The Commonwealth of Massachusetts
Executive Office of Health and Human Services
Department of Public Health
Bureau of Health Professions Licensure
Board of Registration in Pharmacy
239 Causeway Street, Suite 500, Boston, MA 02114

CHARLES D. BAKER
Governor

KARYN E. POLITO
Lieutenant Governor

MARYLOU SUDDERS
Secretary

MONICA BHAREL, MD, MPH
Commissioner

Tel: 617-973-0800
TTY : 617-973-0988
.mass.gov/dph/boards

NOTICE OF PUBLIC HEARING

Notice is hereby given pursuant to M.G.L. c. 30A, § 2, that the **Board of Registration in Pharmacy (Board)** within the Department of Public Health (Department), will hold a public hearing on the proposed rescission of Board regulations at 247 CMR 5.00 and 12.00, proposed amendments to the Board's regulations at 247 CMR 6.00, 9.00 and 15.00, and proposed new regulations at 247 CMR 20.00. These regulations set requirements and procedures for pharmacy licensure (6.00), professional standards of conduct for pharmacy practice (9.00), continuous quality improvement programs (15.00) and reporting requirements (20.00).

The public hearing will be held on **Thursday, June 29, 2017, at 12:00 pm in Room 417A/B (4th Floor), 239 Causeway Street, Boston, Massachusetts 02114**. Hearing testimony may be presented orally or in writing; a written copy of any oral testimony will be requested.

The Department encourages all interested parties to submit written testimony electronically to the following address: Reg.Testimony@state.ma.us. Please submit electronic testimony as an attached Word document or as text within the body of an email, with "BOP: 247 CMR 5.00, 6.00, 9.00, 12.00, 15.00 & 20.00" in the subject line. All submissions must include the sender's full name and address. The Department will post all electronic testimony that complies with these instructions on its website. Parties who are unable to submit electronic testimony should mail submissions to the Office of the General Counsel, Department of Public Health, 250 Washington Street, Boston, Massachusetts 02108. All written testimony must be submitted by **5:00 pm on Friday, July 14, 2017**.

A copy of the Notice of Public Hearing and the proposed amendments to Board regulations may be viewed on the Department's website or obtained from the Office of the General Counsel, at 617-624-5220.

247 CMR 5.00: ORALLY AND ELECTRONICALLY TRANSMITTED PRESCRIPTIONS; PRESCRIPTION MONITORING PROGRAM (PMP) REPORTING REQUIREMENTS

Section

5.01: Foreword

Except for the regulations pertaining to electronically transmitted prescriptions, the Department of Public Health and the Board of Registration in Pharmacy, acting jointly under authority of M.G.L. c. 94C, and every other act thereto enabling, and in accordance with the procedures set forth in M.G.L. c. 30A, hereby establish regulations for the implementation of M.G.L. c. 94C.

.02: Electronically Transmitted Prescriptions

(1) Prescriptions or drug orders may be electronically transmitted from an authorized prescribing practitioner or his or her expressly authorized agent to a pharmacy or pharmacy department of the patient's choice. The prescription or drug order shall be electronically transmitted in a manner that maintains patient confidentiality and in accordance with the requirements of M.G.L. c. 94C, § 23(g) and 105 CMR 721.000 *et seq*.

(2) A pharmacist or pharmacy shall not enter into any agreement concerning the provision of a computer, facsimile machine, computer modem or any other electronic device which would adversely affect a patient's freedom to select the pharmacy or pharmacy department of his or her choice.

(3) A pharmacist or pharmacy shall not provide a computer, facsimile machine, computer modem or any other electronic device to a prescriber or health care facility for the purpose of providing an incentive to refer patients to a particular pharmacy or pharmacy department.

.03: Emergency Situations in Which Controlled Substances in Schedule II May be Dispensed Upon Orally or Electronically Transmitted Prescription

(1) "Emergency situations", for the purpose of permitting the dispensing of any controlled substance in Schedule II upon orally or electronically transmitted prescription, means those situations in which the practitioner who intends to prescribe a controlled substance in Schedule II determines:

(a) That the immediate administration of the controlled substance is necessary for the proper treatment of the intended ultimate user;

(b) that no appropriate alternative treatment is available, including administration of a controlled substance which is not in Schedule II; and

(c) that it is not reasonably possible for the prescribing practitioner to provide a written prescription to be presented to the person dispensing the controlled substance prior to the dispensing.

(2) In case of an emergency situation as defined in 247 CMR 5.03(1), a pharmacist may dispense a controlled substance in Schedule II upon receiving the orally or electronically transmitted authorization of a prescribing practitioner, provided that:

(a) The quantity prescribed and dispensed is limited to the amount adequate to treat the patient during the emergency period.

(b) the prescription contains all information required by M.G.L. c. 94C, § 20(a) except for the actual signature of the prescribing practitioner, and in the case of an oral prescription, or prescription transmitted electronically by computer modem or other similar electronic device, the prescription is immediately reduced to writing by the dispensing pharmacist; and

(c) the dispensing pharmacist makes a reasonable good faith effort to determine that the orally or electronically transmitted authorization was issued by an authorized practitioner, which effort may include a callback to the prescribing practitioner or other good faith efforts to ensure the prescribing practitioner's identity.

(3) Within seven days after authorizing an emergency oral prescription, the prescribing practitioner shall cause a written prescription for the emergency quantity prescribed to be delivered to the pharmacy which must have written on its face "Authorization for Emergency Dispensing" and should comply with federal and state law.

(4) Upon receipt of the written prescription, the dispensing pharmacist shall attach the prescription to the orally or electronically transmitted emergency prescription which had earlier been reduced to writing. The pharmacist shall notify the nearest office of the Drug Enforcement Administration, U.S. Department of Justice, and the Commissioner of Public Health, Massachusetts Department of Public Health, if the prescribing practitioner fails to deliver a written prescription within seven days.

.04: Reporting Requirements to the Prescription Monitoring Program (PMP)

(1) Reporting Requirements (105 CMR 700.012). Every pharmacy registered by the Board and every pharmacy located in a health facility registered with the Commissioner of the Department that dispenses controlled substances in Schedule II pursuant to a prescription shall, in accordance with standards established by the Department, transmit to the Department or its agent, required information for each prescription, in accordance with Prescription Monitoring Program reporting requirements (105 CMR 700.012). Effective January 1, 2011, every pharmacy registered by the Board that dispenses controlled substances in Schedules II-V shall, in accordance with standards established by the Department, transmit to the Department or its agent, required information for each prescription, in accordance with Prescription Monitoring Program reporting requirements (105 CMR 700.012). (M.G.L. c. 94C, §§ 24 and 24A)

(2) . Failure to comply with the Prescription Monitoring Program reporting requirements set forth in 105 CMR 700.012 and/or any state law or regulation relating to such reporting requirements may result in formal disciplinary action being initiated against the licensed pharmacist and/or the pharmacy by the Board and/or other state and federal law enforcement agencies.

REGULATORY AUTHORITY

247 CMR 5.00: M.G.L. c. 112, § 42A; c. 94C, §§ 6 and 24.

247 CMR 6.00: LICENSURE OF PHARMACIES ~~REGISTRATION, MANAGEMENT AND OPERATION OF A PHARMACY OR PHARMACY DEPARTMENT~~

Section

6.01: Authority and Purpose ~~Application for a Registration to Manage and Operate a Pharmacy or Pharmacy Department; Inspection of Proposed Pharmacy or Pharmacy Department~~

Board regulations at 247 CMR 6.00 are promulgated under the authority of M.G.L. c. 112, §§ 38, 39, 39G, 39H, 39I, and 42A and St. 2014, c. 159, § 25 and are designed to describe the licensure application process.

~~(1) In order to be registered by the Board to manage and operate a pharmacy or pharmacy department and be issued a permit to do so, the registered pharmacist who shall~~

~~be responsible for the management and operation of the pharmacy or pharmacy department shall obtain and submit to the Board an application for registration to manage and operate a pharmacy or pharmacy department available from the Board. A completed application shall be:~~

~~(a) fully and properly completed and signed, under the penalties of perjury, by the pharmacist who is to manage and operate the pharmacy or pharmacy department;~~

~~(b) accompanied by a statement of the scheduled hours during which the pharmacy or pharmacy department is to remain open, including the time of opening and closing during regular business hours for each day of the week;~~

~~(c) accompanied by an application, available from the Board, for a Massachusetts controlled substance registration;~~

~~(d) accompanied by an application, available from the Board, for a certificate of fitness, if applicable;~~

~~(e) accompanied by a check or money order made payable, in the proper amount, to the "Commonwealth of Massachusetts Board of Registration in Pharmacy"; and~~

~~(f) accompanied by any additional information as determined by the Board.~~

~~(2) A completed application to operate a pharmacy shall include:~~

~~(a) a copy of the corporation's Articles of Organization, signed and sealed by the Secretary of the Commonwealth if the corporation is incorporated in the Commonwealth;~~

~~(b) a copy of the corporation's Foreign Corporation Certificate, signed and sealed by the Secretary of the Commonwealth pursuant to M.G.L. c. 181, § 4, if the corporation in incorporated in another state;~~

~~(c) a statement of the name and address of each officer and director of the corporation and the position held;~~

~~(d) the d/b/a (doing business as) name of the corporation; and~~

~~(f) if the corporation is not publicly owned, the total amount and type of stock issued to each stockholder and the names and addresses of said stockholder(s).~~

~~(3) The Board shall not register nor permit ownership of a pharmacy or pharmacy department by a practitioner with prescriptive privileges.~~

~~(4) Before acting upon any application for registration to manage and operate a pharmacy or pharmacy department, the Board may require a hearing and, if requested to do so, the applicant shall personally appear before the Board to answer questions to enable the Board to determine that issuance of a permit would be in the best interests of the public health, welfare and safety as set forth in M.G.L. c. 112, § 39.~~

~~(5) The Board may require an inspection of the pharmacy or pharmacy department before final approval of the application is granted. All proposed pharmacies and pharmacy departments shall comply with the following requirements:~~

~~(a) No application for registration to manage and operate a pharmacy or pharmacy department shall be approved unless, upon inspection, the following is~~

maintained on the pharmacy premises:

1. a current copy or electronic version of the Massachusetts List of Interchangeable Drugs (MLID), including the Orange Book, Additional List, Exception List;

2. a current copy or electronic version (with quarterly updates) of a compendia appropriate to the practice setting approved by the pharmacist manager of record.

3. a current copy or electronic version of the Board Regulations (247 CMR);

4. a balance capable of accurately weighing quantities as small as 13 milligrams, which balance shall be tested and sealed by the state or local sealer of weights and measures annually;

5. the equipment necessary to conduct the practice of pharmacy according to the standards set forth by most current edition of the United States Pharmacopoeia;

6. prescription labels which bear the name and address of the proposed pharmacy;

7. appropriate sanitary appliances, including a suitable sink which shall be equipped for hot and cold running water and which shall be situated in or near the area in which prescriptions are to be filled;

8. whenever applicable, at least one bound book for recording sales of controlled substances which may be sold over-the-counter without a prescription; and

9. whenever applicable, at least one book for recording sales of alcoholic beverages and signatures of the purchasers of these beverages.

(b) There shall be within every pharmacy or pharmacy department a prescription area of not less than 300 square feet to accommodate the appropriate pharmaceutical equipment, apparatus, and supplies, and to facilitate the proper preparation and compounding of prescribed medications. This area shall provide for an arrangement and storage of drugs that is calculated to prevent their accidental misuse.

(c) Any pharmacy or pharmacy department which establishes a central intravenous admixture service (CIVAS) or performs sterile compounding shall, in addition to the 300 square feet required by 247 CMR 6.01(5)(b), provide for a separate room referred to as a "clean room" apart from all other areas of the pharmacy or pharmacy department. The pharmacy shall obtain approval from the Board indicating compliance with 247 CMR 6.01 and United States Pharmacopeia General Chapter 797 prior to initial operation of central intravenous admixture services or performance of any sterile compounding. The Board's approval shall be conspicuously posted and visible to the public, on the pharmacy premises. This clean room shall meet the following requirements:

1. There shall be a minimum working area of 72 square feet;

2. it shall be closed on all sides except for a door and an opening to allow for the passage of materials;

3. it shall have a laminar flow hood with either vertical or horizontal air flow;

~~4. the laminar flow hood standards of operation of HEPA (High Energy Particulate Air) filters and prefilters must be determined and certification shall be made annually by a Board-approved hood certification service;~~

~~5. the Board shall be notified before beginning operation of the clean room to verify hood certification;~~

~~6. the area of the clean room shall be under continual positive pressure unless the hood is self-venting; and~~

~~7. applications for construction of a pharmacy with a clean room received after September 30, 1996 shall show the clean room located directly adjacent to the prescription area/department.~~

~~(d) Patient Consultation Area.~~

~~1. A pharmacy must provide a designated consultation area, with signage stating "Patient Consultation Area", designed to provide adequate privacy for confidential visual and auditory patient counseling. The private consultation area must be accessible by a patient from the outside of the prescription dispensing area without having to traverse a stockroom or the prescription dispensing area.~~

~~2. 247 CMR 6.01(5)(d) shall be effective for all new or relocating pharmacies on April 1, 2005. All existing pharmacies must comply with 247 CMR 6.01(5)(d) by January 1, 2007.~~

~~(6) The Board shall issue a permit indicating the pharmacy or pharmacy department's registration number if the Board finds, in its reasonable discretion, that approving the application would be consistent with the best interest of public health, welfare and safety.~~

~~(7) All fees submitted to the Board in connection with an application for registration to operate a pharmacy or pharmacy department, which are reviewed and acted upon by the Board, are nonrefundable.~~

6.02: License Requirements ~~Conditions for Continuing Registration and Operation of a Pharmacy or Pharmacy Department~~

(1) A pharmacy may not dispense any controlled substance unless it holds a Drug Store Pharmacy license or an institutional sterile compounding pharmacy license.

(2) A pharmacy may not engage in any sterile compounding unless it holds:

(a) a Drug Store Pharmacy license and a sterile compounding pharmacy license; or

(b) an institutional sterile compounding pharmacy license.

(3) A pharmacy may not engage in any complex non-sterile compounding unless it holds a Drug Store Pharmacy license and a complex non-sterile compounding pharmacy license.

(4) A pharmacy located outside of Massachusetts may not dispense or ship any

controlled substance into Massachusetts unless it holds a non-resident Drug Store Pharmacy license.

(5) A pharmacy located outside of Massachusetts may not dispense or ship any sterile compounded preparation into Massachusetts unless it holds a non-resident Drug Store Pharmacy license and a non-resident sterile compounding pharmacy license.

(6) A pharmacy located outside of Massachusetts may not dispense or ship any complex non-sterile compounded preparation into Massachusetts unless it holds a non-resident Drug Store Pharmacy license and a non-resident complex non-sterile compounding pharmacy license.

~~Except as provided by exemptions set forth in 247 CMR 12.00: Restricted Pharmacy with respect to restricted pharmacies and 247 CMR 13.00: Registration Requirements and Minimal Professional Standards for Nuclear Pharmacies with respect to nuclear pharmacies, the following conditions shall apply to the continuing operation of a pharmacy or pharmacy department:~~

~~(1) The premises of the pharmacy or pharmacy department shall at all times be kept in a clean and sanitary manner.~~

~~(2) The equipment and publications set forth in 247 CMR 6.01(5)(a) shall be maintained in the pharmacy or pharmacy department at all times.~~

~~(3) The following shall be conspicuously displayed within the pharmacy or pharmacy department:~~

~~(a) the pharmacy permit;~~
~~(b) the pharmacy's Massachusetts controlled substance registration;~~
~~(c) the pharmacy's U.S. Drug Enforcement Administration controlled substance registration; and~~
~~(d) whenever applicable, the pharmacy's certificate of fitness.~~

~~(4) The pharmacy or pharmacy department shall maintain on the premises at all times a sufficient variety and supply of medicinal chemicals and preparations which are necessary to compound and dispense commonly prescribed medications in accordance with the usual needs of the community.~~

~~(5) A pharmacy or pharmacy department shall have a reasonably sized sign affixed to the main entrance of the business or otherwise installed in an easily observable area outside the premises, identifying the presence of a pharmacy or pharmacy department.~~

~~(6) A pharmacy or pharmacy department shall conform to the following security requirements:~~

~~(a) All controlled substances in Schedules II through V shall be stored within the prescription area;~~
~~(b) controlled substances in Schedule VI shall be stored within the~~

prescription area or in the clean room if the clean room is directly adjacent to the prescription area;

(c) controlled substances in Schedules II, III, IV, and V shall be stored in a securely locked and substantially constructed cabinet, or dispersed in the prescription drug storage area throughout the stock of Schedule VI controlled substances in such a manner as to obstruct the theft or diversion of these controlled substances;

(d) there shall be a separate working alarm for the pharmacy or pharmacy department which shall be activated when the pharmacy or pharmacy department is closed;

(e) a pharmacy department must be secured by a floor to ceiling barrier, securely locked and separately alarmed at all times when the pharmacy department is closed;

(f) the pharmacist Manager of Record and the pharmacist on duty shall be responsible for pharmacy security and shall control access to the prescription area;

(g) all drug order deliveries containing controlled substances shall be delivered directly to the pharmacy or pharmacy department or to a secured area if the pharmacy is closed, and the security of those controlled substances is the responsibility of the pharmacist Manager of Record; and

(h) each pharmacy or pharmacy department shall comply with all other security requirements which the Board may deem necessary for the protection of the public.

(7) A pharmacy or a pharmacy department shall conspicuously display, in legible letters not less than one inch high, over, on or adjacent to the main entrance of the pharmacy or pharmacy department, the name of the pharmacist Manager of Record who is responsible for the management and operation of the pharmacy or pharmacy department.

(8) A pharmacy or pharmacy department shall meet the following requirements concerning the posting of hours of operation:

(a) The hours of operation shall be prominently posted at all consumer entrances to the pharmacy and, in the case of a pharmacy department, the hours shall also be posted at all consumer entrances to the retail store and at the pharmacy department;

(b) if the hours of operation of a pharmacy department, subject to the requirements of 247 CMR 6.02(6)(e) and (10), are different from those of the retail store in which it is located, all advertising referring to the pharmacy department shall clearly specify the pharmacy department's hours of operation; and

(c) if the hours of operation of a pharmacy's prescription area, subject to the requirements of 247 CMR 6.02(10), are different from the hours of operation for its non-prescription business, all advertising for the pharmacy shall clearly specify the hours of operation of the pharmacy's prescription area.

~~(9) A pharmacy or pharmacy department shall meet the following requirements concerning registered pharmacists on duty and shall be present at all times when non-pharmacist personal have unrestricted access to the pharmacy or pharmacy department:~~

~~(a) A registered pharmacist shall be on duty and on the pharmacy premises at all times the pharmacy or pharmacy department is open for business and shall be present at all times when non-pharmacist personal have unrestricted access to the pharmacy or pharmacy department;~~

~~(b) each registered pharmacist who is a full-time employee of the pharmacy shall have readily available, or displayed in a conspicuous place, his or her certificate of registration to practice pharmacy and the original or a copy of, his or her current wallet registration card; and~~

~~(c) a registered pharmacist shall not remain on duty for more than 12 hours per day.~~

~~(10) A pharmacy or pharmacy department shall report a theft or loss of a significant amount of controlled substances by submitting to the Board a copy of " Report of Theft or Loss of Controlled Substance" (DEA BND Form 106), within seven days of such theft or significant loss and, where applicable, shall comply with the reporting requirements of the DEA, the Department and the state and local police.~~

6.03: Suitability of Applicant, Licensee, and Interest Holder ~~Requirements for Reporting to the Board a Change in the Management, Operation and/or Ownership of a Pharmacy or Pharmacy Department~~

In its discretion, the Board may determine an applicant or licensee is not suitable to establish or maintain a pharmacy, and that it would not be in the interest of public health, safety, and welfare to issue a license. In making its determination, the Board may consider the following factors:

(1) An applicant, licensee, or interest holder acted in a manner that presented an immediate or serious threat to public health and safety.

