

BOARD OF PHARMACY

Executive Officer: Anne Sodergren ♦ (916) 574-7900 ♦ www.pharmacy.ca.gov

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 [January 15, 2020](#), there were 141,691 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.

On February 24, 2020, Governor Newsom [appointed](#) two new licensee members to the Board: Seung Oh of San Diego, pharmacist-in-charge at Vons Pharmacy in Liberty Station, and Jignesh “Jig” Patel of Roseville, division pharmacy manager for Safeway NorCal Division.

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 two public member vacancies. One public member vacancy is to be appointed by the Senate Committee on Rules, and the other is to be appointed by the Speaker of the Assembly.

On January 29, 2020, the Board [announced](#) the appointment of Anne Sodergren as its new Executive Director, effective January 22, 2020. Executive Officer Sodergren recently served as the Board’s Interim Executive Officer after 10 years of service as the Board’s Assistant Executive Officer. Former Executive Officer Virginia Herold retired in 2018.

HIGHLIGHTS

Proposed Amendments to Renewal Requirements

On February 7, 2020, the Board of Pharmacy published [notice](#) of its intent to amend sections 1702, 1702.1, 1702.2, and 1702.5, Title 16 of CCR, to simplify the 39 separate license types within the Board’s jurisdiction, as set forth in the [proposed text](#). The proposed regulations would consolidate the renewal of license types into two categories: (1) a premises or facility license; and (2) a license issued to an individual, with an exception for the pharmacist and advanced practice pharmacist licenses, as these licensing programs have specialized continuing education requirements that are addressed in other regulations.

According to the [Initial Statement of Reasons](#), as currently written, the Board’s regulations governing licensing categories require frequent amendments to incorporate each new licensing program as they are established, and as the Board’s regulatory jurisdiction continues to increase, it has not been able to update the regulations as frequently as necessary. Thus, the purpose of the proposed regulations is to “provide clarity to the regulated public by increasing the readability of the regulations and ensure consistent application of the renewal requirements.”

The proposed regulations would also require all premises or facility license types to report disciplinary action taken by other government agencies to the Board. The Initial Statement of Reasons states that the proposed regulations will allow the Board “to investigate and ensure that the licensee does not pose a risk to the safety of California residents by continuing to operate.”

The Board accepted public comments on the proposed amendments until March 23, 2020. At this writing, the comments are pending review by the Board.

Board Fines and Disciplines AmerisourceBergen for “Excessive” Opioid Shipments

On January 22, 2020, the Board adopted a [Stipulated Settlement and Disciplinary Order](#) which fined AmerisourceBergen Drug Corporation for shipping “excessive” amounts of opioids and other controlled substances to pharmacies across California. The Board also publicly reprovved AmerisourceBergen’s license through disciplinary action. AmerisourceBergen will not be able to renew its permit until it pays the Board for cost recovery and civil penalties associated with the investigation and enforcement of the matter.

On October 31, 2018, Virginia Herold (Executive Officer of the Board of Pharmacy at the time) filed a Second Amended Accusation No. 4982 ([Exhibit A](#)) against AmerisourceBergen alleging that from January 1, 2012 to March 2015, AmerisourceBergen sold “excessive” amounts

of opioids to several California pharmacies. The accusation alleged several instances in which pharmacies appeared on AmerisourceBergen’s “over threshold report,” yet AmerisourceBergen did not reject all controlled substance orders from those pharmacies as protocol required, and instead continued to furnish controlled substances to the pharmacies.

The accusation alleged four causes for disciplinary action against AmerisourceBergen: first, that AmerisourceBergen failed to comply with its corresponding responsibility to furnish controlled substances for a legitimate medical purpose when it continued to furnish controlled substances to pharmacies that appeared on its “over threshold report”; second, that AmerisourceBergen failed to report suspicious drug orders to the Drug Enforcement Administration; third, that AmerisourceBergen was subject to discipline for clearly excessive furnishing of controlled substances; and fourth, that AmerisourceBergen engaged in unprofessional conduct regarding the factual allegations addressed in the accusation.

On August 23, 2019, AmerisourceBergen signed a Stipulated Settlement and Disciplinary Order for Public Reproval in resolution of Second Amended Accusation No. 4982. AmerisourceBergen is held jointly and severally liable to pay \$10,000 to the Board for its costs associated with the investigation and enforcement of the matter. AmerisourceBergen is also held jointly and severally liable to pay \$140,000 to the Board for the civil penalty associated with discipline in the matter. If AmerisourceBergen fails to pay the Board for its civil penalty, AmerisourceBergen will not be allowed to renew its Wholesaler Permits until it pays the Board in full. The Stipulated Settlement and Disciplinary Order for Public Reproval was entered on January 22, 2020. The decision became effective at 5:00 p.m. on February 21, 2020.

Board Undergoes Sunset Review

On December 1, 2019, the Board of Pharmacy submitted its final Sunset Oversight Review Report ([Volume 1](#), [Volume 2](#)) to the legislature. The Sunset Report updates the legislature on past sunset issues, and outlines current issues facing the Board.

