

December 9, 2020

Gregory Lippe, CPA, CSBP President
c/o Anne Sodergren, CSBP Executive Officer

Transmitted by email

Dear President Lippe:

On behalf of California Council for the Advancement of Pharmacy, I would like to comment on the 2019 Sunset Review document as well as make a comment that may or may not be in the Draft Supplemental document. However, it was mentioned during the November 19, 2020 Full Board meeting that comments were welcomed about the diversity of the board so that will be the second comment.

On page 18 of the Sunset Review PDF or on page 6 of Section 1, it is written that a closed-door pharmacy is a license type, along with community and hospital pharmacy license types. While I am aware there is more than one kind of closed-door pharmacy, I am unaware there is a closed-door license type. LTC pharmacies are closed door (unless, and in the unlikely event the pharmacy sells diapers, at which point they must have business hours posted, a retail counter and allow foot traffic (according to DHCS). Moreover, LTC closed-door pharmacies are licensed as community pharmacies, although they do not “dispense drugs at retail to patients,” but rather they furnish their contracted facilities with the prescriber ordered medication where patients reside.

Please let me know if there is a “closed door” license because I have reviewed the pharmacy license application as well as the law book and can locate no mention of a closed-door license type. If there is one, many of my members would want to have a closed-door license as it would represent LTC pharmacies more accurately than a “community” pharmacy license.

Further, if a closed-door license is non-existent, CCAP requests that “closed door” is removed from the License Type.

Regarding the board’s diversity, I am commenting on the representation of pharmacy practice settings. CCAP contends that there should be a LTC pharmacist/pharmacy owner who is closed-door and only services LTC facilities.

In addition, CCAP recommends that one of the board licensee positions be filled by an independent sterile compounding pharmacist/pharmacy. Recognizing that sterile compounding is performed in LTC pharmacies and hospital pharmacies, the independent sterile compounding pharmacist/pharmacy is severely affected by the federal and state sterile compounding regulations, but who also understands the risks sterile compounding could have upon the consumer. As well, the majority of independent sterile compounding pharmacists/pharmacies also perform non-sterile compounding.

It makes sense that someone of that level in the compounding practice setting should be sitting on the California State Board of Pharmacy to protect consumers.

Thank you for taking California Council for the Advancement of Pharmacy's comments into consideration as you review and edit the Board's Sunset Review document for the Legislative Oversight Committee.

Warm regards,

Paige Talley

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December 10, 2020

The Honorable Anne Sondergren
Executive Director, California State Board of Pharmacy
2720 Gateway Oaks Drive, Suite 100
Sacramento, CA 95833

Dear Director Sondergren,

On behalf of AmerisourceBergen, I write to first express our on-going commitment to safe and efficient delivery of pharmaceuticals to California's pharmacies, hospitals, specialty physician clinics and long-term care facilities, and to ensure the safety and health of the patients they serve. Second, and more specifically, we respectfully request that the California State Board of Pharmacy (BOP) take the following action:

- Extend the deadline for its [existing waiver suspending the requirement that couriers obtain a physical-signature from a licensed pharmacist](#) to complete deliveries of prescription drugs;
- Amend the current waiver, or promulgate a new waiver, to suspend pharmacy law provisions (under Section [4059.5\(a\)](#)) requiring delivery personnel to confirm that the employee accepting the delivery is a pharmacist.
- Engage in further dialogue and work to achieve permanent alteration of the Code to better ensure patient access to critical care.

AmerisourceBergen is a pharmaceutical distribution and services company that distributes more than 30% of all pharmaceuticals in the United States, shipping more than 4 million products daily. In California, everyday AmerisourceBergen safely and securely completes between 2,000 and 2,500 deliveries to pharmacies, hospitals, long-term care facilities and physician offices, all within 12 hours from receiving an order from a customer. AmerisourceBergen operates facilities in Anaheim, Corona, Inglewood, Millbrae, Orange, Sacramento and Visalia; employs 1,045 associates in the state; and serves thousands of healthcare customers and millions of their patients across California.