(2) An applicant, licensee, or interest holder prevented or attempted to impede the work of any duly authorized representative of the Board or the Department or the lawful enforcement of any provision of M.G.L. c. 112, M.G.L. c. 94C, or regulations promulgated thereunder.

(3) An applicant, licensee, or interest holder plans to assume or has assumed ownership of a pharmacy in an effort to circumvent the effect and purpose of 247 CMR 2.00 *et seq.*

(4) An applicant, licensee, or interest holder owned, operated, or held an interest in a pharmacy, healthcare facility, or other entity registered by the Federal Food and Drug Administration ("FDA") or the Federal Drug Enforcement Administration ("DEA"), that was the subject of proceedings resulting in the discipline, suspension, denial, or revocation of the pharmacy license or other professional license or registration.

(5) An applicant, licensee, or interest holder owned, operated, or held an interest in a pharmacy, healthcare facility, or other entity registered by the FDA or the DEA, that entered into a consent agreement in resolution of a complaint against a pharmacy, healthcare facility, or other entity registered by the FDA or DEA resulting in disciplinary action against the pharmacy license or other professional license or registration.

(6) An applicant, licensee, or interest holder owned, operated, or held an interest in a pharmacy, healthcare facility, or other entity registered by the FDA or the DEA, in such a manner that created an immediate or serious threat to public health and safety.

(7) An applicant, licensee, or interest holder failed to demonstrate that he or she has the competence or experience to operate a pharmacy.

(8) An applicant, licensee, or interest holder obtained or attempted to obtain a license by fraud or misrepresentation, including the submission of false information.

(9) An applicant, licensee, or interest holder has prescriptive privileges.

(10) An applicant, licensee, or interest holder held a professional license or registration that was the subject of proceedings resulting in the discipline, suspension, denial, or revocation of the license or registration.

(11) An applicant, licensee, or interest holder entered into a consent agreement in resolution of a complaint against a professional license or registration resulting in disciplinary action against the professional license or registration.

~~(1) Whenever there is a change in the pharmacist Manager of Record of a pharmacy or pharmacy department, an application for a change in pharmacist Manager of Record shall be obtained from and promptly submitted to the Board. A completed application shall be fully and properly completed and signed, under the penalties of perjury, by a duly authorized representative of the pharmacy or pharmacy department and include;~~

~~(a) a sworn statement confirming that a complete inventory of controlled substances in Schedules II, III, IV and V signed by the outgoing pharmacist Manager of Record and the incoming pharmacist Manager of Record has been taken and filed with the pharmacy's controlled substance records. In the event the outgoing pharmacist Manager of Record is unavailable due to death, serious illness, or termination for inappropriate handling of controlled substances, a staff pharmacist may be authorized to sign the inventory, provided the Board is notified at the time the application is submitted why the staff pharmacist is signing the inventory;~~

~~(b) an application for a certificate of fitness, if applicable;~~

~~(c) the pharmacy permit and, if applicable, the pharmacy or pharmacy department's certificate of fitness;~~

~~(d) required fee(s); and~~

~~(e) any additional information as determined by the Board.~~

(2) Whenever there is to be a transfer of ownership of a pharmacy or pharmacy department or if the pharmacy or pharmacy department is to be owned by a person or entity other than the person or entity who was listed on the initial application for registration to manage and operate a pharmacy or pharmacy department, an application for transfer of ownership shall be obtained from, and submitted to, the Board. A completed application shall:

(a) Meet all the requirements of 247 CMR 6.03(1), if there is a change of pharmacist Manager of Record;

(b) state the full name of the new owner;

(c) have attached thereto an official bill of sale; and

(d) if the new owner is a corporation:

1. have attached thereto a copy of the corporation's Articles of Organization, signed and sealed by the Secretary of State, if the corporation is incorporated in the Commonwealth;

2. have attached thereto a copy of the corporation's Foreign Corporation Certificate, signed and sealed by the Secretary of State pursuant to M.G.L. c. 181, § 4, if the corporation in incorporated in another state;

3. indicate of the name and address of each officer and director of the corporation and the position held;

4. indicate the d/b/a name of the corporation; and

5. if the corporation is not publicly owned, indicate the total amount and type of stock issued to each stockholder and the names and addresses of said stockholder(s).

(3) A registered pharmacist who manages and operates a pharmacy or pharmacy department shall, within ten working days of the commencement or termination of employment, report in writing to the Board such commencement or termination of employment.

(4) Upon commencement of the employment of a registered pharmacist, the pharmacist's employer or the pharmacist Manager of Record shall verify with the Board that the pharmacist's personal registration issued by the Board is current.

(5) A corporation or partnership which owns a pharmacy or pharmacy department which is registered by the Board shall notify the Board, within ten working days, in writing, of the following:

(a) Any change in its Articles of Organization;

(b) any change in its Foreign Corporate Certificate;

(c) any change in the d/b/a name of the corporation accompanied by appropriate authorizing documentation;

(d) any change in the names and addresses of its officers and/or directors, and/or in their positions; and

(e) unless the stock of the corporation is publicly traded, any change in the total amount of stock issued or, names and addresses of the stockholders and the

~~kinds and amounts of stock which they respectively own.~~

~~(6) Pursuant to the provisions of M.G.L. c. 112, § 36, a surviving spouse, executor or administrator of a registered pharmacist who has died or the spouse of one who has become incapacitated who has been authorized to continue operation of a pharmacy or pharmacy department shall, within five days of any change in employment of a registered pharmacist, whether by dismissal, resignation, lay-off or additional hiring, notify the Board thereof in writing.~~

6.04: General Application Requirements ~~Requirements for Reporting to the Board Changes in the Configuration, Square Footage or Location of a Pharmacy or Pharmacy Department~~

(1) An application for a Drug Store Pharmacy license, sterile compounding pharmacy license, complex non-sterile compounding pharmacy license, institutional sterile compounding pharmacy license, non-resident Drug Store Pharmacy license, non-resident sterile compounding pharmacy license, and non-resident complex non-sterile compounding pharmacy license shall be made on forms prescribed by, and available from, the Board.

(2) In support of an application for a license to operate a Drug Store Pharmacy, sterile compounding pharmacy, complex non-sterile compounding pharmacy, institutional sterile compounding pharmacy, non-resident Drug Store Pharmacy, non-resident sterile compounding pharmacy, and non-resident complex non-sterile compounding pharmacy, the applicant shall submit:

(a) complete application forms, signed by:

1. the proposed Massachusetts registered pharmacist Manager of Record; and
2. each applicant or an individual authorized to sign on behalf of the applicant(s);

(b) a statement of the scheduled hours during which the pharmacy is to remain open;

(c) a complete application, available from the Board, for a Massachusetts controlled substance registration or a copy of an existing Massachusetts controlled substance registration;

(d) Payment of a non-refundable licensing and application fee as determined by the Executive Office of Administration and Finance;

(e) if the applicant is an entity:

1. a copy of the entity's Articles of Organization, signed and sealed by the Secretary of the Commonwealth if the corporation is incorporated in the Commonwealth, and other information concerning ownership and control, as the Board may require;
2. a statement of the name and address of each officer or director of the entity and the position held;
3. the name under which the business will operate and be known; and
4. if the corporation is not publicly owned, the total amount and type of stock issued to each stockholder and the names and addresses of said

stockholder(s);
(f) certified blueprints depicting the pharmacy layout;
(g) any request(s) for waiver(s) of Board regulation(s);
(h) attestation of intent to engage in compounding, signed by the Manager of Record and applicant(s); and
(i) any additional information, as required by the Board.

(3) The Board may require the applicant(s), interest holder(s), the proposed Manager of Record, and any other person as required by the Board to personally appear before the Board to answer questions to facilitate the Board's determination whether issuance of a pharmacy license would not be in the best interest of public health, safety, and welfare.

(4) The Board may require an inspection of a pharmacy before granting final approval of an application.

(5) The Board may refuse to issue a pharmacy license if the Board finds, in its reasonable discretion, the applicant(s) and any interest holder(s) are not suitable and approving the application would not be in the best interest of public health, welfare, and safety.

(6) All fees submitted to the Board in connection with an application for a pharmacy license are nonrefundable.

(7) A pharmacy shall open within one calendar year of the Board's approval of its application or obtain written permission from the Board to open more than one calendar year after the Board's approval of the application.

(8) A pharmacy license shall be non-transferrable.

(9) Renewal of a Drug Store Pharmacy, sterile compounding pharmacy, complex non-sterile compounding pharmacy, institutional sterile compounding pharmacy, non-resident Drug Store Pharmacy, non-resident sterile compounding pharmacy, and non-resident complex non-sterile compounding pharmacy licenses and controlled substance registrations

(a) Application for renewal of a pharmacy license and controlled substance registration shall be made by a duly authorized representative of the pharmacy in the form and manner determined by the Board. A renewal application form shall be fully and properly completed and submitted to the Board in a timely manner.
(b) A licensee shall submit payment of a non-refundable licensing and application fee as determined by the Executive Office of Administration and Finance
(c) Each renewal application shall be accompanied by an attestation that the pharmacy complied with all mandatory reporting during that licensing period in accordance with 247 CMR 9.00.
(d) The Board may renew a pharmacy license and controlled substance registration if the Board finds, in its reasonable discretion, the licensee(s) and any

interest holder(s) are suitable and approving the application would be consistent with the best interest of public health, welfare, and safety.

~~(1) Any pharmacy or pharmacy department which is being remodeled in a manner which changes the configuration or square footage of the prescription area shall before commencing any remodeling, submit copies of its structural plans to the Board for approval.~~

~~(2) The following requirements shall apply to any pharmacy or pharmacy department moving to a new address. The pharmacy or pharmacy department shall:~~

~~(a) submit to the Board a new application and payment of the appropriate fee in accordance with the requirements of 247 CMR 6.01(1) in advance of any relocation;~~

~~(b) return previously issued permits with the application; and~~

~~(c) a pharmacy or pharmacy department which has moved to a new address shall not begin to operate in said location until the application has been approved by the Board and until the pharmacy or pharmacy department has received from the Board a permit to manage and operate the pharmacy and a controlled substances registration.~~

6.05: Application for a Drug Store Pharmacy License ~~Continuing Responsibilities of All Registered Pharmacists~~

Renewal of a Drug Store Pharmacy License

(1) Renewal of a Drug Store Pharmacy license shall be made in the form and manner determined by the Board in accordance with 247 CMR 6.04(9).

(2) A Drug Store Pharmacy license shall expire on December 31st of each odd numbered year following the date of its issuance.

~~(1) A registered pharmacist who changes his or her mailing address or name shall notify the Board of such change(s) in writing within ten working days of such change(s). In the case of a change of name, the pharmacist shall submit a sworn statement indicating that the pharmacist has changed his or her name with a photocopy of a valid picture identification card and any other documentation that may be required by the Board.~~

~~(2) A registered pharmacist shall not allow or cause to be displayed, in any pharmacy or pharmacy department where said pharmacist is not employed or associated with the pharmacy business, his or her certificate of personal registration to practice pharmacy.~~

~~(3) A pharmacist shall carry, or have readily available at all times where the pharmacist is employed, a certificate of personal registration or an official statement from the Board which indicates that the pharmacist is currently registered by the Board to practice pharmacy.~~

6.06: Application for a Sterile Compounding Pharmacy License ~~Renewal of a Pharmacy Permit~~

(1) In support of an application for a license to operate a sterile compounding pharmacy, the applicant shall also submit:

(a) all documentation identified in 247 CMR 6.04(2);

(b) certified blueprints of the compounding area(s) depicting the location and identifying the ISO classification for each primary and secondary engineering control;

(c) detailed HVAC design plan and written description; and

(d) attestation of intent to engage in compounding, signed by the Manager of Record, pharmacist in charge of sterile compounding, as applicable, and applicant(s).

(2) The applicant shall achieve a satisfactory Board inspection of the proposed sterile compounding pharmacy prior to the issuance of an original sterile compounding pharmacy license.

(3) Renewal of a sterile compounding pharmacy license

(a) Each sterile compounding pharmacy license issued by the Board shall expire on December 31st of each year following the date of its issuance.

(b) In connection with an application to renew a sterile compounding pharmacy license, a licensee shall submit copies of all reports or correspondence pertaining to all inspections by any state or federal agency, or any entity inspecting on behalf of a state or federal agency, occurring within the pending licensing period.

~~(1) Each pharmacy or pharmacy department permit issued by the Board shall expire on December 31st of each uneven numbered year following the date of its issuance.~~

~~(2) Application for renewal of a pharmacy or pharmacy department permit shall be made by a duly authorized representative of the pharmacy on a renewal application form provided by the Board. Such renewal from shall be fully and properly completed and submitted to the Board in a timely manner.~~

~~(3) Each renewal application form submitted to the Board shall be accompanied by a check or money order in the required amount made payable to the "Commonwealth of Massachusetts Board of Registration in Pharmacy".~~

6.07: Application for a Complex Non-Sterile Compounding Pharmacy License ~~Pharmacist Manager of Record~~

(1) In support of an application for a license to operate a complex non-sterile compounding pharmacy, the applicant(s) shall submit:

(a) all documentation identified in 247 CMR 6.04(2);

(b) certified blueprints of the designated compounding room, including placement of containment hood(s);

(c) detailed HVAC design plan and written description; and
(d) attestation of intent to engage in compounding, signed by the Manager of Record, pharmacist in charge of complex non-sterile compounding, as applicable, and applicant(s).

(2) The applicant shall achieve a satisfactory Board inspection of the proposed complex non-sterile compounding pharmacy prior to the issuance of an original complex non-sterile compounding pharmacy license.

(3) Renewal of a complex non-sterile compounding pharmacy license
(a) Each complex non-sterile compounding pharmacy license issued by the Board shall expire on December 31st of each year following the date of its issuance.
(b) In connection with an application to renew a complex non-sterile compounding pharmacy license, a licensee shall submit copies of all reports or correspondence pertaining to all inspections by any state or federal agency, or any entity inspecting on behalf of a state or federal agency, occurring within the pending licensing period.

~~(1) The responsibilities of the pharmacist Manager of Record shall include, but may not be limited, to the following:~~
~~(a) The maintenance of necessary pharmaceutical equipment and reference texts in accordance with the requirements at 247 CMR 6.01(5)(a);~~
~~(b) the proper maintenance of records as required by the Massachusetts Controlled Substances Act (M.G.L. c. 94C), Board regulations at 247 CMR 2.00 et seq., and all other applicable state and federal laws and regulations;~~
~~(c) the maintenance at all times of adequate pharmacy and pharmacy department security consistent Board regulations at 247 CMR 2.00 et seq., and all other applicable state and federal laws and regulations;~~
~~(d) the establishment, monitoring and enforcement of policies and procedures which encourage acceptable standards of practice consistent with Board regulations at 247 CMR 2.00 et seq., and all other applicable federal and state laws and regulations;~~
~~(e) the establishment, monitoring and enforcement of policies and procedures which maintain the standards of professional practice as such standards relate to the dispensing of pharmaceuticals, including the proper supervision of technicians, and the delegation of authority to another pharmacist when not on duty;~~
~~(f) the maintenance of adequate staff in the pharmacy or pharmacy department in order to ensure that the practice of pharmacy shall be carried out in accordance with Board regulations at 247 CMR 2.00 et seq. and all other applicable federal and state laws and regulations;~~
~~(g) the maintenance of records relating to the responsibilities of pharmacy technicians as outlined in 247 CMR 8.02(6);~~
~~(h) notification to the Board in writing of his or her termination as pharmacist Manager of Record within ten working days;~~

~~(i) taking an inventory of controlled substances in Schedules II, III, IV and V, based upon federal biennial inventory requirements, pursuant to the requirements of 247 CMR 6.03(b); and~~

~~(j) the establishment of procedures for validating questionable purported controlled substance prescriptions and for reviewing existing prescription information, to deter the willful and unlawful dispensing of controlled substances.~~

~~(2) A pharmacist Manager of Record shall not be the Manager of Record of more than one pharmacy or pharmacy department at a time.~~

6.08: Applications for Institutional Sterile Compounding Pharmacy Licenses ~~Certificate of Fitness Issued by the Board Permitting the Manufacture and Sale of Alcoholic Beverages~~

(1) In support of an application for a license to operate an institutional sterile compounding pharmacy, the applicant shall also submit:

(a) all documentation identified in 247 CMR 6.04(2);

(b) a copy of the institution's pharmacy-related license(s) and registration(s);

(c) certified blueprints of the compounding area(s) depicting the location and identifying the ISO classification for each primary and secondary engineering control;

(d) detailed HVAC design plan and written description; and

(e) attestation of intent to engage in compounding, signed by the Manager of Record, pharmacist in charge of sterile compounding, as applicable, and applicant(s).

(2) The applicant shall achieve a satisfactory Board inspection of the proposed institutional sterile compounding pharmacy prior to the issuance of an initial institutional sterile compounding pharmacy license.

(3) Renewal of an institutional sterile compounding pharmacy license

(a) Each institutional sterile compounding pharmacy license issued by the Board shall expire on December of each year following the date of its issuance.

(b) In connection with an application to renew an institutional sterile compounding pharmacy license, a licensee shall submit copies of all reports or correspondence pertaining to all pharmacy-related inspections by any state or federal agency, or any entity inspecting on behalf of a state or federal agency, occurring within the pending licensing period.

