

## California State Board of Pharmacy 2720 Gateway Oaks Drive, Suite 100 Sacramento, CA 95833 Phone: (916) 518-3100 Fax: (916) 574-8618

Business, Consumer Services and Housing Agency
Department of Consumer Affairs
Gavin Newsom, Governor



www.pharmacy.ca.gov

To: Board Members

Subject: Discussion and Consideration of Waiver Related to Temporary Provisions for Compounding Certain Parenteral Drug Products Consistent with Provisions of Business and Professions Code Section 4062

<u>Relevant Law:</u> <u>Business and Professions Code section 4062(b)</u> provides the Board with the authority to waive application of any provision of Pharmacy Law or its regulations during a declared federal, state, or local emergency if, in the Board's opinion, the waiver will aid in the protection of the public health or the provision of patient care.

<u>Background</u>: US Department of Health and Human Services Secretary Becerra recently declared public health emergencies as a result of the consequences of Hurricanes Helene and Milton. Following the declarations, the FDA released a <u>guidance document</u>, "Temporary Policies for Compounding Certain Parenteral Drug Products."

In support of the guidance, and consistent with his delegated authority, President Oh approved the issuance of a <u>waiver</u> for 30 days. Since that time, the Board has responded to one submission, advising that it does not object to the pharmacy's intended action. The Board received two other submissions that did not comply with the provisions of the FDA guidance and the Board's waiver; therefore, the Board objected to those submissions.

<u>For Consideration</u>: During the meeting, members will have the opportunity to review the waiver and determine if an extension is appropriate. Should the Board believe such action is appropriate, the following motion could be used.

**Possible Motion**: Consistent with the Board's authority in Business and Professions Code section 4062(b), and the declaration of public health emergencies by HHS Secretary Becerra, the Board extends its current waiver, Temporary Provisions for Compounding Certain Parenteral Drug Products, through January 31, 2025, or until the end of the declared emergency, whichever is sooner.