As a licensed pharmaceutical wholesaler with significant financial investments in the state, AmerisourceBergen is required to comply with California Business and Professions Code mandating that **only** a licensed pharmacist may sign for deliveries of prescription drugs at sites of care. This unnecessary and overburdensome requirement departs from well-established safety standards imposed **in every other state**. While we believe the rule was drafted with best intentions, in practice, it fails to serve its intended purpose of protecting patients and instead creates safety concerns for vulnerable populations who need access to critical medications in a timely manner. Because a licensed pharmacist is not always available to sign for a delivery—due to factors beyond the control of prescription drug wholesalers and their couriers—drivers are often required by California statute to withhold deliveries of urgently needed medications, including drugs that treat critically ill patients suffering from cancer and other life threatening illnesses.



AmerisourceBergen safely and securely completes hundreds of thousands of deliveries every year in California, and millions of deliveries nationwide. We are unaware of even a single incident in which prescription drugs have been diverted because they were signed for by a non-pharmacist. Additionally, it is our understanding that commercial parcel delivery services operating in California are routinely permitted to deliver prescription medications without being subjected to the same onerous signature requirements, effectively undercutting current law.

AmerisourceBergen Asks the BOP to Exercise Its Authority to Expand and Extend Its Suspension of the Signature Requirement and Consider the Need to Permanently Alter the Requirement

The current pandemic has spurred the BOP's laudable decision to temporarily suspend the requirement that delivery drivers obtain a pharmacist's physical signature upon receipt of prescription drug deliveries. We appreciate that the BOP's pharmacy waiver, effective March 17, 2020, suspends the physical signature requirement "until December 21, 2020, or until the emergency declaration¹ is lifted, whichever is sooner".² Based on the BOP's authority³, we ask it to extend the effective date of the end of the suspension of the requirement from December 21, 2020 to 90 days after the end of the emergency declaration.

Further, we respectfully request that the BOP exercise its emergency waiver authority to suspend the requirement found in Section [4059.5\(a\)](#) that *only* a pharmacist be allowed to accept delivery of pharmaceutical product. Said another way, we encourage the BOP to take action that would allow pharmacy technicians and other pharmacy staff to accept deliveries of pharmaceutical products until at least until 90 days after the Governor's pandemic order expires, under the authority expressly granted to the BOP in the California Business and Professions Code sections 4062(b) and 4062(d)⁴. Finally, we would ask that the BOP engage in further discussions regarding a permanent adjustment of the statutory requirement that only pharmacists may take custody of prescription drug deliveries, and instead adopt language allowing pharmacy techs and other qualified pharmacy personnel to do the same.

Thank you for your time and attention to this important matter and please let us know if we can answer any questions or provide any additional information. Feel free to contact Beth Mitchell, Senior Director

¹ <https://www.gov.ca.gov/2020/03/04/governor-newsom-declares-state-of-emergency-to-help-state-prepare-for-broader-spread-of-covid-19/>

² https://www.pharmacy.ca.gov/licensees/waivers/4059_5.shtml.

³ [Section 4062\(b\)](#) *During a declared federal, state, or local emergency, the board may waive application of any provisions of this chapter or the regulations adopted pursuant to it if, in the board's opinion, the waiver will aid in the protection of public health or the provision of patient care.*

[Section 4062\(d\)](#) *Notwithstanding any other law, the board may elect to continue to waive application of any provision of this chapter for up to 90 days following the termination of the declared emergency if, in the board's opinion, the continued waiver will aid in the protection of the public health or in the provision of patient care.* (italics added).

⁴ https://www.pharmacy.ca.gov/laws_regs/lawbook.pdf (see pp. 83-84).



of Government Affairs, at bmitchell@amerisourcebergen.com or at 202-236-8490, or Chris Johnson, Manager of State Government Affairs at Christian.johnson@amerisourcebergen.com or 202-655-6549.

Sincerely,

A handwritten signature in blue ink, appearing to read "C. Zimmerman", with a long horizontal stroke extending to the right.

Chris Zimmerman
Senior Vice President, Corporate Security & Regulatory Affairs
AmerisourceBergen