~~(1) Pursuant to authority granted to it under M.G.L. c. 138, § 29, the Board may issue to a registered pharmacist who is the Manager of Record of a pharmacy or pharmacy department a certificate of fitness permitting the pharmacy to use alcohol for the manufacture of U.S. Pharmacopoeia or National Formulary preparations and all medicinal preparations unfit for beverage purposes, and to sell alcohol as authorized under M.G.L. c. 138.~~

~~(2) A pharmacist Manager of Record, acting on behalf of a pharmacy or pharmacy department, may apply to the Board for the issuance of a certificate of fitness. A completed~~

~~application shall:~~

~~(a) be fully and properly completed and signed, under penalties of perjury, by the pharmacist Manager of Record who shall manage and operate the pharmacy or pharmacy department; and~~

~~(b) be accompanied by a check or money order, in the proper amount, made payable to the "Commonwealth of Massachusetts Board of Registration in Pharmacy."~~

~~(3) An applicant for a certificate of fitness may be required by the Board to furnish evidence satisfactory to the Board that he or she is a proper person to be entrusted with the authority to manufacture and sell alcoholic beverages and that the issuance of such certificate shall promote the public good.~~

~~(4) The Board may require a personal interview with an applicant for a certificate of fitness to determine the merits of any application for such certificate.~~

~~(5) A certificate of fitness which is issued by the Board to a pharmacy or pharmacy department shall be issued in the name of the pharmacist who manages and operates the pharmacy or pharmacy department and is not transferable.~~

~~(6) A pharmacy or pharmacy department under the supervision of its pharmacist Manager of Record shall comply with the following requirements regarding the sale or transfer of alcohol or alcoholic beverages:~~

~~(a) Prescriptions for alcoholic beverages shall be maintained in a separate file and shall not be refilled;~~

~~(b) any authorized sale or transfer of alcohol or alcoholic beverages which can be used for human consumption shall be made by a registered pharmacist, or by an adult non-pharmacist employee at the direction, and under the supervision of, a registered pharmacist on the premises;~~

~~(c) no sale or transfer of any alcohol or alcoholic beverage which can be used for human consumption shall be made to a minor;~~

~~(d) except upon the written prescription of a practitioner, or except as may be otherwise provided by the local licensing authorities, a pharmacy or pharmacy department which is licensed by the local licensing authority under the provisions of M.G.L. c. 138, § 30A to sell or transfer alcoholic beverages shall neither sell nor transfer such alcoholic beverages on Sundays or legal holidays, or during polling hours, or on any day on which a state or municipal election, caucus, or primary is held in the city or town in which said pharmacy or pharmacy department is located;~~

~~(e) a pharmacy or pharmacy department which holds a license, issued by local licensing authorities under the provisions of M.G.L. c. 138, or which holds a certificate of fitness under the provisions of M.G.L. c. 138, §§ 29 and 30, shall not in any way advertise the sale of alcohol, wines, malt beverages, or alcoholic beverages;~~

~~(f) prior to the sale or transfer of any alcoholic beverage, a pharmacy or pharmacy department which is licensed by the local licensing authorities under the provisions of M.G.L. c. 138, § 30A shall record in a bound record book , organized in accordance with M.G.L. c. 138, § 30E, at the time of every sale, the date of the sale or transfer, the name and address of the purchaser, and the kind, quantity, price and intended use of said~~

~~beverage;~~

~~(g) in accordance with the provisions of 247 CMR 6.08(7)(f), whenever a pharmacy or pharmacy department which is licensed by local licensing authorities under the provisions of M.G.L. c. 138, § 30A sells or transfers an alcoholic beverage to a purchaser, said purchaser shall sign in the bound record book a dated statement substantially as follows: "I wish to purchase (name of alcoholic beverage). I certify that I am of statutory age to purchase alcoholic beverages and that the alcoholic beverage is to be used for mechanical, chemical, medicinal purpose." (A line shall be drawn through the words which do not indicate the purpose of the purchase.)~~

~~(h) in accordance with the provisions of 247 CMR 6.08(7)(f), whenever a pharmacy or pharmacy department which is licensed by local licensing authorities under the provisions of M.G.L. c. 138, § 30A transacts a sale or transfer pursuant to the written prescription of a practitioner, in addition to the information required by 247 CMR 6.08 (7)(f), there shall also be recorded in the bound record book the name of the practitioner; and~~

~~(i) a pharmacy or pharmacy department which is licensed by local licensing authorities under the provisions of M.G.L. c. 138, § 30A may display alcoholic beverages only in a small case or on shelving located at the rear of the pharmacy, provided that the total area used for such display shall not exceed 18 square feet.~~

~~(7) The Board or local licensing authorities, may, after giving a hearing to the interested parties, revoke or suspend the certificate of fitness for any cause which they may deem proper, and such revocation shall suspend all authority the pharmacist, pharmacy or pharmacy department was granted by 247 CMR 6.08(7).~~

6.09: Applications for Non-Resident Drug Store Pharmacy, Non-Resident Sterile Compounding Pharmacy, and Non-Resident Complex Non-Sterile Compounding Pharmacy Licenses ~~Closing a Pharmacy or Pharmacy Department~~

(1) Non-Resident Drug Store Pharmacy

(a) In support of an application for a license to operate a non-resident Drug Store Pharmacy, the applicant(s) shall submit:

1. all documentation identified in 247 CMR 6.04(2);
2. certificate of good standing from the state where the pharmacy is located issued within three months of the application submission date; and
3. inspection report from a Board approved inspector, conducted within two years of the application submission date.

(b) The Board may require an additional inspection of a non-resident Drug Store Pharmacy before granting final approval of an application. The Board may require the inspection to be performed by an agent of the Board or by a Board approved inspector. All costs associated with third party inspectors shall be paid by the applicant.

(c) Renewal of a Non-Resident Drug Store Pharmacy License

1. Each non-resident Drug Store Pharmacy license issued by the Board shall expire on December 31st of each odd numbered year following the date of its issuance.

2. In connection with an application to renew a non-resident Drug Store Pharmacy license, a licensee shall submit copies of all reports or correspondence pertaining to all inspections by any state or federal agency, or any entity inspecting on behalf of a state or federal agency, occurring within the pending licensing period.

(2) Non-Resident Sterile Compounding Pharmacy License

(a) In support of an application for a license to operate a non-resident sterile compounding pharmacy, the applicant shall submit:

1. all documentation identified in 247 CMR 6.04(2);
2. certified blueprints of the compounding area(s) depicting the location and identifying the ISO classification for each primary and secondary engineering control;
3. detailed HVAC design plan and written description; and
4. attestation of intent to engage in compounding, signed by the Manager of Record, pharmacist in charge of sterile compounding, as applicable, and applicant(s).

(b) An applicant shall achieve a satisfactory Board inspection of the proposed non-resident sterile compounding pharmacy prior to the issuance of a non-resident sterile compounding pharmacy license. The Board may require the inspection to be performed by an agent of the Board or by a Board approved inspector. All costs associated with third party inspectors shall be paid by the applicant.

(c) Renewal of a non-resident sterile compounding pharmacy license

1. Each non-resident sterile compounding pharmacy license issued by the Board shall expire on December 31st of each year following the date of its issuance.
2. In connection with an application to renew a non-resident sterile compounding pharmacy license, a licensee shall submit copies of all reports or correspondence pertaining to all inspections by any state or federal agency, or any entity inspecting on behalf of a state or federal agency, occurring within the pending licensing period.

(3) Non-Resident Complex Non-Sterile Compounding

(a) In support of an application for a license to operate a non-resident complex non-sterile compounding pharmacy, the applicant shall submit:

1. all documentation identified in 247 CMR 6.04(2);
2. certified blueprints of the designated compounding room, including placement of containment hood(s);
3. detailed HVAC design plan and written description; and
4. attestation of intent to engage in compounding, signed by the Manager of Record, pharmacist in charge of complex non-sterile compounding, as applicable, and applicant(s).

(b) An applicant shall achieve a satisfactory Board inspection of the proposed non-resident complex non-sterile compounding pharmacy prior to the issuance of a non-resident sterile compounding pharmacy license. The Board may require the inspection to be performed by an agent of the Board or by a Board approved

inspector. All costs associated with third party inspectors shall be paid by the applicant(s).

(c) Renewal of a non-resident complex non-sterile compounding pharmacy license

1. Each non-resident complex non-sterile compounding pharmacy license issued by the Board shall expire on December 31st of each year following the date of its issuance.

2. In connection with an application to renew a non-resident complex non-sterile compounding pharmacy license, a licensee shall submit copies of all reports or correspondence pertaining to all inspections by any state or federal agency, or any entity inspecting on behalf of a state or federal agency, occurring within the pending licensing period.

~~(1) Any person who intends to close a pharmacy or pharmacy department registered by the Board shall officially notify the Board in writing, by certified mail, at least 14 days, before the intended closing, unless otherwise authorized by the Board, and shall provide the Board with the following information:~~

~~(a) The name, address and telephone number of the pharmacy or pharmacy department;~~

~~(b) the pharmacy permit number;~~

~~(c) the pharmacy controlled substance registration number issued by the Board;~~

~~(d) the pharmacy certificate of fitness number issued by the Board, if applicable;~~

~~(e) the name of the pharmacist Manager of Record of the pharmacy or pharmacy department;~~

~~(f) the date on which the intended closure shall take place;~~

~~(g) the intended procedures for closing the pharmacy or pharmacy department;~~

~~h) verification that adequate advance notice of the closure has been given to customers of the pharmacy or pharmacy department; and~~

~~(i) the intended procedures for disposal of controlled substances, or the intended procedures for transfer of controlled substance in accordance with 247 CMR 6.10.~~

~~(2) Within ten days of the closure of a pharmacy or pharmacy department, the following shall be completed by the pharmacy or pharmacy department:~~

~~(a) the pharmacy permit shall be returned to the Board;~~

~~(b) the pharmacy controlled substance registration shall be returned to the Board;~~

~~(c) the pharmacy certificate of fitness, if issued, shall be returned to the Board; and~~

~~(d) the Board shall be notified that all controlled substances have been disposed of in accordance with federal regulations at 21 CFR 1307.21.~~

6.10: Change of Manager of Record ~~Distribution of Controlled Substances Upon Discontinuance or Transfer of Business of a Pharmacy or Pharmacy Department~~

(1) A pharmacy shall submit a change of Manager of Record application to the Board for approval whenever there is a change of Manager of Record. The Board may require

the proposed pharmacist Manager of Record to appear before the Board prior to approving or denying an application.

(2) A licensee, or duly authorized representative of the licensee, and the proposed new Manager of Record shall sign an application for change of Manager of Record. A change of Manager of Record application shall include:

(a) an attestation confirming the pharmacy performed an inventory of all controlled substances in Schedules II, III, IV, V, and VI and filed the inventory report with the pharmacy's controlled substance records. The attestation shall be signed by the outgoing Manager of Record and the proposed incoming Manager of Record. In the event the outgoing Manager of Record is unavailable due to death, serious illness, or termination, a staff pharmacist may be authorized to sign the inventory report, provided the Board is notified at the time the application is submitted the reason the staff pharmacist is signing the inventory report;

(b) the original Drug Store Pharmacy license;

(c) required fee(s); and

(d) any additional information, as required by the Board.

(3) In its discretion, the Board may determine a proposed Manager of Record is not suitable to manage a pharmacy, and that it would not be in the interest of public health, safety, and welfare to approve the application for a change of Manager of Record. In making its determination, the Board may consider the following factors:

(a) A proposed Manager of Record acted in a manner that presented an immediate or serious threat to public health and safety.

(b) A proposed Manager of Record prevented or attempted to impede the work of any duly authorized representative of the Board or the Department or the lawful enforcement of any provision of M.G.L. c. 112, M.G.L. c. 94C, or regulations promulgated thereunder.

(c) A proposed Manager of Record owned, operated, held an interest in, or managed a pharmacy, healthcare facility, or other entity registered by the FDA or the DEA, that was the subject of proceedings resulting in the discipline, suspension, denial, or revocation of the pharmacy license or other professional license or registration.

(d) A proposed Manager of Record owned, operated, held an interest in, or managed a pharmacy, healthcare facility, or other entity registered by the FDA or the DEA, that entered into a consent agreement in resolution of a complaint against a pharmacy or other entity registered by the FDA or DEA resulting in disciplinary action against the pharmacy license or other professional license or registration.

(e) A proposed Manager of Record owned, operated, held an interest in, or managed a pharmacy, healthcare facility, or other entity registered by the FDA or the DEA, in such a manner that created an immediate or serious threat to public health and safety.

(f) A proposed Manager of Record failed to demonstrate that he or she has the competence or experience to manage a pharmacy.

(g) A proposed Manager of Record obtained or attempted to obtain a license

by fraud or misrepresentation, including the submission of false information.

(h) A proposed Manager of Record has been disciplined by the Board within five years of the date of the application.

(i) A proposed Manager of Record held a professional license or registration that was the subject of proceedings resulting in the discipline, suspension, denial, or revocation of the license or registration.

(j) A proposed Manager of Record entered into a consent agreement in resolution of a complaint against a professional license or registration resulting in disciplinary action against the professional license or registration.

~~(1) Any person who intends to transfer controlled substances in Schedules II through VI from one pharmacy or pharmacy department to another pharmacy or pharmacy department within the Commonwealth shall officially notify the Board in writing, by certified mail at least 14 days before the intended transfer, unless otherwise authorized by the Board, and shall provide the Board with the following information:~~

~~(a) The name, address and telephone number of the transferor pharmacy or pharmacy department;~~

~~(b) the name, address and telephone number of the transferee pharmacy or pharmacy department.~~

~~(c) the pharmacy permit number of the transferor pharmacy or pharmacy department;~~

~~(d) the pharmacy permit number of the transferee pharmacy or pharmacy department;~~

~~(e) the pharmacy controlled substance registration number of the transferor pharmacy or pharmacy department;~~

~~(f) the pharmacy controlled substance registration number of the transferee pharmacy or pharmacy department;~~

~~(g) the name and pharmacist registration number of the Manager of Record of the transferor pharmacy or pharmacy department;~~

~~(h) the name and pharmacist registration number of the Manager of Record of the transferee pharmacy or pharmacy department;~~

~~(i) the date on which the transfer of the controlled substances will take place; and~~

~~(j) the intended security procedures for transfer of the controlled substances.~~

~~(2) After proper notification, the transfer of controlled substances may occur provided the following procedures are adhered to:~~

~~(a) On the date of the transfer, a complete inventory of all controlled substances in Schedules II through V shall be taken in accordance with federal and state law;~~

~~(b) said inventory shall be signed by the pharmacist Manager of Record of the transferor pharmacy or pharmacy department and the pharmacist Manager of Record of the transferee pharmacy or pharmacy department. In the event that either pharmacist Manager of Record is unavailable due to death, serious illness, or termination for inappropriate handling of controlled substances, a staff pharmacist may be authorized to sign the inventory, provided the Board is~~

~~notified at the time the application is submitted as to why the staff pharmacist is signing the inventory;~~

~~(c) both the transferor and transferee pharmacy or pharmacy department shall maintain a copy of the inventory for two years or as otherwise required by law;~~

~~(d) a copy of said inventory shall be filed with the Board within ten days of the transfer;~~

~~(e) the transferee pharmacy or pharmacy department shall receive all required controlled substance and controlled substance inventory records on the date of the transfer and maintain those records for two years; and~~

~~(f) the transferor pharmacy or pharmacy department shall not possess any controlled substances after the date of transfer.~~

6.11: Transfer of Ownership of a Pharmacy ~~Inspections of Pharmacies and Pharmacy Departments~~

(1) At least 30 days prior to the transfer of ownership of a licensed pharmacy, the licensee shall notify the Board of the proposed transfer of ownership. The outgoing licensee shall comply with 247 CMR 6.12 and 247 CMR 6.13 pertaining to closing a pharmacy and distributing controlled substances.

(2) At least 30 days prior to the transfer of ownership, the proposed new licensee shall submit an application for a license to operate a pharmacy in accordance with 247 CMR 6.04.

(3) In support of the application for a license to operate a pharmacy, the proposed new licensee shall submit the following:

(a) complete application pursuant to 247 CMR 6.04 and 247 CMR 6.05 – 6.08, as applicable;

(b) description of the date and procedure to transfer controlled substances;

(c) inventory report of controlled substances, as required by 247 CMR 6.13;

(d) official bill of sale; and

(e) any additional information, as required by the Board.

(4) In its discretion, the Board may determine the proposed new licensee and any proposed new interest holder is not suitable to establish or maintain a pharmacy and that it would not be in the best interest of public health, safety, and welfare to approve the application. In making its determination, the Board may consider the factors identified in 247 CMR 6.03(1).

~~The Board or its designees may visit a pharmacy or pharmacy department at any time without prior notice and inspect it, its staff, activities, and records to determine compliance with state law and 247 CMR 2.00 et seq. The Board may also inspect pharmacies and pharmacy department premises pursuant to 247 CMR 11.12.~~

6.12: Notifications ~~Deficiency Statements~~

(1) A corporation or partnership which owns a pharmacy shall notify the Board, within 14 days, in writing, of the following:

(a) any change in the name under which the pharmacy operates, accompanied by appropriate authorizing documentation;

(b) any change in the names of its officers or directors; and

(c) any change in the ownership of the pharmacy representing more than 5% interest.

~~After every Board inspection in which any violation of 247 CMR 2.00 et seq. is observed, the Board or its designees shall prepare a deficiency statement citing every violation observed, a copy of which shall be sent to the pharmacy or pharmacy department.~~

6.13: Closing of a Pharmacy ~~Plans of Correction~~

(1) A licensee and a Manager of Record who intend to close a pharmacy shall officially notify the Board in writing, by certified mail, at least 14 days before the intended closure, unless otherwise authorized by the Board, and shall provide the Board with the following information:

(a) the name, address, and telephone number of the pharmacy;

(b) the pharmacy license and controlled substance registration numbers;

(c) the name of the pharmacist Manager of Record of the pharmacy;

(d) the date on which the intended closure shall take place;

(e) the intended procedures for closing the pharmacy;

(f) verification that adequate advance notice of the closure has been given to customers of the pharmacy in accordance with 247 CMR 6.12(3); and

(g) the intended procedures for disposal or transfer of controlled ~~,~~ accordance with 247 CMR 6.13.

(2) A sterile compounding pharmacy, complex non-sterile compounding pharmacy, institutional sterile compounding pharmacy, non-resident sterile compounding pharmacy, and non-resident complex non-sterile compounding pharmacy shall notify the Board in writing, by certified mail, at least 14 days before the intended closure, unless otherwise authorized by the Board, of the identity of the pharmacy licensed by the Board that is suitable and available to provide continuity of care to the closing pharmacy's patients.

(3) Notice to Patients. A licensee or a Manager of Record who intends to close a pharmacy licensed by the Board shall identify each patient who had a prescription filled at the pharmacy within preceding 90 days of the intended closure date. The licensee or a Manager of Record shall send notice of the pharmacy closure to each such patient no later than 14 days prior to the closure date, by first class mail or other Board approved method. The licensee or a Manager of Record shall also post notice in a conspicuous location at the pharmacy informing patients of the intended closure and procedure for requesting a transfer of patient file information.

(4) Transfer of patient files. Upon patient request or as required by law or contract, a

licensee or Manager of Record who intends to close a pharmacy licensed by the Board shall transfer patient files to another pharmacy in a timely manner to meet patient needs.

(5) A licensee and Manager of Record shall submit the following to the Board within 14 days of closure of a pharmacy:

(a) the original license(s) and controlled substances registration; and

(b) an attestation that all controlled substances have been disposed of in accordance with federal regulations at 21 CFR 1307.21.

~~A pharmacy or pharmacy department shall submit to the Board a written plan of correction of violations cited in a deficiency statement prepared pursuant to 247 CMR 6.12 within 15 business days after the deficiency statement is sent. 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 the relevant 247 CMR section will be achieved. The timetable and the compliance dates shall be consistent with achievement of compliance in the most expeditious manner possible. A plan of correction which does not meet the requirements of the relevant 247 CMR section shall be considered unacceptable by the Board and returned to the pharmacy or pharmacy department.~~

6.14: Distribution of Controlled Substances upon Closure or Transfer of Ownership of a Pharmacy, Sterile Compounding Pharmacy, or Complex Non-Sterile Compounding Pharmacy ~~Duty to Report Certain Improper Drug Dispensing to the Board~~

(1) A licensee, Manager of Record, or agent of the licensee who intends to transfer controlled substances in Schedules II through VI from one pharmacy licensed by the Board to another pharmacy licensed by the Board within the Commonwealth shall notify the Board in writing, by certified mail, at least 14 days before the intended transfer, unless otherwise authorized by the Board, and shall provide the Board with the following information:

(a) the name, address, and telephone number of the transferor pharmacy;

(b) the name, address, and telephone number of the transferee pharmacy;

(c) the pharmacy license and controlled substances registration numbers of the transferor pharmacy;

(d) the pharmacy license and controlled substances registration number of the transferee pharmacy;

(e) the name and pharmacist license number of the Manager of Record of the transferor pharmacy;

(f) the name and pharmacist license number of the Manager of Record of the transferee pharmacy;

(g) the date on which the transfer of the controlled substances will take place; and

(h) the security procedures for transfer of the controlled substances.

(2) No sooner than 14 days following notification, the transfer may proceed provided the following procedures are adhered to:

(a) On the date of the transfer, the transferor pharmacy shall take a complete inventory of all controlled substances in Schedules II through VI in accordance with federal and state law;
(b) The pharmacist Manager of Record of the transferor pharmacy and the pharmacist Manager of Record of the transferee pharmacy shall sign the controlled substances inventory report. In the event the transferor pharmacist Manager of Record is unavailable due to death, serious illness, or termination, a staff pharmacist may be authorized to sign the inventory report, provided he or she notifies the Board as to why the staff pharmacist is signing the inventory report;
(c) Both the transferor and transferee pharmacies shall maintain a copy of the inventory report for at least two years or as otherwise required by law. The inventory report shall be readily retrievable;
(d) Both the transferor and transferee pharmacies shall file an attestation with the Board confirming the controlled substance inventory within 10 days of the transfer;
(e) The transferee pharmacy shall receive all required controlled substances and controlled substance inventory records on the date of the transfer and maintain those records for at least two years; and
(f) The transferor pharmacy may not possess any controlled substances after the date of transfer.

