Temporary Provisions for Compounding Certain Parenteral Drug Products

In response to the Department of Health and Human Services (HHS) Secretary Becerra determination that public health emergencies (PHEs) exist as a result of the consequences of Hurricanes Helene and Milton, and consistent with the authority of the Board to waive Pharmacy Law or the regulations adopted pursuant to it, the Board President, through his delegated authority, approves the below waiver in support of the FDA's "Temporary Policies for Compounding Certain Parenteral Drug Products Guidance for Industry" (Guidance), dated October 2024 as provided below.

1. All conditions established in the Guidance are met and only FDA identified drugs are provided pursuant to this waiver and Guidance.
2. The California licensed pharmacy providing the drug product to a hospital or health system is appropriately licensed in California to perform sterile compounding.
3. The California licensed pharmacy notifies the Board of their intent to provide such products to the identified hospital or health system without first obtaining a patient-specific prescription. Such notification shall be submitted via email to compoundingreport@dca.ca.gov. Consistent with the provisions of the Guidance, the Board will respond if the Board does not object.
4. Documentation of compliance with the provisions established in the Guidance shall be maintained for a period of three years and maintained in a readily retrievable manner.

Issued: October 16, 2024
Expiration: January 31, 2025, or until the end of the declared emergency, whichever is sooner.