

December 18, 2024

Michael J. Godek, R.Ph.
Executive Director
Massachusetts Board of Registration in Pharmacy
250 Washington Street
Boston, MA 02108

Dear Executive Director Godek and Members of Board of Registration in Pharmacy:

On behalf of the Alliance for Pharmacy Compounding, I am writing to express our concerns regarding the soon-to-be-implemented nonresident pharmacy licensure regulations in Massachusetts. Specifically, we are concerned about the requirement that nonresident sterile and nonsterile compounding pharmacies must undergo an NABP or equivalent inspection annually, rather than every two years.

If enforced as written, Massachusetts would become the only state to mandate annual inspections for nonresident compounding pharmacies. This unique requirement places a significant and unnecessary burden on nonresident compounding pharmacies, which will now need to secure additional inspections every other year to comply. Paying for yearly inspections that are twice as frequent as any other state—on top of the existing licensure fees charged by the Massachusetts Board of Registration in Pharmacy—would make Massachusetts the most expensive state for nonresident compounding pharmacy licensure in the country and may lead to unintended consequences for patients in the commonwealth.

One example of unintended consequences for patients: Phospholine iodide eyedrops are used to treat a hallmark symptom of Sjögren's Syndrome, severe dry eye, which can lead to significant corneal damage if left untreated. Currently, these eyedrops are only commercially available in one concentration, leaving certain patient populations – specifically, children – without access to an effective, commercially available treatment. One New York-licensed sterile compounding pharmacy has been compounding low-dose phospholine iodide eyedrops for use in children for over 15 years. It is the only pharmacy in the country currently offering these specialized eyedrops. The two main prescribers of these compounded eyedrops are physicians treating patients in Massachusetts. While Sjögren's is often mischaracterized as a rare disease, it is estimated that over four million Americans live with this condition, making it one of the most prevalent autoimmune diseases, underscoring the necessity of accessible, effective treatments like compounded phospholine iodide.

The additional financial burden of out-of-state licensure and yearly inspections threatens to limit Massachusetts patients' access to these compounded preparations. It may be that the New York pharmacy and others like it choose not to renew their Massachusetts license. At a

minimum, as the costs to supply these medications to Massachusetts patients increase, the financial burden for patients will also increase. These eyedrops are but one example of potential patient access issues that may arise due to the new licensing and inspection requirements.

We strongly urge you to reconsider this provision and align the inspection frequency with the standard two-year requirement. The excessive cost and administrative burden of annual inspections may compel many non-resident pharmacies to forgo licensure in Massachusetts, limiting patient access to vital compounded medications. It also puts non-resident pharmacies at an economic disadvantage compared to resident compounding pharmacies, as these requirements do not appear to apply to those located in the state.

Thank you for considering our input on this matter. Should you have any questions, please feel free to contact me at scott@a4pc.org.

Best,

A handwritten signature in black ink, appearing to read 'S. Brunner', written in a cursive style.

Scott Brunner, CAE
Chief Executive Officer

The Alliance for Pharmacy Compounding is the voice for pharmacy compounding, representing more than 500 compounding small businesses – including compounding pharmacists and technicians in both 503A and 503B settings – as well as prescribers, educators, researchers, and suppliers.