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Mass. changing regulations to allow retail-based health clinics

AP Associated Press

By Rodrique Ngowi, Associated Press Writer | July 17, 2007

BOSTON --Massachusetts health officials will propose new regulations to allow for the operation of retail-based medical clinics, saying the move could also encourage not-for-profit hospitals, community health centers and businesses to expand basic medical services.

The proposed changes were triggered by a recent application by CVS Caremark Corp. to open a retail clinic, MinuteClinic, in one of its stores in Weymouth -- a first of its kind in the state, the Department of Public Health said in a statement released late Tuesday.

Current regulations do not cover the operation of retail clinics, Secretary of Health and Human Services JudyAnn Bigby said.

"Rather than considering applications that require numerous waivers, we believe we should consider an alternative set of regulations that, if approved, will make the application process for operating limited service medical clinics transparent to any entity that feels they have a role in their community," Bigby said.

The move will allow not-for-profit hospitals, community health centers and others to expand the provision of basic health services through such facilities, according to the statement.

There are about 500 retail-based health clinics nationwide, said Carolyn Castel, spokeswoman for CVS Caremark Corp., the parent company for MinuteClinic, a Minneapolis-based chain of about 200 clinics in 20 states. It was acquired by CVS Corp. last year.

The company plans to set up between 20 and 30 such facilities during the first stages of operations in Massachusetts, Castel said by telephone from Woonsocket, R.I.

Critics have warned that such retail clinics may pose a conflict of interest that put profits ahead of patient health.

On June 25, the American Medical Association, the nation's largest physicians group, asked state and federal agencies to look into whether pharmacy chain-owned clinics in stores urge patients to get their prescriptions filled on site, which the AMA maintains would pose a conflict. It also said that insurance companies should be banned from waiving or lowering co-payments only for patients who get treatment at store-based clinics.

Fewer than half of patients treated at MinuteClinics have prescriptions written for them, and those who receive one are free to choose where they want them filled, Castel said.

MinuteClinic plans to meet the anticipated spike in demand for health services now that a landmark law requiring all Massachusetts residents to get a health insurance has come into force, CVS Caremark Health Care Services President Chris Bodine said in a statement.

"MinuteClinic can serve a critical health care need by providing convenient, affordable access to quality health care for common medical conditions," Bodine said.

The Department of Public Health's Bureau of Health Care Quality -- responsible for licensing inpatient health care facilities and approving the construction of all health care clinics in the state -- is developing the new regulations on retail clinics.

"We believe this is a win-win situation," Commissioner of the Department of Public Health John Auerbach said. The proposed regulations "could also expand access to health care to very vulnerable populations." ■

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Proposed new text is <u>underlined in bold</u>
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140.001: Purpose

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

140.002: Authority

105 CMR 140.000 is adopted under the authority of M.G.L. c. 111, §§ 3 and 51 through 56.

140.003: Citation

105 CMR 140.000 shall be known and may be cited as 105 CMR 140.000: *Licensure 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.

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:

CLIA means Clinical Laboratories Improvements Amendments as set forth in 42 CFR 493.

Clinic means any entity, however organized, whether conducted for profit or not for profit, which 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, which is advertised, announced, established, or maintained under a name which includes the word clinic, "dispensary", or "institute", and which suggests that ambulatory medical, surgical, dental, physical rehabilitation, or mental health services

are rendered therein. With respect to any entity which 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. 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 school 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 means a pharmacy which is not registered as a retail drug business pursuant to M.G.L. c. 112, § 39 and which is maintained and operated by a clinic.

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

Commissioner means the Commissioner of Public Health or his/her designee.

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

Department means the Massachusetts Department of Public Health.

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

Host location shall mean a licensed health care facility where a mobile diagnostic or treatment unit of a clinic providing mobile medical services docks in order to provide such services.

Licensee means any person holding a license to operate a clinic. In the case of a licensee which is not a natural person, the term licensee shall also mean any shareholder owning 5% or more of any class of the outstanding stock; 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 which is a sole proprietorship; any mortgagee in possession; and any executor or administrator of any licensee which is an estate.

Mental Health Outreach Program means a mental health program off the premises of a clinic or any of its satellite clinics that:

(1) provides services within the same Department of Mental Health area or contiguous Department of Mental Health area of the clinic; and

(2) provides services in clients' homes or other community environments, including physicians' 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 diagnostic or treatment unit shall mean a mobile vehicle containing medical diagnostic or treatment equipment which is used to provide mobile medical services.

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

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

Practice means 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 non-practitioner of any *one* of these services to practitioner(s) shall not by itself mean that such nonpractitioner shares in the control of the practice.

Practitioner means any individual who may diagnose and treat medical, surgical, dental, physical rehabilitation, or mental health problems without limitation within the confines of his/her profession.

Psychiatric Day Treatment Program means a specialized mental health program that provides a planned combination of diagnostic, treatment, and rehabilitative services ~~provided~~ to mentally or emotionally disturbed persons 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 and appropriate behavior patterns, attitudes, and skills for eventual independent functioning in the community. A psychiatric day treatment program shall be provided only by a clinic licensed to provide mental health services.