~~Effective January 1, 2010, a pharmacy licensed by the Board is required to report to the Board any improper dispensing of a prescription drug that results in serious injury or death, as defined by the Board, as soon as is reasonably and practicably possible but not later than 15 business days after discovery or being informed of such improper dispensing. The duty to report to the Board any improper dispensing of a prescription drug that results in serious injury or death, pursuant to M.G.L. c. 112, § 39D and 247 CMR 6.14(2), shall be in addition to the Continuous Quality Improvement (CQI) Program requirements of 247 CMR 15.00. Only those events of improper dispensing of a prescription drug that result in serious injury or death are required to be reported to the Board, in accordance with M.G.L. c. 112, § 39D and 247 CMR 6.14(2).~~

~~(1) Definitions. For purposes of reporting to the Board, as required by M.G.L. c. 112, § 39D:~~

~~(a) Improper Dispensing of a Prescription Drug shall mean the incorrect dispensing of a prescribed medication that is received by a patient, as more particularly described in 247 CMR 15.01: Quality-related Event or QRE.~~
~~(b) Pharmacy, as referenced in 247 CMR 6.14, shall mean a pharmacy, or a group of pharmacies under common ownership and control of one entity, licensed by the Board pursuant to M.G.L. c. 112.~~
~~(c) Serious Injury shall mean an injury that is life threatening, results in serious disability or death, or requires a patient to undergo significant additional treatment measures.~~
~~(d) Serious Disability shall include, but is not limited to, injuries requiring major intervention and loss, or substantial limitation, of bodily function lasting~~

~~greater than seven days (e.g. bodily function related to breathing, dressing/undressing; drinking; eating; eliminating waste products; getting into and out of bed, chair, etc.; hearing; seeing; sitting; sleeping or walking).~~

~~(2) Reporting Responsibility. Effective January 1, 2010, a pharmacy shall file a report with the Board of the improper dispensing of a prescription drug that results in serious injury or death, on a form to be provided by the Board, within 15 business days of the pharmacy discovering or being informed of such improper dispensing. A pharmacy shall provide all records relating to such improper dispensing to the Board upon request.~~

~~(3) Records Retention. The pharmacy shall retain all records relating to the improper dispensing of a prescription drug that results in serious injury or death which is required to be reported to the Board, in accordance with the requirements of M.G.L. c. 112, § 39D and 247 CMR 6.14(2), for a minimum period of two years from the date the report is filed with the Board.~~

6.15: Application for Remodeling, Change in the Configuration, or Change in Square Footage of a Pharmacy ~~Duty to Report Certain Factors of Pharmacy Operations~~

(1) A Drug Store pharmacy, sterile compounding pharmacy, complex non-sterile compounding pharmacy, institutional sterile compounding pharmacy, and a non-resident sterile compounding pharmacy shall apply to the Board for approval to remodel or to change the configuration or square footage of the pharmacy and may not commence any construction work or remodeling until it receives approval from the Board.

(2) A sterile compounding pharmacy, non-resident sterile compounding pharmacy, and institutional sterile compounding pharmacy shall apply to the Board for approval to remodel or to change the configuration or square footage of the pharmacy prior to moving, adding, modifying, removing, or replacing any primary or secondary engineering control and may not move, add, modify, remove, or replace any primary or secondary engineering control until it receives approval from the Board.

(3) In support of an application to change the configuration or square footage of a pharmacy, the applicant shall submit to the Board:

(a) certified blueprints depicting the pharmacy layout, prescription area, counseling area, location and ISO classification of each primary and secondary engineering control, and placement of containment hood(s), as applicable;

(b) a written plan to maintain security of controlled substances during any transportation, if the pharmacy is located in Massachusetts; and

(c) any other information, as required by the Board.

(4) A sterile compounding pharmacy, complex non-sterile compounding pharmacy, institutional sterile compounding pharmacy, and non-resident sterile compounding pharmacy shall submit the following in support of an application to remodel or to change the configuration or square footage of a pharmacy:

(a) containment strategy;

(b) environmental monitoring plan, if applicable;
(c) plan to re-certify primary and secondary engineering controls and containment hoods, if applicable;
(d) continuity of care plan, if applicable; and
(e) any other information, as required by the Board.

~~(1) Definitions.~~
~~(a) Abnormal Results means results of viable and nonviable testing, such as for environmental contaminants and potency, that are not within acceptable United States Pharmacopeia General Chapter 797 standards or criteria.~~
~~(b) Accreditation means a process bywhich a professional association or non-governmental agency grants recognition to a pharmacy for demonstrated ability to meet certain pre-defined criteria.~~
~~(c) Disciplinary actions means actions including, but not limited to revocation, suspension, probation, censure, reprimand, or restriction of the license to operate a pharmacy or practice pharmacy, denial of application for renewal, denial or restriction of privileges or termination from Medicare or Medicaid programs including any adverse actions or fines imposed by a state or federal agency.~~
~~(d) Federal agency means any U.S. Government agency that has regulatory purview over the clinical practice of pharmacy or of pharmacy operations, including, but not limited to, all agencies in the U.S. Department of Health and Human Services, the U.S. Occupational Safety and Health Administration, and the U.S. Department of Justice.~~
~~(e) State agency means any U.S. State or Territory that licenses or otherwise regulates pharmacies or pharmacist practice.~~
~~(f) Sterile compounding means the preparation, mixing, assembling, packaging, and labeling of a drug or device that is required to be prepared in accordance with United States Pharmacopeia General Chapter 797 and dispensed pursuant to a valid prescription as defined by 247 CMR 2.00.~~

~~(2) Every pharmacy licensed pursuant to M.G.L. c. 112, § 39, and pharmacist licensed or registered pursuant to M.G.L. c. 112, § 24, shall report to the Board within seven business days of receipt, in a manner and format determined by the Board, all non-routine notices, correspondence, and disciplinary actions as defined in 247 CMR 6.15.~~

~~(3) Every pharmacy licensed pursuant to M.G.L. c. 112, § 39, and pharmacist licensed or registered pursuant to M.G.L. c. 112, § 24, shall report to the Board any adverse change in status of accreditation, including but not limited to withdrawal, discontinuance, termination, revocation, suspension, probation, or warning. All such reports shall be made within seven business days of an action taken by the accrediting agency, and in a manner determined by the Board.~~

~~(4) Every pharmacy licensed pursuant to M.G.L. c. 112, § 39, and pharmacist licensed or registered pursuant to M.G.L. c. 112, § 24, shall provide the Board with responsive documents sent from a registrant or licensee to a state or federal agency with~~

~~respect to reports or responses submitted pursuant to 247 CMR 6.15(2) and (3). All such materials shall be provided to the board within seven business days of response to the aforementioned state or federal agency.~~

~~(5) Every pharmacy licensed pursuant to M.G.L. c. 112, § 39, that performs central intravenous admixture services (CIVAS), or engages in sterile compounding, shall report to the Board every six months, or upon request by the Board, at a minimum, the following information: (a) total number and type of prescriptions dispensed, distribution data identifying the states in which the prescriptions were distributed, status of any non-resident licenses issued by other states, hood certifications required by 247 CMR 6.01(5)(c)5., and all International Organization for Standardization (ISO) certifications in the pharmacy, status of CIVAS approval(s) where applicable, and any other information required by the Board. (b) All such reports shall be accurate and comply with the Board's reporting requirements. (c) All reports shall be accompanied by an affidavit attesting compliance with all laws and regulations pertinent to sterile compounding and United States Pharmacopeia General Chapter 797. This attestation shall be made under pains and penalties of perjury, and include attestation to the following "this registrant/licensee only dispenses medication pursuant to a valid prescription as defined in M.G.L. c. 94C for a single patient, regardless of whether the medication is prepared for a Massachusetts or out-of-state patient."~~

~~(6) Every pharmacy engaged in sterile compounding and licensed pursuant to M.G.L. c. 112, § 39 shall report within seven business days of identification all errors relating to the preparation of medications in that pharmacy inconsistent with United States Pharmacopeia General Chapter 797 standards or criteria for factors including but not limited to pyrogenicity, stability, improper composition, mislabeling, or sterility.~~

~~(7) Every pharmacy licensed pursuant to M.G.L. c. 112, § 39 shall report within seven business days all abnormal results, including failure of certification as required pursuant to 247 CMR 6.01(5)(c), and identification of environmental contaminants or improper potency in that pharmacy inconsistent with United States Pharmacopeia General Chapter 797 standards or criteria.~~

~~(8) Failure to comply with reporting requirements described in 247 CMR 6.15(2) through (7) or to cooperate fully in the Board's investigation of any such report to the Board shall be grounds for disciplinary action pursuant to 247 CMR 10.03: Grounds for Discipline(1)(q).~~

6.16: Application for Relocation of a Pharmacy to a New Address

A pharmacy licensed by the Board shall apply to the Board for approval to relocate to a new address prior to relocating and may not relocate until it receives approval from the Board. A pharmacy shall submit an application at least 90 days prior to its desired date of relocation, unless otherwise approved by the Board. In support of an application to relocate, a pharmacy shall submit:

(1) an application and payment of the appropriate fee;

(2) certified blueprints depicting the pharmacy layout;

(3) a written plan to maintain security of controlled substances during transportation, if the pharmacy is located in Massachusetts; and

(4) any other information, as required by the Board.

6.17: Provisional Licenses

(1) In its discretion, the Board may issue a provisional license(s) in lieu of a sterile compounding pharmacy license, complex non-sterile compounding pharmacy license, institutional sterile compounding pharmacy license, non-resident Drug Store Pharmacy license, non-resident sterile compounding pharmacy license, or non-resident complex non-sterile compounding pharmacy license provided:

(a) The applicant submitted a complete application for a sterile compounding pharmacy license, complex non-sterile compounding pharmacy license, institutional sterile compounding pharmacy license, non-resident Drug Store Pharmacy license, non-resident sterile compounding pharmacy license, or non-resident complex non-sterile compounding license; and

(b) The applicant demonstrated to the satisfaction of the Board it is in substantial compliance with the laws and regulations governing the practice of pharmacy in Massachusetts and has the potential to achieve full compliance within the provisional licensure period.

(2) A provisional license shall be valid until the earliest of the following events occurs:

(a) the Board converts the provisional license to a sterile compounding pharmacy license, complex non-sterile compounding pharmacy license, institutional sterile compounding pharmacy license, non-resident Drug Store Pharmacy license, non-resident sterile compounding pharmacy license, or non-resident complex non-sterile compounding license;

(b) the provisional license is surrendered, suspended, or revoked; or

(c) one year has passed since the Board issued the provisional license.

(3) In its discretion, the Board may convert a provisional license to a sterile compounding pharmacy license, complex non-sterile compounding pharmacy license, institutional sterile compounding pharmacy license, non-resident Drug Store Pharmacy license, non-resident sterile compounding pharmacy license, or non-resident complex non-sterile compounding pharmacy license when the Board has determined the pharmacy is in full compliance with the laws and regulations governing the practice of pharmacy in Massachusetts.

(4) A provisional license may not be renewed or extended.

REGULATORY AUTHORITY

247 CMR 6.00: M.G.L. c. 112, §§ 38, 39, 39G, 39H, 39I, and 42A ~~and 30~~; ~~c. 138, §§ 29 – 30G;~~ St. 2014, c. 159, § 25.

247 CMR 9.00: PROFESSIONAL PRACTICE STANDARDS ~~CODE OF PROFESSIONAL CONDUCT; PROFESSIONAL STANDARDS FOR REGISTERED PHARMACISTS, PHARMACIES AND PHARMACY DEPARTMENTS~~

Section

~~For purposes of 247 CMR 9.00 "pharmacy" shall include retail, restricted and nuclear pharmacies, and pharmacy departments.~~

9.01: General Practice Standards ~~Code of Professional Conduct for Registered Pharmacists, Pharmacies and Pharmacy Departments~~

(1) A licensee shall conduct professional activities in conformity with M.G.L. c. 112, §§ 24 – 42D, M.G.L. c. 94C, and 247 CMR 2.00 *et seq.*

(2) A licensee may not process a prescription; dispense a drug, device, or other substance; or administer a controlled substance or vaccine in a manner which is intended,

either directly or indirectly, to circumvent any law or regulation governing the practice of pharmacy.

(3) A licensee shall adhere to the most current standards established by each chapter of the United States Pharmacopeia ("USP").

(4) A pharmacist shall practice pharmacy within the scope of his or her education, training, and experience and within the recognized pharmacist scope of practice.

(5) Unless otherwise permitted by law or regulation, a licensee may not re-dispense any medication which has been previously dispensed.

(6) Unless otherwise permitted by law or regulation, a licensee may not dispense, package, label, or compound any medication that was previously processed or dispensed by another pharmacy. Unless otherwise permitted by law or regulation, a drug store pharmacy may not accept or store any medication that was previously processed or dispensed by another pharmacy.

(7) A licensee may not accept or purchase medications designated as "drug samples not for resale" for the purpose of compounding, repacking, dispensing, or in any way reselling said medications.

(8) A pharmacy shall accept a medication that it previously dispensed to a patient if the medication:

(a) was dispensed to the patient in error; or

(b) is suspected to be defective or contaminated.

A medication accepted by a pharmacy pursuant to this section may not be returned to the pharmacy's inventory and must be quarantined and properly disposed. A pharmacy is not required to accept a medication from a patient that was properly dispensed and not defective at the time it was dispensed.

(9) While on duty, a pharmacist shall be responsible for the proper preservation, storage, and security of all controlled substances in the pharmacy.

(10) A licensee may not engage in any fraudulent or deceptive act.

(11) A licensee may not in any way aid or abet the unlawful practice of pharmacy.

(12) A licensee may not offer, solicit, or receive remuneration or anything of value to or from any person who owns, operates, manages, or is an employee of a hospital, nursing home, or other health care facility in return for a referral to a pharmacy, pharmacist, pharmacy technician, or pharmacy intern or the generation of business from sale or furnishing of any drugs, devices, or services to any such persons, or institutions.

(13) A licensee may not dispense or distribute any expired, outdated, defective, contaminated, counterfeit, contraband, or otherwise substandard drug or device to any

person or entity who is not licensed or legally authorized to receive such drug or device.

(14) Unless otherwise permitted by law, a pharmacist connected with, or employed by, a hospital or clinic pharmacy that does not hold a Drug Store pharmacy license may not dispense drugs to any person other than inpatients or outpatients of the hospital or clinic, or to employees of said hospital or clinic, or to said employees' spouses and children who live in the same household with said employees.

(15) A licensee may not provide any practitioner with prescription forms which refer to any pharmacist or pharmacy.

(16) Unless otherwise permitted by law or regulation, a licensee may not limit his or her services to a particular segment or segments of the general public.

(17) A licensee may not refuse to compound simple or moderate non-sterile compounded preparations customary to the community needs except upon extenuating circumstances or by a waiver of Board regulation.

(18) A licensee shall maintain patient confidentiality and may not disclose patient confidential information. Confidential information includes any information which can be associated with a particular individual from which he or she is individually identifiable. Confidential information includes the past, present, and future health or condition of an individual, the provision of health care to an individual, and the payment for the provision of the health care to the individual.

(19) A pharmacist, pharmacy intern, or pharmacy technician may not work in a pharmacy for more than 12 hours without completing an eight hour rest period prior to resuming work in a pharmacy. In the event of an extenuating circumstance, a pharmacist, pharmacy intern, or pharmacy technician may exceed 12 hours in order to act in the best interest of the patient, provided the time in excess of 12 hours is minimized and the licensee documents the extenuating circumstance.

(20) A licensee may not display or allow to be displayed ~~/~~ or her certificate of personal registration in any pharmacy where said licensee is not employed or associated.

(21) A pharmacist, pharmacy intern, and pharmacy technician shall carry, post on the wall of the pharmacy where he or she works, or have readily available at the pharmacy where he or she works, a certificate of personal registration or an official statement from the Board which indicates that the licensee is currently registered by the Board to practice as a pharmacist, pharmacy intern, or pharmacy technician.

(22) A pharmacist shall wear a name tag with at least his or her first name and the title "Registered Pharmacist" or "R.Ph.".

(23) A pharmacy may not allow any individual who is not a Massachusetts registered pharmacist to direct or supervise the practice of pharmacy.

(24) A pharmacist shall maintain an NABP e-profile number.

~~(1) A registered pharmacist shall at all times conduct professional activities in conformity with federal, state and municipal laws, ordinances and/or regulations, including the regulations of the Board.~~

~~(2) A pharmacist shall not dispense drugs, devices, or other substances in a manner which is intended, either directly or indirectly, to circumvent the law.~~

~~(3) A pharmacist shall observe the standards of the current United States Pharmacopoeia.~~

~~(4) Unless otherwise permitted by law, a pharmacist shall not redispense any medication which has been previously dispensed.~~

~~(5) While on duty, a pharmacist shall be responsible for the proper preservation and security of all drugs in the pharmacy or pharmacy department, including the proper refrigeration and storage of said drugs.~~

~~(6) A pharmacist shall not engage in any fraudulent or deceptive act.~~

~~(7) A pharmacist shall not enter into an agreement or arrangement with any person for the purpose of dispensing drugs which have been ordered by coded prescriptions.~~

~~(8) A pharmacist, pharmacy or pharmacy department shall not promise to any person who owns, operates, manages or is an employee of a hospital, nursing home or other health care facility, or to any authorized practitioner, any rebate, refund, discount, commission or other valuable consideration for, or on account of, or based upon income received or resulting from, the sale, or furnishing of any such pharmacist, pharmacy, or pharmacy department, of drugs devices or services to patients of such persons, organizations or facilities.~~

~~(9) A pharmacist shall not in any way aid or abet the unlawful practice of pharmacy.~~

~~(10) A pharmacist shall not dispense or distribute expired, outdated or otherwise substandard drugs or devices or counterfeit drugs or devices to any person or entity who is not licensed or legally authorized to receive such drugs or devices.~~

~~(11) A pharmacist may dispense prescription drugs by mail or common carrier in a manner consistent with federal and state laws and regulations, including the regulations of the Board. All pharmacists shall have available sufficient information to contact the patient and the prescribing practitioner.~~

~~(12) Unless otherwise permitted by law, a pharmacist connected with, or employed by, a hospital or clinic shall not dispense drugs to any person other than inpatients or outpatients, or to employees of said hospital or clinic, or to said employees' spouses and children who live in the same household with said employees.~~

~~(13) A pharmacist, pharmacy, pharmacy department, pharmaceutical organization or pharmacy corporation shall not provide any practitioner with prescription blanks which refer to any pharmacist, pharmacy or pharmacy department.~~

~~(14) A pharmacist shall keep a perpetual inventory of each controlled substance in Schedules II which the pharmacist has received, dispensed or disposed of in accordance with the law. This inventory must be reconciled at least once every ten days.~~

~~(15) Unless otherwise provided for by law, a pharmacist shall not limit his or her services to a particular segment or segments of the general public.~~

~~(16) A pharmacist shall not refuse to compound customary pharmaceutical preparations except upon extenuating circumstances.~~

~~(17) A pharmacist shall not purchase drug samples for the purpose of compounding, dispensing, or in any way reselling these samples.~~

~~(18) A pharmacist shall comply with the mandatory counseling provisions contained in M.G.L. c. 94C, § 21A.~~

~~(19) A pharmacist shall maintain patient confidentiality at all times. Confidential information shall include information maintained by the pharmacist in the patient's records or information which is communicated to the patient as part of patient counseling, which is privileged and may be released only to the patient or to those practitioners and other pharmacists where, in the pharmacist's professional judgment, such release is necessary to protect the patient's health and well being; and to such other persons or governmental agencies authorized by law to receive such confidential information.~~

9.02: Prescriptions by Mail ~~of~~

(1) A pharmacy and pharmacist may dispense prescription drugs by mail or common carrier in a manner consistent with federal and state laws and regulations.

