April 15, 2025

Chair Gary VanDeaver
Vice Chair Liz Campos
Members of the House Committee on Public Health
Texas House of Representatives
Room EXT E2.172
Austin, TX 78768

RE: Comments in Opposition to H.B. 3785 – Labeling Requirements for Compounded Medications

Dear Chairman VanDeaver and Members of the House Committee on Public Health,

On behalf of the Alliance for Pharmacy Compounding, I write to express serious concern about Texas House Bill 3785. The bill proposes expansive and impractical labeling requirements for compounded medications. We urge the Texas Legislature to reconsider this bill in light of existing regulations and the potential negative impact on patient safety and pharmacy workflow.

H.B. 3785 would impose duplicative and contradictory requirements to those already in place through the Texas State Board of Pharmacy (TSBP). Specifically, the bill's mandates to include side effects and "substitute for [drug name]" language directly on the prescription label conflict with established standards for compounding transparency and misrepresent the nature of compounded medications.

Let me be clear: This bill imposes labeling requirements that make claims that pharmacies are prohibited from making under federal law.

Unlike FDA-approved generics, compounded medications are custom-prepared to meet the individual clinical needs of a patient when commercially available options are not appropriate. Section (b)(3) requires the phrase "substitute for," which is not only misleading—it suggests interchangeability with a brand name drug that is unsupported by federal definitions and could cause confusion for both patients and prescribers. APC strongly cautions against any statutory language that blurs the legal and clinical distinction between compounded drugs and commercially manufactured pharmaceuticals.

Likewise, the requirement [Section (b)(9)] to list potential side effects on the label—regardless of whether they are relevant to the compounded formulation—raises both clinical and logistical issues. Labels on compounded medications are already crowded with critical, patient-specific information such as dosing instructions, beyond-use dates, and storage requirements. Mandating side effect listings on the label itself threatens to obscure that vital guidance and increase the risk

of misuse. Current TSBP rules appropriately address this by requiring written drug information or counseling to ensure patients receive side effect information in a more appropriate, readable format.

We support patient education, transparency, and high standards in compounding. But those goals are best achieved by enabling the TSBP to continue its thoughtful, stakeholder-driven revisions to sterile and non-sterile compounding rules. The Board's active rulemaking process already covers key labeling and disclosure standards in alignment with federal compounding regulations and USP guidelines.

For these reasons, we respectfully recommend **withdrawing H.B. 3785** and deferring to TSBP's regulatory process, which is better suited to balance patient safety, clarity, and pharmacy practice realities.

Thank you for your consideration of our perspective. We would welcome the opportunity to discuss this issue further or provide additional insight from the national compounding community.

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.