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

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

Satellite Clinic means a clinic operation off the premises of a clinic at which health services are provided. A mental health outreach program as defined in this section shall not be considered a satellite clinic.

Social Worker means 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 means the primary enterprise of the practitioner(s) as identified with the practitioner's licensing authority.

Specific Service means any one of the following:

(1) Surgical Service. A service that provides diagnosis or care through operative procedures requiring local, regional or general anesthesia.
(2) Dental Service. A service that provides 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 service that provides diagnosis and treatment to mentally or emotionally disturbed persons and their families.
(5) Medical Service. A service that provides diagnosis or treatment of illness or other medical services that are distinct from the services provided under the other "specific services" set forth

herein.
(6) Mobile Medical Service shall mean a service that provides highly technical medical diagnostic or treatment services solely through the routine, temporary placement of a mobile diagnostic or treatment unit at one or more host locations. Examples of highly technical medical diagnostic or treatment services include lithotripsy and magnetic resonance imaging.
(7) Alcoholism Service. A separately identifiable service specifically designed for the treatment and rehabilitation of persons suffering from alcoholism.
(8) Birth Center Service. A service that provides professional midwifery services to low risk childbearing women during pregnancy, birth, and puerperium, and to the infant during the immediate newborn period by nurse-midwives or by obstetricians or family practitioners.
9) Limited Services. A prescribed set of preidentified diagnostic and treatment services not otherwise defined as a Specific Service in 105 CMR 140.020 that do not require a complete physical examination and that may make use of CLIA-waived tests only.

Transfer of Ownership shall include 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 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 non-profit corporation, such changes in the corporate membership and/or trustees as the Department determines to constitute a shift in control 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.

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. Such plans shall be implemented only on an experimental basis and subject to renewal of the approval by the Department at such periods as the Department shall fix.

140.099: Waiver of Requirements Imposed on Clinics
The Commissioner 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 Commissioner finds that:
(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 non-compliance does not jeopardize the health or safety of its patients and does not limit the clinic's capacity to give adequate care; and

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

140.100: Applicability of 105 CMR 140.000 Subpart A

The requirements of 105 CMR 140.100 through 140.109 are applicable to all clinics subject to Department licensure, unless otherwise noted herein.

140.101: Requirement of License

Every entity which falls 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. The requirements specified in 105 CMR 140.101 through 140.108 shall be followed in completing an application for a clinic license, which shall be described herein as a "license".

140.102: Application for a License

(A) Applications for licensure shall be made on forms prescribed by, and available from, the Department. The term "application" as used herein shall include initial and renewal applications. Every application shall be notarized and signed under the pains and penalties of perjury by the applicant or a person authorized to act on behalf of the applicant.

(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 and control that identifies:

(a) If owned by an individual, partnership or trust, the names and ownership percentages of such individual, partners or trustees, except that, 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 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) A copy of its by-laws and articles of incorporation, partnership agreement, trust instrument, or other charter, and if ownership of the clinic has been transferred, satisfactory documentary evidence (such as a contract or a deed) showing that ownership of the clinic has been transferred to the applicant, which demonstrates legal capacity to provide the services for which the license is sought.

(3) Any information required by the Commissioner as part of the application, including such additional information concerning ownership and control as the Commissioner may require.

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.

(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. To avoid public confusion or misrepresentation, this name shall not be changed 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 pursuant to M.G.L. c. 111, § 51 by a building inspector of the Department of Public Safety stating that 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 pursuant to M.G.L. c. 111, § 51 by the head of the local fire department stating that 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. Written approval of the Commissioner shall be obtained prior to said new construction or alterations or additions. Standards for review and approval of plans shall be established as administrative guidelines by the Department, based on the American Institute of Architects' *Guidelines for Design and Construction of Hospital and Health Care Facilities.* In the case of a clinic that provides mobile medical services, plans for siting at each host location shall be submitted by the clinic or the host location.

(F) Limited Services List. An applicant for a limited services clinic license shall include on the licensure application a list of the limited services that it proposes to provide.

140.104: Timing of Application

~~(A) In the case of an original license, including a change in location but not a transfer of ownership, the application shall be submitted subsequent to a determination of need by the Department except where exempt from determination of need under M.G.L. c. 111, § 51, or subsequent to receipt of approval for transfer of site.~~

(~~B~~A) In the case of a transfer of ownership, the application shall be submitted no later than 48 hours following the transfer. *See* 105 CMR 140.105.

(~~C~~B) In the case of a renewal license, the application shall be submitted three months prior to expiration of the license.

~~(D) In the case of amendment to a license for the addition of a satellite clinic, the application shall be submitted subsequent to a determination of need by the Department for the satellite clinic except where exempt from determination of need under M.G.L. c. 111, § 51.~~

140.105: Transfer of Ownership and Change in Location

(A) The Department shall be notified immediately in writing of any proposed change in name or location of a facility. 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 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 48 hours of the transfer ~~of~~ or such longer period in advance as the Commissioner shall prescribe. If the Notice of Intent 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, 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 which 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.

