

**TITLE 185: COMMONWEALTH HEALTH CARE PROFESSIONS  
LICENSING BOARD**

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**CHAPTER 185-10  
COMMONWEALTH HEALTH CARE PROFESSIONS  
LICENSING BOARD REGULATIONS**

<b>Part 3600</b>	<b>Pharmacy</b>
§ 185-10-3601	Licensing
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**Part 3600 - Pharmacy.**

**§ 185-10-3601 Licensing.**

- (a) The following Persons located within the Commonwealth, and the following Persons located outside the Commonwealth that provide services to patients within the Commonwealth, shall be licensed by the Board and shall bi-annually renew their license with the Board:
  - (1) persons engaged in the Practice of Pharmacy;
  - (2) persons engaged in the Manufacture, production, sale, or Distribution or Wholesale Distribution of Drugs or Devices;
  - (3) pharmacies where Drugs or Devices are Dispensed, or Pharmacist Care is provided; and
  - (4) pharmacy Benefits Managers.
- (b) Where operations are conducted at more than one location, each such location shall be licensed by the Board.
- (c) Each Pharmacy shall have a Pharmacist-in-Charge. Whenever an applicable rule requires or prohibits action by a Pharmacy, responsibility shall be that of the owner and/or pharmacy permit holder and the Pharmacist-in-Charge of the Pharmacy, whether the owner and/or pharmacy permit holder is a sole proprietor, partnership, association, corporation, or otherwise.
- (d) Each Pharmacy located outside of the Commonwealth that ships, mails, Distributes, or Delivers Drugs or Devices in the Commonwealth, shall designate a registered agent in the Commonwealth for service of process. A copy of any such service of process shall be mailed to such Agent by the Board by certified mail, return receipt requested, postage prepaid, at the address such Agent has been designated on its application for licensure in the Commonwealth.
- (e) The Board may enter into agreements with other states, territories, or with third parties for the purpose of exchanging information concerning the licensure and inspection of entities located in this jurisdiction and those located outside of the Commonwealth.
- (f) The Board may deny or refuse to renew a license if it determines that the granting or renewing of such license would not be in the public interest.
- (g) The Board shall establish the standards that a Person or Entity must meet for initial and continued licensure under this act and may require periodic inspections for purposes of licensure or licensure renewal of the Pharmacy.
- (h) The Board may enter into an agreement with a third party to undertake inspections of facilities of a Person seeking initial or continued licensure where such third party maintains a program which has standards acceptable to the Board that must be met for any such Person to be accredited or certified by such third party. The Board may rely on such accreditation or certification in determining eligibility for initial licensure or licensure renewal.

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**§ 185-10-3605            Application.**

- (a) The Board shall specify by rule the licensure procedures to be followed, including but not limited to, specification of forms for use in applying for such licensure and times, places, and applicable fees. Applicants shall fill out the forms provided by the Board.
- (b) Applicants for licensure to Distribute, Wholesale Distribute, Manufacture, sell, purchase, and/or produce Drugs or Devices, and applicants for licensure as a Pharmacy Benefits Manager, shall file with the Board of Pharmacy a verified application containing such information as the Board requires of the applicant relative to the qualifications for a license.
- (c) Licenses issued by the Board pursuant to this Part shall not be transferable or assignable.
- (d) Licensed practitioners allowed to prescribe medications are not allowed to be an owner, officer, director or shareholder of a corporation may not be considered as an applicant;\*
- (e) The Board shall specify by rule minimum standards for responsibility of any Person, Pharmacy, or Pharmacy Benefits Manager that has employees or personnel engaged in the Practice of Pharmacy, or Manufacture, Distribution, Wholesale Distribution, production, sale, or use of Drugs or Devices in the conduct of their business. If the licensed Person is a Pharmacy located in the Commonwealth, that portion of the facility to which such license applies shall be operated only under the direct supervision of a Pharmacist licensed to practice in the Commonwealth.
- (f) Applicants must provide and certify the following:
  - (1) The name, address, and contact information of the individual requesting the license;
  - (2) The name(s) under which the applicant does business;
  - (3) The name of the Pharmacist-in-Charge of the facility to be licensed;
  - (4) A copy of the Commonwealth license for the applicants Pharmacist in Charge;
  - (5) The names and contact information of all of the individual owners and/or corporate officers;
  - (6) If the applicant is a corporation, a copy of the corporation's articles of incorporation and a letter of good standing from the jurisdiction of incorporation;
  - (7) A copy of the applicants Commonwealth business license;
  - (8) A statement by all of the owners, corporate officers, pharmacists, technical staff, and any other individual with decision making responsibilities, stating whether:
    - (i) they have been arrested or involved in litigation and/or arbitration;
    - (ii) have ever had their professional license disciplined for any reason;
    - (iii) ever had a denial of a personal license, permit, certificate, or registration for a privileged, occupational, or professional activity;

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- (iv) denials of a business or industry license or related finding of suitability, or participation in a group that has been denied a business or industry license or related finding of suitability;
  - (v) Administrative actions or proceedings related to the pharmaceutical industry or participation in a group that has been the subject of such administrative actions or proceedings;
  - (vi) guilty findings or pleadings or pleas of nolo contendere to any offense, federal or state, related to prescription Drugs and/or controlled substances or participation in a group that has been found or pled guilty or that has pled nolo contendere to any such offense;
  - (vii) surrender, voluntary or otherwise, of licensure, permit, or certificate of registration relating to the pharmaceutical industry, or participation in a group that has surrendered, voluntary or otherwise, any such licensure, permit, or certificate of registration.
- (9) A map showing the physical location of the pharmacy;
- (10) A floor plan of the pharmacy showing the essential areas for appropriately securing pharmaceutical products, securing controlled substances, compounding area, private patient counseling area, and prescription preparation area.

\* So in original.

**§ 185-10-3610            Notifications.**

All licensed Persons shall report to the Board the occurrence of any of the following:

- (a) permanent closing;
- (b) change of ownership, management, location, or Pharmacist-in-Charge of a Pharmacy;
- (c) any theft or loss of Drugs or Devices;
- (d) any conviction of any employee of any State or Federal Drug laws;
- (e) any criminal conviction or pleas of guilty or nolo contendere of all licensed or registered personnel;
- (f) disasters, accidents, or any theft, destruction, or loss of records required to be maintained by State or Federal law;
- (g) occurrences of Significant Adverse Drug Reactions as defined by Rules of the Board;
- (h) illegal use or disclosure of Protected Health Information; or
- (i) any and all other matters and occurrences as the Board may require by rule.