(2) A pharmacist shall verify that packing, shipping, and transportation processes do not adversely affect the integrity or stability of medications dispensed by mail.

(3) A pharmacy shall maintain policies and procedures regarding packing, shipping, transporting, and delivering controlled substances.

~~(1) A prescription may be transferred between pharmacies or pharmacy departments, at the patient's request, for the purpose of dispensing authorized refills on the prescription provided that:~~

~~(a) refills remain on the prescription; and~~

~~(b) the prescription authorizing the refill has not expired.~~

~~(2) The procedure for transferring a prescription between pharmacies or pharmacy departments for prescriptions issued for controlled substances in Schedules III, IV and V shall be as follows:~~

(a) The transferring pharmacist must record the following information:

1. Write the word "VOID" on the face of the invalidated prescription;

2. record on the reverse of the invalidated prescription the name, address and DEA registration number of the pharmacy to which it was transferred and the name of the pharmacist receiving the prescription information; and

3. record, on a written transfer log or by entry into a computerized system, the prescription number, date of the transfer, the name or identification of the pharmacist transferring the information and the name of the pharmacy or pharmacy department to which the prescription is transferred.

(b) The transferring pharmacist shall cancel all refills remaining on the transferred prescription.

(c) The pharmacist receiving the transferred prescription information shall complete the following:

1. Write the word "transfer" on the face of the transferred prescription; and

2. write all information required by state and federal law to be on the prescription and include:

a. the date of issuance of the original prescription;

b. the original number of refills authorized on the original prescription; c. the date of original dispensing;

d. the number of valid refills remaining and date of last refill; and

e. the pharmacist's name, address, DEA number and original prescription number from which the prescription information was transferred; and the name of the transferor pharmacist.

(d) The pharmacist receiving the transferred information shall inform the patient that the original prescription's refills have been canceled at the pharmacy or pharmacy department from which it has been transferred.

(3) The procedure for transferring a prescription between pharmacies or pharmacy departments for prescriptions issued for controlled substances in Schedule VI shall be as follows:

(a) The transferring pharmacist or certified pharmacy technician must record, on a written transfer log or by entry into a computerized system the following: the prescription number; date of the transfer; the name or identification of the pharmacist transferring the information; and the name of the pharmacy or pharmacy department to which the prescription is being transferred.

(b) The transferring pharmacist or certified pharmacy technician shall cancel all refills remaining on the transferred prescription.

(c) The pharmacist or certified pharmacy technician receiving the transferred prescription information shall:

1. write the word "transfer" on the face of the transferred prescription;

2. write all information required by state and federal law to be on the prescription including:

a. the date of issuance of the original prescription;

b. the original number of refills authorized on the original prescription;

c. the date of original dispensing;

d. the number of valid refills remaining and date of last refill; and

e. the pharmacy's name, address, DEA number and original prescription number from which the prescription information was transferred; and the name of the transferor pharmacist.

(d) The pharmacist or certified pharmacy technician receiving the transferred prescription shall inform the patient that the original prescription's refills have been canceled at the pharmacy or pharmacy department from which it has been transferred.

(4) Prescriptions authorizing refills for Schedule III through V controlled substances may be transferred between pharmacies or pharmacy departments on a one-time only basis except as otherwise permitted by law.

(5) Prescriptions authorizing refills for Schedule VI controlled substances may be transferred between pharmacies or pharmacy departments within one year of the date of issuance.

(6) Both the original and transferred prescriptions must be maintained for a period of two years from the date of last refill.

9.03: Advertising

(1) A pharmacist or pharmacy may not utilize false, deceptive, or misleading advertising.

(2) An advertisement for a particular prescription drug may not contain any representation, either expressed or implied, concerning that drug's safety, effectiveness, or indications for use.

(3) An advertisement for a particular prescription drug shall include the following information:

(a) the proprietary name of each drug, if any;

(b) the established or generic name of each drug, if any;

(c) the quantity of each active ingredient per dosage unit;

(d) the dosage form of each drug; and

(e) the cash price of the prescription drug, including any professional or handling fees and any mailing and delivery fees.

(4) An advertisement for a prescription drug may contain a description of professional or convenience services provided by the pharmacy.

(5) The requirements of 247 CMR 9.03 shall apply to all pharmacy advertisements and promotional materials regardless of the format.

~~(1) A pharmacist shall not utilize false, deceptive or misleading advertising.~~

~~(2) Whenever a pharmacist advertises the consumer price for a particular prescription drug, said advertisement shall not contain any representation, either expressed or implied, concerning that drug's safety, effectiveness, or indications for use.~~

~~(3) Any pharmacist who advertises a prescription drug in a manner which provides price information to consumers shall include the following information regarding each advertised prescription drug:~~

~~(a) The proprietary name, if any;~~

~~(b) the established or generic name, if any;~~

~~(c) the quantity of active ingredient per dosage unit of the prescription drug product whenever the prescription contains a single active ingredient;~~

~~(d) the strength of the prescription whenever said product contains more than one active ingredient by a relevant strength that can be associated with the product without indicating each active ingredient; the established name and quantity of each active ingredient shall not be required whenever said product contains more than one active ingredient;~~

~~(e) the dosage form; and~~

~~(f) the price charged for filling a prescription.~~

~~(4) A pharmacist who advertises prescription drugs in a manner which provides price information to consumers may identify professional or convenience services provided by the pharmacy or pharmacy department, or may include other written, printed or graphic matter, provided that no information included in such advertising shall be false, deceptive or misleading.~~

~~(5) Whenever a pharmacist advertises prescription drugs in a manner that provides price information to consumers, any stated price with respect to a particular prescription drug shall include all charges to the consumer. These charges shall include, but not be limited to, any professional or handling fees and any mailing and delivery fees. This advertising may indicate each separate fee which is to be added to the price of the prescription drug .~~

~~(6) The requirements of 247 CMR 9.03 apply to all prescription drug advertisements, including price lists, catalogs, and other promotional material, whether mailed, posted in a pharmacy, placed in a newspaper, or aired on radio or television, which serve to provide consumers with information regarding the price charged for prescriptions.~~

9.04: Requirements for Dispensing and Refilling Prescriptions

(1) A pharmacist shall verify each prescription and is responsible for ensuring each prescription is properly filled and properly dispensed.

(2) A pharmacy shall maintain a workflow that promotes accuracy and patient safety

during the processing, verification, and dispensing of prescriptions.

(3) A pharmacy shall utilize a computerized pharmacy system for dispensing and refilling prescriptions and for maintaining patient profiles.

(4) A pharmacy shall utilize computerized prescription scanning, barcode scanning, and product imaging technology or other technology approved by the Board.

(5) A licensee shall ensure the label affixed to a prescription drug container is clearly printed by a computerized pharmacy system. In the event of printing or equipment failure, a prescription label may be legibly handwritten or typed during an emergency period not to exceed 48 hours.

(6) A pharmacy that provides bed-side delivery service of discharge prescriptions to patients in an inpatient healthcare facility must obtain patient consent to provide such services and may not restrict a patient's freedom of choice of pharmacy services. A pharmacy that provides bed-side delivery service shall deliver any medications directly to the patient or patient's agent.

(7) A licensee shall adhere to 105 CMR 721.060 when dispensing a controlled substance in Schedule II in an emergency situation.

(8) A pharmacist who refills a prescription for a controlled substance in Schedules III through VI shall record the following information in the computerized pharmacy system or on the written prescription:

(a) the date of dispensing;
(b) the amount of drug dispensed;
(c) his or her initials; and
(d) attestation to refilling controlled substance prescriptions in accordance with 21 CFR s. 1306.22.

(9) A prescription that has been filled or refilled shall be deemed to have been dispensed for the full face amount of the prescription, unless otherwise indicated in the computerized pharmacy system or on the written prescription.

(10) Whenever a prescription drug has been distributed solely under a generic name, the dispensing pharmacist shall record in the computerized pharmacy system the NDC number, the name of the manufacturer, or, if the manufacturer's name is not available, the name of the distributor, packer, or repacker.

(11) Only a pharmacist, pharmacy intern, or certified pharmacy technician who has the approval of the pharmacist on duty may receive new prescriptions over the telephone from a prescriber or authorized agent.

(12) A pharmacist or individual acting on behalf of a pharmacy may not collect prescriptions at industrial plants, places of business, or other sites where specific groups

of people are regularly employed or affiliated, unless the following requirements are met:

(a) the prescriptions are written for persons regularly employed at, or affiliated with, such plant, place of business, or other such site or the immediate family members living at the same address of persons regularly employed at, or affiliated with, such plant, place of business, or other such site;

(b) a pharmacist, pharmacy employee, or authorized agent of the pharmacy collects the prescriptions in person;

(c) a pharmacist, pharmacy employee, or authorized agent of the pharmacy dispenses the prescription medications directly to the patient or patient's agent;

(d) a pharmacist, pharmacy employee, or authorized agent of the pharmacy returns all prescription medications that he or she does not dispense directly to a patient or patient's agent to the pharmacy. Prescription medications may not be left or stored at the delivery location; and

(e) the pharmacist and pharmacy shall be responsible for the conduct of any pharmacy employee or authorized agent acting on the pharmacist's behalf.

(13) In order to determine whether a prescription is within date, the date the prescription was written or the "do not fill before" date shall not be counted. The last day of the period shall be counted.

(14) A pharmacy may not dispense any medication that was processed or verified outside its licensed pharmacy premises unless said process and verification was performed by an on-site Massachusetts registered pharmacist or performed in a pharmacy licensed by the Board.

(15) A pharmacist may not fill or dispense any prescription for a hydrocodone-only extended release medication that is not in an abuse deterrent form unless:

(a) the medication is stored in a securely locked and substantially constructed cabinet at all times while on pharmacy premises;

(b) the medication is dispensed in a container with a child proof safety cap or within a locked box;

(c) the prescriber has supplied a new Letter of Medical Necessity for each prescription that includes the patient's diagnoses and treatment plan, verifies other pain management treatments are inadequate, and indicates a risk assessment was performed and the prescriber and patient entered into a Pain Management Treatment Agreement or indicates that the prescriber has determined that a Pain Management Treatment Agreement is not clinically indicated due to the severity of the patient's medical conditions, and the pharmacist keeps the Letter of Medical Necessity in a readily retrievable manner;

(d) each prescription is accompanied by a written warning approved by the Board regarding the specific dangers of hydrocodone-only extended release medication that is not in an abuse deterrent form;

(e) the pharmacist provides counseling that includes a review of the written

warning supplied in accordance with 247 CMR 9.04(15)(d) and may include:

1. the name and description of the medication;
2. the dosage form, dosage, route of administration and duration of drug therapy;
3. special instructions and precautions for preparation, administration and use by the patient;
4. common adverse or severe side effects or interactions and therapeutic contraindications;
5. techniques for self-monitoring drug therapy;
6. proper storage;
7. prescription refill information;
8. action to be taken in the event of a missed dose; and
9. signs and symptoms of an acute overdose.

(f) the pharmacist reviews the patient's history on the online Prescription Monitoring Program and documents the results.

(16) A prescription for a Schedule VI medication is valid for one year from the date of issue. A licensee may not refill a Schedule VI prescription after one year. In the event that a prescription expires and the pharmacist is unable to obtain authorization in a timely manner the pharmacist in his or her professional judgment may dispense a quantity not to exceed seven days.

(17) Requirements for Positive Identification for Dispensing of a Controlled Substance in Schedule II through V:

(a) For the purposes of this section, Customer Identifier means the identification number on a valid government issued identification, as specified by the Department, which a licensee obtains by inspecting the identification of the ultimate user or agent of the ultimate user to whom a prescription is dispensed.

(b) A licensee shall require that a Customer Identifier be presented by the ultimate user or agent of the ultimate user to whom a prescription for a controlled substance in Schedules II through V, or a controlled substance classified as an additional drug in accordance with 105 CMR 700.012(A)(1) is dispensed.

(c) A licensee may dispense a controlled substance in Schedule II through V or an additional drug without requiring a customer identifier provided that:

1. the licensee has reason to believe that the failure to dispense the controlled substance or additional drug would result in a serious hardship for the ultimate user or agent of the ultimate user, and documents the reason; and
2. the ultimate user or agent of the ultimate user prints his or her name and address on the reverse side of the prescription or in an electronic or paper prescription log and signs his/her name thereto.

(d) The Commissioner may waive or modify the requirement for a customer identifier for prescription refills, prescription deliveries or other activities

specified in the PMP Data Entry and Data Submitters Guide.

~~(1) Whenever a prescription drug has been distributed solely under a generic name, the dispensing pharmacist shall record on the prescription the name of the manufacturer or, if the manufacturer's name is not available, the name of the distributor, packer, or repacker.~~

~~(2) The information on the label which the pharmacist, pharmacy intern, pharmacy technician or pharmacy technician trainee affixes to a prescription drug container shall be clearly printed or typed.~~

~~(3) Only a pharmacist, pharmacy intern, and certified pharmacy technician who has the approval of the pharmacist on duty may receive new prescriptions over the telephone from a prescriber or authorized agent.~~

~~(4) A pharmacist who refills a prescription for a controlled substance in Schedules III through VI shall record on the prescription:~~

~~(a) the date of dispensing;~~
~~(b) the amount of the drug dispensed; and~~
~~(c) his or her initials.~~

~~(5) A dispensing pharmacist who does not indicate the quantity of a drug dispensed on the back of a prescription which the pharmacist has refilled shall be deemed to have dispensed a refill for the full face amount of the prescription.~~

~~(6) Subject to the provisions of federal regulations at 21 CFR 1306, an automated data-processing system may be used as an alternative to the provisions of 247 CMR 9.04 (4) and (5). This data-processing system may be used for the storage and retrieval of information pertaining to the refilling of prescriptions for controlled substances in Schedules III through VI.~~

~~(7) A pharmacist or anyone acting on behalf of a pharmacy or pharmacy department shall not collect prescriptions at industrial plants, places of business, or other sites where specific groups of people are regularly employed or affiliated, unless the prescriptions meet the following requirements:~~

~~(a) the prescriptions are for persons regularly employed at, or affiliated with, such plant, place of business or other such site;~~
~~(b) the prescriptions are collected in person by a pharmacist, pharmacy employee, or authorized agent of the pharmacy;~~
~~(c) the prescriptions are distributed in person to the patients or an authorized agent of the patient by a pharmacist, pharmacy employee, or authorized agent of the pharmacy; and~~
~~(d) the pharmacist shall be responsible for the conduct of any pharmacy employee or authorized agent acting on the pharmacist's behalf, and for verifying the authority of any person purporting to act on a patient's behalf; nothing in 247 CMR 9.04(7) shall be deemed to permit conduct of a prescription business in violation of any other regulation of the Board.~~

~~(8) A pharmacist may not fill or dispense any prescription for a hydrocodone-only extended release medication that is not in an abuse deterrent form unless:~~

~~(a) the medication is stored in a securely locked and substantially constructed cabinet at all times while on pharmacy premises;~~

~~(b) the medication is dispensed in a container with a child proof safety cap or within a locked box;~~

~~(c) the prescriber has supplied a new Letter of Medical Necessity for each prescription that includes the patient's diagnoses and treatment plan, verifies other pain management treatments are inadequate, and indicates a risk assessment was performed and the prescriber and patient entered into a Pain Management Treatment Agreement or indicates that the prescriber has determined that a Pain Management Treatment Agreement is not clinically indicated due to the severityof the patient's medical conditions, and the pharmacist keeps the Letter of Medical Necessity in a readily retrievable manner;~~

~~(d) each prescription is accompanied by a written warning approved by the Board regarding the specific dangers of hydrocodone-only extended release medication that is not in an abuse deterrent form;~~

~~(e) the pharmacist provides counseling that includes a review of the written warning supplied in accordance with 247 CMR 9.04(8)(d) and may include, but is not limited to:~~

~~1. the name and description of the medication;~~

~~2. the dosage form, dosage, route of administration and duration of drug therapy;~~

~~3. special instructions and precautions for preparation, administration and use by the patient;~~

~~4. common adverse or severe side effects or interactions and therapeutic contraindications;~~

~~5. techniques for self-monitoring drug therapy;~~

~~6. proper storage;~~

~~7. prescription refill information;~~

~~8. action to be taken in the event of a missed dose; and~~

~~9. signs and symptoms of an acute overdose.~~

~~(f) the pharmacist checks the patient's history on the online Prescription Monitoring Program.~~

9.05: Interchangeable Drugs ~~of Prescription Files~~

(1) Medical Emergencies

(a) In a medical emergency a pharmacist may fill a prescription marked “no substitution” by dispensing a less expensive interchangeable drug product as allowed by the *Massachusetts List of Interchangeable Drugs* if the particular brand is not in stock; similarly, a pharmacist may fill a prescription not marked “no substitution” in a medical emergency by dispensing the brand name product as written if he or she has no less expensive interchangeable drug product in stock to be dispensed.

(b) In such instances, the pharmacist must record the date, hour, and nature of the medical emergency on the back of the prescription or in the computerized pharmacy system and the person purchasing the drug product must indicate acceptance of this deviation from the law in writing. All such prescriptions shall be clearly identifiable and available for review by the Board.

(2) Oral Prescriptions. Upon receiving an oral prescription for a brand name drug product, a pharmacist shall in ascertain whether or not the prescriber wishes "no substitution" to be marked on the prescription and record this information with all other required information in the computerized pharmacy system.

(3) Generic Prescriptions. Upon receiving a prescription for a generic name drug product with no manufacturer specified by the prescriber, a pharmacist may select, regardless of whether or not the prescriber has marked "no substitution" on the prescription, any legally marketed drug product whether or not it appears in the *Massachusetts List of Interchangeable Drugs*, in accordance with the prescriber's intent and the normal exercise of professional judgment.

(4) Labeling

(a) When a less expensive generic drug product has been dispensed, the words "interchange" plus the generic name and manufacturer of the product shall appear on the label in the following manner: "Interchange": (Generic name of less expensive drug product dispensed plus manufacturer)

(b) When a less expensive brand name drug product has been dispensed, the words "interchange" plus either the generic name and manufacturer of the product or the less expensive brand name dispensed shall appear on the label in the following manner: "Interchange": (generic name of less expensive brand drug plus manufacturer of brand name of less expensive drug product)

(c) In addition to the above, the brand name of the prescribed drug product may also appear on the label in the following manner: "Interchange": (name of less expensive generic drug product plus manufacturer or brand name drug product actually dispensed) for (brand name drug product dispensed)

(d) Abbreviations are permissible as long as they are understandable. For example, "IC" may be used for "interchange" and manufacturer's names may be abbreviated as shown in the *Massachusetts List of Interchangeable Drugs.*

(e) This section shall only apply to prescriptions dispensed by a retail pharmacy with a Drug Store Pharmacy License.

~~A pharmacist shall maintain prescription files as follows:~~

~~(1) Prescriptions for controlled substances in Schedule II shall be segregated from all other records and shall be maintained in a separate file identified as such.~~

~~(2) Prescriptions for controlled substances in Schedules III, IV, and V shall be maintained in a separate file identified as such.~~

~~(3) Prescriptions for controlled substances in Schedule VI, prescriptions for non-controlled substances, and prescriptions for syringes and instruments adaptable to hypodermic administration, shall be segregated from all other records and shall be maintained together in a separate file identified as such.~~

9.06: Opioid antagonists ~~for Verifying a Practitioner's Prescriptive Authority~~

(1) For purposes of this section:

(a) High overdose area shall mean a geographical area that appears on a list published by the Board, in consultation with the Department of Public Health, of areas with high incidence of opiate overdose.

