

September 11, 2023

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

Dear President Oh and Director Sodergren:

The Alliance for Pharmacy Compounding wishes to offer input on Attachment 5, titled Draft Compounding Policy Statement, in advance of your next board meeting.

The Alliance for Pharmacy Compounding is the voice for pharmacy compounding, representing more than 600 compounding small businesses – including more than 4,000 compounding pharmacists and technicians in both 503A and 503B settings – as well as prescribers, educators, researchers, and suppliers.

APC supports the Board's statutory mission to protect California consumers, and we believe it is in the interest of the pharmacy compounding profession to have robust enforcement of reasonable regulation that safeguards patient safety. But equally important is the board's role in enunciating clear direction for licensees and inspectors regarding enforcement of its policies.

Our concern is that the policy statement referenced in Attachment 5 does not make clear what the Board's enforcement expectations are regarding the transition to compliance with the new USP standards and which standards of compliance pharmacy compounders will be held to. That lack of clarity about the Board's intentions and expectations makes it difficult, to say the least, compounders to know and understand how to comply.

Notably, Attachment 5 states that "pharmacies are encouraged to begin transitioning to the new USP standards," but that encouragement raises concerns about which compliance standards pharmacies will be held to come November 1. Do they continue following the current California law *alongside* new USP chapters come November 1? If so, there are certain conflicts between current California law and the new USP chapters. To which standard will licensees be held?

For example, for an aqueous suspension, at present should a beyond-use-date of 14 days refrigerated (current USP 795) or 35 days room temp (revisions to USP 795 effective November 1, 2023) be used? Or can the 35-day BUD only be used *after* November 1? We would presume that using the 35-day BUD is contingent on being compliant with the rest of the revisions to 795 before using BUDs associated with those revisions, but that is not stated in your proposed policy.

We urge the board to consider rescinding existing regulation related to compounding effective November 1, 2023, *except for BPC 4126.8: Compounding consistent with USP*. By eliminating those older, outdated rules, both compounders and the board will have a clear understanding of what is expected from compounders – and, importantly, from regulators.

We do understand that California Board of Pharmacy staff have proposed additional regulation and restriction of sterile compounding, in particular, that go beyond the national standards established by USP in Chapter <797>. As we've stated previously in communication to the Board, such additional regulations may be well and good, provided the Board can demonstrate in science and practice how that regulation keeps patients safer by reducing risk of contamination. Thus far, the Board has not enunciated the "why" behind those additional restrictions, but it should, lest the board seem arbitrary in its oversight of compounding pharmacies. The Board should do so for its own credibility as well as to provide licensees a clear understanding of why the compliance steps required by the new regulation is necessary.

We certainly respect and support your mission to protect Californians. Yet we are concerned that policies referenced here are vague and leave California licensees with no bright-line standard for compliance. At a minimum, we request that the Board release a detailed statement explaining its expectations for transitioning to the new standards.

Thank you for considering our input. Please direct any questions to APC's Savannah Cunningham at savannah@a4pc.org.

Best,

A handwritten signature in black ink, appearing to read 'S. Brunner', written in a cursive style.

Scott Brunner, CAE
Chief Executive Officer