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, sterile compounding facilities, non-resident pharmacies, centralized hospital packaging facilities, wholesale drug facilities, outsourcing 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 March 21, 2021, there were 141,086 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 early 2021, Ryan Brooks of San Francisco resigned following more than 12 years of service as a public member of the Board. Mr. Brooks was first appointed to the Board in 2008 by Governor Arnold Schwarzenegger and worked primarily as a past chairperson and longtime member of the Board's Communication and Public Education Committee. After Mr. Brooks' resignation, Governor Gavin Newsom appointed Mr. Brooks to the Medical Board of California on February 2, 2021.

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 vacancy is to be appointed by the Speaker of the Assembly and the other is to be appointed by the Governor.

HIGHLIGHTS

New Laws Regarding Security Prescription Form Requirements and CURES Reporting

On January 1, 2021, two laws imposing security prescription requirements on pharmacists and other licensees went into effect after nearly three years in the making. In September 2018, California first enacted AB 1753 (Low) (Chapter 479, Statutes of 2018), which introduced new formatting and printing requirements for written prescriptions of controlled substances. According to the author, the purpose of AB 1753 is to curb the "criminal enterprises [that] derive tremendous

profit through prescription pad theft and fraud" as "addiction to pharmaceutical opioids grows." *[see 24:1 CRLR 83–84]*

In March 2019, California enacted AB 149 (Cooper) (Chapter 4, Statutes of 2019), which details the specific security formatting requirements and includes a transition period from the date of passage to December 31, 2020, to support an orderly shift by prescribers to compliant prescription forms. Pursuant to AB 149, Health and Safety Code sections 11162.1 and 11162.2 set forth that all paper prescriptions for controlled substances must be written on California Security Prescription Forms, forms that can only be printed by approved printers in the California Department of Justice's Security Prescription Printer Program. The security prescription forms contain fifteen security elements, including a barcode, unique serial number, and watermark to curtail counterfeit prescriptions. *[see 24:2 CRLR 70]*

On January 1, 2021, the transition period for AB 149 ended. As a result, except for limited emergency situations, pharmacists are unable to fill controlled substances' written prescriptions that are not on a compliant form. To assist prescribers and furnishers with the change, the Board of Pharmacy, the Medical Board of California, and the California Department of Justice released a joint statement on November 19, 2020, to answer frequently asked questions about the new requirements. The Board recommended to those who prescribe controlled substances and who have not acquired forms compliant with AB 149 to order them as soon as possible, or in lieu of using the new prescription forms, prescribers also have the option to utilize electronic prescribing, which becomes mandatory in 2022 pursuant to AB 2789 (Wood) (Chapter 438, Statutes of 2018). By 2022, all healthcare practitioners authorized to issue prescriptions must be able to electronically transmit prescriptions for both controlled and non-controlled substances unless specified exceptions are met.

Additionally, AB 149 revised data reporting requirements for controlled substances. Beginning January 1, 2021, the dispensing of a controlled substance must be reported to the Controlled Substance Utilization Review and Evaluation System (CURES) within one working day after the medication is released to the patient. Previously, the deadline to report was seven days after dispensing. According to the bill's author, by mandating a tighter timeline, the law ensures that prescriptions filled using illegal forms can be linked to prescription data collected through the CURES database.

Justice Department Sues Walmart over its Role in the Opioid Crisis

***United States of America v. Walmart Inc. and Wal-Mart Stores Easy, LP,* Case No: 1:99-mc-09999 (D. Del. 2020)**. On December 22, 2020, the United States Department of Justice filed a complaint in the U.S. District Court for the District of Delaware against Walmart for unlawfully dispensing and distributing substances in violation of the Controlled Substance Act (CSA).

The civil complaint alleges that Walmart knowingly filled thousands of opioid prescriptions that were not issued for "legitimate medical purposes" or within the "ordinary course" of pharmacy practice. The complaint also alleges that Walmart received hundreds of thousands of suspicious opioid orders that it failed to report as required by the Drug Enforcement Administration (DEA). The Justice Department alleges that these actions helped to fuel the prescription opioid crisis. For example, one case cited in the complaint describes that a Walmart pharmacy in Pennsylvania continued to fill thousands of prescriptions for a known "pill mill" doctor who is now under indictment after five patients died.

