

# BOARD OF PHARMACY

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*Protection of the public shall be the highest priority for the California State Board of Pharmacy in exercising its licensing, regulatory, and disciplinary functions. Whenever the protection of the public is inconsistent with other interests sought to be promoted, the protection of the public shall be paramount.*

— Business and Professions Code § 4001

**T**he California State Board of Pharmacy is a consumer protection agency within the state Department of Consumer Affairs (DCA). The Board is charged with enforcing the Pharmacy Law, Business and Professions Code section 4000 et seq. The Board’s regulations are located in Division 17, Title 16 et seq. of the California Code of Regulations (CCR).

The Board of Pharmacy grants licenses and permits to pharmacists, advanced practice pharmacists, pharmacy interns, pharmacy technicians, pharmacies, pharmacy corporations, nonresident pharmacies, wholesale drug facilities, veterinary food-animal drug retailers, out-of-state distributors, clinics, hypodermic needle and syringe distributors, and an extensive array of associated individuals and entities. As of October 27, 2022, there were 140,227 current licensees. In addition, the Board regulates all sales of dangerous drugs, controlled substances, and poisons.

The Board consists of 13 members, six of whom are public members. The Governor appoints four public members. The Senate Rules Committee and the Speaker of the Assembly each appoint one public member. The remaining members are pharmacists appointed by the Governor, five of whom must be active practitioners. Additionally, Business and Professions Code section 4001(c) requires that the membership of the Board include at least one pharmacist representative from each of the following practice settings: an acute care hospital, an independent community

pharmacy, a chain community pharmacy, and long-term health care or skilled nursing facility. Furthermore, the Board must include a pharmacist who is a member of a labor union that represents pharmacists. All Board members are appointed to four-year terms.

At this writing, the Board has no vacancies nor any new appointments.

## **HIGHLIGHTS**

### **Board of Pharmacy Reissues Pharmacy Law Waiver**

On December 5, 2022, the California Board of Pharmacy’s President reissued a pharmacy law [waiver](#) for prescribers dispensing medication to emergency room patients. This waiver lasts approximately six months, from December 5, 2022, to May 28, 2023. The reissue of the waiver was created within the scope of Governor Newsom’s declaration of a [State of Emergency](#), the federal government’s declaration of national emergency, and California Business and Professions Code section 4062, which California’s Board of Pharmacy is bound by. Although Governor Newsom previously [announced](#) the State of Emergency would end on February 28, 2023, as provided in section 4062, the Board may elect to continue to waive application of any provisions for up to 90 days following termination of the declared emergency.

California’s Board of Pharmacy states the [waiver](#) effectively “[w]aive(s) provisions related to the prohibition against a prescriber to dispensing medications to an emergency room patient if the medication dispensed is a short-acting, beta-agonist inhalation products.” These provisions are part of Business and Professions Code section 4068(a), which states: “Notwithstanding any provision of this chapter, a prescriber may dispense a dangerous drug, including a controlled substance, to an emergency room patient if all of the following apply”: and lists seven requirements for section (a) to be met. The waiver effectively waives the requirements of subsections (1), (5),

and (6), which require (1): a pharmacy to be closed and no pharmacist in the hospital, (5): “The prescriber determines that it is in the best interest of the patient that a particular drug regimen be immediately commenced or continued, and the prescriber reasonably believes that a pharmacy located outside the hospital is not available and accessible at the time of dispensing to the patient,” and (6): “The quantity of drugs dispensed to any patient pursuant to this section are limited to that amount necessary to maintain uninterrupted therapy during the period when pharmacy services outside the hospital are not readily available or accessible, but shall not exceed a 72-hour supply.” The waiver of subsections (1), (5), and (6) only applies if the drug dispensed is a short-acting, beta-agonist inhalation drug (commonly known as SABAs). SABAs are used as a fast-acting, temporary relief for asthma symptoms. The most common SABAs are albuterol and levalbuterol and dispensed in an inhaler.

## **Board of Pharmacy Approves Amendment for Pharmacists Furnishing Opioid Antagonists**

At its February 6–7, 2023 [meeting](#) (at 10:11:15), the Board of Pharmacy [approved](#) the [recommendations](#) from the Licensing Committee to move forward with changing regulatory language related to the authority of a licensed pharmacist to furnish opioid antagonists to the public without a prescription. The proposed changes are consistent with provisions of Business and Professions Code section 4052.01, as amended in [SB 1259 \(Laird\) \(Chapter 245, Statutes of 2022\)](#), and include a proposed amendment to Title 16, of the California Code of Regulations (CCR) section 1746.3. A full text with the amended and revised language can be found on the Medical Board of California’s [website](#).

