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 § 4001.1

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 October 8, 2020, there were 141,956 current licenses. 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 Committee on Rules 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 a 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.

In October of 2020, the California Senate Rules Committee appointed Jason Weisz of San Diego as a public member of the California State Board of Pharmacy. Mr. Weisz is a senior district representative with California Senate President Pro Tempore Toni G. Atkins. His focus has been working on health care and business issues. His Board term expires in 2024.

At this writing, the Board has one licensee vacancy who must work in the area of long-term health care or a skilled nursing facility. This vacancy is to be appointed by the Governor. The Board also has one other public member vacancy to be appointed by the Speaker of the Assembly.

HIGHLIGHTS

Board's Emergency Regulation Related to HIV Preexposure and Postexposure Treatment Extended to February 2021

At its September 17, 2020 meeting, the Board voted to readopt emergency regulations to add section 1747, Title 16 of the CCR to establish a training program for pharmacists to independently furnish HIV preexposure prophylaxis (PrEP) and postexposure prophylaxis (PEP) medications, drugs that reduce HIV infection. The Board also approved the actual training material, which will be recorded and made available on the Board's website at no cost to licensees. The Office of Administrative Law (OAL) initially approved the emergency regulations on April 30, 2020, for a period of 180 days. The regulations were set to expire on October 28, 2020.

At its January 29, 2020 meeting [Item VII.a], the Board approved proposed language to establish the training program requirements necessary for pharmacists to furnish HIV PrEP and PEP pursuant to SB 159 (Wiener) (Chapter 532, Statutes of 2019). *[25:2 CRLR 44–45]*

In the initial finding of emergency, the Board stated that pharmacists are well-positioned to independently initiate and furnish HIV PrEP and PEP, as pharmacists are healthcare professionals who are highly accessible to patients within their communities. The regulation ensures that pharmacists have the training necessary to independently initiate and furnish HIV PrEP and PEP.

Also, at its January 29, 2020 meeting, the Board approved the proposed text to establish the regulations through the permanent rulemaking process. The Board submitted the formal rulemaking package to the Department of Consumer Affairs Legal Office on February 7, 2020, and the package is currently under review.

According to the Board's Regulations Manager, after consulting with OAL, the Board later determined that readoption was not immediately necessary in light of Executive Orders N-40-20 and N-66-20, which combined authorized a 120 calendar-day extension on APA deadlines, including the expiration date of emergency regulations. Pursuant to the Executive Orders, the expiration date of the Board's emergency rulemaking action to adopt these regulations has been extended to February 26, 2021.

Board's Community Pharmacy Staffing Regulation Takes Effect

On September 15, 2020, OAL approved the Board's proposed regulations on community pharmacy staffing. The regulations add section 1714.3, Title 16 of the CCR to establish standards

for community pharmacy staffing levels. The regulation implements SB 1442 (Wiener) (Chapter 569, Statutes of 2018), which added section 4113.5 to the Business and Professions Code to prohibit a community pharmacy from requiring a pharmacist to engage in the practice of pharmacy while the pharmacy is open to the public unless another employee is present and working in the pharmacy, or an employee of the establishment is made available to assist the pharmacist. According to the bill's sponsor, the United Food & Commercial Workers, because many community pharmacies are not the primary focus of the business where the pharmacy is located, it is common for a pharmacist to be the only employee assigned to the pharmacy area. *[24:1 CRLR 91–92]*

As stated in the initial statement of reasons, the goal of the regulation is to ensure pharmacists do not have to work alone, since they often must perform non-pharmacy functions that may distract from their licensed functions and affect their professional judgment. The Board's regulation outlines the criteria a pharmacy must meet to comply with the statute, such as the process for pharmacists to request assistants so as to not work alone, and the training necessary for pharmacy employees to fill the role of an assistant.

The Board approved the proposed text on July 25, 2019. The 45-day public comment period began on February 28, 2020 and ended on April 13, 2020. However, due to Governor Newsom's Declaration of Emergency during the COVID-19 pandemic, the Board extended the comment period through April 30, 2020. The regulation was filed with the Secretary of State and took effect on September 15, 2020.

