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

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 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.

On March 19, 2024, Governor Newsom <u>appointed</u> three new members and reappointed one member to the Board.

• Jeff Hughes, a public member, has been a Wellness Business Agent at the Orange County Professional Firefighters IAFF since 2020, was previously a Fire Captain at the Orange County Fire Authority from 1994 to 2020, and a Firefighter/Engineer for the City of Buena Park Fire Department from 1985 to 1994;

• Jason Newell, a public member, has been Principal and Co-Founder of System2Solutions since 2020 and Co-Founder and Program Director for the Leveraging Equal Access Program since 2015. Satinder Sandhu, PharmD, has been an Area Healthcare Supervisor of Northern California for Walgreens since 2019. He held various positions with Walgreens from 1992 to 2019; and

• Seung Oh, PharmD and President of the Board, was reappointed by the Governor. Oh, was initially appointed by Governor Newsom in 2020. He was a pharmacist-in-charge for Vons Pharmacy from 2014 to 2020, a staff pharmacist at Safeway Pharmacy in 2014, and a pharmacist and director of operations at Rainbow Pharmacy from 2013 to 2014.

At the time of this writing, there are no Board vacancies.

MAJOR PUBLICATIONS

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

• <u>2024 Lawbook for Pharmacy</u>, Board of Pharmacy, 2024 (presents pharmacy law from Business and Professions Code 4000 et seq., excerpts from the California Uniform Controlled Substances Act, excerpts from the Confidentiality of Medical Information Act, and excerpts from the Public Resources Code).

• <u>*The Script*</u>, Board of Pharmacy, March 2024 (special issue detailing newly enacted AB 1286, the Patient Safety Measure; provides a summary of changes to medication error reporting, minimum staffing provisions, staffing decisions, pharmacy technician expanded duties, unprofessional conduct, and surgical clinic provisions; includes frequently asked questions and answers to assist licensees with understanding AB 1286).

RULEMAKING

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

• **Designation of Pharmacist-in-Charge:** On March 1, 2024, the Board published notice and modified text to amend section 1709.1 of Title 16, Division 17, Article 2 of the CCR to specify a requirement for an interim Pharmacist in Charge (PIC) to complete the board-provided PIC Overview and Responsibility training course within two years before the date of application, identified in subdivision (a) of the regulations. The public comment period will begin on April 29, 2024, and end on May 14, 2024. This rulemaking action was initially <u>noticed</u> on November 8, 2024. *[29:1 CRLR 24]*

• **Opioid Antagonist Protocol:** On February 9, 2024, the Board gave <u>notice</u> of <u>modified regulatory language</u> for this proposal. The Board's rulemaking was initially <u>noticed</u> on October 17, 2024. This regulatory action would amend section 1746.3 of Title 16, Division 17 of the CCR, related to procedures for furnishing opioids. According to the <u>Initial Statement of</u> 24

<u>Reasons</u>, this regulatory proposal seeks to update the current standardized procedures or protocols to regulate furnishing any FDA-approved opioid antagonists, not just naloxone hydrochloride. As of this writing, the regulation is pending with the Board staff.

• **Disciplinary Guidelines:** On December 1, 2023, the Board posted a <u>notice</u> of proposed regulatory action to amend section 1760 of Article 8 of Division 17 of Title 16 of the CCR. The amendments would update the guidelines used to discipline licensees, having previously released the <u>proposed regulatory language</u> on November 11, 2023. According to the <u>Initial Statement of Reasons</u>, the proposed action includes the requirement to disclose the respondent's email address, use gender-inclusive language, and use updated terms for consistency throughout the "<u>Disciplinary Guidelines</u>." Further, the action proposes clarification of relevant terms, changes to categories of violations, additional optional terms, language regarding reinstatement of a license, timeframes for when actions must be taken, and it addresses probation under specified conditions.

• Notice to Consumers: On March 26, 2024, the Board published an Order of Adoption and a Final Statement of Reasons. The Board initially noticed the proposed regulatory changes on February 9, 2023, in furtherance of its consumer awareness initiative. According to the Initial Statement of Reasons, the proposed text revised section 1707.6 of the CCR regarding Notice and Language posters that existing law requires to be posted in pharmacies to inform patients of their right to obtain prescription drugs. Specifically, the proposed action requires the Notice to include a QR code that links consumers to a translation of the text in 16 languages to be determined by the U.S. Department of Health and Human Services and the California Department of Health Care Services. Further, the proposal requires pharmacies to post a statement of patient rights per Business and Professions Code section 733 and Business and Professions Code section 4122 on their written receipts. After further modification in December, the Board submitted the rulemaking

package to OAL for approval. OAL <u>approved</u> the regulations on April 5, 2024 and the changes will become effective July 1, 2024.

• **Temporary Licenses for Military Spouses/Domestic Partners:** On February 7, 2024, the Board published an <u>Order of Adoption</u>. On March 30, 2024, the Board published its <u>Final Statement of Reasons</u>. The Board initially <u>noticed</u> the proposed regulatory action to add section 1706.6 to Article 1 of Title 16, Division 17 of the CCR on March 1, 2023. The <u>proposed</u> regulatory action concerning temporary licenses for military spouses/domestic partners. According to the <u>Initial Statement of Reasons</u>, the proposal would define the provisions that must be met to obtain a temporary license. The Board issued <u>notice</u> of a <u>second modified text</u> on December 1, 2023. OAL <u>approved</u> the regulations on April 5, 2024; changes became effective on March 21, 2024.

LEGISLATION

• <u>AB 3026 (Dixon)</u>, as introduced on February 2, 2024, would amend section 4062 of the Business and Professions Code. This bill would allow the Board to waive application of any provision of the Pharmacy Law and corresponding regulations following the termination of a declared public emergency if it believes the waiver will protect public health or the administration of patient care. The bill would change the maximum waiver period from 90 days to 60 days. *[A. B&P]*

• <u>AB 1902 (Alanis)</u>, as amended on March 12, 2024, would amend section 4076.6 and add section 4076.8 to the Business and Professions Code. This bill would require pharmacists dispensing a prescription drug to provide translated directions for the drug's use in languages the Board makes available. Further, this bill would require dispensers to provide at no additional cost

accessible labels on prescription containers for people who inform the pharmacy that they identify as blind, low-vision, or otherwise print disabled. *[A. Appr]*

• <u>AB 2445 (Wallis)</u>, as introduced on February 13, 2024, would amend section 4076.8 to the Business and Professions Code. This bill would expand the scope of the existing crime for pharmacists to dispense prescription drugs containing opioids without special labeling. This bill would require pharmacists to also provide a personal use pharmaceutical disposal system to the patients receiving prescription drugs containing opioids. The state would govern this system according to the Legislature's framework, which it has not enacted yet. *[A. B&P]*

• <u>SB 1365 (Glazer)</u>, as introduced on February 16, 2024, would amend section 4115 of the Business and Professions code. This bill would allow a pharmacy to have up to six pharmacy technicians perform packaging, manipulative, repetitive, or other nondiscretionary tasks under only one pharmacist's supervision, and prohibit a ratio of pharmacy technicians performing such tasks if it exceeds a six to one ratio. *[S. BP&ED]*