

Publications

November 21, 2024 • Updates

Santa is Bringing Long-Awaited Regulatory Changes to Massachusetts Pharmacy Licensure

After almost a decade of waiting, Massachusetts has announced that it will open its licensing process for non-resident pharmacies. Yesterday, the Massachusetts Board of Registration in Pharmacy published a memo announcing that regulations related to the licensure of non-resident pharmacies will be promulgated in December 2024 and that the Board will begin accepting applications on January 1, 2025. The Board has established a grace period for applications through March 31, 2025. After May 1, 2025, any pharmacy dispensing into Massachusetts must be licensed.

Non-resident pharmacies currently serving patients in Massachusetts will be impacted by these new licensure regulations and need to take action now. To apply for Massachusetts non-resident pharmacy licensure, each pharmacy will need at least one pharmacist (who does not need to be the pharmacist-in-charge) who holds an individual Massachusetts pharmacist license. Normally, the pharmacist licensure process takes between 30-60 days. We expect the Massachusetts Board to see an influx of pharmacist applications related to this change and the licensure process may take significantly longer. There will also be inspection related requirements based on the type of pharmacy services (compounding, sterile, non-sterile) offered.

Key Dates:

- **December 2024:** New regulations implementing non-resident pharmacy licensure.
- **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.

Important Requirements:

- **Non-Resident Pharmacist Licensure:** At least one pharmacist at each licensed non-resident pharmacy must hold a Massachusetts pharmacy license. This pharmacist does not have to be the designated pharmacist-in-charge for the pharmacy.

Related People

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Related Capabilities

- Licensure, Enrollment & Certification
- Pharmacy

- **Inspections:** Upon initial licensure, a non-resident pharmacy must provide an inspection conducted within 2 years of the application submission date. The inspection must be conducted by a resident state inspector utilizing the NABP Universal Inspection Form, General Pharmacy Inspection, a resident state inspector with the resident state's general pharmacy compliance inspection form OR by a Board-approved inspector. Currently the NABP and Gates Healthcare Associates are approved by the Massachusetts Board of Registration in Pharmacy.
- **PMP Reporting:** Non-resident pharmacies must report Schedule II-V controlled substance prescriptions and gabapentin prescriptions dispensed into Massachusetts to the state prescription monitoring program.
- **Pharmacist-in-Charge:** Each non-resident pharmacy must designate a pharmacist-in-charge, and any changes to the pharmacist-in-charge must be reported within 14 calendar days of the change.

The Board noted that it has no plans for non-resident licensure of non-dispensing pharmacies, wholesalers, distributors, 3PLs, or manufacturers.

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.