

Insights

Massachusetts to Require Licensure for Non-Resident Pharmacies in 2025

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The Massachusetts Board of Registration in Pharmacy (the "Board") announced, via updated Non-Resident Licensure FAQs on November 19, 2024, that it will now require non-resident pharmacies to be licensed in order to dispense prescription products into the state. Massachusetts has historically permitted pharmacies to dispense to patients in the state without holding a license, so long as the pharmacy is in good standing in the state where it is located. However, under the new regulations, non-resident pharmacies must hold a Massachusetts license to dispense prescription drugs into the state beginning on May 1, 2025. The Board began accepting license applications for non-resident pharmacies on January 1, 2025.

The Board's registration requirements are summarized below:

Pharmacist Registration

At least one pharmacist at each non-resident pharmacy must hold a Massachusetts pharmacist license. This license can be held by *any* pharmacist – it does not need to be the pharmacist in charge. The process for obtaining pharmacist licensure in Massachusetts is predicted to take 30-60 days. *Therefore, it is strongly recommended that any pharmacies doing business in Massachusetts, including shipping pharmaceuticals to Massachusetts patients, begin the individual pharmacist licensure process now.*

Compounding Pharmacies

Pharmacies that are engaged in either sterile or complex non-sterile compounding are required to obtain a pharmacy specialty license, in addition to the non-resident pharmacy license.

Reporting

The non-resident pharmacy must now report to the state's Prescription Monitoring Program information for Schedules II – V and gabapentin prescriptions that are dispensed into Massachusetts.

Inspection

Retail pharmacy applicants are required to submit proof that an on-site inspection has been conducted within the last two years, and compounding pharmacy applicants are required to submit proof of inspection occurring within in the last year. Inspections must be conducted by the resident state or a Board-approved inspector utilizing National Board of Pharmacy ("NABP") or the state standards. For compounding pharmacies, this will include United States Pharmacopeia <800> Form or the NABP Universal Inspection Forms <795> and <797>. It is important to note that, at this time, non-resident licensure is not being offered for non-dispensing pharmacies, wholesalers, distributors, 3PLs, or manufacturers.

For any pharmacy that is operating on a national level, it is important that the pharmacy familiarize itself with the Massachusetts registration requirements and Board FAQs, and that the pharmacy keep apprised of any regulations and deadlines related thereto that may be issued by the Board. In addition to the initial registration, pharmacies will now need to include Massachusetts in their policies and procedures related to pharmacy license



renewals and follow any other reporting requirements that the state requires.

If you have questions about licensure issues for your pharmacy or related policies and procedures, please contact Stephanie Eckerle and Madison Hartman Harada or your regular Krieg DeVault attorney.

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