

247 CMR: BOARD OF REGISTRATION IN PHARMACY

247 CMR 6.00: LICENSURE OF PHARMACIES

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6.01: Authority and Purpose

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

6.02: License Requirements

- (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 shall have a designated

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Massachusetts licensed pharmacist in charge.

(5) 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.

(6) 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.

(7) 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.

6.03: Suitability of Applicant, Licensee, and Interest Holder

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.

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- (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 they have 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.

6.04: General Application Requirements

- (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:
 - (i) the proposed Massachusetts licensed pharmacist Manager of Record or, in the case of a non-resident pharmacy, the designated Massachusetts licensed pharmacist in charge; and
 - (ii) 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

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by the Executive Office of Administration and Finance;

- (e) blueprints or architectural drawings depicting the pharmacy layout;
- (f) any request(s) for waiver(s) of Board regulation(s); and
- (g) any additional information, as required by the Board.

(3) The Board may require the applicant(s), interest holder(s), 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 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 20.00.

(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.

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6.05: Application for 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.

6.06: Application for a Sterile Compounding Pharmacy License

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

6.07: Application for a Complex Non-Sterile Compounding Pharmacy License

- (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 dedicated 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).

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- (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.

6.08: Application for an Institutional Sterile Compounding Pharmacy License

- (1) In support of an application for a license to operate an institutional sterile compounding pharmacy, the applicant shall 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 or equivalent architectural drawing 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 or 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 original 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 31st of each year following the date of its issuance.
 - (b) A licensee shall submit with an application to renew an institutional sterile compounding pharmacy license 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.

6.09: Applications for Non-Resident Drug Store Pharmacy, Non-Resident Sterile Compounding Pharmacy, and Non-Resident Complex Non-Sterile Compounding Pharmacy Licenses

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- (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:
 - (i) all documentation identified in 247 CMR 6.04(2);
 - (ii) proof of good standing from the state where the pharmacy is located dated within three months of the application submission date; and
 - (iii) 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
 - (i) 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.
 - (ii) 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:
 - (i) all documentation identified in 247 CMR 6.04(2);
 - (ii) certified blueprints of the compounding area(s) depicting the location and identifying the ISO classification for each primary and secondary engineering control;
 - (iii) detailed HVAC design plan and written description; and
 - (iv) attestation of intent to engage in compounding, signed by the Massachusetts licensed designated pharmacist in charge, 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
 - (i) 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.
 - (ii) In connection with an application to renew a non-resident sterile compounding pharmacy license, a licensee shall submit copies of all

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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 Pharmacy License
- (a) In support of an application for a license to operate a non-resident complex non-sterile compounding pharmacy, the applicant shall submit:
- (i) all documentation identified in 247 CMR 6.04(2);
 - (ii) certified blueprints of the dedicated compounding room, including placement of containment hood(s);
 - (iii) detailed HVAC design plan and written description; and
 - (iv) attestation of intent to engage in compounding, signed by the Massachusetts licensed designated pharmacist in charge, 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 complex non-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
- (i) 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.
 - (ii) 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.
- (4) A non-resident pharmacy shall submit an application to the Board for approval whenever there is a change of a Massachusetts licensed designated pharmacist in charge. The application shall be made on forms prescribed by, and available from, the Board. The application must be submitted within 90 days of the termination or resignation of the previous pharmacist in charge.

6.10: Change of Manager of Record for Resident Pharmacies

- (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

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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 through V and controlled substances in Schedule VI required to be reported to MassPAT 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 they have 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.

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- (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.

6.11: Transfer of Ownership of a Pharmacy

- (1) At least 14 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 14 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 through 6.09, as applicable;
 - (b) description of the date and procedure to transfer controlled substances;
 - (c) inventory report of controlled substances, as required by 247 CMR 6.14;
 - (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.

6.12: Notifications

A licensee shall notify the Board, within 14 days, in writing, of any change in the name under which the pharmacy operates, accompanied by appropriate authorizing documentation.

6.13: Closing of a Pharmacy

- (1) A Massachusetts pharmacy 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;

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- (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) verification that adequate advance notice of the closure has been given to customers of the pharmacy in accordance with 247 CMR 6.13(4); and
- (f) the intended procedures for disposal or transfer of controlled substances in accordance with 247 CMR 6.14.

(2) A non-resident pharmacy that intends 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 number;
- (c) the date on which the intended closure shall take place; and
- (d) verification that adequate advanced notice of the closure has been given to Massachusetts customers of the pharmacy in accordance with 247 CMR 6.13(4).

(3) 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.

(4) 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 attempt to notify each such patient of the pharmacy closure at least 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. A non-resident Drug Store Pharmacy, non-resident sterile compounding pharmacy, and non-resident complex non-sterile compounding pharmacy shall notify all Massachusetts patients of the closure in accordance with 247 CMR 6.13(4).

(5) 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.

(6) 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 or transferred in

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accordance with 21 CFR 1301.52 and 247 CMR 6.14.

The provisions in 247 CMR 6.13(6) shall not apply to non-resident pharmacies.

(7) The provisions in 247 CMR 6.13(3) and 247 CMR 6.13(4) are not required for institutional sterile compounding pharmacies.

6.14: Distribution of Controlled Substances upon Closure or Transfer of Ownership of a Drug Store Pharmacy, Sterile Compounding Pharmacy, or Complex Non-Sterile Compounding Pharmacy

(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 licensed pharmacy 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 V and all controlled substances in Schedule VI that are required to be reported to the prescription monitoring program.
- (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 they notify 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.

(f) The transferor pharmacy may not possess any controlled substances after the date of transfer.

6.15: Application for Remodeling, Change in the Configuration, or Change in Square Footage of a Pharmacy

(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 secondary engineering control and may not move, add, modify, remove, or replace any 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) blueprints or architectural drawings depicting the pharmacy layout, prescription area, and counseling area;
- (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) certified blueprints depicting compounding area(s) and the location and ISO classification of each primary and secondary engineering control, and placement of containment hood(s), as applicable;
- (b) containment strategy;
- (c) environmental monitoring plan, if applicable;
- (d) plan to re-certify primary and secondary engineering controls and containment hoods, if applicable;
- (e) continuity of care plan, if applicable; and
- (f) any other information, as required by the Board.

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) blueprints or architectural drawings depicting the pharmacy layout; and
- (3) 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

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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, 39J, and 42A; St. 2014, c. 159, § 25.

DRAFT