Tenille Davis testimony to California Board of Pharmacy

June 18, 2024

Good morning, President Oh, Director Sodergren, and members of the California State Board of Pharmacy. My name is Tenille Davis, and I am Chief Advocacy Officer with the Alliance for Pharmacy Compounding. I'm also an experienced compounding pharmacist. Thank you for this opportunity to comment on the California proposed regulations concerning compounded drug products.

Our association represents a significant portion of the compounding industry, and we have serious concerns about certain provisions in the proposed regulations. While we understand and respect the Board's mission to protect California citizens, we believe that some of these proposals will have unintended negative consequences on patient care and access to medications their doctors have judged necessary for those patients. We have submitted detailed comments in writing. In total we identify 57 specific places where the proposed regulations exceed what is required in federal law and by the compounding chapters of the U.S. Pharmacopeia. In none of those instances has the Board demonstrated how these excessive regulations make patients safer.

Allow me to hit some high points.

First, the proposed prohibition on compounding with FDA Interim Bulks list items in Category 1, such as glutathione, methylcobalamin, and DMPS, is particularly troubling. These substances are vital for patients who have no other suitable treatment options. For example, glutathione is essential for patients with oxidative stress disorders, while methylcobalamin is crucial for those with certain neurological conditions. DMPS is used in the emergency room to treat heavy metal poisoning. Denying access to these compounded medications could significantly impact patient health and well-being. And I must note: FDA clearly allows compounding of items on the interim bulks lists, and it could be argued that FDA and federal law pre-empt California's ability to treat those substances differently. Additionally, the California Board has indicated in writing as recently as yesterday to an attorney that it is FDA that determines whether a drug can be distributed and/or sold, not the Board.

The proposed regulations on allergenic extract compounding are excessively stringent. The requirement to use a dedicated Primary Engineering Control (PEC) solely for allergenic extracts, and the classification of these extracts under Category 1 or 2 with short beyond-use dates, will severely limit patient access to necessary treatments. These requirements go beyond federal standards and do not offer a clear benefit in terms of patient safety. They seem to be regulations for the sake of more regulations, a way for the Board to penalize ethical, conscientious compounders rather than enforce current regulation on non-compliant pharmacies.

For some of the proposed regulations, the industry products and services available are not set up to support compliance even if compounders licensed in your state aim to comply. For example, excipient suppliers that must be FDA registered manufacturers, and the printed original manufacturer name and address being printed on the certificate of analysis of the API are not currently the standards in the industry.

Importantly, despite the Board's assertion that these changes will not have an economic impact on small businesses, many compounding pharmacies are indeed small businesses and will face significant financial burdens to comply, potentially driving some out of business. We don't argue that there should not be a cost of compliance, but we do argue that the Board is required to acknowledge and properly estimate that cost. Those costs will not only impact the pharmacies but also the patients who rely on their specialized services.

In conclusion, we respectfully request that the Board reconsider these provisions and align more closely with national standards, such as those established by the United States Pharmacopeia. Doing so will help ensure that patients in California continue to have access to essential compounded medications while maintaining safety and compliance. And you'll provide clear, bright-line compliance standards for pharmacies.

Thank you for your consideration of our input.