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

Ownership and control information submitted under the requirements of 105 CMR 140.000 or otherwise required by the Commissioner shall be kept current by each licensee. Any document which amends, supplements, updates or otherwise alters any ownership and control document required to be filed shall be filed with the Department within 30 days of the execution thereof. Any changes in, or additions to, the content of the information contained in any ownership or control document required to be filed shall be reported to the Department within 30 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 that the applicant complies with 105 CMR 140.000;

(B) the Commissioner has conducted an investigation of the proposed licensee(s) and determined that 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 that there is need for the facility at the designated location unless the facility is exempt from 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 governing health facility operation, and 105 CMR. 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 which resulted in convictions, or guilty pleas, or pleas of nolo contendere, or admission of sufficient facts; and

(4) the proposed licensee's history of statutory and regulatory compliance for health care facilities in other jurisdictions, including proceedings in which the proposed licensee was involved which proposed or led to a limitation upon or a suspension, revocation, or refusal to grant or renew a health care facility license or 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~~,~~ or satellite clinic 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 or satellite clinic (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

An inspection or other investigation shall be made 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 days after the deficiency statement is sent.

(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 licensees of either the acceptance or rejection of the plan. An unacceptable plan must be amended and resubmitted within five days of the date of notice.

140.120: Issuance of License

Upon the approval of the application for a license ~~by the Public Health Council~~, 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) that 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) Ordinarily, a clinic license shall be issued by the Department for a period of two years.

(B) The Department may in the alternative issue a provisional license for a period of no more than one year to a clinic which is not in full compliance with applicable requirements but which the Department finds is in substantial compliance with such requirements and demonstrates potential for achieving full compliance within the provisional licensure period. Consecutive provisional licenses shall not be issued to a clinic.

(C) 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. Upon receipt of a renewal license, the clinic shall return the expired license to the Department by certified mail.

(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.

140.122: Coverage of License

A license is valid only for the premises and the specific services authorized by the Department. ~~A~~ No clinic may ~~shall not~~ perform cardiac catheterization services.

140.123: Posting of Clinic License and DPS Certificate

The current license from the Department, and copies thereof, and the current Department of Public Safety (DPS) certificate, where relevant, shall be posted in a conspicuous place in the clinic, and in any of its satellite clinics.

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 decides that 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 ~~partially~~ 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 as determined pursuant to 105 CMR 140.102 and 140.103.

(B) Lack of responsibility and suitability to operate a clinic, as determined pursuant to 105 CMR 140.109.

(C) Failure to submit the required license fee.

(D) Violation of any state statute pertaining to clinic licensure.

(E) Failure to give proper patient care to clinic patients.

(F) 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.

(G) Denial of entry to agents of the Department.

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 *et seq.* 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 that 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 that a licensee is not suitable or responsible or that 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 *et seq.*
(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 that the licensee is not suitable or responsible and/or that 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 hereunder has been denied, a proposed licensee may appeal to a hearing officer pursuant to 801 CMR 1.00 *et seq.*

(2) In cases of denial of an original license, the hearing officer shall determine whether the proposed licensee has proved by a preponderance of the evidence that s/he 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 that the Department of Public Safety or the head of the local fire department has denied any applicant or licensee a certificate of inspection pursuant to M.G.L. c. 111, § 51, and that an appeal, if requested, has been duly denied by the Department of Public Safety, the Commissioner may:

(1) inform the applicant or licensee that the Department has been notified that 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

(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 hereunder 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 that 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 that 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: ~~Public Health Council and Judicial~~ Review of Decision of Hearing Officer

(A) The decision of a hearing officer in any adjudicatory proceeding conducted pursuant to 105 CMR 140.132 shall be reviewed by the Commissioner ~~and the Public Health Council~~. ~~Their~~ 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 the Public Health Council~~ and its right to judicial review pursuant to M.G.L. c. 30A, § 14.

140.200: Applicability of 105 CMR 140.000 Subpart B

The requirements of 105 CMR 140.200 through 140.221 are applicable to all clinics subject to Department licensure, unless otherwise noted herein.

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 for storage of patient records.

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 that is 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 assure minimum sound transmission.

140.204: ~~Utility Area~~ Clean Storage and Soiled Holding Areas

Each clinic, except clinics providing only mental health services or limited services, shall provide a clean supply storage room and a soiled workroom or soiled holding room, ~~utility area~~ which ~~is~~ are apart from any examination, treatment or dressing area. The clean work area shall contain a counter, handwashing sink with hot and cold water and storage for clean supplies~~;~~. T~~t~~he 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

Each clinic shall provide conveniently located handwashing and toilet facilities adequate for patients and personnel, as appropriate to the services provided by the clinic. 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. The clinic shall provide a handwashing facility with hot and cold water and blade type operating handles or knee or foot controls, immediately available and convenient to each examination and treatment area. A limited services clinic that is located on the premises of another entity may share handwashing and toilet facilities with that entity.

