

**Commonwealth of Massachusetts
Board of Registration in Pharmacy**

Licensure Policy 13-01

Title	Staff Action on Licensure Applications and Notices
Purpose	The Board of Registration in Pharmacy adopts this policy to authorize Board staff to approve and process certain applications or notices concerning individual licensure, or changes in the operation of licensed pharmacies, provided that the application or notice meets criteria specified in this policy.
Date Adopted	Approved on January 8, 2013, Revised February 2 nd , 2017
Definitions	<p><u>Adverse History</u> means that the applicant discloses or Board Staff has evidence of:</p> <ol style="list-style-type: none"> 1. Disciplinary sanction(s) or non-disciplinary restriction(s) on an applicant's professional license, registration or certification that is imposed by the issuing jurisdiction or agency either by order or by consent agreement between the jurisdiction or agency and the applicant; 2. Complaint(s) or proceeding(s) against any professional license, registration or certification held by the applicant pending before the issuing jurisdiction or agency; 3. Criminal conviction(s) against the applicant (other than a minor traffic violation for which a fine of \$100 or less was imposed); and/or 4. Pending criminal investigation(s) or criminal proceeding(s) against the applicant in relation to any violation (other than a minor traffic violation for which a fine of \$100 or less was imposed). <p><u>Plan Review Group</u> means a team that reviews and approves certain applications for remodeling, change in configuration, or change in square footage of a pharmacy on a monthly basis for sterile compounding, institutional sterile compounding, and complex non-sterile compounding pharmacies. The Plan Review Group consists of at least three of the following individuals: (1) the Director of Pharmacy Compliance or his/her designee; (2) Quality Assurance Pharmacist(s); (3) Pharmacy Program Analyst; (4) Director of Pharmacy Investigations or his/her designee; or (5) Pharmacy Investigator(s).</p> <p><u>Registration in Good Standing</u> means a registration that is not expired, surrendered (disciplinary or non-disciplinary), suspended, revoked or on probation (disciplinary).</p> <p><u>Under Common Ownership</u> means that the one or more licensed pharmacies has substantially the same owner(s) as the applicant. In making this determination, staff may consider owners to include any combination of the following: individuals, associations, partnerships, corporations and corporate ownership.</p>
Authorization to Approve	<p><u>Nuclear Pharmacists</u></p> <p>The Board authorizes designated staff ("Board staff") to review the following applications and to act on them in accordance with the corresponding criteria.</p> <ol style="list-style-type: none"> 1. Application for Registration as a Nuclear Pharmacist. Board staff may approve an application for registration as a nuclear pharmacist provided that: <ol style="list-style-type: none"> a. The applicant is a registered pharmacist in Massachusetts pursuant to

	<p>M.G.L. ch.112, § 24 with a registration in good standing;</p> <ul style="list-style-type: none"> b. The applicant has no adverse history, or adverse history that has been previously subject to a good moral character evaluation and has since been resolved, or c. Adverse history that has been subject of a complaint before the Board that has since been resolved. <p>2. The applicant has provided adequate proof of educational and training requirements, including:</p> <ul style="list-style-type: none"> a. Two hundred (200) contact hours of formal academic training in the area of radiopharmaceutical preparation and handling; and <ul style="list-style-type: none"> i. A statement by a qualified nuclear pharmacist attesting that the applicant has completed either three (3) months of full-time or five hundred (500) hours of actual on-the-job practical experience in the field of radioactive drugs and radiopharmaceutical services in a nuclear pharmacy under the qualified nuclear pharmacist's supervision; <u>or</u> ii. Written confirmation prepared by the instructor of a Board-approved college of pharmacy that the applicant has completed three (3) months of full-time or five hundred (500) hours of actual experience in a structured nuclear pharmacy training program. b. The applicant certifies that he or she has read and understands all applicable state and federal statutes and regulations regarding the operation of a nuclear pharmacy and the handling of radiopharmaceuticals and radioactive materials including M.G.L. Chapter 94C and M.G.L. Chapter 112 and 247 CMR 13.00 et seq. <p><u>Application for Change in Manager of a Pharmacy</u></p> <p>Board staff may approve an application for change of Manager of Record of a pharmacy provided that:</p> <ul style="list-style-type: none"> 1. The proposed Manager of Record is a registered pharmacist in Massachusetts pursuant to M.G.L. ch.112 §24 with a registration in good standing; 2. The proposed Manager of Record has: <ul style="list-style-type: none"> a. No adverse history, or b. Adverse history that has been previously subject to a good moral character evaluation and has since been resolved, or c. Adverse history that has been the subject of a complaint before the Board that has since been resolved. <p><u>Notice of Closing of a Community Pharmacy or Pharmacy Department</u></p> <ul style="list-style-type: none"> 1. Board staff may accept notification of the closing of a community pharmacy submitted pursuant to, and in compliance with, 247 CMR 6.09 and 6.10. 2. Board staff shall report to the Board and the Office of Public Protection any notification or evidence of the closing of a community pharmacy that fails to comply with 247 CMR 6.09 and 6.10. <p><u>Application to Manage and Operate a New Community Pharmacy</u></p> <p>Board staff may approve an application to manage and operate a new community</p>
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pharmacy provided that:

