

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

The 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 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 December 31, 2021, there were 141,390 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.

On May 19, 2022, Governor Newsom [appointed](#) Jessica Crowley, PharmD, of Los Angeles as a pharmacist who is a member of a chain community pharmacy. She has been a staff pharmacist for Pavilions Pharmacy since 2020 and held several positions at CVS Pharmacy.

On June 24, 2022, Governor Newsom [appointed](#) both Renee Armendariz Barker of San Carlos and Jignesh Patel of Roseville to the Board. Ms. Barker has been sterile products manager at the Lucile Packard Children’s Hospital Stanford since 1998. Mr. Patel has been a division pharmacy manager for Safeway NorCal Division since 2006 and he has held several positions at Safeway since 1999.

On September 9, 2022, Governor Newsom [appointed](#) Kartikeya Jha of Fresno to the Board. Mr. Jha has been district director of operations at Omnicare—a CVS health company—since 2019.

At this writing, the Board has no vacancies.

HIGHLIGHTS

Board Releases Monkeypox Treatment Waiver

On August 1, 2022, Governor Gavin Newsom declared a [state of emergency](#) in the state of California due to the emerging threat of the Monkeypox outbreak. At its August 25, 2022, [meeting](#), the Board of Pharmacy voted to approve, pursuant to Business and Professions Code section 4062, a waiver of pharmacy law provisions to allow for the dispensing of Tecovirimat (TPOXX), oral

antiviral medication to an emergency room patient under specified conditions, until 90 days following the end of the emergency declaration.

Following the meeting, effective August 3, 2022, the Board issued a [waiver](#) that allows prescribers to dispense the oral antiviral medication, TPOXX, to emergency room patients. This waiver will waive Business and Professions Code sections 4068(a)(1), 4068(a)(5), 4068(a)(6), 4076.5, and 4427.2(a), as well as any other section related to prescribers dispensing medicine to emergency room patients. The medication can be prescribed under the condition that it is being provided to a patient receiving care in an emergency room in California, the medication is being prescribed and dispensed according to Food and Drug Administration (FDA) and Centers for Disease Control (CDC) guidelines, and that verbal consultation and appropriate confirmation of patient's medical history has been conducted by the provider.

This waiver remains valid until 90 days after the end of the declared emergency.

Pharmacists' Refusal to Fill Prescriptions for Contraceptives Could be Violation of Federal Anti-Discrimination Law

On July 13, 2022, the U.S. Department of Health and Human Services Office for Civil Rights (OCR) released [guidance](#) for pharmacies regarding their obligations to patients requesting reproductive health care. After the United States Supreme Court's decision in [Dobbs v. Jackson Women's Health Organization](#), 142 S. Ct. 2228 (2022), many reproductive healthcare providers have been searching for legal guidance when navigating what types of healthcare they are permitted to offer their patients. The document released by the OCR highlights the important role pharmacists play in the health care system and that under federal civil rights laws, pharmacists are obligated to serve their patients without discrimination.

The release cites section 1557 of the Affordable Care Act 42 U.S.C.S § 18116, which states that an entity receiving federal funding cannot discriminate against an individual on the basis of sex or disability. Denying the right to access healthcare on the basis of pregnancy or potential for pregnancy is in violation of the ACA's sex discrimination policy. The OCR reiterated the importance of pharmacies in the American health care system stating that pharmacies tend to be the most accessible and most accessed health care providers in the United States, thus reiterating how important it is for pharmacies to follow these guidelines.

The OCR states that it is imperative that women and pregnant people have access to healthcare without hindrance or discrimination and that healthcare includes reproductive care. Failure to follow such guidelines will violate federal civil rights laws and could have disastrous consequences for those seeking care.

