April 21, 2025

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 the Board of Registration in Pharmacy:

On behalf of The Alliance for Pharmacy Compounding, I write to request that the Massachusetts Board of Registration in Pharmacy reconsider and clarify its April 3, 2025, memorandum regarding the dispensing by 503A pharmacies of drug products compounded by FDA-registered 503B outsourcing facilities.

Under federal law, specifically Section 503B of the Food, Drug & Cosmetic Act, FDA-registered outsourcing facilities may distribute compounded drug products to state-licensed pharmacies, provided those products are dispensed by the receiving pharmacy to a patient pursuant to a valid prescription. Importantly, FDA's 2023 draft guidance—titled *"Distribution of Compounded Drug Products Under Section 503B of the Federal Food, Drug, and Cosmetic Act"*— defines and supports this practice, making clear that outsourcing facilities may distribute compounded drugs to a 503A pharmacy that will then dispense those products for individual patients.

Although FDA refers to this activity as "wholesaling," the pharmacy compounding profession more accurately describes it as 503B sourcing, a practice that has become common and necessary—especially as drug shortages become more severe. This sourcing model allows 503A pharmacies to provide timely access to medications, compounded under Current Good Manufacturing Practice (cGMP) conditions by 503Bs. Most states, including those with historically conservative pharmacy policies (Arkansas, California, Nevada), allow and actively support this approach.

Unfortunately, Massachusetts' current position has resulted in access barriers for patients and confusion among pharmacists. Some Massachusetts pharmacies now report hesitancy from state inspectors or licensing staff to permit 503B-sourced medications to be used—even when clearly intended for patient-specific dispensing. The April 3 memo uses the phrase "re-dispensing," even though 503B outsourcing facilities do not commonly dispense directly to patients, they typically *distribute* compounded medications in bulk. This is particularly concerning at a time when hospitals and prescribers are relying on compounding more than ever due to persistent drug shortages.

We recognize and support the Board's commitment to ensuring patient safety. However, we believe that clear alignment with FDA's guidance—and with the practices allowed in nearly every other

state—will both improve access and ensure consistent regulatory expectations. For that reason, we respectfully request that the Board:

- Clarify that Massachusetts-licensed 503A pharmacies may dispense medications received from FDA-registered 503B outsourcing facilities pursuant to patient-specific prescriptions.
- Align state policy with FDA's position as reflected in the 2023 draft guidance and in consistence with Section 503B of the FD&C Act.

We appreciate the Board's consideration of this request and would welcome the opportunity to engage further on this matter. Our shared goal is to ensure that Massachusetts patients continue to have access to high-quality, appropriately regulated compounded therapies when they are needed most.

Sincerely,

Scott Brunner, CAE
Chief Executive Officer

The Alliance for Pharmacy Compounding is the voice for pharmacy compounding, representing more than 600 compounding small businesses – including compounding pharmacists and technicians in both 503A and 503B settings – as well as prescribers, educators, researchers, and suppliers.