1. There is at least one other community pharmacy registered with the Board held under common ownership with the applicant;
2. All other community pharmacies registered with the Board and held under common ownership with the applicant have a registration in good standing with:
 - a. No adverse history, or
 - b. Adverse history that has been previously subject to a good moral character evaluation and has since been resolved, or
 - c. Adverse history that has been the subject of a complaint before the Board that has since been resolved.
3. The proposed Manager of Record has registration in good standing with:
 - a. No adverse history, or
 - b. Adverse history that has been previously subject to a good moral character evaluation and has since been resolved, or
 - c. Adverse history that has been the subject of a complaint before the Board that has since been resolved.
4. The application demonstrates the ability to comply with all requirements for registration set forth in 247 CMR 6.00. et seq.
5. The application sets forth a business model that is substantially similar to business models previously approved by the board
6. The application includes a certified blueprint that depicts a floor plan and layout that is substantially similar to floor plans and layouts previously approved by the board
7. The attestation which accompanies that application indicates that the applicant will not engage in complex non-sterile or sterile compounding unless appropriate licensure has been obtained
8. The applicant does not require any waivers of any provisions of 247 CMR.

Application for Renovation, Expansion or Relocation of Community Pharmacies

Board staff may approve an application to renovate or expand an existing registered pharmacy or an application to relocate an existing pharmacy, provided that:

1. Any and all other pharmacies registered with the Board and held under common ownership with the applicant have a registration in good standing with:
 - a. No adverse history, or
 - b. Adverse history that has been previously subject to a good moral character evaluation and has since been resolved, or
 - c. Adverse history that has been the subject of a complaint before the Board that has since been resolved.
2. The proposed Manager of Record has registration in good standing with:
 - a. No adverse history, or
 - b. Adverse history that has been previously subject to a good moral character evaluation and has since been resolved, or
 - c. Adverse history that has been the subject of a complaint before the Board that has since been resolved.
3. The application demonstrates the ability to comply with all requirements for registration set forth in 247 CMR 6.00. et seq.
4. The application sets forth a business model that is substantially similar to business models previously approved by the board.

	<ol style="list-style-type: none"> 5. The application includes a certified blueprint that depicts a floor plan and layout that is substantially similar to floor plans and layouts previously approved by the board. 6. The attestation which accompanies that application indicates that the applicant will not engage in sterile compounding. 7. The applicant does not require any waivers of any provisions of 247 CMR. <p><u>Application for Remodeling, Change in the Configuration, or Change in Square Footage of Sterile Compounding, Institutional Sterile Compounding, or Complex Non-Sterile Compounding Pharmacies</u></p> <p>The Plan Review Group may approve an application for remodeling, change in the configuration, or change in square footage of an existing sterile compounding pharmacy, institutional sterile compounding pharmacy, or complex non-sterile compounding pharmacy provided that:</p> <ol style="list-style-type: none"> 1. At least three members of the Plan Review Group agree with the approval; 2. The application satisfies requirements described in 247 CMR 6.00; 3. The application describes the renovation, expansion, repair, and/or service to be performed; 4. The proposed renovation, expansion, repair, and/or service: <ol style="list-style-type: none"> a. Is in response to a deficiency cited during an inspection or the need for an urgent repair (e.g., damage from a broken pipe, storm-related repairs, etc.); b. Does not change the square footage of a secondary engineering control; c. Does not involve the moving, adding, modifying, removing, or replacing any secondary engineering control; and d. Does not involve major repairs or replacement of HVAC systems; 5. The application describes a strategy to mitigate the effects of the construction work and maintain quality assurance during the construction period; and 6. The applicant does not require waivers of any provisions of 247 CMR 2.00 <i>et seq.</i>
Report to Board	Board Staff shall submit a report of applications approved pursuant to this policy to the Board on a monthly basis.