Ninth Circuit Court Sides with the Board's Regulation and Licensure of Outsourcing Facilities Created Under Federal Law

Fusion IV Pharm., Inc. v. Sodergren, 809 F. App'x 438 (9th Cir. 2020). On June 17, 2020, the United States Court of Appeal for the Ninth Circuit affirmed the district court's grant of judgment on the pleadings in Fusion IV Pharmaceuticals, Inc.'s (Fusion IV) suit against Anne Sodergren in her official capacity as the Interim Executive Officer of the California State Board of Pharmacy. Fusion IV is a federally registered outsourcing facility that compounds drugs in California for interstate distribution. Fusion IV filed suit against Ms. Sodergren and the Board in the federal district court in 2019 challenging California Business and Professions Code section 4129, which requires outsourcing facilities to be concurrently licensed by the Board and the federal Food and Drug Administration (FDA) if such facilities compound non-patient specific drug products for distribution within or into California.

In *Fusion IV Pharm., Inc. v. Sodergren*, Fusion IV claimed the Board's licensing requirements are preempted by the Drug Quality and Security Act (DQSA) and violate the Commerce Clause of the United States Constitution. The district court rejected both arguments. On June 17, 2020, the Ninth Circuit affirmed the district court's decision that California's requirements are not preempted by the DQSA, and that Fusion IV failed to establish that the requirements impose a "substantial burden" on interstate commerce in violation of the Commerce Clause.

The Board's win creates a federal appellate court precedent stating that outsourcing facilities are subject to a state pharmacy board's oversight and regulation. Now, outsourcing

facilities engaging in interstate commerce in California, like Fusion IV, must comply with the Board's licensing regulations.

MAJOR PUBLICATIONS

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

- ***Opioid Use Disorder Sample Collaborative Practice Agreement***, California Board of Pharmacy, October 2020 (Pursuant to Business and Professions Code sections 4050–4052.2, a three-page sample collaborative practice agreement for pharmacists to provide medication-assisted treatment to patients with opioid use disorder (OUD) in collaboration with a medical care provider; formally identifies the functions that the undersigned pharmacist may perform, including referral criteria, assessment, medication management, treatment plans, documentation requirements, and references.) *[see 25:1 CRLR 63–65]*

- ***Guidance on COVID-19 Testing Under Executive Orders N-25-20, N-39-20 and N-75-20, and DCA Waiver DCA-20-45***, August 25, 2020, California Department of Consumer Affairs, and California Board of Pharmacy (Provides authority and permissible practices for pharmacies, pharmacists, and pharmacy technicians with respect to COVID-19 testing, including ordering, collecting specimens for, performing, and interpreting the results for authorized tests; includes resources for further guidance on collection and testing in laboratories.)

RULEMAKING

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

- **Substantial Relationship Criteria: Implementation of AB 2138 (Chiu) (Chapter 995, Statutes of 2018)**: On April 27, 2020, the Board ended its 45 day public comment period on its proposed regulation to amend sections 1769 and 1770, Title 16 of the CCR to adopt "substantial relationship" criteria for determining whether applicants' past criminal convictions or unprofessional conduct are relevant to work as a pharmacist for purposes of denying a license. On March 13, 2020, the Board formally noticed the regulation. *[25:2 CRLR 45]* The regulation is currently undergoing review by OAL.

- **Automated Drug Delivery Systems**: On September 25, 2020, the Board published notice of the availability of modified text for a 15 day comment period with respect to its proposal to amend sections 1711 and 1713, and add section1715.1, Title 16 of the CCR with respect to the Board's oversight of Automated Drug Delivery Systems (ADDS). The Board originally published notice with respect to these regulations on July 3, 2020. The proposed regulation would require that records related to the use of ADDS, developed as part of the quality assurance review established by Business and Professions Code section 4427.6(i), be submitted to the Board. *[See 24:1 CRLR 88–90]* According to the Initial Statement of Reasons, the proposed regulation will ensure that the Board is aware of potential quality issues and will allow the Board to investigate possible concerns with respect to the use of automated drug delivery systems. The Board is currently reviewing the public comments.

- **Dangerous Drug Distributers**: On May 29, 2020, the Board published notice of its intent to amend sections 1780, 1781, 1782, and 1783, Title 16 of the CCR to update its specific licensing requirements pertaining to dangerous drug distributors, including third-party logistics providers. According to the Initial Statement of Reasons, this proposal will require third-party logistics providers to transport and store dangerous drugs under conditions that make it more likely

that the drugs will be safe and effective when received by the consumer. The public comment period expired on July 13, 2020.