In its [Sunset Oversight Review Report](#), the Board listed uniform standards for substance abusing licensees as a current issue facing the Board. The Board reported that since [SB 1441 \(Ridley-Thomas\) \(Chapter 548, Statutes of 2008\)](#) standards were finalized, the Board has implemented new standards due to its licensees' "proximity to dangerous drugs and controlled substances." The Board reported that in February 2017, it adopted new disciplinary guidelines in accordance with SB 1441 standards. Since then, the Board reported that it has also adopted new standards relating to drug testing of licensees. The Board reports on its drug testing findings at its meetings on a quarterly basis.

The Board's [Report](#) also listed its Consumer Protection Enforcement Initiative (CPEI) as a current issue. The Board reported that its CPEI was "designed to ensure that investigations are completed and final action is taken against a licensee within 12 to 18 months . . . [via] policy changes designed to remove barriers to investigations, a new computer system that would meet the boards' need to collect information and monitor performance, and additional staff resources." The CPEI regulations took effect in 2014. The Board reported that it is continuing to identify timely barriers to investigations. In the Report, the Board proposed regaining authority from the legislature in the following areas, as it relates to investigations of licensees: (1) consideration of convictions of felony financial crimes; (2) consideration of acts that would be grounds for denial of a federal registration to distribute controlled substances; (3) consideration of acts that involve fraud in violation of state or federal law related to health care; (4) consideration of convictions

related to identity theft; and (5) consideration of convictions related to the sale of counterfeit products.

The final current issue the Board listed in its Report related to the [BreEZe Online Services System](#), DCA's licensing and enforcement system. The Board reported that it was originally scheduled to be included in DCA's second release of BreEZe but was removed from the release. The Board reported that it has initiated its own Business Modernization effort in order to "determine the specific needs of the [B]oard and identify feasible system alternatives." As part of its Business Modernization plan, the Board reported that it has allowed individual licensees to submit payments and renew their licenses online. The Board reported that it will continue to assess opportunities for online transactions for which a fee is not required.

In preparation for the Board's sunset hearing, legislative staff prepared a [Background Paper](#) addressing 24 current issues for the Board to respond to under the topics of administrative issues, fiscal issues, licensing issues, education and examination issues, enforcement issues, practice issues, implementation issues, technical cleanup, and continued regulation of the pharmacy profession by the California State Board of Pharmacy. Of note, the legislature seeks the Board's insight about whether its composition is adequate and properly safeguards against potential anticompetitive conduct; whether its statute should be amended to clarify that the Executive Officer of the Board must be independent and not a licensee of the Board; several matters pertaining to the potential licensing of advanced practice pharmacists and pharmacy technicians; the recent subversion of the California Pharmacy Jurisprudence Examination; continued education for opioids, medication-assisted treatments, and pharmaceutical compounding.

The Board's sunset hearing was originally scheduled for March 17, 2020. Due to the Governor's statewide emergency declaration resulting from the impact of COVID-19, the hearing

has been [postponed](#). At this writing, a new hearing date has not been announced.

MAJOR PUBLICATIONS

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

- [*California Practice Standards and Jurisprudence Examination \(CPJE\) for Pharmacists and North American Pharmacist Licensure Examination \(NAPLEX\) Statistics*](#), California Board of Pharmacy, November 2019 (presents statistical data for all candidates who took the CPJE between April and November 2019, as well as NAPLEX statistics associated with any candidate who took the CPJE between April and November 2019, regardless of when the NAPLEX may have been taken).
- *Sunset Review Report [Volume 1](#), [Volume 2](#)*, California Board of Pharmacy, December 1, 2019 (provides licensing and enforcement statistics, updates the legislature on past sunset issues, and outlines current issues facing the Board) (see HIGHLIGHTS).

RULEMAKING

- *Emergency Regulation—HIV Preexposure and Postexposure Prophylaxis Furnishing* (On April 10, 2020, the Board published its [Notice of Intent to an File Emergency Regulation](#) to [add](#) section 1747, Title 16 of the CCR to implement [SB 159 \(Wiener\) \(Chapter 532, Statutes of 2019\)](#), and establish criteria for a training program for pharmacists to independently furnish HIV preexposure prophylaxis (PrEP) and HIV postexposure prophylaxis (PEP) medications directly to patients without a prescription. The proposed regulation would also establish the recordkeeping requirements for a pharmacist who has completed the training program. According to the [Finding of Emergency](#), sections 4052.02(g) and 4052.03(g) of the

Business and Professions Code require the Board to adopt emergency regulations to implement the training program in accordance with the Centers for Disease Control guidelines, and in consultation with the Medical Board of California, by July 1, 2020. The Board approved the emergency rulemaking at its January 29, 2020 [meeting](#). The five working-day public comment period for the proposed regulation expires on April 17, 2020.)

