Alliance for Pharmacy Compounding

February 21, 2025

Anne Sodegren, Executive Officer
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California State Board of Pharmacy
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Subject: *Opposition to the Passage of the Proposed Compounding Regulations*

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

The Alliance for Pharmacy Compounding asks that the California State Board of Pharmacy not to pass the proposed compounding regulations as currently written. As stakeholder feedback has indicated, these regulations are just not ready for implementation and there is no buy-in from the healthcare community. A broad coalition of hospital pharmacists, compounding pharmacies, physicians, academic medical centers, and healthcare institutions have consistently raised concerns about the unintended consequences of these rules. Yet, the Board appears poised to move forward without addressing these concerns meaningfully.

We do appreciate the many hours this Board has taken to review iterations of the proposed compounding regulations. Unfortunately, they are still filled with ambiguities and unnecessary obstacles to patient access. We understand the desire to finally pass these regulations and "move on." However, it is of the utmost importance to get these regulations right, as the lives of Californians will be affected. The Board must not – as it appears to be doing – put the expediency of the process ahead of patient access to necessary medications, particularly when the Board has not shown a justification for some of the new rules or indicated how the rules make patients safer.

Additionally, we are troubled that it appears that no written responses to the final round of public comments will be provided before the vote, as has been customary in the past. Instead, the Board intends to include responses in the Final Statement of Reasons, which suggests that the third modified text is functionally the final version—leaving no room for substantive changes before adoption. If that is the case, the Board is prioritizing expediency over stakeholder input and may be violating state administrative procedures rules.

This rulemaking process has not provided a true opportunity for public engagement. The two-minute time slots for public comment, without the ability for follow-up or meaningful discussion, have shut down dialogue and prevented pharmacists from responding to Board members' misunderstandings about the real-world impact of these regulations. A fundamental misunderstanding persists among some Board members regarding USP general chapters and the high standards those chapters already set for patient safety. Members of the Board also have made statements falsely suggesting the availability of

stability studies for the specialized formulations of nebulized medications that are needed by Californians.

The consequences of passing these regulations as written will be harmful to public health. Patients will lose access to critical medications and the care of pharmacists due to overly restrictive and duplicative requirements that go beyond USP standards without improving safety. Critical concerns that remain unresolved include:

- Restrictions on immediate-use compounding that exceed USP standards, unnecessarily limiting access to time-sensitive medications.
- Additional bulk drug testing requirements for Category 1 drugs, which duplicate testing already performed under USP standards, adding unnecessary costs and delays.
- Requiring adherence to guidelines set in USP Chapters above 1000, even though those chapters are not intended for enforcement by USP.

Before finalizing any new rules, we strongly urge the Board to form a task force of pharmacists from community hospitals, academic medical centers, rural hospitals, community pharmacies, and compounding pharmacies to share their expertise. This task force should include USP committee members to provide accurate, real-world insight. This approach would ensure the Board is fully informed before implementing regulations that could disrupt patient care.

The Board must also acknowledge that California's approach to compounding regulation is outdated. USP standards have now set the national benchmark for patient safety while balancing medication access. Rather than layering unnecessary and conflicting state regulations on top of USP standards, the Board should listen to the pharmacists in the profession—who have overwhelmingly opposed these proposed regulations precisely because they go too far and do not make patients safer.

Given these concerns, we urge the Board to enforce existing USP standards in the interim while taking the necessary time to become better informed on the realities of compounding practice. Patients' ability to receive care is at stake, and it is simply too important to rush forward with misguided regulations. Please heed the hundreds of people who have spoken up at previous meetings who have overwhelmingly opposed these regulations.

We strongly urge the Board to reject these regulations and engage in a true, informed dialogue with the healthcare community before proceeding.

Sincerely,

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