- **Automatic Refill Programs**: On September 25, 2020, the Board published notice of the availability of modified text for a 15 day public comment period regarding the Board's proposed addition of section 1717.5, Title 16 of the CCR to establish requirements for automatic drug refill programs. The Board originally published notice with respect to this regulation on July 10, 2020. According to the Initial Statement of Reasons, this proposal will benefit patients by preventing unwanted, unnecessary, or discontinued prescriptions from being auto-refilled. The proposal will also make patients better able to manage their prescriptions and less likely to take a duplicate prescription for the same medication. The Board is currently reviewing comments on the modified text.

- **Off-Site Storage**: On May 19, 2020, the Board published notice of the availability of modified text with respect to its proposal to amend section 1707, Title 16 of the CCR to update the circumstances under which the Board may grant a waiver of the requirement that pharmacies must maintain their records on the premises. The Board originally published notice of its intent to modify this regulation on February 7, 2020. *[25:2 CRLR 46]* The public comment period on the modified text expired on June 3, 2020. The proposed regulation is currently undergoing review by the Department of Consumer Affairs.

LEGISLATION

- **SB 1474 (Committee on Business, Professions and Economic Development)**, as amended August 26, 2020, and as it applies to the Board of Pharmacy, amends sections 4001 and 4003 of the Business and Professions Code to extend the Board's sunset date from January 1, 2021

to January 1, 2022 in light of the COVID-19 pandemic. Governor Newsom signed SB 1474 on September 29, 2020 (Chapter 312, Statutes of 2020).

- **AB 2077 (Ting)**, as amended May 20, 2020, amends section 4145.5, and repeals sections 4142 and 4326, of the Business and Professions Code to authorize a physician or pharmacist to furnish hypodermic needles and syringes for human use to a person eighteen years or older without a prescription. The bill also removes the penalty associated with obtaining a hypodermic needle or syringe without a prescription. According to the author, the purpose of this amendment is to continue to stem the spread of HIV and viral hepatitis. Governor Newsom signed AB 2077 on September 29, 2020 (Chapter 274, Statutes of 2020).

- **AB 1710 (Wood)**, as amended August 24, 2020, amends section 4052.8 of the Business and Professions Code to authorize pharmacists to independently order and administer an FDA authorized or approved COVID-19 vaccine in order to increase public access to COVID-19 tests. Governor Newsom signed AB 1710 on September 24, 2020 (Chapter 123, Statutes of 2020).

- **SB 118 (Committee on Budget and Fiscal Review)**, as amended July 29, 2020, and as it applies to pharmacists, amends section 4021.5 of the Business and Professions Code to revise the definition of a correctional pharmacy, require the quarterly inspection of correctional clinics by a pharmacist, and revise provisions to allow for removal and administering or furnishing of a drug in cases where a delay in therapy may cause patient harm. Governor Newsom signed SB 118 on August 6, 2020 (Chapter 29, Statutes of 2020).

The following bills, reported in Volume 25, No. 2 (Spring 2020), died in committee or otherwise failed to be enacted during the 2019–2020 legislative session: AB 2983 (Holden), relating to automatic refills for dangerous drugs, and SB 1084 (Umberg), regarding the dispensing of certain controlled substances.

LITIGATION

- ***Merck & Co. v. United States Dep't of Health & Human Servs.*, 962 F.3d 531 (D.C. Cir. 2020).** On June 16, 2020, the District of Columbia Circuit Court affirmed the District Court's finding that the U.S. Department of Health and Human Services' Centers for Medicare and Medicaid Services (CMS) exceeded its regulatory authority when it adopted a rule requiring manufacturers to disclose in television advertisements the wholesale acquisition cost of many prescription drugs and biological products for which payment was available under Medicare or Medicaid.

- ***Fusion IV Pharm., Inc. v. Sodergren*, 809 F. App'x 438 (9th Cir. 2020).** On June 17, 2020, the Ninth Circuit affirmed the district court's decision that the requirements set forth in section 4129 of the Business and Professions Code regarding outsourcing facilities are not preempted by the Drug Quality and Security Act (see HIGHLIGHTS).