140.206: Janitor's Closet

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

140.207: Storage Space

Each clinic shall provide storage space adequate and suitable for equipment and bulk office supplies.

140.208: Ventilation

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

140.209: Accessibility to Handicapped Individuals

Clinic facilities used for patients shall be accessible to handicapped individuals. Clinics licensed at the time of promulgation of 105 CMR 140.000 shall provide program accessibility to handicapped individuals.

(A) Mobile Medical Services

(1) A mobile medical service shall be connected to the host location(s) by an enclosed passageway that satisfactorily protects patients from inclement weather and temperature extremes. If the passageway is temporary and used solely as a link between the mobile medical vehicle and the host location, the passageway need not be of the construction type specified in the Guidelines for Construction and Equipment of Hospital and Medical Facilities but shall meet any requirements set by the Department of Public Safety and local building inspector.

(2) A mobile medical service shall be accessible to patients only through emergency, ambulatory care or radiology service areas and not through inpatient or non-patient areas of the host location. An exception to this requirement may be granted if the clinic demonstrates satisfactorily to the Commissioner that physical plant limitations preclude compliance with this requirement and that the alternate location of the mobile medical service will provide patients with adequate safety, comfort, and access to needed services and will protect both inpatients and outpatients from disruptions and violations of privacy.

(3) A mobile medical service shall meet the physical plant requirements set forth in 105 CMR 140.000, either directly or through written arrangements for shared service areas with the host locations. Contracts and/or lease arrangements for use of space at host locations shall be submitted to the Department with plan review requests.

140.210: Quantity and Type

Each clinic shall have supplies and equipment appropriate in quantity and type to the specific service(s) which the clinic renders its patients.

140.211: Maintenance and Sanitation

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 which require 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 or his designee. A recognized method of checking clinic sterilizer performance shall be in effect.

(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 ~~assure~~ ensure the safe disposal of hazardous and infectious waste.

140.212: Linen and Laundry

(A) 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.

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

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

140.220: Fire Safety Plan

Each clinic shall develop and maintain a written plan for dealing with fire. The clinic shall make a copy of the plan available to all staff members. Each fire safety plan shall specify persons to be notified, locations of alarm signals and fire extinguisher, evacuation routes, procedures for evacuating handicapped 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 ~~or his designee~~ for review.

140.300: Applicability of 105 CMR 140.000 Subpart C

The requirements of 105 CMR 140.300 through 140.380 are applicable to all clinics subject to Department licensure, unless otherwise noted herein.

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 by-laws, 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 that assure employees are free of communicable disease.
(c) Patient admission 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 which the clinic provides.
(j) Smoking on the premises. Such policies shall assure the comfort of all patients including patients in waiting areas.
(k) Procedures for complying with laws and regulations relating to reportable diseases and conditions.
(l) ~~p~~Procedures for assuring that all patients of a clinic that provides mobile medical services at host locations are provided with written information that clearly identifies the clinic, and not the host location, as the licensed health care facility responsible for the service provided.

(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 keep in one centralized location on its premises records indicating all the services rendered to clinic patients, except that limited services clinics with electronic medical record systems need not store paper records on the premises. Records shall contain sufficient information to justify the diagnosis(es) and treatment, and to document the results accurately. A mobile medical service shall maintain patient records on the premises of the clinic and not at host locations.

(B) Each patient shall have a single integrated record, except that mental health, dental, alcoholism, and, upon approval of the Commissioner ~~or his/her designee~~, other records, may be filed separately on the premises, 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, indicating name and title. Each page of each patient's record shall have two unique forms of identification. The record with respect to each patient shall include the following:

(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.

(C) Retention of Medical Records.
(1) In accordance with M.G.L. c. 111, § 70 each clinic~~s~~ shall maintain records of the diagnosis and treatment of patients under ~~their~~ its care for 30 years after the discharge or the final treatment of the patient to whom it relates.
(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 that are generated to report 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.
The purpose of this requirement is to establish a minimum retention period and does not preclude clinics from maintaining records for a longer period of time.
(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/her authorized representative. The clinic may charge a reasonable fee for copying, not to exceed the rate of copying expenses.

(D) Each clinic shall maintain patient records under lock or code and use them in a manner to protect the confidentiality of the information contained therein. Printed copies of electronically stored records shall be disposed of in a manner which assures the confidentiality of patient information.

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

140.303: Posting of Notice of Patients' Rights

Each clinic shall have visibly posted a notice which has the heading "NOTICE OF PATIENTS' RIGHTS" in block letters at least one inch high and which contains 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, each patient, upon admittance to the clinic, shall be given a written document containing all the rights provided by M.G.L. c. 111, § 70E.

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 referring patients to another provider of the same services that is as geographically close as possible and that is open at those hours. A limited services clinic may provide a taped message that directs patients to other providers. These arrangements shall be reflected in a written policy that is made available to all the clinic's patients.

140.305: Emergency Transfer

(A) Each clinic shall have a written agreement with a nearby hospital providing emergency services for the transfer there of patients for emergency treatment beyond that provided by the clinic.