(b) "Naloxone Pamphlet" shall mean a Board approved pamphlet that provides information about naloxone and responding to an overdose.

(c) Opioid antagonist shall mean naloxone or any other drug approved by the United States Food and Drug administration as a competitive narcotic antagonist used in the reversal of overdoses caused by opioids;

(d) Opioid Antagonist Training shall mean a training program approved by the Commissioner of the Department of Public Health, or the Commissioner's designee pursuant to M.G.L. c. 94C, § 19B(c).

(e) Standing order shall mean a written, standardized procedures or protocols developed by an actively practicing physician registered with the Commissioner of the Department of Public Health, if such procedures or protocols are filed at the pharmacist's place of practice and with the Board before implementation;

(2) High overdose area:

(a) A pharmacy located in a high overdose area shall maintain a standing order and a continuous supply of naloxone rescue kits or other Board approved opioid antagonists readily available for dispensing.

(b) A pharmacy that is not located a high overdose area may maintain a standing order and may dispense naloxone rescue kits or other Board approved opioid antagonists pursuant to a standing order or a prescription, provided that the pharmacy comply with all other provisions in this section.

(3) The pharmacist Manager of Record of a pharmacy that maintains a standing order shall:

(a) file the standing order with the Board upon obtaining it and yearly thereafter; and

(b) ensure that all pharmacists employed by the pharmacy have completed opioid antagonist training and demonstrate that they understand both the standing order and the "opioid antagonist information pamphlet."

(4) A pharmacist shall complete opioid antagonist training before dispensing a naloxone rescue kit or other Board approved opioid antagonist pursuant to a standing order.

(5) A pharmacy that dispenses a naloxone rescue kit or other Board approved opioid

antagonist shall provide counseling and the "Naloxone pamphlet" at the time of dispensing.

(6) A pharmacy that does not have a naloxone rescue kit or other Board approved opioid antagonist readily available for dispensing at the time requested shall refer the requestor to the nearest location that has a naloxone rescue kit or other Board approved opioid antagonist readily available.

(7) A pharmacy that assembles opioid antagonist rescue kits shall affix a label to the outer package noting "Opioid Antagonist Rescue Kit" and the expiration date, which shall be based on the expiration dated of the included naloxone hydrochloride unit.

~~A prescription written by a practitioner may be filled only if the pharmacist called upon to fill such prescription, in the exercise of that pharmacist's professional judgment, determines that:~~

~~(1) The prescription is issued pursuant to a valid patient/practitioner relationship and for a legitimate medical purpose by an authorized practitioner acting in the course of his or her professional practice;~~

~~(2) the prescription is authentic; and~~

~~(3) the dispensing is in accordance with M.G.L. c. 94C, § 19(a).~~

9.07: Daily Dosage Planners ~~Patient Records, Conducting a Prospective Drug Utilization Review and Patient Counseling~~

At the patient's or patient's agent's request a pharmacy and pharmacist may dispense medications in a daily dosage planner provided the following requirements are met:

(1) A pharmacy or pharmacist may not place any medication in a daily dosage planner that was previously dispensed by a different pharmacy.

(2) The pharmacy designates a space that allows for the orderly placement of equipment, materials, and medications, for the proper preparation of daily dosage planners, and for the prevention of cross-contamination.

(3) The pharmacy maintains policies and procedures pertaining to daily dosage planners that include cleaning, labeling, dispensing, and proper hand hygiene.

(4) The pharmacy cleans and stores daily dosage planners in a manner that prevents contamination to the pharmacy environment or specialty patient packaging.

(5) The pharmacy labels each daily dosage planner with all information required by M.G.L. c. 94C, § 21 for each medication.

(6) A pharmacist shall visually inspect and verify the contents of a daily dosage planner prior to dispensing.

~~The purpose of 247 CMR 9.07 is to enhance the public health and welfare by requiring that pharmacists offer consultation to patients regarding their prescriptions in order to promote optimum therapeutic outcomes, avoid patient injury and reduce medication errors.~~

~~(1) Patient Records.~~

~~(a) A pharmacist or pharmacist's designee shall maintain a confidential record for all patients for whom prescriptions are dispensed. The patient record system shall provide for the immediate retrieval of information necessary for the pharmacist to identify previously dispensed drugs at the time the prescription is presented for dispensing. The pharmacist or pharmacist's designee shall make a reasonable effort to obtain, record and maintain the following information:~~

~~1. name, address, telephone number, date of birth or age, and gender of the patient for whom the prescription is intended;~~

~~2. individual history, including known drug allergies and drug reactions;~~

~~3. a comprehensive list of medications and relevant devices dispensed by the pharmacy; and~~

~~4. the pharmacist's comments relevant to the patient's drug therapy.~~

~~(b) A pharmacist shall maintain the patient's record for a period of not less than 12 months from the date of the last entry in the profile record, except as otherwise required by state and federal law. This record may be computerized.~~

~~(2) Prospective Drug Utilization Review.~~

~~(a) A pharmacist shall conduct a prospective drug utilization review ("DUR") before each new prescription is dispensed or delivered to a patient or a person acting on behalf of the patient. This DUR may include a review of the patient record and each new prescription presented for dispensing, for the purpose of promoting therapeutic appropriateness, by making a reasonable effort to identify the following:~~

~~1. over-utilization or under-utilization;~~

~~2. therapeutic duplication;~~

~~3. drug-disease contraindication;~~

~~4. drug-drug interaction;~~

~~5. incorrect drug dosage or duration of drug treatment;~~

~~6. drug-allergy interactions;~~

~~7. clinical abuse or misuse; and~~

~~8. any significant change in drug, dose or directions.~~

~~(b) Upon identifying any of the above, the pharmacist shall take appropriate measures to ensure the proper care of the patient which may include consultation with the prescribing practitioner and/or direct consultation with the patient.~~

~~(c) The review shall be based upon current standards which may include the following:~~

1. The American Hospital Formulary Service Drug Information;
2. the United States Pharmacopoeia Drug Information;
3. the American Medication Association Drug Evaluations; and
4. other peer-reviewed medical literature.

(3) Patient Counseling.

(a) The pharmacist or pharmacist's designee shall offer the services of the pharmacist to discuss, with all persons presenting new prescriptions, issues that in the pharmacist's professional judgment are deemed to be significant for the health and safety of the patient.

(b) The pharmacist's designee shall be an individual appropriately trained to make the offer to counsel and under the direct supervision of the pharmacist.

(c) A sign of not less than 11 inches in height by 14 inches in width shall be posted in a conspicuous place, adjacent to the area where prescriptions are dispensed, informing customers of their rights, pursuant to 247 CMR 9.07 and to M.G.L. c. 94C, § 21A, to counseling by a pharmacist where their prescription was filled. Said sign shall read, in letters not less than ½ inch in height: "Dear patients, you have the right to know about the proper use of your medication and its effects. If you need more information please ask the pharmacist."

(d) When the offer to counsel is accepted, the pharmacist shall provide such information which, in the pharmacist's professional judgment, is necessary for the patient to understand the proper use of the patient's prescription which may include the following:

1. Name and description of the medication;
2. dosage form, dosage, route of administration and duration of therapy;
3. special directions and instructions for preparation, administration and use by the patient;
4. common severe side and adverse effects or interactions and therapeutic contraindications or precautions with legend and non-legend medications which the pharmacist deems relevant;
5. techniques for self-monitoring drug therapy;
6. proper storage;
7. prescription refill information; and
8. action to be taken in the event of a missed dose or adverse reaction.

(e) The offer to counsel shall be made to the patient, or the person acting on behalf of the patient when confidentiality can be maintained, either by face to face communication or telephone. If the patient does not pick up the prescription at a pharmacy or the offer is not made by telephone then the offer must be made in writing. This offer must provide a toll-free telephone service to facilitate communication between such person and the pharmacist and must state the following: "Dear patient, you have the right to know about the proper use of your medication and its effects. If you need more information please ask the pharmacist". Printed material containing information on the drug may accompany this written offer to counsel provided the patient is informed that said information

~~is not comprehensive and that the patient should call for further information if needed.~~

~~(f) Counseling must be made by a pharmacist, or a pharmacy intern under the direct supervision of the pharmacist if deemed appropriate by the pharmacist.~~

~~(g) Counseling must be available at all times when a pharmacy is open for business.~~

~~(h) The provisions of 247 CMR 9.07 shall apply to pharmacists who directly dispense medications to outpatients and patients being discharged from hospitals, institutions and clinics.~~

~~(i) The provisions of 247 CMR 9.07 shall not apply to any drug dispensed to an inpatient at a hospital, nursing home or any other setting where medication is administered by an authorized individual, except to the extent required by the Federal Health Care Financing Administration pursuant to the provisions of 42 USC 1396r-8.~~

9.08: Specialty Packaging

(1) A pharmacy or pharmacist may utilize specialty packaging, including oral-liquid-single-dose packaging, single-drug-single-dose packaging, and multi-drug-single-dose packaging provided the following requirements are met:

(a) The pharmacy designates a space that allows for the orderly placement of equipment, materials, and medications, for the proper preparation of the specialty packaging, and for the prevention of cross contamination.

(b) The pharmacy maintains policies and procedures pertaining to each type of specialty packaging utilized that include cleaning, labeling, dispensing, proper hand hygiene, quarantine, and reverse distribution.

(c) The specialty packaging does not conflict with the USP-DI monograph or FDA-approved labeling.

(d) The medications are compatible with packaging components and with each other.

(e) The specialty packaging is designed to prevent the container from being re-closed, to show evidence of having been opened, and in such a manner that the label cannot be altered or removed.

(f) A pharmacist shall visually inspect and verify the contents of each specialty package prior to dispensing.

(g) A licensee may not place a quantity of drugs in specialty packaging that exceeds the capacity of the container or that may cause damage to the individual dosage forms.

(2) Oral-Liquid-Single-Dose

(a) A licensee may not dispense a medication in an oral-liquid-single-dose package unless the package has a child proof safety cap.

(b) A licensee may not place more than one commercially available medication into an oral-liquid-single-dose package unless compounded pursuant to a prescription.

(3) Single-Drug-Single-Dose Packaging

(a) A pharmacy or pharmacist may utilize single-drug-single-dose packaging for medications in Schedules II – VI.

(b) If a pharmacy or pharmacist places a medication in a single-drug-single-dose package prior to the receipt of a patient specific prescription, the pharmacy and pharmacist shall properly label the package and utilize a bar-code scanning or similar technology to ensure proper identification of the pre-packaged medication at the time of dispensing.

(4) Multi-Drug-Single-Dose Packaging

(a) A licensee may not dispense more than a 34 day supply of medication in a multi-drug-single-dose package.

(b) A licensee may not dispense Schedules II or III controlled substances in a multi-drug-single-dose package.

(c) A licensee may not dispense medications to be taken on an as needed basis in a multi-drug-single-dose package.

(d) A licensee may not dispense a Schedule IV or V controlled substance in a multi-drug-single-dose package unless the medication is prescribed for maintenance therapy.

(5) Return and Repackaging of Multi-Drug-Single-Dose Packaging

(a) A pharmacy or pharmacist may accept a return of a multi-drug-single-dose package that the pharmacy previously dispensed to a patient for the purpose of repackaging and re-dispensing to that same patient.

(i) If a patient's medication was discontinued, a pharmacy may remove the discontinued drug(s) from the multi-drug-single-dose package and re-dispense the remaining medications in the multi-drug-single-dose package to the same patient.

(ii) If a patient's drug therapy changed, a pharmacy may remove the discontinued drug(s) from the multi-drug-single-dose package(s) and may add a new medication(s) to the multi-drug-single-dose package and re-dispense the multi-drug-single-dose package to the same patient.

(iii) A pharmacy shall label the multi-drug-single-dose package in accordance with 247 CMR 9.08(6) prior to re-dispensing.

(iv) A pharmacy shall implement policies and procedures pertaining to security and accountability of controlled substances during return and repackaging.

(b) A licensee may not return any medication removed from a multi-drug-single-dose package to inventory. A licensee may not dispense any medication removed from a multi-drug-single-dose package to any patient other than the patient who returned the multi-drug-single-dose package.

(c) A pharmacy shall maintain a record that accounts for and documents any repackaging, removal, or re-dispensing of any medication it previously dispensed in a multi-drug-single-dose package. The record shall identify the pharmacist.

(6) A pharmacy and pharmacist shall label each oral-liquid-single dose, single-drug-single-dose, and multi-drug-single-dose package with the following information:

(a) information required by M.G.L. c. 94C, § 21 for each medication in the package;

(b) the name, strength, physical description, and total quantity of each drug dispensed;

(c) the dispensing or preparation date and a beyond-use date, which may not exceed the shortest expiration date on the original manufacturer's container or 90 days, for each drug contained in a multi-drug-single-dose package; and

(d) the telephone number of the pharmacy.

(7) If a cell is removable, a pharmacy shall label a multi-drug-single-dose package with a label of sufficient size to properly and clearly label each cell with each drug name and strength.

9.09: Emergency Medication Kits

(1) A pharmacy shall maintain a policy and procedure for the proper dispensing of emergency medication kits that includes labeling, verification by a registered pharmacist, expiration date checking, restocking, and cleaning of the container.

(2) A pharmacist, pharmacy intern, or pharmacy technician shall prepare, package, and seal emergency medication kits.

(3) An emergency medication kit shall contain a list of contents on the outside cover and within the box. Each emergency medication kit shall have a label on the outside cover that states the earliest expiration date of the medications in the kit.

(4) A pharmacy shall reconcile used emergency medication kits with prescriptions or orders.

(5) A pharmacy and pharmacist shall fill Emergency Medication Kits for Long Term Care Facilities in accordance with 105 CMR 150.008(E).

9.10: Automated Pharmacy Systems

(1) A pharmacy may dispense Schedule VI controlled substances for refill prescriptions from an Automated Pharmacy System ("APS") to a patient or a patient's agent during or after pharmacy hours of operation provided the following requirements are met:

(a) The APS is located within 20 feet of the pharmacy.

(b) The APS is secured against or within a wall or floor in a manner that prevents unauthorized access and removal.

(c) The APS is monitored by video surveillance.

(d) The pharmacy notifies the Board in writing of its intent to use an APS. The notification shall include:
1. the name and address of the pharmacy;
2. APS hours of operation;
3. type of APS system; and
4. a description of how the APS system is to be used.

(e) The APS maintains the following electronic data for each prescription it dispenses:
1. name of the pharmacy;
2. name of the patient;
3. name of the prescriber;
4. prescription number;
5. name, strength, dosage form, and quantity of the drug dispensed;
6. date and time of dispensing;
7. identity of the pharmacist who verified the prescription; and
8. identity of the person to whom the drug was released.

(f) The pharmacy provides the patient an opportunity for a pharmacist consultation during all hours that the APS is in operation for dispensing.

(g) The pharmacy allows the patient to choose whether or not to use an APS.

(2) A pharmacy with an APS shall maintain policies and procedures that include:
(a) the name and address of the pharmacy where APS is used;
(b) the APS manufacturer's name, model, serial number, and other identifying information;
(c) a description of how the APS is used by the pharmacy;
(d) quality assurance procedures;
(e) APS operation, safety, security, accountability, accuracy, patient confidentiality, and access;
(f) procedures to be followed in the event of a malfunction, including that any malfunction is immediately reported to the pharmacist on duty;
(g) procedures to identify, analyze, and report each dispensing error, in accordance with 247 CMR 20.00; and
(h) stocking the APS.

(3) A pharmacy shall ensure the stocking and return of all prescription medications in the APS occurs in the following manner:
(a) a pharmacist, pharmacy intern, or certified pharmacy technician stocks and returns prescription medications;
(b) the APS, pharmacist, pharmacy intern, or certified pharmacy technician records all stocking and return activities, including the identification of each person who accessed the APS;
(c) the pharmacy may not stock medications in an APS that require refrigeration or reconstitution;
(d) the APS utilizes two separate verifications, such as bar code verification, electronic verification, weight verification, radio frequency identification (RFID), or another similar process, to ensure that the proper medication is

dispensed from the system.

9.11: Pharmacy Processing Automation

(1) A pharmacy may utilize Pharmacy Processing Automation ("PPA") to count, fill vials or specialty packages, and label, provided the following requirements are met:

(a) a pharmacist, pharmacy intern, or certified pharmacy technician stocks the PPA;

(b) a pharmacist verifies the stocking of the PPA;

(c) the PPA, pharmacist, pharmacy intern, or certified pharmacy technician records all stocking and return activities, including the identification of each person who accessed the PPA;

(d) the PPA utilizes two separate verifications, such as bar code verification, electronic verification, weight verification, radio frequency identification (RFID), or another similar process, to ensure that the proper medication is dispensed from the system;

(e) Schedule II controlled substances are not stocked in or dispensed from a PPA;

(f) the PPA prevents unauthorized access by utilizing passwords, biometric scanning, or other coded identification; and

(g) lot numbers are not comingled in a single cell.

(2) The pharmacist manager of record or ~~/~~ or her designee shall have sole responsibility to assign, discontinue, or change access to the PPA.

(3) The pharmacy shall implement and maintain policies and procedures pertaining to the PPA that include:

(a) system access;

(b) controlled substance accountability;

(c) routine cleaning and maintenance of the PPA and measures to prevent cross-contamination;

(d) documentation of lot numbers and expiration dates of each medication added to the PPA in order to respond to recalls in the event lots are comingled; and

(e) responding to a recall event.

9.12: Automated Dispensing Devices

(1) Unless otherwise prohibited by law, a pharmacy may dispense controlled substances from an automated dispensing device ("ADD") located in a health care facility, provided it satisfies the following:

(a) The ADD only dispenses controlled substances for immediate administration to inpatients and outpatients of the health care facility pursuant to a valid prescription or medication order.

(b) The ADD appropriately stores, secures, and accounts for controlled substances.

(c) The ADD limits access to authorized individuals;

(2) A pharmacy shall establish and maintain policies and procedures pertaining to ADDs that include use, access, quality assurance, accountability, accuracy, security, and patient confidentiality.

(3) A pharmacy shall maintain in a readily retrievable manner an accurate record of all the controlled substances that are delivered to an ADD prior to and after loading in the machine.

(4) The Pharmacist manager of record or pharmacist designee shall review user access reports at least quarterly.

(5) A pharmacist, pharmacy intern, or certified pharmacy technician shall verify the inventory provided for loading or loaded into the ADD is correct.

(6) A registered pharmacy technician or technician in training may not load controlled substances in schedules II – V into the automated dispensing device.

(7) Medications returned to the ADD return bin or returned to the pharmacy shall be verified by a pharmacist prior to reloading into the ADD dispensing compartment.

(8) Unless an emergent or urgent need exists, a pharmacist shall review medication orders and prescriptions prior to removal of any controlled substances from an automated dispensing device. In the case of removal of medications for emergent or urgent need, a pharmacist shall review the order within 24 hours.

(9) A pharmacy shall maintain a listing of all locations of ADDs that it operates. This listing shall be readily retrievable and retained for at least two years.

9.13: Return to Stock

(1) In the event a pharmacy fills and prepares a prescription but the patient does not pick up the medication, the pharmacy may return the medication to stock. A pharmacy shall ensure the following conditions are satisfied if it returns a medication to stock:

(a) A pharmacy may not return a medication to the manufacturer's stock bottle or PPA. A pharmacy shall keep a medication to be returned to stock in the original patient container or place medication an appropriate container and shall affix a label to the container containing the following information:

1. product name;
2. strength or concentration;
3. name of the manufacturer, supplier, or NDC number; and
4. the expiration date assigned at the time of filling;

(b) Only a pharmacist, pharmacy intern, or pharmacy technician may return medications to stock. A pharmacist shall verify any return to stock

performed by a pharmacy intern or pharmacy technician. A pharmacy technician in training may not return a medication to stock. A pharmacy technician may not return a Schedule II medication to stock.