The amendment replaces language, screening criteria, training requirements, and more. First, the language in section 1746.3 of the CCR was changed from “naloxone hydrochloride,” a drug more commonly known as NARCAN, to “opioid antagonist.” This change shifts the view of opioid overdose drugs from the specific definition of “naloxone hydrochloride” to any opioid antagonist, which is a drug that is designed to quickly reverse an overdose by negating the effects of opioids. “Opioid antagonists” are used most commonly during heroin, morphine, and oxycodone overdoses. The amended language also replaces the former requirement to provide a Pharmacy Board-approved fact sheet with an FDA-approved medication guide.

These amendments update three major requirements in furnishing opioid antagonists. First, the training requirement for pharmacists is updated, so pharmacists must complete training in a school of pharmacy recognized by the Board. Second, the labeling requirements for opioid antagonists is updated so the labeling is consistent with other prescription medications dispensed. Third, the patient’s physician is notified when the patient requests so, and if the patient does not affiliate with a physician, a written record is made of the drug furnished plus a recommendation to consult with an appropriate health care provider.

In addition, the amendment removes the screening criteria for furnishing an opioid antagonist, so individuals seeking this drug have access similar to what is already provided in schools and libraries. The amendment also removes privacy and documentation language to promote uniformity with other pharmaceutical products.

Finally, the amendment allows a pharmacist to advise in the selection of an opioid antagonist and any additional items the pharmacist may recommend when appropriate.

# MAJOR PUBLICATIONS

The following reports or studies have been conducted by or about the Board of Pharmacy during this reporting period:

- [California State Board of Pharmacy CPJE Statistics](#), Board of Pharmacy, March 2023 (displays pass/fail data for all candidates who took the CPJE examination between October 2022 and March 2023).
- [The Script](#), Board of Pharmacy, January 2023 (describes the Board’s major projects in a bi-yearly newsletter; provides notification of a new law, AB 852, concerning additional exemptions to requirements for the use of e-prescriptions; discusses the end of the COVID-19 State of Emergency for California on February 28, 2023; and provides a compilation of statutory changes in Pharmacy law in 2023).

# RULEMAKING

The following is a status update on recent rulemaking proceedings that the Board of Pharmacy has initiated:

- **Compounding Self-Assessment:** On January 20, 2023, Office of Administrative Law [approved](#) the Board’s [proposed amendments](#) modifying the Compounding [Self-Assessment form](#), effective April 1, 2023. This text amends section 1735.2, Title 16 of the CCR, and according to the [Initial Statement of Reasons](#), the purpose of the text is to update the self-assessment forms with new law and regulations that have been adopted since 2012 and repeal information on forms that have been superseded or appealed since 2012. The Board originally published [notice](#) of its intent to amend these sections on June 23, 2022. [[28:1 CRLR 26](#)]

- **Notice to Consumers:** On February 9, 2023, the Board published [notice](#) of the [modified text](#) and a 45-day comment period concerning its proposal to amend section 1707.6 to Article 2 of Division 17 of Title 16 of the CCR, related to notice of consumers' rights. According to the [Initial Statement of Reasons](#), this regulation seeks to educate consumers about their rights and how to take their medications to encourage consumers to discuss medications with their pharmacists. The 45-day comment period was open from February 24, 2023, to April 10, 2023.

- **Temporary Licenses for Military Spouses/Domestic Partners:** On March 1, 2023, the Board published [notice](#) of [additional text](#) and a 45-day comment period concerning its proposal to add section 1706.6 to Article 1 of Division 17 of Title 16 of the CCR, related to issuance of temporary licenses for military spouses/domestic partners. The added language aims to require CBP to issue temporary licenses to qualified military spouses and partners under specified conditions. According to the [Initial Statement of Reasons](#), this regulation will expedite licensure processes, eliminate barriers to employment, and increase the number of licensed healthcare individuals in the field of pharmacy in California for military spouses and partners who travel with their partner that are licensed in a state other than California. The 45-day comment period is open from April 14, 2023 to May 30, 2023.

- **ADDS Self-Assessment:** On April 5, 2023, the Board published [notice](#) of [additional modified text](#) for a 15-day comment period concerning its proposal to amend section 1715.1, Title 16 of the CCR, related to self-assessment forms. According to the [Initial Statement of Reasons](#), the proposed regulation would update self-assessment forms to reflect current laws instead of outdated self-assessment forms. At this writing, the Board is waiting for a comment period, beginning on April 21, 2023, and ending on May 6, 2023.

