247 CMR 21.00: REGISTRATION OF OUTSOURCING FACILITIES

Section

21.01: Purpose

247 CMR 21.00 is designed to describe the registration application process.

21.02: Outsourcing Facility Registration Requirements

(1) Registration under 247 CMR 21.02 is limited to outsourcing facilities located in Massachusetts. Outsourcing facilities located outside Massachusetts shall register in accordance with 247 CMR 21.04.

(2) An application for an outsourcing facility registration shall be made on forms prescribed by, and available from, the Board.

(3) In support of an application for an outsourcing facility registration, the applicant shall submit:

(a) complete application forms;

(b) a complete application, available from the Board, for a Massachusetts controlled substance registration;

(c) check or money order made payable in the proper amount to the "Commonwealth of Massachusetts Board of Registration in Pharmacy";

(d) proof of a valid, current registration with the FDA pursuant to section 503B of the Federal Food, Drug, and Cosmetic Act;

(e) proof of an inspection by the FDA in connection with the section 503B of the Federal Food, Drug, and Cosmetic Act registration within the two years immediately preceding the application;

(f) if the applicant is an entity:

1. a certificate of good standing and legal existence issued by the Secretary of State, or the equivalent, in the state in which the entity was organized or formed, and other information concerning ownership and control, as the Board may require;
2. a statement of the name and address of each officer, director, or partner of the entity and the position held;
3. the "doing business as" name of the entity;
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); and

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

(4) The Board may require the applicant(s), interest holder(s), and any other person to personally appear before the Board to answer questions to enable the Board to determine whether issuance of an outsourcing facility registration would be in the best interest of public health, safety, and welfare.

(5) All fees submitted to the Board in connection with an application for an outsourcing facility registration are nonrefundable.

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(6) An outsourcing facility registration shall be non-transferrable.

21.03: Provisional Outsourcing Facility Registration Requirements

(1) A non-resident outsourcing facility is not eligible for a provisional outsourcing facility registration.

(2) In the event an applicant for an outsourcing facility registration was not inspected by the FDA within the two years immediately preceding the application, the Board may issue a provisional outsourcing registration, provided the applicant otherwise submitted a complete application for an outsourcing facility registration.

(3) An entity with a provisional outsourcing facility registration may compound sterile drug preparations, but may not distribute or dispense a sterile drug preparation within or outside the Commonwealth until it has been inspected by the FDA and received a Massachusetts outsourcing facility registration.

(4) A provisional outsourcing facility registration shall be valid until the earliest of the following events occurs:

(a) the Board converts the provisional outsourcing facility registration to an outsourcing facility registration;

(b) the provisional outsourcing facility registration is surrendered, suspended, or revoked; or

(c) the provisional outsourcing registration expires on December 31st of the first odd numbered year following the date of issuance.

(5) The Board may convert a provisional outsourcing facility registration to an outsourcing facility registration upon the applicant's or registrant's submission of proof of an inspection by the FDA in connection with section 503B of the Federal Food, Drug, and Cosmetic Act, provided the Board determines the inspection results do not constitute grounds for denial as set forth in M.G.L. c. 112, § 36E(e).

(6) A provisional outsourcing facility registration issued on or after September 1st of an odd numbered year may be renewed. No other provisional outsourcing facility registration may be renewed or extended.

(7) A provisional outsourcing facility registration shall be non-transferrable.

21.04: Non-resident Outsourcing Facility Registration Requirements

(1) In support of an application for a registration to operate a non-resident outsourcing facility, the applicant(s) shall submit:

(a) complete application forms;

(b) check or money order made payable in the proper amount to the "Commonwealth of Massachusetts Board of Registration in Pharmacy";

(c) proof of a valid, current registration with the FDA pursuant to section 503B of the Federal Food, Drug, and Cosmetic Act;

(d) proof of an inspection by the FDA in connection with the section 503B of the Federal Food, Drug, and Cosmetic Act registration within the two years immediately preceding the application;

(e) if the applicant is an entity:

1. a certificate of good standing and legal existence issued by the Secretary of State, or the equivalent, in the state in which the entity was organized or formed, and other information concerning ownership and control, as the Board may require;

2. a statement of the name and address of each officer, director, or partner of the entity and the position held;

3. the "doing business as" (d/b/a) name of the entity; 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);

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(f) if the outsourcing facility is licensed or registered by the state in which it is located, proof of good standing from the licensing or registering authority in that state that was issued within three months; and
(g) any additional information, as required by the Board.