(2) A pharmacy shall maintain a policy and procedure regarding returning medications to stock.

(3) In the event of a recall, a pharmacy may not dispense any medication that has been returned to stock and is potentially subject to the recall unless it can confirm the specific lot number is not included the recall.

9.14: Transfer of Prescriptions

(1) A pharmacy shall transfer a prescription to another pharmacy, at the request of a patient or his/ or her agent, in a timely manner so as not to delay patient therapy, if the following conditions are met:

(a) the pharmacy has not yet dispensed the initial prescription for Schedule VI medication or refills remain on a prescription for Schedule III, IV, V, or VI medication;

(b) the prescription has not expired; and

(c) the transfer is not otherwise prohibited by law.

The transferee pharmacy may act as the patient's agent in order to facilitate a transfer.

(2) A pharmacy that transfers a prescription shall maintain the original prescription for at least two years from the date of the last transfer.

(3) A pharmacy that receives a transferred prescription shall maintain the transferred prescription for at least two years from the date of last refill.

(4) A pharmacy may not charge a fee for transferring a prescription.

(5) In order to transfer a prescription in Schedules III, IV, or V, the transferring pharmacist or pharmacy intern shall:

(a) Document the transfer and invalidate the original prescription in the computerized pharmacy system or by writing the word "void" on prescription;

(b) Record in the computerized pharmacy system or on the reverse side of the invalidated prescription the name, address, and DEA registration number of the pharmacy receiving the transfer and the name of the pharmacist receiving the prescription information;

(c) Record in the computerized pharmacy system or on a transfer log, the prescription number, if applicable, date of the transfer, name of the pharmacist transferring the prescription, and the name of the pharmacy receiving the prescription; and

(d) Cancel all refills remaining on the transferred prescription at the original pharmacy.

(6) A licensee may not transfer a Schedule III, IV, or V prescription if that prescription was previously transferred.

(7) In order to transfer a prescription in Schedule VI, the transferring pharmacist, pharmacy intern, or certified pharmacy technician shall:

(a) Record in the computerized pharmacy system or in a transfer log the following information:

1. the prescription number;
2. date of the transfer;
3. the name or identification of the pharmacist transferring the prescription; and
4. the name of the pharmacy to which the prescription is transferred.

(b) Cancel all refills remaining on the transferred prescription.

(8) A licensee may not transfer a prescription authorizing refills for Schedule VI controlled substances more than one year from the date the prescription was issued.

(9) A pharmacist or pharmacy intern who receives a transferred prescription in Schedule III, IV, V, or VI shall:

(a) Document the transfer in the computerized pharmacy system or by writing the word "transfer" on the face of the transferred prescription; and

(b) Record in the computerized pharmacy system or by writing on the prescription the following information:

1. the date of issuance of the original prescription;
2. the number of refills authorized on the original prescription;
3. the date of original dispensing;
4. the number of valid refills remaining and date of last refill; and
5. the pharmacy's name, address, DEA number and original prescription number from which the prescription information was transferred; and the name of the transferor pharmacist.

(c) Inform the patient that the prescription's refills were canceled at the pharmacy from which it was transferred.

9.15: Verifying a Practitioner's Prescriptive Authority

(1) A pharmacist who is eligible to register for the Massachusetts Prescription Monitoring Program ("PMP") shall register with and maintain login information for PMP.

(2) A pharmacist may not fill a prescription unless the pharmacist, in the exercise of his or her professional judgment, determines that:

(a) the prescription was issued for a legitimate medical purpose by a practitioner acting in the usual course of his or her professional practice;

(b) there is a valid patient-practitioner relationship;

(c) the prescription is authentic; and

(d) the dispensing is in accordance with M.G.L. c. 94C, § 19(a).

(3) A pharmacy shall maintain a policy and procedure pertaining to verifying a practitioner's prescriptive authority.

9.16: Maintenance of Prescription Files

(1) A pharmacist and pharmacy shall maintain prescription files, purchasing and return records, and disposal and destruction records in a readily retrievable manner for at least two years.

(2) Prescriptions for Schedule II controlled substances shall be segregated if maintained in paper format, electronically separable if maintained in electronic format, and available at the time of an inspection.

(3) Prescriptions for Schedule III, IV, and V controlled substances shall be segregated if maintained in paper format, electronically separable if maintained electronic format, and available at the time of an inspection.

(4) Prescriptions for Schedule VI controlled substances shall be segregated if maintained in paper format, electronically separable if maintained in electronic format, and available at the time of an inspection.

(5) A pharmacy shall be able to print copies of electronic prescriptions.

(6) A pharmacist and pharmacy shall maintain a confidential patient profile for each patient to whom a prescription is dispensed. The computerized pharmacy system shall provide for the immediate retrieval of information necessary for the pharmacist to identify previously dispensed drugs at the time the prescription is presented for dispensing. The pharmacist or pharmacist's designee shall make a reasonable effort to obtain, record, and maintain the following information:

(a) name, address, email address, telephone number, date of birth or age, and gender of the patient for whom the prescription is intended;
(b) patient history, including known drug allergies and drug reactions;
(c) a comprehensive list of medications and relevant devices dispensed by the pharmacy; and
(d) the pharmacist's comments relevant to the patient's drug therapy.

9.17: Prospective Drug Utilization Review

(1) A pharmacist shall conduct a prospective drug utilization review ("DUR") before each new prescription or medication order is dispensed or delivered to a patient or a patient's agent. The DUR may include a review of computerized alerts, the patient record, and each new and renewed prescription or medication order for the purpose of promoting therapeutic appropriateness, by making a reasonable effort to identify the

following:

(a) over-utilization or under-utilization;
(b) therapeutic duplication;
(c) drug-disease contraindication;
(d) drug-drug interaction;
(e) drug-food interaction;
(f) incorrect drug dosage or duration of drug treatment;
(g) drug-allergy interactions;
(h) abuse or misuse;
(i) any significant change in drug, dose, or directions; and
(j) any age related contraindications.

(2) Upon identifying any of the above, a pharmacist shall take appropriate measures to ensure the proper care of the patient which may include consultation with the prescribing practitioner or direct consultation with the patient or patient's agent. A pharmacist shall document any measures taken in response to a drug utilization review.

(3) The DUR shall be based upon current standards which may include the following:

(a) the American Hospital Formulary Service Drug Information;
(b) the United States Pharmacopoeia Drug Information;
(c) the American Medical Association Drug Evaluations;
(d) Plumb's Veterinarian Reference; and
(e) other peer-reviewed medical literature.

(4) The DUR shall include a review of the patient's active prescription medication profile within the preceding ~~(~~) months.

(5) The DUR shall include any over-the-counter medication, herbal medicine, or nutritional supplement that is included in the patient profile or disclosed to the pharmacist or pharmacy by the patient or patient's agent.

9.18: Patient Counseling

(1) A pharmacist or pharmacist's designee shall offer the counseling services of the pharmacist to each person who receives a prescription medication.

(2) A pharmacist shall ensure his/her designee is appropriately trained to make the offer to counsel and under the direct supervision of the pharmacist.

(3) Counseling shall be made by a pharmacist or a pharmacy intern. A pharmacy technician or other individual may not counsel any patient.

(4) A pharmacist or pharmacy intern shall provide counseling on each new drug therapy and each drug therapy that in the pharmacist's professional judgment is deemed to be significant for the health and safety of the patient.

(5) When counseling a patient, a pharmacist or pharmacy intern shall provide such information which, in the pharmacist's professional judgment, is necessary for the patient to understand the proper use of the patient's prescription which may include the following:

(a) name, description, and indication of the medication;
(b) dosage form, dosage, route of administration and duration of therapy;
(c) special directions and instructions for preparation, administration, and use by the patient;
(d) common side and adverse effects or interactions and therapeutic contraindications or precautions with legend and non-legend medications and other substances which the pharmacist deems relevant;
(e) techniques for self-monitoring drug therapy;
(f) proper storage and disposal;
(g) prescription refill information; and
(h) action to be taken in the event of a missed dose or adverse reaction.

(6) A pharmacy shall have a designated patient consultation area, with signage stating "Patient Consultation Area," designed to provide adequate privacy for confidential visual and auditory patient counseling. The private consultation area shall be accessible by a patient from the outside of the prescription dispensing area without having to traverse a stockroom or the prescription dispensing area.

(7) A pharmacy shall post sign of not less than 11 inches in height by 14 inches in width in a conspicuous place, adjacent to each area where prescriptions are dispensed, for the purpose of informing customers of their right to counseling by a pharmacist. Said sign shall read, in letters not less than ½ inch in height: "Dear patients, you have the right to know about the proper use of your medication and its effects. If you need more information please ask the pharmacist."

(8) A pharmacist or pharmacist's designee shall maintain patient confidentiality when counseling and making the offer to counsel.

(9) A pharmacy and pharmacist shall ensure counseling is available at all times when a pharmacy is open for business.

(10) The provisions of 247 CMR 9.18 do not apply to pharmacists while practicing in an inpatient setting, unless otherwise required by law or regulation.

9.19: Pharmacy Operation

(1) A pharmacy shall maintain the following on the pharmacy premises:

(a) a current copy or electronic version of the *Massachusetts List of Interchangeable Drugs*, including the Orange Book, Additional List, Exception List;
(b) a current copy or access to electronic version with quarterly updates of a

compendia appropriate to the practice setting approved by the pharmacist manager of record;

(c) a current copy or access to electronic version of laws and regulations governing the practice of pharmacy, including, M.G.L. c. 94C, M.G.L. c. 112, §§ 24 – 42A, 105 CMR 700.000, 105 CMR 720.00, and 105 CMR 721.00, and 247 CMR 2.00 – 21.00;

(d) a current copy or access to electronic version of Plumb's Veterinarian Reference or other veterinary reference approved by the Board;

(e) a balance capable of accurately weighing quantities as small as 10 milligrams, which shall be tested and sealed by the state or local sealer of weights and measures at least once every year. All new balances shall have "legal for trade" designation;

(f) the equipment, supplies, and medications necessary to conduct the practice of pharmacy in accordance with the usual needs of the community and scope of practice of the pharmacy;

(g) the equipment necessary to perform simple and moderate non-sterile compounding;

(h) policies and procedures to ensure supplies, tools, utensils, and equipment are used and maintained in a manner that avoids cross contamination and ensures accuracy;

(i) a potable water supply in or near the prescription area in order to wash hands and equipment. The sink shall have hot and cold water, soap or detergent, and single use towels;

(j) a designated compounding area for simple and moderate non-sterile compounding; and

(k) dedicated equipment for highly cross-sensitive medications and hazardous drugs.

(2) A pharmacy that obtained its Drug Store pharmacy license prior to July 1, 2015 shall have a prescription area that is at least 300 square feet. A pharmacy that obtained its Drug Store pharmacy license on or after July 1, 2015 shall have a prescription area that is at least 325 square feet.

(3) A pharmacy shall ensure the accuracy and performance of electronic counting machines for solid dosage forms and other electronic measuring devices are certified at least once every two years by a qualified vendor.

(4) The prescription area shall provide for the arrangement and storage of drugs, supplies, and equipment that is calculated to prevent their accidental misuse and that:

(a) stores products intended solely for animal use in a designated area;

(b) stores hazardous drugs in a designated area;

(c) separates ophthalmic from otic medications;

(d) quarantines products subject to recall, return, or disposal with proper storage and security;

(e) identifies high alert high risk drugs and look alike sound alike drugs as identified by ISMP; and

(f) separates internal from external use medications.

(5) A pharmacy shall store medications in the manufacturer's stock bottles or in containers that are clearly labeled with the product name, strength or concentration, NDC number, manufacturer or supplier, lot number, expiration date, and date that the medication was transferred out of its original stock bottle.

(6) A pharmacy shall be clean and sanitary and in good repair at all times.

(7) Pharmacy equipment shall be clean and sanitary and in good repair at all times.

(8) A pharmacy in Massachusetts shall conspicuously display within the pharmacy:
(a) the pharmacy's Massachusetts Drug Store pharmacy license;
(b) other pharmacy license issued by the Board, as applicable;
(c) the pharmacy's Massachusetts controlled substance registration; and
(d) the pharmacy's U.S. Drug Enforcement Administration registration.

A non-resident pharmacy shall maintain the documents identified in 247 CMR 9.19(8) in a readily retrievable manner.

(9) A pharmacy shall post on the wall or maintain the following in readily retrievable location:
(a) immunization certifications and current CPR card for each pharmacist and pharmacy intern that perform immunizations;
(b) current power of attorney ("POA") forms required for DEA 222C forms, as applicable;
(c) Collaborative Drug Therapy Management Agreements;
(d) written finding from the Board waiving any Board regulations; and
(e) standing orders, if any.

(10) A pharmacy shall have a sign affixed to each customer entrance that is easily observable from the outside and clearly identifies the presence of a pharmacy.

(11) A pharmacy shall conspicuously display, in legible letters not less than one inch high, over, on, or adjacent to the main entrance of the pharmacy, the name of the pharmacist Manager of Record and whether the pharmacy is a sterile compounding pharmacy or complex non-sterile compounding pharmacy.

(12) A pharmacy shall effectuate a recall of medication that is or may be defective in any way.

(13) A pharmacy shall obtain and document consent from a patient or patient's agent prior to enrolling that patient in an automatic refill program. A pharmacy may not include any drug with a Narrow Therapeutic Index in an automatic refill program.

(14) A pharmacy shall meet the following requirements concerning the posting of

hours of operation:

(a) The hours of operation shall be prominently posted at all consumer entrances to the pharmacy and, in the case of a pharmacy located within a retail establishment, the hours shall also be posted at all consumer entrances to the retail store and at the pharmacy; and

(b) if the hours of operation of a pharmacy located within another retail establishment are different from those of the retail establishment, all advertising referring to the pharmacy shall clearly specify the pharmacy's hours of operation.

(15) A pharmacy shall maintain a written continuity of care plan that describes the manner in which patient needs will be met in the event the pharmacy is unexpectedly unable to provide pharmacy services. The pharmacy shall notify the Board if pharmacy operations are unexpectedly suspended fore more than 24 hours.

(16) Registered Pharmacists on Duty

(a) A registered pharmacist shall be on duty and on the pharmacy premises at all times the pharmacy is open for business and shall be present at all times when non-pharmacist personnel have unrestricted access to the pharmacy.

(b) While on duty, a pharmacist shall:

(i) ensure compliance with supervisory ratios in accordance with 247 CMR 8.06;

(ii) maintain proper storage and security of controlled substances;

(iii) report problems with sanitary conditions or good repair to Manager of Record;

(iv) limit access to all pharmacy areas to authorized personnel;

(v) be familiar with applicable Board approved audit tool(s); and

(vi) have access to all pharmacy records and be able to provide requested records to Board investigators.

(17) Temporary Absence of a Pharmacist

(a) In any pharmacy that is staffed by a single pharmacist, the pharmacist may leave the pharmacy prescription area temporarily for necessary and appropriate breaks and meal periods without closing the pharmacy or removing ancillary staff from the pharmacy if the pharmacist reasonably believes that the security of the controlled substances and devices will be maintained in his or her absence. A pharmacist must remain on the pharmacy premises, but is not required to remain in the prescription area. A temporary absence shall not exceed 30 minutes per six hours.

(b) During a pharmacist’s temporary absence, a pharmacy may not provide any prescription medication to a patient or a patient’s agent unless the prescription is a refill medication that the pharmacist has checked and determined not to require the consultation of a pharmacist prior to being released to the patient. A new prescription which has been previously prepared, visibly checked by a pharmacist, and had a drug utilization

performed by a pharmacist, may be picked up by a patient provided that a log, including the patient's phone number, of all such transactions is kept. The pharmacist upon return from break and within a reasonable time shall call the patient to review any pertinent counseling deemed appropriate.

(c) During a pharmacist's temporary absence, the pharmacy technical support staff may continue to perform the non-discretionary duties. However, any duty performed by any member of the ancillary staff shall be reviewed by a pharmacist upon his or her return to the pharmacy.

(d) In pharmacies where there are two or more pharmacists on duty, the pharmacists shall stagger their breaks and meal periods so that the pharmacy is not left without a pharmacist for a temporary period.

(e) A pharmacy shall maintain written policies and procedures regarding the operation of the pharmacy during the temporary absence of a pharmacist.

(18) Upon commencement of the employment of a registered pharmacist, pharmacy intern, pharmacy technician, or other licensed health care provider, the pharmacy shall verify that the individual's license to practice is current.

(19) A pharmacy shall store and dispose of waste in a sanitary and timely manner.

(20) A pharmacy shall maintain an e-Profile Number from the National Association of Boards of Pharmacy ("NABP") or other national database, as required by the Board.

(21) A pharmacy shall perform a self-inspection within seven days of any renovation, expansion, relocation, or change of Manager of Record, and at least one time per year, utilizing a Board-approved inspection tool for routine compliance, sterile compounding, and non-sterile compounding, as applicable. The pharmacy shall retain the completed self-inspection tool for at least two years.

(22) A pharmacy shall maintain a readily accessible policy and procedure for computer downtime which shall include:

(a) a process for filling prescriptions during downtime;

(b) a process for ensuring prescriptions dispensed during computer downtime are duly recorded in the patient's medication profile of the computerized pharmacy system when it becomes operational;

(c) continuity of care, if necessary; and

(d) process for performing an appropriate drug utilization review.

(23) The requirements of 247 CMR 9.19(2), (12), (15), and (18) do not apply to non-resident pharmacies.

9.20: Non-Resident Pharmacies

A non-resident pharmacy shall comply with all Massachusetts laws and regulations governing the practice of pharmacy when filling, dispensing, or shipping medications into Massachusetts.

9.21: Security of Controlled Substances

(1) A pharmacy shall store all controlled substances within the secured prescription area and in a safe and secure manner.

(2) A pharmacy shall store Schedule II controlled substances in a securely locked and substantially constructed cabinet and in such a manner as to obstruct theft and diversion.

(3) A pharmacy shall store Schedules III, IV, and V controlled substance in a securely locked and substantially constructed cabinet or dispersed throughout the stock of Schedule VI controlled substances and in such a manner as to obstruct theft and diversion.

(4) A pharmacy shall maintain a centrally monitored security system that is able to detect a breach in security and is designed to prevent theft. A pharmacy shall activate the security system when the pharmacy is closed.

(5) A pharmacy shall maintain surveillance cameras in a manner designed to record theft and diversion of controlled substances. A pharmacy shall retain video records for at least 30 days or, in the case of known or suspected theft or diversion, at least two years.

(6) A pharmacy that is located within another retail establishment shall be secured by a floor to ceiling barrier, securely locked and separately alarmed at all times when the pharmacy is closed.

(7) The pharmacist Manager of Record and the pharmacist on duty are responsible for pharmacy security and shall control access to the prescription area.

(8) All drug order deliveries containing controlled substances shall be delivered directly to the pharmacy.

(10) Schedule II Perpetual inventory

(a) A pharmacy and pharmacist shall maintain a perpetual inventory of each controlled substance in Schedule II which the pharmacy has received, dispensed, or disposed of. The perpetual inventory may be in a hard copy, written format or in an electronic format. The perpetual inventory shall reflect the amount of each Schedule II controlled substance that is located on the pharmacy premises.

(b) The perpetual inventory record shall include the names and strengths of each Schedule II control substance, quantity of each drug purchased or added to inventory, starting inventory, prescription numbers, dispensed quantity, remaining balance, and pharmacist identification for each transaction.

(c) A pharmacy shall reconcile the perpetual inventory for each Schedule II controlled substance at least once every ten days by performing an

accurate physical count of inventory on hand and comparing that number with the perpetual inventory. The Manager of Record shall investigate any discrepancy and report any significant loss or suspected theft in accordance with federal and state requirements.

