

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 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 September 30, 2023, there were 137,952 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 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.

During the coverage period, the Board had no new appointments. At this writing, the Board has two public-member vacancies.

HIGHLIGHTS

Board of Pharmacy Approves Rulemaking Action on Temporary License for Military Spouses

On June 21, 2023, Board [voted](#) to approve an action amending section 1706.6 to Title 16, Division 17, Article 2 of the CCR regarding Temporary License for Military Spouses. The proposed regulation reflects the Board's efforts to implement [AB 107 \(Salas\) \(Chapter 693, Statutes of 2021\)](#), effective July 1, 2023, which required the Board to issue temporary licenses to qualified military spouses and partners under specified conditions. Previously, DCA would issue a temporary license to an applicant who meets certain requirements, such as marriage or in domestic partnership to an active-duty military member who is assigned to California, as well as active licensure in another state, district, or territory of the United States. However, the process for the DCA to issue a temporary license was long, expensive, and onerous for military spouses. Further, the applicants would need to reapply multiple times in certain cases.

According to the [initial statement of reasons](#), the Board will add section 1706.6 to the CCRs to clarify the provisions the applicant must meet in order to obtain a temporary license. This regulation will expedite the licensure processes, eliminate barriers to employment, and increase

the number of licensed healthcare individuals in the pharmacy field in California for military spouses and partners who travel with their partner and are licensed in a state other than California.

On June 8, 2023, the Board published its [modified text](#). The Board initially noticed the proposed amendments in March. *[28:2 CRLR 21]* At its June 21, 2023, [meeting](#), Board President Seung Oh stated that, having reviewed the materials, including the comments received and staff's recommendations, he agreed with the recommendations, including the modified text. The present Board members unanimously voted to approve the modified regulation language, initiate a 15-day public comment period, and authorize the Executive Officer to take all steps necessary to complete the rulemaking and adopt the proposed regulation as noticed if no adverse comments were received during that time. According to the [notice of modified text](#), the public comment period ended July 12, 2023. The proposed regulation was not included on the agenda for the Board's [August 30, 2023](#) or [September 12, 2023](#) meetings. It was submitted to OAL for review on October 18, 2023, and will be approved or denied by December 4, 2023.

MAJOR PUBLICATIONS

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

- [Standard of Care Report](#), Board of Pharmacy, Fall 2023 (report to the legislature, as required by Business and Professions Code section 4301.3, detailing the Board's efforts in evaluating whether a transition to a standard of care enforcement model would be feasible and appropriate for the regulation of pharmacy).
- [The Script](#), Board of Pharmacy, October 2023 (describes the Board's major projects in a bi-yearly newsletter; provides notification of a new law, AB 1286, concerning

reporting of medication errors; discusses inspections, self-assessment, and the CURES evaluation system; provides inspection results reported by the Enforcement and Compounding Committee; and announces the Board's updated policy statement on new compounding standards).

RULEMAKING

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

- **Designation of Pharmacist-in-Charge:** On November 8, 2023, the Board posted a [notice](#) of proposed regulatory action to amend section 1709.1 of Title 16, Division 17, Article 2 of the CCR, related to the designation of a pharmacist-in-charge. According to the [Initial Statement of Reasons](#), this regulation would require an attestation by a proposed Pharmacist-in-Charge (PIC) that affirms their acceptance of the responsibility for the pharmacy's compliance with all state and federal laws and regulations pertaining to the practice of pharmacy and to further affirm that it is unlawful for any pharmacy owner to commit any act that would subvert or tend to subvert the efforts of a PIC to comply with all laws. Additionally, the proposed regulation would require PICs to complete a training course prior to their approval by the Board. The stated goal of the proposed rulemaking is to ensure that potential PICs are aware of and accept responsibility for the legal obligations of their designated position. The proposed regulation is currently in a 45-day public comment period, which began November 17, 2023, and will end on January 2, 2024.
- **Notice to Consumers:** At its April 19–20, 2023, [meeting](#), the Board voted to adopt the regulation text as [noticed](#) on February 24, 2023. The [proposed](#) rulemaking would 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. At this writing, the proposed regulation is pending review by Board.