- ***Implementation of [AB 2138 \(Chiu\) \(Chapter 995, Statutes of 2018\)](#)*** (On March 13, 2020, the Board formally [noticed](#) its intent 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. According to the [Initial Statement of Reasons](#), the Board proposes to adopt these regulations to implement AB 2138, and to provide clarity and transparency to applicants and licensees by listing the specific criteria the Board must consider when making the substantial relationship determinations applicable to criminal convictions. The public comment period expires on April 27, 2020.)

- ***Community Pharmacy Staffing*** (On February 28, 2020, the Board published [notice](#) of its intent to [add](#) section 1714.3 to Title 16 of the CCR to establish standards for community pharmacies’ staffing levels. According to the [Initial Statement of Reasons](#), the proposal constitutes the Board’s efforts to implement [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 of the pharmacy is present and working in the pharmacy, or an employee of the establishment is always made available to assist the pharmacist. Given the COVID-19 pandemic, the Board [extended](#) the public comment period until April 30, 2020.)

- ***Off-Site Storage*** (On February 7, 2020, the Board published [notice](#) of its intent 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. According to the [Initial Statement of Reasons](#), the proposed amendments would give the Board discretion to grant a waiver of the requirement that records must be retained on the licensed premises, and to remove the blanket restriction requiring denial of a waiver if a licensed entity has failed to produce records or has falsified records pursuant to Section 4081 of the Business and Professions Code. The public comment period expired on March 23, 2020. At this writing, the comments are pending review by the Board. Naloxone Fact Sheet.)

- ***Naloxone Fact Sheet*** (On January 27, 2020, OAL approved, and the Board [formally adopted](#), the Board’s proposed amendment to section 1746.3, Title 16 of the CCR to provide the Board’s Executive Officer with the authority to approve alternative fact sheets for distribution to patients after being furnished naloxone hydrochloride by a pharmacist, and to require fact sheets to be translated into alternate languages. [[25:1 CRLR 70–71](#)] The new regulation became effective April 1, 2020.)

- ***Fee Schedule*** (On November 12, 2019, OAL approved, and the Board [formally adopted](#), the Board’s proposed amendment to section 1749, Title 16 of the CCR to increase application, renewal, and other fees to their statutory maximums. [[25:1 CRLR 71–72](#)] The new regulation became effective April 1, 2020.)

LEGISLATION

- [AB 2077 \(Ting\)](#), as introduced: February 5, 2020, would amend section 4145.5, and repeal sections 4142 and 4326, of the Business and Professions Code to allow the retail sale

or furnishing of a hypodermic needle or syringe to those 18 years of age or older without a prescription and deletes the penalty associated with obtaining a hypodermic needle or syringe without a prescription. According to the author, the purpose of this bill is to continue to “stem the spread of HIV and viral hepatitis.” *[A. Health]*

- [AB 2288 \(Low\)](#), as introduced February 14, 2020, would add section 4052.11 to the Business and Professions Code to require a pharmacist to offer to a patient to dispense a Schedule II controlled substance containing an opioid as a partial fill if the prescription is for greater than seven days. *[A. B&P]*

- [AB 2857 \(Committee on Business and Professions\)](#), as introduced February 21, 2020, would amend Section 4001 of the Business and Professions Code to specify that each appointing authority for the Board has power to remove from office at any time any member of the Board appointed by that authority for continued neglect of duties required by law, or for incompetence, or unprofessional or dishonorable conduct. *[A. B&P]*

- [AB 2983 \(Holden\)](#), as amended March 12, 2020, would add section 4063.5 to the Business and Professions Code to prohibit a pharmacy from automatically contacting a prescriber to authorize a prescription for any dangerous drug or device to be refilled for more than a seven-day supply unless the prescriber or patient has expressly authorized the pharmacy to automatically contact the prescriber to refill that prescription. The bill would require a pharmacy to obtain separate authorization for each prescription and would prohibit a pharmacy from requesting more than the number of refills authorized in the original prescription. *[A. B&P]*

- [SB 1084 \(Umberg\)](#), as amended March 23, 2020, would add Article 12.5 (commencing with Section 4178) to Chapter 9 of Division 2 of the Business and Professions Code to, with certain exceptions, require a pharmacist to dispense certain controlled substances in a

lockable vial, provide an educational pamphlet on controlled substances to the patient, and, if the lockable vial uses an alphanumeric passcode or other code, include the code in any patient notes. The bill would also require the manufacturer of the controlled substance to reimburse the pharmacy each month for the cost of lockable vials used by the pharmacy. *[S. BP&ED]*

LITIGATION

- *Fusion IV Pharmaceuticals, Inc, et al. v. Anne Sodergren, et al., Docket No. 19-55791 (9th Cir.)*. On March 22, 2020, the Ninth Circuit Court of Appeals issued an order setting oral argument on Fusion IV Pharmaceuticals, Inc’s appeal of the district court’s [order](#) denying its petition for a judicial declaration that state regulation of outsourcing facilities by the Board of Pharmacy is preempted by the Drug Quality and Security Act, and violates the Commerce Clause of the U.S. Constitution. Fusion IV is a federally registered outsourcing facility which compounds drugs in California for interstate distribution. Oral argument is set for June 1, 2020.