(B) Each clinic which provides 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's record on the patient to such facility, agency, or provider.

(D) Each clinic shall have a written plan and procedures for the emergency transfer including the transport of clinic patients.

140.306: Serious Complaint Procedure

Each clinic shall develop a written procedure that assures prompt and complete investigations of all serious complaints which are filed against 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 an employee or member of the professional staff;

(B) Establishment of a reporting procedure which assures that the designated administrator will receive within one day from clinic staff, in writing, reports of serious complaints;

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

(1) A process of fact-gathering that he or she will utilize, including provision for interviewing of a patient complainant;
(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

Each clinic shall file a written report with the Department of any serious incident occurring on the premises covered by its license and which seriously affects the health and safety of its patients. Such written report shall be filed within one week of the occurrence of the incident; provided however, that each clinic shall also immediately report by telephone to the Department any of the following which occurs on premises covered by its license:

(1) fire;
(2) suicide;
(3) serious criminal acts; or
(4) pending or actual strike action by its employees, and contingency plans for operation of the clinic.

~~140.308: Annual Statistical Report~~

~~Each clinic shall file an annual statistical report with the Department of Public Health on a form provided by 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.

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. 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 carry out adequately 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 by the clinic 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 holds itself out as providing. 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.

(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. A nutritionist is 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.

140.317: Social Services

If a clinic provides social services, the clinic shall retain on at least a part-time basis a licensed certified social worker or a licensed independent practitioner of clinical social work to provide or

supervise the service.

140.318: In-Service Training for Health Care Staff

There shall be a program of on-going in-service training to 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

A satellite clinic must meet, 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 physician, dentist or podiatrist legally authorized to issue prescriptions.

140.341: Compliance with Applicable Laws and Regulations

A clinic must register annually under the Controlled Substances Act with the Board of Registration in Pharmacy and the Department ~~of Public Health~~ 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. A registered pharmacist shall be employed by the clinic 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 which 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 which 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 assure appropriateness of continuing drug therapy;
(5) procedures for reporting and preventing medication errors and reporting adverse drug reactions;
(6) methods to assure compliance with the Generic Drug Law 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 Pharmacists*;
(7) a drug recall procedure which can be readily implemented; and
(8) systems for the control and accountability of all drugs. Such policies must assure compliance with up to date standards for product quality, security and record keeping systems.

140.345: Drug Handing and Administration

A clinic with a pharmacy shall comply with the requirements of 105 CMR 140.345, 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.

(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.

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.

(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 that a record system is kept that is sufficient to maintain control over the requisitioning and administration of controlled substances. The record keeping 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.

(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 physician 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 ~~provide at least one book or other standard source of information pertaining to current drugs~~ 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, Approval and Licensing of Clinical Laboratories* and 42 CFR 493, Clinical Laboratories Improvements Amendments (CLIA).

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, which 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 ~~or his designee~~.

140.352: Affidavits Concerning Clinical Laboratory Services

Each clinic shall submit an annual affidavit to the Commissioner ~~or his designee~~ specifying the nature of all its testing services, the individuals performing the tests, the individuals responsible for the accuracy of the tests, the methods of testing employed, the quality control practices employed and any other information required by the Department.

140.360: Compliance with Applicable Laws and Regulations

Each clinic which provides diagnostic radiology shall comply with M.G.L. c. 111, § 5B and 105 CMR 120.000: *To Control the Radiation Hazards of Radioactive Material and Machines which Emit Ionizing Radiation*. Clinics providing such service must register with the Department's Division of Radiation Control pursuant to 105 CMR 120.100.

130.361: Radiologist

Each clinic which 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 which 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 *et seq.*

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, shall obtain and maintain a license issued pursuant to 105 CMR 127.000 *et seq.*

140.365: Inapplicability to Dental Services

The provisions of 105 CMR 140.361 through 140.362 are inapplicable to clinic dental services.

140.370: Evaluation of Quality

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

(1) be defined in writing and approved by ~~the~~ its governing body;
(2) identify an individual to be responsible for the implementation and continuity of the program;
(3) be re-evaluated 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 which 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 which meets the requirements of 105 CMR 135.000.

(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

(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, 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;
(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 140.000 Subpart D

The requirements of 105 CMR 140.400 through 140.404 are applicable to clinics subject to Department licensure which are specifically licensed 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 meet the requirements of M.G.L. c. 112, § 43A.

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 which are not part of the clinic's services.

(B) Each clinic shall have policies and procedures for recalling clients on a periodic basis as appropriate for the client'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 as a surgical service.

(B) Conscious intravenous sedation may only be performed by individuals with appropriate training as established separately by the Commissioner or his designee as administrative guidelines.

140.500: Applicability of 105 CMR 140.000 Subpart E

The requirements of 105 CMR 140.500 through 140.560 are applicable to clinics subject to Department licensure which are specifically licensed to provide mental health services.

