

247 CMR 11.00: REGISTRATION UNDER THE CONTROLLED SUBSTANCES ACT (M.G.L. c. 94C)

Section

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~~11.01: Controlled Substance Registration~~

~~For the purposes of 247 CMR 11.00, the term "registrant" shall mean the individual to whom a controlled substance registration is issued by the Board.~~

~~For the purposes of 247 CMR 11.00, the term "pharmacy" shall mean a retail, restricted, and nuclear pharmacy and a pharmacy department.~~

11.0~~12~~: Requirement of a Controlled Substance Registration

(1) In accordance with the Massachusetts Controlled Substances Act, M.G.L. c. 94C, the Board may issue a controlled substance registration to a ~~qualified owner or operator of~~ pharmacy, outsourcing facility, or ~~of a~~ wholesale drug business ~~who~~ that intends to engage in any activity for which a controlled substance registration is required by law.

(2) No pharmacy, outsourcing facility, or wholesale drug business shall engage in any activity for which registration is required until a controlled substance registration has been issued by the Board.

11.0~~23~~: Standard for Issuance of a Controlled Substance Registration

The Board shall issue a controlled substance registration to an applicant unless it determines that the issuance of that registration would be inconsistent with the public interest. In determining the public interest, the Board shall consider, but shall not be limited to considering, the following factors:

- (1) The maintenance of effective controls against diversion of controlled substances;
- (2) compliance with applicable federal, state and local laws and regulations;
- (3) any conviction of the applicant under any federal and/or state law relating to any controlled substance;
- (4) past experience in the manufacture or distribution of controlled substances;
- (5) furnishing by the applicant of false or fraudulent material in any application filed under the provisions of M.G.L. c. 94C or other applicable state or federal law or regulation;
- (6) suspension or revocation of the applicant's federal registration to manufacture, distribute or dispense controlled substances as authorized by federal law; and

- (7) any other factors relevant to, and consistent with, the public health and safety.

11.034: Requirement of a Pharmacy License~~Permit~~, Outsourcing Facility Registration, or Wholesale Druggist License

All applicants for a controlled substance registration shall be determined by the Board to be qualified to receive from the Board a pharmacy license, outsourcing facility registration, or a Board pharmacy permit or a Board wholesale druggist license before being issued a controlled substance registration.

11.045: Application for a Controlled Substance Registration

Application for a controlled substance registration shall be made on a form provided by the Board. All applications submitted to the Board shall:

- (1) be fully and properly completed, and
- (2) be accompanied by a check or money order payable to the "Commonwealth of Massachusetts Board of Registration in Pharmacy" in the appropriate amount, which shall be non-refundable.

11.056: Separate Registration Required

A separate controlled substance registration shall be required at each principal place of business where the licensee or registrant manufactures, distributes or dispenses controlled substances.

11.067: Expiration of a Controlled Substance Registration

A controlled substance registration issued by the Board shall be valid as follows:

- (1) Pharmacy: The controlled substance registration issued to a pharmacy shall be valid for two years beginning January 1st of each even-numbered year.
- (2) Outsourcing facility: The controlled substance registration issued to an outsourcing facility shall be valid for two years beginning January 1st of each even numbered year.
- (32) Wholesale druggist: The controlled substance registration issued to a wholesale druggist shall be valid for one year beginning on December 1st of each year.

11.078: Renewal of a Controlled Substance Registration

- (1) A registrant may renew a controlled substance registration on a renewal form provided by the Board. All renewal applications submitted to the Board shall:
 - (a) be submitted in a timely manner;~~;~~
 - (b) be fully and properly completed;~~;~~ and
 - (c) be accompanied by a check or money order payable to the "Commonwealth of Massachusetts Board of Registration in Pharmacy" in the appropriate amount, which shall be non refundable.
- (2) Renewal of a controlled substance registration shall be made prior to the following dates:
 - (a) December 31st of each odd-numbered year for a pharmacy;
 - (b) December 31st of each odd-numbered year for an outsourcing facility; and
 - (cb) November 30th of each year for a wholesale druggist.
- (3) Failure by a registrant to renew a controlled substance registration in a timely manner may result in the imposition of a late renewal fee.

