel the parent or guardian on the importance of establishing and maintaining a relationship with a pediatric or family practice for ongoing medical and well-child care.

(3) 105 CMR 140.1001(E)(2) shall not apply to a limited services clinic that is a satellite of, or is otherwise affiliated with, a health care facility licensed pursuant to M.G.L. c. 111, § 51, an accountable care organization or provider organization subject to M.G.L. c. 6D, or other licensed practitioners.

(F) Each limited services clinic shall develop policies and procedures designed to identify and limit, if necessary, the number of repeat encounters with individual patients.

(1) Each limited services clinic shall develop policies and procedures regarding the referral of such patients to primary care practitioners or other appropriate settings, including community health centers.

(2) Each limited services clinic shall develop policies and procedures designed to limit repeat visits for routine childhood immunizations other than the influenza vaccine.

(3) In the event the limited services clinic is a satellite of, or is otherwise affiliated with, a health care facility licensed pursuant to M.G.L. c. 111, § 51, an accountable care organization or provider organization subject to M.G.L. c. 6D, or other licensed practitioners, the limited services clinic may develop alternate mechanisms for assuring continuity of care within the system.

(4) No limited services clinic may refer a patient to a named non-primary care provider unless the limited services clinic is a satellite of, or is otherwise affiliated with, a health care facility licensed under M.G.L. c. 111, § 51, an accountable care organization or provider organization subject to M.G.L. c. 6D, or other licensed practitioners, and the non-primary care provider practices in the facility or is affiliated with the accountable care organization or provider organization or is otherwise affiliated with the limited services clinic.

(G) Each limited services clinic shall provide a copy of the medical record of each visit to the patient at the end of the visit or as soon as available and, with the patient's consent, provide a facsimile or electronically transmitted copy of the medical record of the visit to the patient's primary care provider, if any. Such copies or transmissions shall be provided at no charge to the patient. For pediatric immunizations the limited services clinic shall maintain documentation of the transmission.

(H) If the limited services clinic is located within a retail location, the clinic shall have policies and procedures ensuring that clinic personnel do not promote the use of services provided by the host retail location.

(I) Required Disclosures.

(1) The limited services clinic shall prominently post or otherwise disclose a description of the services provided and shall provide a clear written statement informing the patient to seek care from his or her primary care provider or an emergency provider for other complaints or conditions.

(2) The limited services clinic may not use false or misleading information in its advertising including, but not limited to, information related to its services, practitioners, or that it may act as a patient's primary care provider.

(3) If a limited services clinic is located within a retail location, the clinic shall prominently post a statement informing the patient he or she may obtain any prescription medications or other recommended supplies at any location and is not required to purchase such supplies from the host retail location.

(4) Each limited services clinic providing immunizations shall follow Department guidelines to disclose whether it receives vaccines free of charge through the Massachusetts Immunization Program and notifying patients there may be a difference in cost between immunization services provided at a limited services clinic and a primary care provider's office.



140.1001: continued

(J) No limited services clinic may use any name implying that it may act as the patient's primary care provider. If a limited services clinic is an affiliate or satellite of a licensed health care facility, the name of the limited services clinic shall be sufficiently different from the parent facility such that members of the public can readily understand that the services offered are more limited in scope from those offered by the parent.

(K) Each limited services clinic shall make interpreter services available as appropriate to the population served. Such services may be provided by a telephone interpreting service.

(L) If a limited services clinic is located within a retail location that sells tobacco products, the clinic shall prominently post information regarding tobacco usage, the content of which is determined by the Department's Tobacco Control Program.

140.1002: Physical Plant Environment Requirements in Limited Services Clinics

(A) Notwithstanding general access requirements from the Facility Guidelines Institute's *Guidelines for Design and Construction of Health Care Facilities*, a limited services clinic located on the premises of another entity is not required to provide separate exterior entrances or designated parking or to provide a patient waiting area or reception area separate from the public area of the host entity.