(2) All fees submitted to the Board in connection with an application for a non-resident outsourcing facility registration are nonrefundable.

(3) A non-resident outsourcing facility registration shall be non-transferrable.

21.05: Renewal of an Outsourcing Facility Registration and Non-resident Outsourcing Facility Registration

(1) An outsourcing facility registration and non-resident outsourcing facility registration shall expire on December 31st of each odd numbered year following the date of its issuance.

(2) Renewal of an outsourcing facility registration and non-resident outsourcing facility registration shall be made in the form and manner determined by the Board.

(3) In support of an application for a renewal of an outsourcing facility registration or a non-resident outsourcing facility registration, the applicant shall submit:
(a) proof of a valid, current registration with the FDA pursuant to section 503B of the Federal Food, Drug, and Cosmetic Act;
(b) check or money order made payable in the proper amount to the "Commonwealth of Massachusetts Board of Registration in Pharmacy"; and
(c) any additional information, as required by the Board.

21.06: Grounds for Denial, Revocation, Suspension, and Non-renewal

Grounds for denial of a registration, revocation or suspension of a registration, or non-renewal of a registration shall include, but shall not be limited to:

(1) failure to maintain a current, valid registration with the FDA pursuant to section 503B of the Federal Food, Drug, and Cosmetic Act;

(2) an inspection by the FDA that results in a warning letter that prohibits commercial distribution by the registered facility of sterile drug preparations within or outside of the commonwealth;

(3) material misrepresentation, omission, or falsification of any information furnished to the Board;

(4) failure to comply with reporting requirements established by the Board with respect to registration with or inspections by the FDA;

(5) failure to adhere to the most current standards established under cGMP;

(6) the lack of suitability of the applicant or registrant; or

(7) in the case of outsourcing facilities located in Massachusetts, the failure to maintain a current, valid Massachusetts controlled substances registration.

21.07: Suitability of Applicant, Registrant, and Interest Holder

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

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

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(2) An applicant, registrant, 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 or M.G.L. c. 94C.

(3) An applicant, registrant, or interest holder plans to assume or has assumed ownership of an outsourcing facility in an effort to circumvent the effect and purpose of 247 CMR 2.00.

(4) An applicant, registrant, or interest holder owned, operated, or held an interest in an outsourcing facility, 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 which resulted in the discipline, suspension, denial, or revocation of the outsourcing facility registration or other professional license or registration.

(5) An applicant, registrant, or interest holder owned, operated, or held an interest in an outsourcing facility, 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 an outsourcing facility, pharmacy, healthcare facility, or other entity registered by the FDA or DEA resulting in the imposition of discipline upon the outsourcing facility registration or other professional license or registration.

(6) An applicant, registrant, or interest holder owned, operated, or held an interest in an outsourcing, 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, registrant, or interest holder failed to demonstrate that he or she has the competence or experience to operate an outsourcing facility.

(8) An applicant, registrant, or interest holder obtained or attempted to obtain a registration by fraud or misrepresentation or by submitting false information.

(9) An applicant, registrant, or interest holder is licensed and authorized to prescribe controlled substances.

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

(11) An applicant, registrant, or interest holder entered into a consent agreement in resolution of a complaint against a professional license or registration resulting in the imposition of discipline upon the professional license or registration.

21.08: Transfer of Ownership of an Outsourcing Facility

(1) 247 CMR 21.08 shall only apply to outsourcing facilities located in Massachusetts.