RULEMAKING

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

- **Self-Assessment of an ADDS:** On October 6, 2022, the Board published [notice of proposed action](#) that would alter CCR section 1735.2 to update the self-assessment form that pharmacists-in-charge must complete. The [proposed text](#) will require pharmacists to comply with all up-to-date laws through a new self-assessment form which should help to simplify a process that is already taking place by Pharmacists in Charge (PIC). This proposed action is currently in the open comment period and the Board will accept written comments until December 27, 2022.
- **Pharmacy Technicians:** On August 22, 2022, the regulation was [adopted](#). The Board originally published [notice](#) of its intent to amend these sections on October 22, 2021. *[See*

[27:1 CRLR 80](#)] The Board published [notice of modified text](#) on January 28, 2022, and a 15-day public comment period for its proposal to amend sections 1793.5 and 1793.6, and adopt section 1793.65, Title 16 of the CCR to update the pharmacy technician application form, update the requirements for schools providing training courses for pharmacy technicians, and add pharmacy technician certification programs accredited by the National Commission for Certifying Agencies programs. The [modified text](#) proposed adding criminal background check on the applicant consistent with the background checks proscribed in section 4202(c) of the Business and Professions Code, information on course training, a requirement that applicants are 18 years or older, and a final exam. In addition, the modified text removes applicant questions about mental health, and removes some about disciplinary action and status as a third-party wholesaler [*see* [27:2 CRLR 63](#)]. The regulation becomes effective on January 1, 2023.

- **Notice of Temporary Closure:** On May 18, 2022, this regulation was [adopted](#). On January 28, 2022, the Board published [notice of modified text](#) and a 15-day public comment period for its proposal to adopt section 1708.1, Title 16 of the CCR, to require pharmacies to notify the Board of a temporary closure of a licensed facility as soon as any closure exceeds three consecutive calendar days. The Board originally published notice of its intent to adopt this section on October 29, 2021. [*see* [27:1 CRLR 82](#)] The modified text provides an exception for correctional pharmacies and updates the text to exclude holidays and routine closures. [*see* [27:2 CRLR 64](#)] The regulation became effective October 3, 2022.

- **Wholesaler/3PL Self-Assessment Form:** On August 23, 2022, the regulation was [adopted](#). On February 15, 2022, the Board published [notice](#) of the availability of [modified text](#) for a 15-day comment period concerning its proposal to amend section 1784, Title 16 of the CCR, related to Wholesaler/3PL Self-Assessment. The Board originally published [notice](#)⁸ of its

proposed rulemaking on September 17, 2021. The regulation provides clarifying language regarding the application of this section and identifies the individual who must complete the self-assessment based on the license type. [see [27:1 CRLR 75–76](#)] According to the [Initial Statement of Reasons](#), this regulation requires third-party logistics providers to complete the self-assessment, which continues the requirements that were applied previously when these entities were licensed as wholesalers. [see [27:2 CRLR 66](#)] The regulation became effective on October 1, 2022.

- **Inventory Reconciliation:** On July 29, 2022, the regulation was [adopted](#). The Board originally published [notice](#) of its proposed amendments on September 17, 2021. Concerning its proposal to amend section 1715.65, Title 16, of the CCR to address frequent compliance questions the Board receives and address the ongoing diversion of non-Schedule II controlled substances from pharmacies and clinics. The regulation goes into effect on January 1, 2023. [see [27:1 CRLR 70–72](#); [27:2 CRLR 61–63](#)]

- **Pharmacy/Hospital Self-Assessment Forms:** On June 23, 2022, the regulation was [adopted](#). On February 15, 2022, the Board published [notice](#) of the availability of [modified text](#) for a 15-day comment period concerning its proposal to amend section 1715, Title 16 of the CCR, related to Pharmacy/Hospital Self-Assessment Forms. The Board originally published notice of its proposed rulemaking on November 12, 2021. [see [27:1 CRLR 82](#)] According to the [Initial Statement of Reasons](#), the regulation specifies the requirements of pharmacy self-assessment forms further. [see [27:2 CRLR 66](#)] The regulation became effective October 1, 2022.