(B) Notwithstanding general space requirements from the Facility Guidelines Institute's *Guidelines for Design and Construction of Health Care Facilities*, each limited services clinic shall have a minimum floor area of 56 square feet for each examination room, exclusive of fixed casework.

(C) Those provisions of the Facility Guidelines Institute's *Guidelines for Design and Construction of Health Care Facilities* that pertain to services a particular limited services clinic does not provide (e.g., venipuncture) shall not apply to the limited services clinic.

(D) Each limited services clinic shall provide a hand sanitizer dispenser outside each treatment room.

(E) In accordance with 105 CMR 140.203, each limited services clinic must provide consultation, examination, treatment and dressing areas appropriate to the services provided by the clinic. Any limited services clinic intending to substantially alter or expand the scope of services provided at a clinic location must notify the Department and conform with appropriate physical plant requirements prior to implementation of any such change.

105 CMR 140.1100: Electronic Health Records in Community Health Centers

(A) Definitions applicable to 105 CMR 140.1100:

Centers for Medicare & Medicaid Services (CMS). The agency within the federal Department of Health and Human Services responsible for administering Medicare, Medicaid, and the Children's Health Insurance Program.

Certification Commission for Healthcare Information Technology (CCHIT). The nonprofit organization authorized by the Office of the National Coordinator for Health Information Technology to test and certify EHR technology to the certification criteria specified in 45 CFR Part 170.

Certified Electronic Health Record (Certified EHR) Technology. EHR technology tested and certified by CCHIT or another agency or organization approved by ONC-HIT to test and certify EHR technology.

CMS Stage 1 Meaningful Use Criteria. The Stage 1 meaningful use objectives and measures specified in 42 CFR Part 495.

140.1100: continued

CMS Stage 2 Meaningful Use Criteria. The Stage 2 meaningful use objectives and measures specified in 42 Part 495.

Community Health Center (CHC). A federally-qualified health center operating in conformance with federal rules for community health centers under 42 U.S.C. 254b and currently participating in the Massachusetts Medicaid program, or a community health center with an active provider agreement with MassHealth under 130 CMR 405.000: *Community Health Center Services*.

Computerized Provider Order Entry (CPOE). A system that enables the provider to directly enter medication orders, laboratory orders, and radiology orders from a computer or other electronic device. The order is then documented or captured in a digital, structured, and computable format for use in improving the safety and efficiency of the ordering process.

Electronic Health Record (EHR) Technology. Computer technology that records patient health-related information and:

- (1) includes patient demographic and clinical health information, such as medical history and problem lists;
- (2) has the capacity to:
  - (a) provide clinical decision support;
  - (b) support provider order entry;
  - (c) capture and query information relevant to health care quality;
  - (d) exchange electronic health information with, and integrate such information from other sources; and
  - (e) protect the confidentiality, integrity and availability of health information stored and exchanged.

Eligible Professional. An eligible professional as defined in 42 CFR 495.100 or a Medicaid eligible professional as defined in 42 CFR 495.304.

Office of the National Coordinator for Health Information Technology. The agency within the federal Department of Health and Human Services responsible for authorizing organizations to test and certify EHR technology to the certification criteria specified in 45 CFR Part 170.

2011 Edition EHR Certification Criteria. The 2011 EHR certification criteria in 45 CFR Part 170.

2014 Edition EHR Certification Criteria. The 2014 EHR certification criteria specified in 45 CFR Part 170.

(B) Implementation of Electronic Health Records.

