

March 21, 2025

Anne Sodegren, Executive Officer
Seung Oh, President
California State Board of Pharmacy
2720 Gateway Oaks Drive, Suite 100
Sacramento, CA 95833

President Oh, Director Sodegren, and Members of the California State Board of Pharmacy:

The Alliance for Pharmacy Compounding again urges the California State Board of Pharmacy to reject the proposed compounding regulations in their current form. The feedback from a broad coalition of stakeholders—hospital pharmacists, compounding pharmacies, physicians, academic institutions, and healthcare organizations—has been clear: these regulations are unworkable, unnecessary, and detrimental to patient care. Yet, despite extensive opposition, the Board seems determined to move forward without making the meaningful revisions needed to align these regulations with patient needs and practical compounding practices.

We acknowledge the significant time invested in this rulemaking process. However, that sunken cost does not justify pushing forward regulations that impose unclear, duplicative, and excessively burdensome requirements without clear evidence of benefit. The goal must be to ensure patient access to safe and necessary medications, not to create barriers that disrupt care without justification. Unfortunately, these regulations prioritize procedural finality over patient well-being, and the Board has failed to demonstrate how the proposed rules enhance patient safety.

The public comment process has been inadequate. Restricting pharmacists and other experts to two-minute speaking slots—without opportunities for meaningful discussion—has stifled necessary debate and left significant misunderstandings unaddressed. Several Board members have demonstrated a fundamental lack of knowledge regarding USP standards and their existing safeguards for patient safety. Moreover, some have incorrectly suggested that stability studies exist for certain compounded medications, such as nebulized formulations, when in reality, such studies are extremely limited or nonexistent.

To ensure that any regulatory changes are based on expertise and real-world applicability, we strongly urge the Board to convene a task force of pharmacists from diverse practice settings—including hospitals, academic medical centers, rural facilities, and compounding pharmacies. This group should also include USP committee members to provide authoritative insight. A collaborative approach is essential to crafting regulations that truly enhance patient safety without unnecessary disruption.

The Board must recognize that USP standards already set a rigorous, evidence-based national benchmark for compounding safety. Imposing additional, conflicting state-specific regulations serves only to create confusion and limit patient access to vital treatments. Rather than advancing these flawed regulations, the Board should commit to enforcing existing USP standards while taking the time necessary to engage in meaningful dialogue with healthcare professionals.

These regulations are not supported by the very professionals responsible for patient care. Instead, they appear to serve the interests of groups with financial incentives to limit compounding—a fact that has not gone unnoticed by the compounding and broader healthcare communities. The few public comments in

support of these regulations have been made by Big Pharma and groups backed by pharmaceutical companies. We urge the Board to step back, listen to the overwhelming opposition, and pursue a regulatory approach that prioritizes patients over politics.

Sincerely,

A handwritten signature in black ink, appearing to read 'S. Brunner'.

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.