11:089: Changes in the Name, Address and/or Status of Registrant

- (1) The controlled substance registration of any registrant shall automatically terminate and become invalid if:
 - (a) — the person named on the controlled substance registration dies;
 - (ab) the pharmacy, outsourcing facility, or wholesale business named on the controlled substance

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registration ceases to exist;

- (be) the name and/or address of the pharmacy, outsourcing facility, or wholesale business to which the controlled substance resignation was issued changes; or
- (cd) the pharmacy, outsourcing facility, or wholesale business to which the controlled substance registration was originally issued is sold.

(2) A registrant affected by 247 CMR 11.09(1) shall notify the Board in writing within ~~14~~^{ten} days of such change(s).

(3) A registrant affected by 247 CMR 11.09(1) ~~shall~~^{may} make application to the Board for the issuance of a new controlled substance registration. Such application may be submitted to the Board before the effective date of such change. The Board shall review such application as a first-time application for a controlled substance registration.

(4) A registrant affected by 247 CMR 11.09(1) shall promptly provide written notice thereof to the regional office of the U.S. Drug Enforcement Administration.

~~11.0910:~~ Transfer or Assignment of a Controlled Substance Registration Prohibited

A controlled substances registration issued by the Board, or any authority conferred thereby, shall not be assigned or transferred.

~~11.101:~~ Wholesale Druggist Activities Limited

A wholesale druggist which is registered to distribute a controlled substance or class of controlled substances shall be authorized to distribute only that controlled substance or class of controlled substances.

~~11.112:~~ Inspection of Registered Premises

The Board or its authorized agents may inspect, in accordance with Board regulations, the establishment of a registrant or of an applicant for a controlled substances registration.

~~11.13: Records and Inventories~~

~~Registrants shall keep records and maintain inventories in conformance with the record keeping and inventory requirements of the federal "Comprehensive Drug Prevention and Control Act of 1970", or any amendment thereof, and 21 U.S.C. § 301 et seq. (Federal Food, Drug and Cosmetic Act), and with all other applicable state laws and regulations.~~

~~11.124:~~ Revocation and Suspension of Registration; Grounds; Effect

(1) The Board may suspend or revoke a controlled substance registration issued by it after a hearing pursuant to the provisions of M.G.L. c. 30A upon a finding that the registrant:

- (a) has furnished false or fraudulent material information in any application filed under the provisions of M.G.L. c. 94C;
- (b) has been convicted under any state or federal law of any criminal violation relating to his or her fitness to be registered under M.G.L. c. 94C;
- (c) has had his or her state or federal controlled substance registration to manufacture, distribute, dispense, administer or possess controlled substances ~~suspended~~^{suspended} or revoked, or has voluntarily surrendered said controlled substance registration;
- (d) is, upon good cause, found to be unfit or unqualified to manufacture, distribute, dis-pense, or possess any controlled substance; or
- (e) has violated any provision of M.G.L. c. 94C and/or any other applicable federal or state laws and regulations.

(2) The suspension or revocation by the Board of a controlled substance registration shall be grounds for the suspension or revocation of the ~~retail pharmacy's permit~~^{pharmacy license, outsourcing facility registration}, or wholesale druggist's license issued by the Board.

(3) The Board may limit revocation or suspension of a controlled substance registration issued by it to the particular controlled substance with respect to which grounds for revocation or suspension exist.

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(4) Whenever the Board has substantial reason to believe that a registrant to whom it has issued a controlled substance registration has committed a criminal violation of any provision of M.G.L. c. 94C, the Board shall promptly report all pertinent facts to the district attorney in the county where the violation is believed to have occurred or to the attorney general.