- **ADDS Self-Assessment:** At its April 19–20, 2023, [meeting](#), the Board voted to approve the staff recommended [proposed text](#), and authorize the Executive Officer to take all steps necessary to complete the rulemaking and adopt the proposed regulation amending section 1715.1 of Article 2 of Division 17 of Title 16 of the CCR if no comments requiring Board response are received during the second 15-day comment period, which ended May 6, 2023. 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 proposed regulation is under review by DCA.

LEGISLATION

- [AB 1341 \(Berman\)](#), as amended August 23, 2023, amends sections 1206.7 and 4052.04 of the Business and Professions Code and sections 11215 and 101161 of the Health and Safety Code. This bill authorizes 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 repeals the expansion of professionals authorized to test samples for SARS-CoV-2 on July 1, 2028. Furthermore, AB 1341 authorizes licensed pharmacists to administer a narcotic controlled substance in the treatment of a person with substance use disorder for addiction to a controlled substance when acting under the direction of a physician and surgeon. At its April 19–20, 2023, [meeting](#), the Board voted to support AB 1341 if amended to make this authority to furnish COVID-19 oral therapeutics to patients permanent. Governor Newsom signed AB 1341 on September 30, 2023 (Chapter 276, Statutes of 2023).

- [AB 1557 \(Flora\)](#), as amended June 6, 2023, amends section 4071.1 of the Business and Professions Code. This bill authorizes a pharmacist located and licensed in California to perform medication chart order reviews from a remote location within California on behalf of health care facilities licensed under Health and Safety Code section 1250, under specified conditions. Further, this bill removed a provision that made the authorization of electronically entered prescription inapplicable to controlled substances. At its April 19–20, 2023, [meeting](#), Chairperson Crowley noted that the Board would not act on this matter, as AB 1557 was already Board-sponsored, but remarked that the Committee had received public comment in support of the measure. Governor Newsom signed AB 1557 on September 1, 2023 (Chapter 141, Statutes of 2023).

- [AB 663 \(Haney\)](#), as amended August 21, 2023, amends section 4110.5 of the Business and Professions Code to allow controlled substances that treat opioid use disorder to be carried and dispensed at county-operated mobile pharmacy units. Further, this bill authorizes a county, city and county, or special hospital authority to operate one or more mobile units as part of the held pharmacy license and must notify the Board of its intention to operate a mobile unit as soon as possible (no later than five business days after operation of a mobile unit). At its April 19–20, 2023, [meeting](#), the Board unanimously voted to support AB 663. Governor Newsom signed AB 663 on October 8, 2023 (Chapter 539, Statutes of 2023).

- [AB 1286 \(Haney\)](#), as amended September 8, 2023, amends sections 4113, 4113.6, 4115, 4192, 4204, 4301, 4113.1 and 4316.5 of the Business and Professions Code. This bill requires pharmacies to report all medication errors to an entity approved by the Board and to maintain records, as prescribed. It also authorizes a pharmacist-in-charge to make staffing decisions to ensure sufficient personnel are present in the pharmacy to prevent fatigue, distraction, or other conditions

that may interfere with a pharmacist’s ability to practice competently and safely. Further, AB 1286 authorizes a physician-in-charge or pharmacist on duty to notify store management if there is an immediate risk of death, illness, or irreparable harm to patients, personnel, or pharmacy staff and requires the store management to report to the Board if the immediate risk is not resolved within twenty-four hours. The bill adds additional self-assessment and inspection requirements as part of the renewal process for a clinic license and expands the list of specified actions that constitute unprofessional conduct. AB 1286 was a Board-sponsored bill. At its April 19–20, 2023, [meeting](#), Chairperson Crowley noted that the provisions in the measure have the potential to significantly reduce medication errors and improve patient care. Governor Newsom signed AB 1286 on October 8, 2023 (Chapter 470, Statutes of 2023).

- [AB 782 \(McKinnor\)](#), as amended August 21, 2023, would have amended section 4126.8 of the Business and Professions Code. This bill would have excluded reconstitution of a drug pursuant to a manufacturer's directions, tablet splitting or crushing, capsule opening, or the addition of a flavoring agent from the Pharmacy Law’s definition of compounding. Further, this bill would of required a pharmacy to retain documentation when a flavoring agent was added to a prescription and to make the documentation available to the Board. On October 8, 2023, Governor Newsom [vetoed](#) the bill, stating the bill “would create standards for California that do not meet the United States Pharmacopeia-National Formulary’s guidelines regarding compounding that have been put in place to minimize patients’ risk of harm.”