(2) At least 60 days prior to the transfer of ownership of an outsourcing facility, the registrant shall notify the Board of the proposed transfer of ownership. The outgoing registrant shall comply with 247 CMR 21.10 pertaining to the transfer of controlled substances.

(3) Within 60 days of a transfer of ownership, the proposed new registrant shall submit an application for a registration to operate an outsourcing facility in accordance with 247 CMR 21.02.

(4) In support of the application for a registration to operate an outsourcing facility, the proposed new registrant shall submit:

(a) a complete application pursuant to 247 CMR 21.02;
(b) an inventory report of controlled substances as required by 247 CMR 21.11; and
(c) any additional information, as required by the Board;

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(5) A proposed new registrant may not distribute or dispense any sterile drug preparation unless and until the Board approves its application for a outsourcing facility registration in accordance with 247 CMR 21.02.

21.09: Notifications

A registrant shall notify the Board, within 14 days, in writing, of the following:

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

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

(3) any change in the ownership of the outsourcing facility representing more than 5% interest;

(4) an inspection by the FDA;

(5) receipt of an FDA Form 483 or Warning Letter; and

(6) any disciplinary or adverse action taken by the FDA or a state licensing or registering authority.

21.10: Closing of an Outsourcing Facility

(1) 247 CMR 21.10 shall only apply to outsourcing facilities located in Massachusetts.

(2) A registrant that intends to close a outsourcing facility 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 outsourcing facility;
(b) the outsourcing facility registration and controlled substance registration numbers;
(c) the date on which the intended closure shall take place;
(d) the intended procedures for closing the outsourcing facility;
(e) verification that adequate advance notice of the closure has been given to customers and patients of the outsourcing facility; and
(f) the intended procedures for disposal of controlled substances, or the intended procedures for transfer of controlled substance in accordance with 247 CMR 21.11.

(3) A registrant shall submit the following to the Board within 14 days of closure of an outsourcing facility:

(a) the original registration and controlled substances registration; and
(b) an attestation that all controlled substances have been disposed of in accordance with applicable state and federal laws and regulations.

21.11: Transfer of Controlled Substances Upon Closure or Transfer of Ownership of an Outsourcing Facility

(1) 247 CMR 21.11 shall only apply to outsourcing facilities located in Massachusetts.

(2) A registrant or agent of the registrant who intends to transfer controlled substances in Schedules II through VI from one outsourcing facility registered by the Board to another outsourcing facility registered 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 outsourcing facility;
(b) the name, address, and telephone number of the transferee outsourcing facility;
(c) the outsourcing facility registration and controlled substances registration numbers of the transferor facility;

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(d) the outsourcing facility registration and controlled substances registration number of the transferee facility;
(e) the date on which the transfer of the controlled substances will take place; and
(f) the security procedures for transfer of the controlled substances.

(3) 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 outsourcing facility shall take a complete inventory of all controlled substances in Schedules II through VI in accordance with federal and state law;
(b) The transferor outsourcing facility and the transferee outsourcing facility shall sign the controlled substances inventory report;
(c) Both the transferor and transferee facilities 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 facilities shall file an attestation with the Board confirming the controlled substance inventory within ten days of the transfer;
(e) The transferee outsourcing facility 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 outsourcing facility may not possess any controlled substances after the date of transfer.

21.12: Application for Relocation of an Outsourcing Facility to a New Address

(1) A outsourcing facility registered 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.

(2) An outsourcing facility 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, an outsourcing facility shall submit:
(a) a complete application;
(b) a written plan to maintain security of controlled substances during transportation, if the outsourcing facility is located in Massachusetts; and
(c) any other information, as required by the Board.

(3) An outsourcing facility may compound sterile drug preparation at the new location, but may not distribute or dispense a sterile drug preparation within or outside the Commonwealth until the new location has been inspected by the FDA.

REGULATORY AUTHORITY

247 CMR 21.00: M.G.L. c. 94C, § 6; c. 112, §§ 36E and 42A.