



June 22, 2026

California State Board of Pharmacy  
2720 Gateway Oaks Drive, Suite 100  
Sacramento, CA 95833

**Subject:** Agenda Item VIII – Support for Rescinding Proposed Rulemaking (CCR §§ 1750 and 1750.1)

Dear Members of the Board,

On behalf of OSRX, we appreciate the opportunity to provide comments regarding Agenda Item VIII and the proposal to rescind the October 26, 2022 motion to initiate rulemaking to add sections 1750 and 1750.1 to Title 16 of the California Code of Regulations.

We support the Board’s decision to rescind the proposed rulemaking.

Outsourcing facilities operating in California are already subject to a comprehensive and well-established regulatory framework. Pursuant to Business and Professions Code section 4129.2(b), a nonresident outsourcing facility must compound sterile and nonsterile drug products distributed into California in compliance with applicable Board regulations and federal current good manufacturing practices (cGMP) applicable to outsourcing facilities. These facilities are also subject to FDA oversight and inspection, as well as inspections conducted by the California State Board of Pharmacy.

Given this existing framework, OSRX does not believe the proposed regulations are necessary. California law already requires compliance with federal cGMP requirements and provides the Board with oversight authority through licensure and inspection activities. The Board has not identified a demonstrated gap in oversight, compliance, or public protection that would be addressed by the creation of new regulatory sections. Rather, the proposed regulations would largely duplicate requirements and expectations that are already established through federal law, existing state law, and ongoing regulatory oversight.

As a California-licensed outsourcing facility and long-standing Board licensee, OSRX has operated under this framework for many years. Our experience has been that the applicable requirements are clear, comprehensive, and consistently enforced. Board inspections have been appropriately aligned with existing legal and regulatory requirements and have provided effective oversight of outsourcing facility operations.

The proposed self-assessment provisions further illustrate the limited value of the rulemaking. While self-assessments may serve as an internal quality management tool, they are inherently self-reported and represent only a point-in-time evaluation. Compliance is more effectively assessed through objective measures, including inspections, records review, quality system performance, corrective and preventive actions, and demonstrated adherence to applicable



regulatory requirements. As a result, codifying additional self-assessment requirements would not materially enhance oversight or improve compliance beyond the mechanisms already in place.

More broadly, regulatory requirements should provide a clear and measurable benefit to public protection. Where comprehensive oversight mechanisms already exist, the addition of duplicative regulatory provisions can increase administrative burden and complexity without producing corresponding improvements in compliance or patient safety.

### **Conclusion**

For these reasons, OSRX respectfully supports rescission of the proposed rulemaking for CCR sections 1750 and 1750.1. Existing California law already incorporates federal cGMP requirements applicable to outsourcing facilities and, together with FDA and Board oversight, provides a robust framework for ensuring compliance and protecting public health. Rescission appropriately avoids unnecessary and duplicative regulations while promoting clarity, efficiency, and consistency in the regulation of outsourcing facilities.

Thank you for your consideration.

Sincerely,  
Amy Frost, PharmD  
Chief Pharmacy Officer – PIC  
OSRX, Inc