(5) If the Board suspends or revokes a controlled substances registration issued by it, all controlled substances which are affected by such suspension or revocation order at the time of suspension or the effective date of the revocation order shall be placed under embargo pursuant to the procedures prescribed in M.G.L. c. 94, §§ 189 and 189A. No disposition may be made of substances under such embargo until the time for taking an appeal has elapsed or until all appeals have been concluded unless a court, upon application therefor, orders the sale of perishable substances and the deposit of the proceeds of the sale with the court. Upon a revocation order becoming final, all controlled substances may be forfeited to the Commonwealth.

(6) The Board shall promptly notify the U.S. Drug Enforcement Administration and, where appropriate the Department of Public Health of all orders suspending or revoking a controlled substances registration and all forfeitures of controlled substances.

11.135: Summary Suspension of a Controlled Substance Registration

(1) The Board may, without hearing, suspend or refuse to renew any controlled substance registration issued by it if it finds that there is an imminent danger to the public health or safety which warrants this action; provided, however, that the Board promptly affords the registrant an opportunity for a hearing in accordance with M.G.L. c. 30A, 801 CMR 1.01 and 247 CMR 10.00.

(2) Any suspension summarily imposed by the Board shall continue in effect until the conclusion of the final hearing on the merits of any Order to Show Cause issued by the Board in connection with its investigation of the pharmacy, outsourcing facility, or wholesale druggist, including judicial review thereof, unless sooner dissolved by a court of competent jurisdiction, or withdrawn by the Board.

(3) The procedure for summary suspension is as follows:

(a) Closure of Pharmacy, Outsourcing Facility, or Wholesale Druggist: Upon receipt by the Board of reliable information that a registrant is an imminent and serious threat to the public health or safety, the Board shall vote to take summary action on the registrant's controlled substances registration. Upon the Board's vote to summarily suspend such registration, Board Agents are authorized to:

1. immediately close the registrant's establishment or business;
2. at the registrant's expense, replace the locks on all doors to the registrant's establishment or business and retain the key(s);
3. conspicuously display at the entrance(s) to the registrant's establishment or business a sign, in letters no less than one inch in height and one inch wide, stating: "THE REGISTRATION OF THIS PHARMACY/ ESTABLISHMENT HAS BEEN SUSPENDED BY ORDER OF THE MASSACHUSETTS BOARD OF REGISTRATION IN PHARMACY."; and
4. conduct an inventory and audit of all drugs and record of drugs within the registrant's establishment or business.

(b) Order of Suspension: The Board shall promptly issue an Order of Suspension of Controlled Substance Registration and shall send such Order, with a Notice of Hearing as set forth in 247 CMR 11.15(3)(c), to the establishment's owner or pharmacy's Manager of Record by certified mail, or shall deliver such Order and Notice of Hearing by hand.

(c) Hearing on Necessity for the Summary Action: The Board shall convene a hearing on the necessity for the summary suspension of a controlled substance registration within seven days after the order of suspension. The establishment's owner and/or pharmacy's Manager of Record shall be notified of the date, time and place of the hearing.

At the hearing, the Board shall receive testimony and documentary evidence limited to determining whether the summary suspension of the controlled substance registration shall continue in effect pending a final hearing on the merits of any Order to Show Cause issued by the Board against the pharmacy or establishment in connection with its investigation.

Following the hearing, the Board shall vote on whether to continue the summary suspension in effect and shall promptly notify the registrant in writing of its decision.

(4) The Board's summary suspension of a controlled substance registration shall be grounds for the summary suspension of a pharmacy license, outsourcing facility registration, the pharmacy's permit or

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wholesale druggist's license issued by the Board. The summary suspension of a pharmacy license, outsourcing registration, ~~pharmacy's permit~~ or wholesale druggist's license ~~permit~~ shall continue in effect pending a final hearing on the merits of any Order to Show Cause issued by the Board against the pharmacy, outsourcing facility, or wholesale druggist in connection with its investigation, including judicial review thereof, unless sooner dissolved by a court of competent jurisdiction or withdrawn by the Board.

REGULATORY AUTHORITY

247 CMR 11.00: M.G.L. c. 112, §§ 30 and 42A; c. 94C, §§ 6, 7 and 10 through 15.

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