- [AB 317 \(Weber\)](#), as amended June 8, 2023, amends section 1368.5 of the Health and Safety Code and section 10125.1 of the Insurance Code. This California Pharmacists Association-sponsored bill requires a health care service plan and certain disability insurers that offer coverage for a service within the scope of pharmaceutical practice to pay or reimburse the

cost of services performed by a pharmacist at an in-network or out-of-network pharmacy, as specified, if the service plan or insurer has an out-of-network pharmacy benefit. The Board voted to support this bill, noting at its April 19–20, 2023, [meeting](#) that AB 317 would allow for payment of services that could fund additional positions in the pharmacy. Governor Newsom signed AB 317 on October 7, 2023 (Chapter 322, Statutes of 2023).

- [SB 372 \(Menjivar\)](#), as amended September 1, 2023, adds section 27.5 to the Business and Professions Code. This bill requires a board within DCA to update a licensee’s or registrant’s license or registration by replacing references to the former name or gender on the license or registration, as specified, if a board receives documentation, as described, from the licensee or registrant demonstrating that the licensee or registrant’s legal name or gender has been changed. The bill also prohibits a board from publishing the licensee’s or registrant’s former name or gender online, and instead requires the Board to post an online statement to direct the public to contact the Board for more information. Further, for specific licensees or registrants, the Board is prohibited from posting enforcement records online, but required to post a statement online that the individual was previously subject to an enforcement action and can inquire further by contacting the Board. The Board did not discuss SB 372 at any meeting that took place during this coverage term. Governor Newsom signed SB 372 on September 23, 2023 (Chapter 225, Statutes of 2023).

- [SB 544 \(Laird\)](#), as amended September 8, 2023, amends sections 11124, 11123.5, and 11123.2 of the Government Code. This bill amends the Bagley-Keene Open Meeting Act with regard to meeting conduct when a meeting is held via teleconferencing (*see 29:1 CRLR 121*). At its April 19–20, 2023, [meeting](#) the Board unanimously voted to support SB 544. Governor Newsom signed SB 544 on September 22, 2023 (Chapter 216, Statutes of 2023). The changes took effect on January 1, 2024.

- [AB 557 \(Hart\)](#), as amended September 1, 2023, amends section 54953 of the Government Code. This bill revises the authority of legislative bodies under the Brown Act to hold a teleconference meeting under abbreviated teleconferencing procedures when a declared state of emergency is in effect. The Board did not discuss AB 557 at any meeting that took place during this coverage term. Governor Newsom signed AB 557 on October 8, 2023 (Chapter 534, Statutes of 2023).

- [SB 816 \(Roth\)](#), as amended September 8, 2023, amends sections 4119.01, 4119.11, 4128.2, 4161, 4210, and 4400 of the Business and Professions Code. This bill reorganizes and revises the fee schedule for specified licenses issued to both increase and decrease the amounts charged for the original issuance and renewal of those licenses, as well as for temporary licenses. It also establishes the fee schedule for the application and licensing fees of remote dispensing site pharmacies. These provisions of SB 816 will become operative on January 1, 2025. Additionally, SB 816 specifies conditions that must be met for pharmacies to utilize Automated Drug Delivery Systems (ADDS), Automated Unit Dose Systems (AUDS), and Automated Patient Dispensing Systems (APDS). SB 816 is a Board-sponsored bill. Governor Newsom signed SB 816 on October 10, 2023 (Chapter 723, Statutes of 2023).

- [SB 887 \(Committee on Business, Professions and Economic Development\)](#), as amended September 8, 2023, as it applies to the Board, amends section 4427.8 of the Business and Professions Code. This bill extends the deadline by which the Board must report to the legislature on the regulation of automated drug delivery system (ADDS) units from January 1, 2024, to January 1, 2025, to coincide with the Board's sunset evaluation process. Governor Newsom signed SB 887 on October 8, 2023 (Chapter 510, Statutes of 2023).

The following bills, reported in Volume 28, No. 2 (Spring 2023), died in committee or

otherwise failed to be enacted in 2023: [AB 602 \(Pellerin\)](#), pregnancy-related services; [AB 1619 \(Dixon\)](#), cannabis or cannabidiol interactions; [SB 524 \(Caballero\)](#), furnishing prescription medications; and [SB 339 \(Wiener\)](#), HIV preexposure prophylaxis and postexposure prophylaxis.