April 21, 2025

Massachusetts Joint Committee on Public Health
Massachusetts Legislature
24 Beacon St.
Boston, MA 02133

Dear Members of the Joint Committee on Public Health:

On behalf of The Alliance for Pharmacy Compounding, I appreciate the opportunity to submit comments regarding Senate Bill S.1497, which seeks to restrict the distribution and dispensing of compounded medications, particularly those prepared by FDA-registered 503B outsourcing facilities.

We share the bill sponsor's commitment to ensuring patient safety, especially regarding compounded medications. However, we are concerned that S.1497, as written, would have unintended consequences that could limit patient access to critical therapies—particularly in cases of drug shortages or when commercially manufactured drugs are clinically unsuitable for a patient.

503B Sourcing to 503A Pharmacies Is Permitted Under Federal Law

Under the federal Food, Drug & Cosmetic Act (Section 503B), FDA-registered outsourcing facilities may compound and distribute medications for prescriber office use and to state-licensed pharmacies for subsequent dispensing to individual patients, provided that certain labeling and compliance conditions are met. The FDA's 2023 draft guidance on this topic explicitly supports this practice, acknowledging that 503Bs may distribute compounded products to 503A pharmacies when those products are subsequently dispensed pursuant to valid patient-specific prescriptions.

Although the bill is likely well-intentioned, several of its provisions—such as those restricting the transfer or "resale" of compounded medications by 503A pharmacies—would effectively prohibit 503B sourcing, even when used for lawful, prescription-based dispensing. This would place Massachusetts outside the regulatory norm; nearly every other state allows this type of pharmacy-provider relationship, which has become a critical part of the compounding ecosystem.

The "Not for Resale" Labeling Language Is Being Misapplied

The language in the bill concerning "not for resale" labeling appears to conflate legitimate patient dispensing with the commercial resale of products. In fact, FDA's labeling requirements are meant to prohibit wholesalers from redistributing compounded drugs, not to prevent pharmacies from dispensing 503B-sourced medications directly to patients under a prescription. Many medications

that patients rely on may be unavailable from manufacturers but can be accessed through outsourcing facilities under strict FDA oversight.

Patients Benefit When 503As Source from 503Bs

Far from being a safety risk, 503B outsourcing facilities are subject to Current Good Manufacturing Practices (cGMP), the same as drug manufacturers, and rigorous FDA inspection protocols. When 503A pharmacies source from these entities, they are providing patients with medications of high manufacturing quality. Moreover, in times of drug shortages—as Massachusetts and the nation have increasingly experienced—503B sourcing allows pharmacies to continue meeting patient needs without disruption.

Request for Amendment or Withdrawal

We respectfully urge the committee to reconsider the bill or amend it to explicitly allow for the practice of 503A pharmacies sourcing compounded medications for patient-specific dispensing from FDA-registered 503B outsourcing facilities. Doing so would maintain alignment with federal law, preserve patient access to safe and necessary compounded therapies, and avoid placing Massachusetts pharmacies at a regulatory disadvantage.

We welcome the opportunity to engage further on this topic and share specific examples of how 503B sourcing supports patient care and pharmacy compliance across the country.

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.