



July 17, 2024

Anne Sodergren, Executive Officer
Seung Oh, President
California State Board of Pharmacy
2720 Gateway Oaks Drive, Suite 100
Sacramento, CA 95833

Dear President Oh, Director Sodergren, and Members of the California State Board of Pharmacy,

I am writing to express our deep concern regarding the proposed amendments to California Business and Professions Code (BPC) 4112, which would require all pharmacists, including those working for non-resident pharmacies, to be licensed in California to hold a non-resident pharmacy license. As the trade association representing compounding pharmacies, we believe this regulation would impose significant burdens on businesses and disrupt patient access to essential medications.

The proposed changes would require non-resident pharmacies that ship, mail, or deliver controlled substances, dangerous drugs, or dangerous devices into California to ensure that every pharmacist involved in the dispensing or compounding process is licensed in California. This requirement is not only onerous but also impractical, particularly for larger national compounding pharmacies and entities like central fill operations that employ hundreds of pharmacists.

The primary concern is that such a regulation would force out-of-state compounding pharmacies to re-evaluate their ability to serve California patients. The additional administrative and financial burden of obtaining California licenses for every individual pharmacist could deter these pharmacies from shipping medications into the state altogether. This would lead to significant disruption in patients' access to critical compounded medications, potentially jeopardizing their health and well-being.

Our experience with similar regulations in other states highlights the potential consequences. For example, Nevada recently considered a similar requirement but ultimately decided against it due to the undue burden it would place on pharmacies and the negative impact on patient access to medications. The law in question in Nevada requires any pharmacist compounding or dispensing prescriptions for controlled substances or dangerous drugs for Nevada patients to be registered with the Board. Historically, this has been interpreted to mean that the out-of-

state facility and, in some cases, the pharmacist-in-charge must be licensed in Nevada. However, the potential reinterpretation to include every individual pharmacist would have created an unmanageable regulatory environment, mirroring the challenges presented by the proposed changes in California. Ultimately, Assembly Bill 107, enacted by the Nevada Legislature on May 31, 2023, reversed a previous interpretation by the Nevada Board of Pharmacy that mandated out-of-state pharmacists needed to obtain a Nevada pharmacist license when dispensing or compounding prescriptions for Nevada patients.

Additionally, we must draw attention to Kentucky's recent refiling of a controversial regulation that would require all non-resident pharmacists to obtain a Kentucky license. This proposal has sparked significant controversy and concern within the pharmacy community, highlighting the impracticality and potential disruption such regulations could cause. If implemented, it would have established a burdensome precedent, further complicating the regulatory landscape for pharmacies operating across state lines and ultimately affecting patient care and access to medications. It was ultimately withdrawn after stakeholder feedback.

We strongly urge the California Board of Pharmacy to reconsider the proposed amendments to BPC 4112. We recommend maintaining the current regulatory framework, which requires non-resident pharmacies and the pharmacist-in-charge to be licensed in California. This approach ensures patient safety and access to medications without imposing undue burdens on pharmacies.

Thank you for considering our concerns. We are committed to working with the Board to find solutions that balance regulatory oversight with the practical needs of pharmacies and the patients they serve.

Sincerely,

A handwritten signature in black ink, appearing to read 'S. Brunner', with a stylized, cursive script.

Scott Brunner, CAE
Chief Executive Officer
scott@a4pc.org