(d) A pharmacy shall require any perpetual inventory adjustment be performed only by the pharmacist Manager of Record. In the absence of the Manager of Record, a pharmacist designee may make the changes and report to Manager of Record.

(e) A pharmacy shall maintain an accurate record of all controlled substances returned to a reverse distributor or disposed of in accordance with state and federal laws and regulations and in the case of Schedule II drugs shall maintain proper DEA forms.

(f) A pharmacy technician or other unlicensed individual may not make any entry into or adjust the perpetual inventory.

(11) Each requirement of 247 CMR 9.21 shall apply to controlled substances that are expired, quarantined, or pending reverse distribution.

(12) The requirements of 247 CMR 9.21 do not apply to non-resident pharmacies.

9.22: Proper Storage of Refrigerated and Frozen Medications

(1) A pharmacy shall maintain policies and procedures to ensure proper refrigeration equipment is available, of adequate size, and utilized to maintain proper refrigeration and freezer temperatures. The policies and procedures shall include a protocol to respond to any out of range temperature, including an assessment of the integrity of the medication.

(2) A pharmacy shall utilize a combination refrigerator/freezer or a standalone refrigerator or standalone freezer. Freezer units shall be frost-free with an automatic defrost cycle. A pharmacy may not utilize an appliance that contains a freezer compartment within the refrigerator space, such as a dorm-style refrigerator.

(3) A pharmacy shall maintain a refrigerator temperature of 36º to 46º F (2º to 8º C). A pharmacy shall maintain a freezer temperature of 14º to -13º F (-25º to -10º C).

(4) A pharmacy shall utilize a certified calibrated analogue thermometer or certified calibrated digital thermometer equipped with an out of range alarm or notification for monitoring refrigerator and freezer temperatures.

(5) A pharmacy shall maintain daily temperature logs to clearly identify out of range temperatures and shall document actions taken in response to an out of range temperature. A pharmacy shall maintain records for at least one year.

(6) A pharmacy may not store any food or beverage in a refrigerator or freezer used to store medications.

9.23: Pharmacist Manager of Record

(1) A pharmacy shall designate a Manager of Record who is registered as a pharmacist in Massachusetts.

(2) A Manager of Record is responsible for the following:

(a) operation of the pharmacy in compliance with M.G.L. c. 112, §§ 24 – 42D, M.G.L. c. 94C, and 247 CMR 2.00 *et seq.*;

(b) the proper maintenance of records as required by M.G.L. c. 112, §§ 24 – 42D, M.G.L. c. 94C, and 247 CMR 2.00 *et seq.*;

(c) planning and maintaining adequate staffing that promotes patient safety;

(d) the establishment, monitoring, and enforcement of policies and procedures which maintain the standards of professional practice, compliance with state and federal laws and regulations governing the practice of pharmacy, and adequate staffing.

(e) the maintenance of records relating to the responsibilities of pharmacy technicians as outlined in 247 CMR 8.02(6);

(f) notification to the Board in writing of his/her termination or resignation as pharmacist Manager of Record within ten days;

(g) taking an inventory of controlled substances in Schedules II, III, IV and V, in accordance with 21 CFR § 1304;

(h) maintaining a copy of all standing orders for medications dispensed by the pharmacy;

(i) ensuring that all licensees working in the pharmacy have completed continuing education requirements;

(j) approving security access to the pharmacy, pharmacy's computer systems, and pharmacy automation; and

(k) ensuring technician training program is Board approved and up to date.

(3) A Manager of Record may not be the Manager of Record of more than one pharmacy at a time.

(4) A Manager of Record shall work at least 30 hours per week at the pharmacy he/she manages.

(5) Temporary Absence of a Manager of Record

(a) A pharmacy shall appoint an Interim Manager who is registered by the Board prior to any planned absence of the Manager of Record that is expected to last 30 days or longer.

(b) A pharmacy shall appoint an Interim Manager who is registered by the Board within five days of any unplanned absence of the Manager of Record that is likely to last 30 days or longer.

(c) Prior to his or her absence, a Manager of Record shall perform a controlled substances inventory that is signed by the Manager of Record and the Interim Manager. If the Manager of Record is unexpectedly not available, another registered pharmacist shall perform the controlled

substances inventory.

(d) In the event a Manager of Record is away from his or her position for 100 days or more, the pharmacy shall submit an application for a change of Manager of Record.

9.24: Inspections and Investigations of Pharmacies

(1) The Board or its designee(s) may visit any pharmacy licensed by the Board at any time without prior notice and inspect the pharmacy staff, activities, and records to determine compliance with laws and regulations governing the practice of pharmacy.

(2) All costs associated with inspections of non-resident pharmacies shall be paid by the non-resident pharmacy or applicant.

(3) A pharmacy shall provide all documents requested by the Board or its designee(s) in connection with an inspection or investigation.

9.25: Plans of Correction

(1) A pharmacy shall submit to the Board a written plan of correction for each violation cited in a statement of deficiency or inspection report within 21 days or in the timeframe directed by the Board. A pharmacy shall prepare and submit a plan of correction in the manner and format specified by the Board.

(2) A plan of correction shall describe the corrective action in response to each violation cited in a statement of deficiency or inspection report, expected completion or implementation date for the plan of correction, and individual(s) responsible for each action.

(3) The Manager of Record and the licensee who supervises the Manager of Record's practice of pharmacy, if applicable, shall sign the plan of correction.

(4) A pharmacy shall achieve compliance with the laws and regulations governing the practice of pharmacy in the most expeditious manner possible.

(5) A plan of correction which does not meet the requirements of the relevant 247 CMR section shall be considered unacceptable by the Board and returned to the pharmacy. The pharmacy shall submit a revised plan of correction within seven days.

REGULATORY AUTHORITY

247 CMR 9.00: M.G.L. c. 94C, §§ 6, 19B and 19C, and c. 112, §§ 12D, 30, and 42A.

~~247 CMR: BOARD OF REGISTRATION IN PHARMACY~~

~~247 CMR: 12.00: RESTRICTED PHARMACY~~

~~Section~~

~~.01: Authority~~

~~The Board may, under authority granted to it by M.G.L. c. 112, § 39A, register a restricted pharmacy for the limited transaction of a drug business as defined in M.G.L. c. 112, § 37. A restricted pharmacy may furnish pharmacy services only to beneficiaries, as defined in M.G.L. c. 151D, § 1, of a trust, fund, pension plan, combination plan, or profit sharing plan which is subject to the provisions of M.G.L. c. 151D.~~

~~.02: Limitation on the Functions and Operations of a Restricted Pharmacy~~

~~Registration as a restricted pharmacy shall not authorize such a restricted pharmacy to function or operate as a retail pharmacy as defined in M.G.L. c. 112, § 39.~~

~~.03: Application for an Initial Registration~~

~~(1) Application for an initial permit to operate as a restricted pharmacy shall be made by the plan administrator or trustee of the trust, fund, pension plan, combination plan, or profit sharing plan on a form provided by the Board.~~

~~(2) A restricted pharmacy shall comply with the requirements for the issuance of a pharmacy permit as provided by 247 CMR 6.00.~~

~~.04: Renewal of a Permit~~

~~A restricted pharmacy shall comply with the requirements for permit renewal as provided by 247 CMR 6.00.~~

~~.05: General Requirements for the Operation of a Restricted Pharmacy~~

~~(1) A restricted pharmacy may, after written notice to the Board, limit its operation to a specific schedule of drugs.~~

~~(2) A restricted pharmacy shall be exempt from the application of 247 CMR 9.01(15).~~

~~(3) A restricted pharmacy shall be subject to all applicable provisions of 247 CMR except as specifically exempted by the Board.~~

~~REGULATORY AUTHORITY~~

~~247 CMR 12.00: M.G.L. c. 112, §§ 39A and 42A.~~

247 CMR: BOARD OF REGISTRATION IN PHARMACY

247 CMR 15.00: CONTINUOUS QUALITY IMPROVEMENT PROGRAM

Section

15.01: (Reserved)

~~Quality Improvement Program or CQI Program means a system of standards and procedures to identify and evaluate quality-related events and improve patient care.~~

~~Related Event or QRE means the incorrect dispensing of a prescribed medication that is received by a patient, including:~~

~~(a) a variation from the prescriber's prescription order, including, but not limited to:~~

~~1. dispensing an incorrect drug;~~
~~2. dispensing an incorrect drug strength;~~
~~3. dispensing an incorrect dosage form;~~
~~4. dispensing the drug to the wrong patient; or~~
~~5. providing inadequate or incorrect packaging, labeling, or directions; or~~

~~(b) a failure to identify and manage:~~

~~1. over-utilization;~~
~~2. therapeutic duplication;~~
~~3. drug-disease contraindications;~~
~~4. drug-drug interactions;~~
~~5. incorrect drug dosage or duration of drug treatment;~~
~~6. drug-allergy interactions; or~~
~~7. clinical abuse/misuse.~~

~~, as referenced in 247 CMR 15.00, means a pharmacy, or a group of pharmacies under common ownership and control of one entity, licensed by the Board pursuant to M.G.L. c. 112.~~

~~Personnel means pharmacist, pharmacy intern, pharmacy technician and pharmacy support personnel.~~

15.02: Continuous Quality Improvement Program

(1) Continuous Quality Improvement Program Requirements. Each pharmacy shall establish a Continuous Quality Improvement (CQI) Program for the purpose of detecting, documenting, assessing and preventing Quality Related Events (QREs). At a minimum, a CQI program shall include provisions to:

(a) designate an individual or individuals responsible for monitoring CQI Program compliance with the requirements of 247 CMR 15.00;

(b) identify and document QREs;
(c) minimize impact of QREs on patients;
(d) analyze data collected in response to QREs to assess causes and any contributing factors;
(e) use the findings of the analysis to formulate an appropriate response and develop pharmacy systems and workflow processes designed to prevent QREs; and
(f) provide ongoing education at least annually in the area of CQI to pharmacy personnel.

~~(2) Date. The CQI Program requirements of 247 CMR 15.00 shall be implemented by each pharmacy by December 31, 2005.~~

15.03: Quality Related Event Discovery, Notification and Documentation

(1) QRE Discovery and Notification. All pharmacy personnel shall be trained to bring any QRE to the attention of the pharmacist on duty or the pharmacist Manager of Record immediately upon discovery. The pharmacist who has discovered or been informed of a QRE shall immediately provide:
(a) notification to the patient or patient's representative, the prescriber (if indicated in the professional judgment of the pharmacist) and other members of the healthcare team;
(b) directions for correcting the error; and
(c) instructions for minimizing the negative impact on the patient.

(2) QRE Documentation.
(a) A QRE shall be initially documented by the pharmacist who has discovered or been informed of the QRE on the same day the QRE is discovered by or described to the pharmacist.
(b) QRE documentation shall include a description of the event that is sufficient to permit categorization and analysis of the event. QRE documentation shall include:
1. the date when the pharmacist discovered or received notification of the QRE and the name of the person who notified the pharmacy;
2. the names and titles of the persons recording the QRE information and performing the QRE analysis;
3. a description of the QRE reviewed; and
4. documentation of the contact with the patient, or patient's representative, and prescribing practitioner (if indicated in the professional judgment of the pharmacist), and other members of the healthcare team.

(3) QRE Analysis and Response.
(a) QRE Analysis. The investigative and other pertinent data collected in response to QREs shall be analyzed, individually and collectively, to assess the cause and any contributing factors such as system or process failures. The QRE analysis and assessment shall include:
1. a consideration of the effects on quality assurance related to workflow processes, technological support, personnel training and staffing levels;
2. any recommended remedial changes to pharmacy policies,

procedures, systems, or processes; and

3. the development of indicators that identify means against which a pharmacy's program intends to measure its standards over a designated period of time.

(b) Response. Each pharmacy shall inform pharmacy personnel of changes to pharmacy policies, procedures, systems, or processes resulting from recommendations generated by the CQI Program.

15.04: Records

(1) Each pharmacy shall maintain a written copy of its CQI Program description on the pharmacy premises. The CQI Program description shall be readily available to all pharmacy personnel.

(2) Each pharmacy shall maintain a record of all QREs for a minimum period of two years from the date of the QRE report.

(3) QRE records shall be maintained in an orderly manner and filed by date.

(4) QRE records may be stored at a site other than the pharmacy where the QRE occurred.

~~.05: Duty to Report Certain Improper Drug Dispensing to the Board~~

~~Effective January 1, 2010, a pharmacy licensed by the Board is required to report to the Board any improper dispensing of a prescription drug that results in serious injury or death, as defined in 247 CMR 6.14(1), within 15 business days of the pharmacy discovering or being informed of such improper dispensing, in accordance with the requirements of M.G.L. c. 112, § 39D and 247 CMR 6.00.~~

REGULATORY AUTHORITY

247 CMR 15.00: M.G.L. c. 112, §§ 37 through 39 and 42A.

247 CMR 20.00: REPORTING

Section

20.01: Format of Reports

All reports required by 247 CMR 20.00 shall be made in the manner and format determined by the Board.

20.02: Duty to Report Certain Improper Drug Dispensing and Serious Adverse Drug Events to the Board

(1) A Manager of Record of a pharmacy shall report to the Board any improper dispensing of a prescription drug that results in serious injury or death within seven business days of discovery of the improper dispensing.

(2) A Manager of Record of a pharmacy, shall report any serious adverse drug event that occurs as a result of a patient's interaction with any drug or pharmaceutical manufactured, produced, or compounded at the pharmacy, to:

(a) the Board;
(b) the Federal Food and Drug Administration MedWatch Program; and
(c) the Betsy Lehman Center for Patient Safety and Medical Error Reduction.

A Manager of Record shall report a serious adverse drug event within seven business days of the knowledge of the serious adverse drug event by any pharmacy employee.

(3) The duty to report to the Board improper dispensing of a prescription drug that results in serious injury or death or a serious adverse drug event shall be in addition to the Continuous Quality Improvement (CQI) Program requirements of 247 CMR 15.00.

(4) A pharmacy shall retain all records relating to the improper dispensing of a prescription drug that results in serious injury or death and all records relating to serious adverse drug events for a minimum period of five years from the date the report is filed with the Board. The records shall be readily retrievable.

(5) The reporting requirements in 247 CMR 20.02 do not apply to non-resident pharmacies.

20.03: General Reporting Requirements

(1) Each licensee shall maintain his or her personal demographic information, including mailing address, phone number, and email address, in the licensee's Massachusetts Department of Public Health on-line licensing profile. A licensee shall update the on-line licensing profile within 14 calendar days of a change of mailing address, phone number, or email address.

(2) In the event of a change in name, a licensee shall submit a sworn statement indicating that the licensee has changed his or her name along with a photocopy of a valid picture identification card and any other documentation that may be required by the Board within 14 calendar days.

(3) Every individual licensed by the Board shall report to the Board, within 14 calendar days, any arrest, pending criminal charge, or conviction.

(4) Each pharmacy and individual licensed by the Board shall report to the Board, within 14 calendar days, any disciplinary action, as defined in 247 CMR 2.00, or loss of certification.

(5) Each pharmacy licensed by the Board shall report to the Board, within 14 calendar days, any adverse change in accreditation status.

(6) Each pharmacy licensed by the Board shall provide the Board with a copy of each inspection report, investigation report, or FDA warning letter, received from a local, state, or federal agency that pertains to the pharmacy or the practice of pharmacy within 14 calendar days of receipt.

(7) A pharmacy located in Massachusetts shall report a theft or loss of a significant amount of controlled substances by submitting to the Board a copy of "Report of Theft or Loss of Controlled Substance" (DEA BND Form 106), within seven days of such theft or significant loss and, where applicable, shall comply with the reporting requirements of the DEA, the Department and the state and local police.

20.04: Orally and Electronically Transmitted Prescriptions and Reporting Requirements to the Prescription Monitoring Program (PMP)

(1) Every pharmacy licensed by the Board that dispenses controlled substances in Schedules II thorough V pursuant to a prescription shall, in accordance with standards established by the Department, transmit to the Department or its agent, required information for each prescription, in accordance with Prescription Monitoring Program reporting requirements (105 CMR 700.012).

(2) Failure to comply with the Prescription Monitoring Program reporting requirements set forth in 105 CMR 700.012 or any state law or regulation relating to such reporting requirements may result in formal disciplinary action being initiated against the

licensed pharmacist or the pharmacy by the Board or other state and federal law enforcement agencies.

20.05: Change of Manager of Record

(1) A pharmacy shall notify the Board within 14 calendar days of the resignation or termination of its Manager of Record. An application for change of Manager of Record shall satisfy this requirement.

(2) A Manager of Record shall notify the Board of his or her resignation or termination as Manager of Record within 14 calendar days.

20.06: Compounding Pharmacies

(1) Each sterile compounding pharmacy, complex non-sterile compounding pharmacy, institutional sterile compounding pharmacy, non-resident sterile compounding pharmacy, and non-resident complex non-sterile compounding pharmacy shall report to the Board annually, or upon request by the Board, the following information:

(a) a list of sterile and complex non-sterile prescriptions dispensed within and outside of the commonwealth, as well as the volume of these prescriptions;

(b) the states in which the sterile and complex non-sterile prescriptions were dispensed and the status of any non-resident licenses issued by other states;

(2) Each sterile compounding pharmacy, institutional sterile compounding pharmacy, and non-resident sterile compounding pharmacy shall report, within seven business days of identification, any out of specification result relating to the potency, pyrogenicity, stability, improper composition, contamination, or sterility of a compounded sterile product.

(3) Each sterile compounding pharmacy, institutional sterile compounding pharmacy, and non-resident sterile compounding pharmacy shall report above action level environmental monitoring results or failure of certification of primary or secondary engineering control, as required by 247 CMR 17.XX.

(4) A Manager of Record of a sterile compounding pharmacy, complex non-sterile compounding pharmacy, or institutional sterile compounding pharmacy shall:

(a) disclose to the board the location, name and title of all principal managers and the name and Massachusetts license number of the designated Manager of Record;

(b) certify the sterile compounding pharmacy's compliance with reasonable informational requests made by the Board;

(c) certify to the Board that the Manager of Record has fulfilled continuing education requirements for sterile compounding and ensured that all pharmacy staff has received the appropriate training and education

required by law and regulation before engaging in compounding;

(d) submit to the Board the names and titles of all individuals employed by the sterile compounding pharmacy, complex non-sterile compounding pharmacy, or institutional sterile compounding pharmacy; and

(e) annually, and within 30 days after any transfer of ownership or change in corporate officers, management personnel or Manager of Record, file a report containing the information disclosed under clause (a).

20.07: Non-Resident Pharmacies

(1) A non-resident pharmacy, non-resident sterile compounding pharmacy, and non-resident complex non-sterile compounding pharmacy shall comply with all provisions of 247 CMR 20.00 unless otherwise provided.

(2) The designated pharmacist in charge of a non-resident pharmacy shall submit the following to the Board:

(a) the location, name, and title of all principal managers and the name and Massachusetts license number of the designated pharmacist in charge;

(b) a letter or documentation from the in-state Board of Registration in Pharmacy certifying that the pharmacist in charge is in good standing with the in-state board of registration:

(c) a letter or documentation from the in-state Board of Registration in Pharmacy certifying that the non-resident pharmacy maintains a current, unrestricted license, permit, or registration to operate the pharmacy; and

(d) a list of all prescriptions dispensed in Massachusetts.

A non-resident pharmacy shall submit this information on an annual basis and within 30 days after any transfer of ownership or change in corporate officers, management personnel or Manager of Record.

(3) A non-resident pharmacy shall report to the Board any improper dispensing, into Massachusetts, of a prescription drug that results in serious injury or death within even business days of discovery of the improper dispensing.

REGULATORY AUTHORITY:

M.G.L. c. 94C, § 6; M.G.L. c. 112, §§ 39G, 39H, 39I, and 42A.