140.510: Mental Health Services

For purposes of 105 CMR 140.500 through 140.550, each clinic licensed to provide mental health services shall operate a mental health program that provides, in accordance with the requirements of 105 CMR 140.520, at least the following services:

(1) intake services;
(2) evaluation and diagnostic services;
(3) treatment planning services;
(4) treatment services which include:
    (a) case consultation, psychotherapy and counseling, and
    (b) pharmacotherapy;
(5) emergency services; and
(6) referral services.

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. Initial contact must be made with a potential client for purposes of accumulating and recording all pertinent client information for evaluation and diagnostic services and/or for referral to an appropriate professional person or agency.

(B) Evaluation and Diagnostic Services.

(1) Evaluation and diagnostic services must be documented and shall include an assessment made to determine the patient's physical health, psychological, social, economic, educational, functional or development status, vocational assets and disabilities, and a comprehensive drug history. The assessment shall be conducted by appropriate professional health care providers.
(2) When the initial evaluation indicates further assessment, the clinic program must conduct or make arrangements for necessary testing, physical examination and/or consultation by qualified mental health and/or medical professionals.
(3) When appropriate, a diagnostic evaluation shall include the finding of a formal mental status examination and a diagnosis.
(4) A diagnostic evaluation as defined in 105 CMR 140.520(B)(1) through (3) must be completed before a treatment plan is developed.

(C) Treatment Planning Services.

(1) The client's assigned mental health professional must prepare a written treatment plan based on information gathered during the intake, evaluation and diagnostic process.
(2) The treatment plan must include at least the following information:
    (a) problems and needs relevant to treatment and discharge expressed in behavioral,

descriptive terms;
(b) the client's strengths and skills;
(c) treatment goals with time guidelines for accomplishing goals;
(d) evidence of client involvement in formulation of the treatment plan;
(e) clearly defined staff responsibilities and assignments for implementing the plan;
(f) the date the plan was last reviewed and/or revised; and
(g) 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 treatment goals as a result of implementing the treatment modalities.

(2) Pharmacotherapy services. These services must include, but are not limited to, an assessment of the client's psychiatric symptoms and disorders, health status including medical conditions and medications, use of alcohol and drugs and prior experience with psychiatric medications, as well as medication prescribing, reviewing, and monitoring by a psychiatrist or registered nurse clinical specialist. These requirements do not preclude the one time administration of a medication in an emergency in accordance with a physician's order. The services may also include administration of prescribed medications by appropriately licensed individuals.

(E) Emergency Services. There must be provisions for 24 hours a day, seven days a week clinic coverage to include evaluation, diagnosis, and disposition services for the client's presenting crisis, including short-term intervention and/or referral. Emergency services, offered during the hours in which the clinic is not open, must provide at least the following:

(1) Telephone coverage. Qualified professionals must be available to talk with clients over the telephone and, if indicated, to arrange for further care and assistance directly or through referrals. A current on-call roster must be maintained. A tape-recorded message will not fulfill this requirement.

(2) Emergency referrals. In addition to the requirements set forth in 105 CMR 140.305(A), (C), and (D), the referral arrangements must be reflected in a written policy. There must be both written policies and written procedures for voluntary and involuntary commitments to psychiatric hospitals, which clearly spell out the clinic's responsibility.

(F) Referral Services.

(1) In addition to emergency referrals set forth in 105 CMR 140.520(E)(2), referrals to appropriate health care providers must be made as health needs are identified that are beyond the scope of services provided by the clinic's mental health service.

(2) When the assessment of a client's health status indicates the need for a physical examination and the clinic does not have the staff or equipment necessary to conduct a physical examination, the client may be referred to another health care provider to obtain a physical examination.

(3) If a client is referred by the clinic's mental health service for a physical examination, a copy of the physical findings and/or examination report must be requested and included in the client's record.

(4) A patient's refusal to have a physical examination must be documented in the medical record.

(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 an adequate number of qualified personnel to fulfill the program's objectives.

(B) Multi-Disciplinary Staff.

(1) A multi-disciplinary staff must be available as appropriate for the clients' needs.

(2) A multi-disciplinary staff must be comprised of mental health professionals who meet the requirements set forth under 105 CMR 140.530(C). The staff may also include other related mental health professionals necessary for the provision of intake, evaluation, diagnostic and treatment services.

(C) Personnel Qualifications.

(1) Except as otherwise provided in 105 CMR 140.530(C)(2), the multidisciplinary staff must include:

(a) 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 eligible for such certification; and

(b) at least two of the following mental health professionals:

(i) Psychologist. A clinical or counseling 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.

(ii) Psychiatric Social Worker. A social worker, as defined in 105 CMR 140.020 who has at least one year's post graduate experience in a mental health setting.

(iii) 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.

(iv) 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 4.13.

(v) 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.

(vi) Licensed Alcohol and Drug Counselor. An alcohol and drug counselor licensed by the Department pursuant to 105 CMR 168.000.

(vii) Other Licensed Mental Health and Substance Abuse Practitioners. Other mental health and substance 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 abuse professionals.

(2) 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 below for one of the professionals listed in 105 CMR 140.530(C)(1)(b):

(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.

