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Alliance for Pharmacy Compounding

November 9, 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:

I write to request clarification of the California Board of Pharmacy's position and enforcement posture regarding the compounding of a drug that is "essentially a copy" of an FDA-approved drug when that drug appears as "currently in shortage" on the FDA drug shortage list.

The Alliance for Pharmacy Compounding is the voice for pharmacy compounding, representing more than 600 compounding pharmacies and facilities across the U.S., including compounding pharmacists and technicians in both 503A and 503B settings, as well as prescribers, educators, researchers, and suppliers.

The California BOP's mission is to protect California consumers, including assuring that California patients can access compounded medications that are prepared in accordance with federal and state law, FDA guidance, and USP standards. Continued patient access is at the crux of this inquiry.

We've recently received reports from our members of conflicting and confusing statements by California BOP staff regarding semaglutide compounding during this ongoing period – 20 months now – in which the branded products are on FDA's shortage list.

As you know, FDA does not consider a compound to be "essentially a copy" of a commercially available drug when the FDA-approved drug is listed as "currently in shortage" on the FDA drug shortage list. FDA-approved semaglutide drugs have been listed as "currently in shortage" on the FDA Drug Shortage List continuously since March 2022. The Federal Food, Drug, and Cosmetic Act defines a drug shortage as a period of time when the demand or projected demand for the drug within the United States exceeds the supply of the drug.

However, we are told that California inspectors have told some California-licensed pharmacies based in other states that they may not ship compounded semaglutide into California because the FDA-approved drugs are available from some wholesalers, and that availability trumps the FDA Drug Shortage List. If that is the California BOP's position, it contradicts the U.S. Food, Drug & Cosmetic Act and FDA guidance.

At the same time, we are hearing from some California-based compounding pharmacies that inspectors or other Board staff have advised them that they may continue to prepared compounded semaglutide in various dosage forms, including sublingual, while the FDA-approved drugs appear on the shortage list as long as the compounding is done in accordance with state and federal law and USP guidance – including that only semaglutide base, the API in the FDA-approved drugs, is used.

Will you please provide the following:

- A statement of the California BOP's stance on compounding a copy of an FDA-approved drug when it appears as "currently in shortage" – and with specific reference to semaglutide compounding?
- If the California BOP's position deviates from FDA guidance, please describe the rationale for and legal basis on which the BOP has taken a position that is different.
- If the California BOP's position deviates from FDA guidance, please provide documentation of any formal action by the Board that ratified that position.

Thank you for your attention to this request. I appreciate the work the Board and its staff do. I know that your responsibilities are many and I am grateful for your attention to this.

If you have questions, please contact me at scott@a4pc.org.

Sincerely,

Scott Brunner, CAE
Chief Executive Officer