

Publications

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Massachusetts Issues Additional Update to Non-Resident Pharmacy Rules

Following the release of a memo last month detailing upcoming regulations, the Massachusetts Board of Registration in Pharmacy released its long-awaited regulatory changes for non-resident pharmacy licensure last week by updating 247 CMR 6.00. As we previously advised, all out-of-state pharmacies shipping into Massachusetts are impacted by these updated regulations. Pharmacies should prepare to submit applications as soon as they are released in January, as the Board anticipates processing delays.

Upcoming Key Dates:

- **January 1, 2025:** Board begins accepting applications.
- **January 1, 2025 - March 31, 2025:** Applications accepted and considered timely.
- **May 1, 2025:** Enforcement begins for unlicensed pharmacies dispensing prescription products into Massachusetts.

In addition to information that was previously announced, the updated regulations impose several new requirements for Massachusetts-licensed pharmacies.

Reporting Requirements

Nonresident pharmacies are subject to various reporting requirements under 247 CMR 6.00 and 247 CMR 20.00, including:

- **Relocation:** Non-resident pharmacies licensed by the Board are required to report certain changes. A pharmacy is required to apply to the Board at least 90 days prior to a planned change of location.
- **Closure:** Pharmacies that intend to close are required to provide 14 days advance notice to the Board and to any Massachusetts patient who has received a prescription in the preceding 90 days.
- **Changes of Ownership:** Pharmacies are required to report changes in ownership to the Board at least 14 days in advance. The proposed new owner is required to submit a new application at least 14 days prior to closing.
- **Dispensing Errors:** Within 7 days of discovery, pharmacies are required to report to the Board any improper dispensing into Massachusetts of a drug that results in

Related People

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Related Capabilities

- Licensure, Enrollment & Certification
- Pharmacy

serious injury or death.

- **Controlled Substance Dispensing:** Non-resident pharmacies are required to submit controlled substance dispensing data for prescriptions shipped to Massachusetts patients to the Massachusetts Prescription Monitoring Program.

Provisional Licenses

Subject to its discretion, the Board may issue a provisional license for a sterile compounding pharmacy, complex non-sterile compounding pharmacy, institutional sterile compounding pharmacy, non-resident pharmacy, non-resident sterile compounding pharmacy, or non-resident complex non-sterile compounding pharmacy in place of a full license for an applicant that has demonstrated that it is in substantial compliance with Board regulations and is likely to achieve full compliance within a year. The provisional license is valid until the Board converts the provisional license to a full license; the provisional license is surrendered, suspended, or revoked; or a year passes since the issuance.

Other Requirements

Under Massachusetts law, all prescription-only drugs are classified as controlled substances and listed, for state law purposes, as Schedule VI. As part of the non-resident application process, pharmacies will apply for a Massachusetts Controlled Substances Registration (“MCSR”). Even pharmacies that do not dispense typical controlled substances (i.e., those listed in Schedules II-V) will need to ensure that an MCSR is issued prior to dispensing into Massachusetts.

Polsinelli will continue to monitor Massachusetts’ updates to its pharmacy regulations. For questions about how these regulations apply to your pharmacy, or for assistance with obtaining non-resident pharmacy licensure in Massachusetts, please contact a member of our Pharmacy Law practice group.