(D) Responsibilities of Clinic Physicians and Psychiatrists.

(1) The clinic shall designate a psychiatrist or other physician to be responsible for the establishment of medical policies and supervision of all medical services.

(2) The following duties shall be performed by clinic psychiatrist(s) or physician(s):

(a) prescribing and monitoring or supervising the prescription of all medications, and

(b) evaluating non-psychiatric, physical health problems and making referrals, when appropriate.

(3) Clinic psychiatrist(s) shall:

(a) participate in case reviews as appropriate,

(b) provide case consultation as necessary, and

(c) participate in the clinic's quality assurance program for the mental health service.

(E) Supervision. All staff members other than those meeting the qualifications set forth in 105 CMR 140.530(C) must be clinically supervised on a regular basis by professional staff members as defined in 105 CMR 140.530(C). 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 client's treatment plan and progress.

(B) Case review shall be conducted by one or more members of the multidisciplinary staff as defined in 105 CMR 140.530(C).

(C) Case review shall not be completed by the mental health professional(s) responsible for implementing the client's treatment plan.

(D) Case reviews must be conducted as necessary but at least once a year. The frequency of case reviews shall be based upon the client's current problems, specific and concrete goals and treatment.

140.550: Additional Record Keeping Requirements

(A) Progress notes or statements must be recorded by the mental health professionals who are responsible for implementing the client's treatment plan.

(B) Progress notes or statements must be completed after every client contact or attempted contact, provided, however, that progress notes for clients seen in psychiatric day treatment programs must be completed on a weekly basis.

140.560: Mental Health Outreach Programs

(A) A mental health outreach program must be operated by a clinic that is 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 programs shall meet all requirements set forth in 130 CMR 429.440.

(D) Outreach services may include diagnostic services and treatment services, including emergency services provided to clients in their homes or other community environments, including physicians'

offices or community health centers.

(E) When outreach services must be provided in buildings that have community health or social service uses, including but not limited to, schools, community health centers, community centers, housing projects and visiting nurse agencies, the clinic shall retain an agreement, with the responsible party for the outreach site, that stipulates that the site will be maintained in a safe and sanitary manner.

(F) Outreach sites shall not include commercial office space rented by the licensed clinic.

(G) Records on outreach clients shall be maintained on the premises of the clinic. Records shall not be stored at the outreach site.

(H) The clinic shall establish policies and procedures regarding access by outreach program staff to client records that meet all state and federal requirements for confidentiality.

(I) Medications shall not be stored or administered at the outreach site unless under the auspices of a community health center.

(J) Any signs, advertising or other identification of an outreach program shall clearly indicate that it is an outreach program sponsored by the clinic.

(K) The professional services director of the clinic must meet regularly with outreach program staff members and have direct contact with outreach program clients as necessary.

(L) The clinic must notify the Department prior to operating an outreach program and identify the location(s) where outreach services are provided.

(M) The number of outreach clients and visits shall not account for the majority of the clinic's clients and visits.

140.600: Applicability of 105 CMR 140.000 Subpart F

(A) The requirements of 105 CMR 140.600 through 140.614 are applicable to clinics subject to Department licensure which are specifically licensed 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 pursuant to 105 CMR 140.600(B).

(E) A clinic shall not 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 that are set forth in 42 CFR 416.42(a)(I) relating to

anesthesia risk and evaluation; 416.44(a)(1) and (2) relating to physical environment; 416.44(c) relating to emergency equipment; and 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 which 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 which includes each individual's name, profession, specialty and the surgical procedures s/he is permitted to perform or the type of anesthesia s/he 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 (or eligibility) 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 that perform only dental surgery shall designate a dentist who is board certified or eligible for certification 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: Pre-operative Evaluation

(A) A physician shall perform a physical examination, review the patient's medical history, and review the results of pertinent pre-operative 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 pre-operative 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 pre-operative 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 *Subpart F - Surgical Services*, an anesthesiologist is a physician who is certified or eligible for certification 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 pre-operative and post-operative anesthesia care.

140.607: Adequate Assistance

(A) No surgical procedure shall be initiated without adequate assistance present in the operating room.

(B) Only registered nurses shall function as circulating nurses.

(C) The person administering general anesthesia 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 pre-operative 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 post-operative 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 post-operative evaluation and shall enter his/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, and whom to contact for follow-up care.

140.611: Reports on Surgery and Anesthesia Related Complications

Each clinic shall record all surgery-related or anesthesia-related complications that result in serious morbidity or death of a patient in the patient's medical record, and report such complications in writing to the Department, on such forms and in such a manner as the Department may prescribe.

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 140.601, each clinic licensed to perform surgery shall meet the physical environment and safety requirements of 105 CMR 140.612.

(A) Each clinic licensed to perform surgery that uses 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 pre-operative, post-operative and pathological diagnoses;
(2) whether adequate pre and post operative 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 in which the need for blood replacement is anticipated.

(B) Transfusions shall be permitted as part of the clinic's surgical services in accordance with the Blood Bank Regulations at 105 CMR 135.410 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 which 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)(B) and (C).