# LEGISLATION

- [SB 524 \(Caballero\)](#), as amended April 10, 2023, would amend section 4052 and add and repeal section 4052.04 of the Business and Professions Code to allow California pharmacists to prescribe Paxlovid, a COVID-19 treatment, directly to patients. SB 524 would also authorize pharmacists to provide direct treatment for certain conditions, such as COVID-19, influenza, STIs, strep throat, and conjunctivitis. The bill's purpose is to increase accessibility for Californians, especially those who are in rural areas or those who cannot afford a lengthy trip to the emergency room for easily treatable conditions. This bill was sponsored by the California State Board of Pharmacy, and the Board is set to vote on this proposal on April 19, 2023. [*S. Health*]
- [SB 339 \(Weiner\)](#), as amended March 14, 2023, would amend section 4052 of the Business and Professions Code to require the California Board of Pharmacy to adopt emergency regulations to implement allowing pharmacists to furnish a course of PrEP (a drug used for HIV preventative care called preexposure prophylaxis) by July 1, 2024. The California State Board of Pharmacy is set to vote on this bill on April 19, 2023. [*S. Health*]
- [AB 1341 \(Berman\)](#), as amended March 29, 2023, would amend and repeal section 1206.7 and add to and repeal from section 4052.04 of the Business and Professions Code to authorize pharmacists to continue to furnish COVID-19 oral therapeutics to patients who test positive for SARS-CoV-2 (COVID-19) until January 1, 2025. The bill would repeal the expansion of professionals authorized to test samples for SARS-CoV-2 on July 1, 2028. The California State Board of Pharmacy is set to vote on this bill on April 19, 2023. [*A. Appr*]
- [AB 602 \(Pellerin\)](#), as introduced February 9, 2023, would add to section 4604.1 of the Business and Professions Code to require the Board of Pharmacy to create a report submitted

to the legislature on how many times a prescription is refilled without the patient's authorization and complaints from patients when their prescription is not filled. The bill would also require the California Board of Pharmacy to ensure that California pharmacists are aware of their authority to refill a prescription. The California State Board of Pharmacy is set to discuss this bill at its meeting on April 19, 2023. *[A. B&P]*

- [AB 1557 \(Flora\)](#), as amended April 12, 2023, would amend section 4071.1 of the Business and Professions Code to authorize a pharmacist located and licensed in California to verify medication chart orders for appropriateness. A pharmacist would be able to verify orders only on behalf of a licensed hospital and from a location outside of the hospital. The California State Board of Pharmacy is set to discuss this bill at its meeting on April 19, 2023. *[A. B&P]*

- [AB 1619 \(Dixon\)](#), as amended March 23, 2023, would add to section 4074.1 of the Business and Professions Code to affix an auxiliary label to a prescription container that contains marijuana. The California State Board of Pharmacy is set to discuss this bill at its meeting on April 19, 2023. *[A. B&P]*

- [AB 663 \(Haney\)](#), as amended April 12, 2023, would amend section 4110.5 of the Business and Professions Code to allow controlled substances that treat opioid use to be carried and dispensed at county-operated mobile pharmacy units. The California State Board of Pharmacy is set to discuss this bill at its meeting on April 19, 2023. *[A. Appr]*

- [AB 1286 \(Haney\)](#), as introduced February 16, 2023, would amend sections 4113, 4113.5, 4115, 4192, 4204, and 4301 of, and add to sections 4113.1 and 4316.5 of the Business and Professions Code to authorize pharmacists-in-charge to make staffing decisions and close a pharmacy if a workplace hazard arises, and allows pharmacy technicians more responsibilities. The



California State Board of Pharmacy is set to discuss this bill at its meeting on April 19, 2023. [A. B&P]

- [AB 269 \(Berman\)](#), as amended February 8, 2023, as it applies to the Board, adds and repeals section 4176 of the Business and Professions Code to allow for entities approved by the State Department of Health for COVID-19 testing and dispensing may acquire, dispense, and store oral COVID-19 therapeutics at their locations with the approval of a prescribing physician or a registered nurse under the direction of a prescribing physician. Section 4176(f) repeals the entirety of section 4176 on January 1, 2024.

Governor Newsom sign AB 269 on March 2, 2023 (Chapter 1, Statutes of 2023). As an urgency statute, this bill took effect immediately upon his signature.