

247 CMR: BOARD OF REGISTRATION IN PHARMACY

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

Section

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

(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 is 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

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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 Pharmacopoeia 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.

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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: Conditions for Continuing Registration and Operation of a Pharmacy or Pharmacy Department

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.

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- (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: Requirements for Reporting to the Board a Change in the Management, Operation and/or Ownership of a Pharmacy or Pharmacy Department

- (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.

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(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 is 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: Requirements for Reporting to the Board a Change in the Configuration, Square Footage, or Location of a Pharmacy or Pharmacy Department

(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:

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- (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 Continuing Responsibilities of All Registered Pharmacists

- (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: Renewal of a Pharmacy Permit

- (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 form 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: Pharmacist Manager of Record

- (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;

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- (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: Certificate of Fitness Issued by the Board Permitting the Manufacture and Sale of Alcoholic Beverages

(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;

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- (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: Closing of a Pharmacy or Pharmacy Department

- (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.



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- (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: Distribution of Controlled Substances Upon Discontinuance or Transfer of Business of a Pharmacy or Pharmacy Department

- (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: Inspections of Pharmacies and Pharmacy Departments

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.

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### 6.12: Deficiency Statements

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: Plans of Correction

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: 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 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: Duty to Report Certain Factors of Pharmacy Operations(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 by which 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."

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(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).

REGULATORY AUTHORITY

247 CMR 6.00: M.G.L. c. 112, §§ 42A and 30; c. 138, §§ 29 through 30G.