140.700: Applicability of 105 CMR 140.000 Subpart G

For the purpose of 105 CMR 140.700 through 140.702, the term "physical rehabilitation services" shall mean physical therapy, occupational therapy or speech therapy services.

The requirements of 105 CMR 140.700 through 140.702 are applicable to clinics subject to Department licensure which are specifically 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 42 CFR 405.1702(d). A "physical therapist assistant" shall be a person who meets the requirements of 42 CFR 405.1702(e).

For the purpose of 105 CMR 140.700 through 140.702, a "qualified speech pathologist" shall be a person who meets the requirements of 42 CFR 405.1702(j).

For the purposes of 105 CMR 140.700 through 140.702, a "qualified occupational therapist" shall be a person who meets the requirements of 42 CFR 405.1202(f). An "occupational therapy assistant" shall be a person who meets the requirements of 42 CFR 405.1202(g).

140.800: Applicability of 105 CMR 140.000 Subpart H

The requirements of 105 CMR 140.800 and 140.801 are applicable to clinics subject to Department licensure which are specifically licensed to provide alcoholism services.

140.801: Alcoholism Services

A clinic offering a separate, identifiable program specifically designed to care for persons suffering

from alcoholism must meet the programmatic and staffing requirements set forth by the Division of alcoholism in regulations promulgated under M.G.L. c. 111B, § 6B.

140.900: Applicability of 105 CMR 140.000 Subpart I

The requirements of 105 CMR 140.901 are applicable to clinics subject to Department licensure which are specifically licensed to provide birth center services.

140.901: Birth Center Services

A clinic offering birth center services as defined in 105 CMR 140.020 shall meet the requirements set forth in 105 CMR 142.000 *et seq.*

140.910: Applicability of 105 CMR 140.000 Subpart J

The requirements of 105 CMR 140.911 through 140.912 are applicable to clinics subject to Department licensure that are specifically licensed to provide medical services or mobile medical services and that provide lithotripsy services.

140.911: Physical Environment

In addition to the facilities and equipment specifically required in other applicable sections of 105 CMR 140.000, mobile medical services offering lithotripsy services 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 onsite;
(6) accessibility to intensive care unit services on-site if host location is a licensed hospital; and
(7) radiology services including cystoscopy facilities.

140.912: Anesthesia Requirements

A clinic providing lithotripsy services under regional or general anesthesia shall meet the provisions included under 105 CMR 140.600 through 140.614 Subpart F - Surgical Services.

140.913: Agreements for Inpatient Services

The clinic shall have a formal written agreement for inpatient emergency and intensive care unit services with a health care facility licensed by the Department of Public Health to provide such services.

140.1000: Applicability of 105 CMR 140.000 Subpart K

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

140.1001: Policies and Procedures for Limited Services Clinics

(A) Each limited services clinic shall develop policies and procedures that identify the limited services that the clinic will provide.

(1) The limited services clinic shall provide only those services indicated on its licensure application.

(2) No limited services clinic may provide any service for which it is not licensed.

(B) Each limited services clinic shall develop policies and procedures that delineate its method for diagnosing and treating patients in each of its limited services categories, and for determining when patient needs are beyond the scope of the services that it provides.

(C) Each limited services clinic shall develop policies and procedures that specify 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.

(E) Each limited services clinic shall maintain a roster of primary care physicians 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.

(1) The limited services clinic shall provide patients who do not have a primary care physician with a referral from the list maintained pursuant to 105 CMR 140.1001 (E).

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

(1) Each limited services clinic shall develop policies and procedures that require the referral of such patients to primary care physicians or other appropriate settings.

(2) In the event that the limited services clinic is a satellite of, or is otherwise affiliated with a licensed health care entity that provides a full range of services, the limited services clinic may develop alternate mechanisms for assuring continuity of care within the system.

(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 to the patient's primary care physician, if any. Such copies shall be provided at no charge to the patient.

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

(I) Required Disclosures

(1) Each limited services clinic shall prominently post the limited services that are provided and shall provide a clear statement that indicates that the patient should seek care from his or her physician or an emergency provider for all other complaints or conditions.

(2) If a limited services clinic provides any form of advertising, the clinic must submit all advertising materials to the Department for prior approval. A limited services clinic may not use any advertising materials, including internet sites, that have not been reviewed and approved by the Department.

(3) If a limited services clinic is located within a retail location, the clinic shall prominently post a statement that indicates that the patient 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.

(J) No limited services clinic may use any name that implies that it provides a full range of medical services. 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.

140.1002 Physical Plant Environment Requirements in Limited Services Clinics

(A) Notwithstanding general access requirements from the American Institute of Architects' *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 to provide a patient waiting area that is separated from the public area of the host entity.

(B) Notwithstanding general space requirements from the American Institute of Architects' *Guidelines for Design and Construction of Health Care Facilities*, each limited services clinic shall have a minimum floor area of 50 square feet for each examination room, exclusive of fixed casework.

REGULATORY AUTHORITY

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