- (1) A Community Health Center shall provide documentation to the Department demonstrating the CHC has implemented Certified EHR Technology, its eligible professionals have registered with CMS and attested to compliance with CMS EHR Meaningful Use Criteria, and at it utilizes CPOE, as specified in 105 CMR 140.1100 and in guidelines of the Department.
- (2) No later than October 1, 2016, a CHC shall:
  - (a) implement Certified EHR Technology, as specified in 45 CFR Part 170 and in guidelines of the Department;
  - (b) attest at least 70% of eligible professionals employed by the CHC have registered with CMS and attested to compliance with CMS Stage 1 meaningful use criteria, as specified in guidelines of the Department; and
  - (c) utilize CPOE, as specified in guidelines of the Department.
- (3) After October 1, 2016 the Department may require that a higher percentage of eligible professionals employed by the CHC register with CMS, attest to compliance with CMS EHR Meaningful Use Criteria, and utilize CPOE as specified in guidelines of the Department.
- (4) Review of Meaningful Use.
  - (a) A CHC shall, upon request of the Department, submit documentation to the Department pertaining to its use of Electronic Health Record Technology and meaningful use by eligible professionals, as specified in guidelines of the Department.

140.1100: continued

- (b) A CHC shall keep documentation supporting its eligible professionals' demonstration of meaningful use for six years following the EHR reporting period for each eligible professional, as defined in 42 CFR 495.4.

140.1200: Definitions Applicable to 105 CMR 140.1201

The following definitions apply to 105 CMR 140.1201:

Appropriate Patient. A patient whose attending health care practitioner has:

- (1) diagnosed a terminal illness or condition reasonably expected to cause the patient's death within six months, whether or not treatment is provided, provided the attending health care practitioner determines discussion of the palliative care services is not contraindicated; or
- (2) determined that discussion of palliative care services is consistent with the patient's clinical and other circumstances and the patient's reasonably known wishes and beliefs.

Attending Health Care Practitioner. A physician, nurse practitioner, or physician assistant who has primary responsibility for the care and treatment of the patient within or on behalf of the clinic; provided if more than one physician, nurse practitioner, or physician assistant share that responsibility, each of them shall have a responsibility under 105 CMR 140.1201, unless there is an agreement to assign that responsibility to one such person.

Hospice Care Services. Care provided by an entity licensed pursuant to 105 CMR 141.000.

Palliative Care. The attempt to prevent or relieve pain and suffering and to enhance the patient's quality of life and may include, but is not limited to, interdisciplinary end-of-life care and consultation with patients and family members.

140.1201: Provision of Information on Palliative Care and End-of-life Options

(A) Each clinic shall distribute to appropriate patients in its care, directly or through professionally qualified individuals, culturally and linguistically suitable information regarding the availability of palliative care and end-of-life options. This obligation shall be fulfilled by providing the patient with:

- (1) A Department-issued informational pamphlet; or
- (2) A similar informational pamphlet that meets the specifications in 105 CMR 140.1201(B).

(B) At a minimum, the informational pamphlet shall include:

- (1) A definition and explanation of advanced care planning, palliative care services and hospice services; and
- (2) All other requirements as defined in guidelines of the Department.

(C) Each clinic shall provide its attending health care practitioners the information in 105 CMR 140.1201(A) for distribution to appropriate patients in a timely manner.

(D) Each clinic shall have a policy to guide its attending health care practitioners for identifying appropriate patients and ensuring they receive an informational pamphlet. Such policies shall be made available to the Department upon request.

(E) Each clinic shall inform all physicians, nurse practitioners, and physician assistants providing care within or on behalf of the facility of the requirements of M.G.L. c. 111, § 227(c) to offer to provide end-of-life counseling to patients with a terminal illness or condition.

(F) Where the patient lacks capacity to reasonably understand and make informed decisions, the information in 105 CMR 140.1201(A) shall be provided to the person with legal authority to make health care decisions for that patient.

(G) The clinic shall make available to the Department proof it is in compliance with 105 CMR 140.1201(A) and (C) through (E) upon request or at the time of inspection.

105 CMR: DEPARTMENT OF PUBLIC HEALTH

140.1300: Severability

The provisions of 105 CMR 140.000 are severable. If any provision of 105 CMR 140.000 is declared unconstitutional or invalid by a court of competent jurisdiction, the validity of the remaining portions shall not be so affected.

REGULATORY AUTHORITY

105 CMR 140.000: M.G.L. c. 111, §§ 3 and 51 through 56.