June 3, 2024

Lori Martinez
Board of Pharmacy
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Sacramento, CA 95833

Submitted via electronic mail to, Lori.Martinez@dca.ca.gov

SUBJECT: Board of Pharmacy Proposed Regulations: Amend title of Article 4.5 and Repeal sections 1735 through 1735.8 of Article 4.5, adopt new titles and sections 1735 through 1735.14 of Division 17 of Title 16 of the California Code of Regulations

Dear Ms. Martinez,

On behalf of more than 400 hospitals and health systems, the California Hospital Association (CHA) appreciates the opportunity to comment on the Board of Pharmacy's (BoP) proposed regulations for nonsterile compounding, sterile compounding, and hazardous drugs.

The BoP plays a key role in partnering with hospitals and their pharmacies to promote quality and safety for patients. Ensuring the safe distribution of medication to patients is a core function of pharmacy practice, and pharmacists are integral in preventing medication errors, ensuring safe drug interactions, and helping avert other adverse medication events for patients. By following laws and regulations, hospital pharmacies and their pharmacists contribute to building trust and confidence with patients, health care professionals, and regulatory bodies. Hospitals are deeply committed to patient safety and regulatory compliance and offer the following feedback for your consideration and action:

Lack of Necessity

Generally, these regulations will not meaningfully enhance protection of, or promote the health and safety of, Californians. Federal law already requires compounding of drug preparations to be consistent with standards in the current version of the United States Pharmacopeia (USP)-National Formulary.

The USP is an independent, scientific nonprofit organization focused on helping ensure a supply of safe, quality medicines. When developing compliance standards, the USP follows a deliberative and evidence-based process to determine when regulations are necessary before becoming legally recognized as the standard of practice. Each step undergoes rigorous scientific review, including input from experts, stakeholders, the public, industry, academia, and regulatory agencies. Input from these diverse perspectives informs regulation development and details legal recognition, conformance, testing practices, and terminology. USP scientists and experts have developed countless effective and evidence-

based regulatory standards, including those governing nonsterile compounding (USP 795), sterile compounding (USP 797), and hazardous drugs (USP 800).

USP standards are referenced in federal regulations enforced by the Food and Drug Administration (FDA), ensuring compliance with the Food, Drug, and Cosmetic Act. Violations of these federal rules could subject licensees to enforcement by the FDA or the U.S. Department of Justice. Hospitals and their pharmacies prioritize compliance with these rigorous requirements.

In addition to conforming with USP standards, hospitals are required to comply with a variety of other federal and state laws and regulations and undergo regular enforcement reviews to maintain their federal certification and state license to operate as hospitals.

Given the existing and extensive federal set of USP compliance standards — developed with scientific rigor, stakeholder input, legal recognition, and a commitment to public health and safety — the necessity and value of these proposed regulatory additions and amendments should be evaluated.

Additionally, the BoP has not provided substantial evidence that hospital pharmacies are failing to follow either the BoP's current regulations or the detailed federal USP standards. No evidence has been presented by the BoP suggesting systemic challenges or indicating patients have been placed in harm's way, or that hospital pharmacies are not meeting safety standards that might necessitate additional BoP regulations.

Duplicative and Resource-Intensive

A lack of high-quality empirical evidence supporting the need for additional regulations is likely to generate confusion and redundancy, and not accomplish, as stated in the Initial Statement of Reason, an "effective and less burdensome" process.

These duplicative regulations will divert patient care dollars from hospitals' finite resources, increase compliance confusion and uncertainty, reduce efficiency, and increase the risk of legal penalties. Striking a balance between necessary oversight and minimizing confusing and inefficient compliance standards is critical to foster a sustainable health care system for the needs of patients today and in the future.

Benefit and Cost Impact Is Unclear

While regulations are necessary for quality and safety, finding a balance between regulations and cost effectiveness remains a critical challenge in health care. In the past decade hospitals have expended millions of dollars to comply with the evidence-based USP standards. These proposed regulations will unnecessarily increase the costs and slow down the compounding process without evidence of the need to do so — at a time when hospitals are at once trying to hold health care cost growth in check and when nearly 50% are losing money every day in caring for patients.

The substantial cost of these proposed regulations on hospital pharmacies has not been articulated or recognized, and there has not been a comprehensive benefit-cost analysis to assess whether these regulations will achieve their intended goals without an undue impact on resources for patient care. For example, one hospital system in California has estimated, conservatively, the annual cost of compliance with these proposals would exceed $7 million annually in supply and labor costs alone.

The California Legislature and the California Department of Health Care Access and Information are working diligently to lower health care costs. Every additional requirement a hospital must fulfill raises costs, which runs counter to this shared goal. These considerations must be balanced when creating new regulations.

There is abundant and effective regulatory guidance provided by the USP and the BoP's proposed regulations would have too many unintended consequences to advance at this time and without a deeper analysis.

CHA appreciates the opportunity to discuss these perspectives. If you have questions, please contact me at slowe@calhospital.org or 916-240-8277.

Sincerely,

Sheree Lowe
Vice President, State Policy