LEGISLATION

- [SB 872 \(Dodd\)](#), as amended June 15, 2022, adds section 4110.5 to the Business and Professions Code to allow a city, county, or special hospital authority to operate a licensed

mobile pharmacy to dispense prescription medication to individuals in a specified area in need of such services. Those who support the bill argue that mobile pharmacies will help vulnerable populations access much needed medications that are otherwise difficult for them to consistently access. Assembly amendments specified that controlled substances will not be dispensed from such mobile pharmacies. Governor Newsom signed SB 872 on August 29, 2022 (Chapter 220, Statutes of 2022).

- [SB 1259 \(Laird\)](#), as amended June 13, 2022, amends section 4052.01 of the Business and Professions Code to authorize a pharmacist to furnish an opioid antagonist approved by the federal FDA, including, but not limited to, naloxone hydrochloride (NARCAN). Governor Newsom signed SB 872 on September 2, 2022 (Chapter 245, Statutes of 2022).

- The following bills reported in Volume 27, Issue 2 (Spring 2022), died in committee or otherwise failed to be enacted in 2022: [SB 939 \(Pan\)](#), prescription drug pricing; [SB 1346 \(Becker\)](#), surplus medication collection and distribution; [AB 2265 \(Arambula\)](#), pharmacists to dispense a Schedule II or Schedule IIN controlled substance in a lockable vial; [AB 2055 \(Low\)](#), administration of CURES database from DOJ to the Board; [SB 988 \(Hueso\)](#), Compassionate Access to Medical Cannabis Act or Ryan’s Law; [SB 958 \(Limón\)](#), Medication and Patient Safety Act; [SB 1365 \(Jones\)](#), require boards to post on its internet website a list of criteria used to evaluate applicants with criminal convictions; [AB 1662 \(Gipson\)](#), disqualification from licensure: criminal conviction.

LITIGATION

- *United States of America v. Walmart Inc. and Wal-Mart Stores Easy, LP*, Case No: 20-cv-01744 (D. Del. 2020). On December 22, 2020, the United States Department of Justice filed a complaint against Walmart for facilitating opioid misuse and abuse by knowingly and

unlawfully filling “thousands upon thousands of invalid controlled-substance prescriptions” in violation of the Controlled Substance Act. [see [25:2 CRLR 64–65](#)] Walmart [announced](#) that they would agree to a \$3.1 billion settlement to resolve all ongoing legal disputes. Walmart’s announcement follows similar announcements from CVS Health and Walgreen Co. who have also agreed to multi-billion-dollar settlements. The settlement agreement would have to be accepted by several state and local governments and that process has not yet begun.

- ***City of San Francisco, et al. v. Purdue Pharma L.P. et al., Case No: 3:18-cv-07591-CRB (N.D. Cal.)***. On August 10, 2022, Judge Charles Breyer’s ruling for the U.S. District Court for the Northern District of California marks the first bench trial to find Walgreens liable for public nuisance claims in the nationwide multidistrict litigation stemming from the ongoing opioid epidemic. Breyer found that Walgreens breached its regulatory obligations to take reasonable steps to prevent opioids from being diverted and harming the public for several years. The next trial phase will determine the extent Walgreens must abate the public nuisance it helped to create. “[Walgreens] did not maintain an effective system for identifying suspicious orders,” Breyer wrote in his 112-page [opinion](#). Breyer said the evidence at trial showed that tens of thousands of prescriptions dispensed through Walgreens were written by doctors with suspect prescribing patterns. The city also demonstrated at trial that Walgreens did not provide pharmacists with sufficient time, staffing, or resources to perform due diligence on these prescriptions, according to the judge. “Pharmacists experienced constant pressure to fill prescriptions as quickly as possible, and a shortage of resources to review them before dispensing,” Breyer wrote. “As a result of Walgreens’ fifteen-year failure to perform adequate due diligence, Plaintiff proved that it is more likely than not that Walgreens pharmacies dispensed large volumes of medically illegitimate opioid prescriptions that were diverted for illicit use and that substantially contributed to the opioid

epidemic in San Francisco.”

In a November 4, 2022 [order](#), Judge Breyer vacated all trial dates after being advised that the parties were in settlement negotiations.