Previously, on October 22, 2020, Walmart filed a complaint for declaratory relief to head off the Justice Department's claims in the United States District Court for the Eastern District of

Texas. In the preemptive countersuit against the U.S. Department of Justice, Attorney General William Barr, the U.S. Drug Enforcement Administration and its acting administrator, Walmart argued that its pharmacists blocked thousands of questionable opioid prescriptions as part of the company's good faith effort to help address the opioid crisis. Walmart argued in the complaint that allowing the Justice Department to hold Walmart liable for CSA violations would turn pharmacists into "doctor police," forcing pharmacists to come between doctors and patients in a way Congress never intended. Finally, in the complaint for declaratory relief, Walmart argued that the Justice Department tried to shift blame for the DEA's own failures to police doctors. Despite these arguments, on February 4, 2021, the Texas court dismissed Walmart's request for a federal declaration, finding that the court had no subject-matter jurisdiction. Walmart filed a notice of appeal of the court's dismissal on March 5, 2021.

In the Department of Justice's current lawsuit, if Walmart is found liable for violating the CSA, it could face civil penalties of up to $67,627 for each unlawful prescription filled and $15,691 for each suspicious order not reported. Thus, Walmart's civil penalties for nationwide violations of the CSA could total billions of dollars. Furthermore, the suit's outcome may impact the pharmacy industry as a whole by imposing new duties on pharmacists to question licensed doctors on controlled substance prescriptions.

The Board Undergoes Sunset Review

On December 1, 2020, the Board published its Sunset Review Supplemental Report (Volume 1, Volume 2) in preparation for its Sunset Review Oversight Hearing before the Assembly Business and Professions Committee and the Senate Business, Professions and Economic Development Committee. The Board's enabling act, section 4000, et seq. of the

Business and Professions Code is scheduled to "sunset" or be repealed on January 1, 2022, if it is not extended during sunset review.

The Board initially published its Sunset Review Report (Volume 1, Volume 2) on December 1, 2019, in preparation for the Board's original sunset date on January 1, 2021. Because of the COVID-19 pandemic, the legislature passed SB 1474 (Committee on Business, Professions and Economic Development) (Chapter 312, Statutes of 2020) to provide a one-year extension of the Board's sunset date from January 1, 2021, to January 1, 2022. As a result, the Board released the Supplemental Report to augment the Board's Sunset Review Report. While the Board's Sunset Review Report included a summary of the Board's activities over the previous four years *[see 25:2 CRLR 42–43]*, the Supplemental Report covers the one-year supplemental reporting period.

As stated in the combined Sunset reports, the Board sponsored and enacted ten pieces of legislation, made 28 regulation changes, and issued two major studies over the last five years. The Board's Supplemental Report also highlights the Board's response to the pandemic—specifically, the Board's issuance of pharmacy law waivers to increase access to COVID-19 testing and the Board's partnerships with other agencies to release guidance documents on pandemic protocol. In addition to the new issues identified in the Board's Sunset Review Report, the Supplemental Report identifies three supplemental issues related to the issuance of waivers that the Board would like the legislature to consider during the review process. As waivers are temporary in nature, the Board believes that permanent changes in several areas would be in consumers' best interest. First, the Board seeks permanent statutory changes to allow pharmacists to perform point-of-care, Clinical Laboratory Improvement Amendments of 1988 ("CLIA")-waived tests for influenza and COVID-19. Second, the Board seeks permanent expansion of authority for pharmacy technicians to administer influenza and COVID-19 vaccinations under specified conditions. Third, the Board

believes its authority to issue temporary licenses for testing facilities should be permanently extended to all facility license types issued by the Board.

The Legislative Background Paper for the California State Board of Pharmacy was originally published prior to March 2020 *[see 25:2 CRLR 42–43]*; however, when the sunset review hearing was postponed due to the COVID-19 pandemic, the legislative staff updated and republished a new background paper in preparation for the rescheduled hearing on November 18, 2020. In the background paper, the legislative staff raised 26 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, COVID-19 pandemic issues, technical clean-up, and continued regulation of the pharmacy profession by the Board.

First, the background paper raised several concerns related to the Board's administrative composition. Specifically, the legislature requested that the Board: clarify whether an active licensee or member of the Board is prohibited from filling the position of Executive Officer, provide solutions to addressing the Board's current vacancy rate, and specify what efforts it has taken to ensure its decision-making is subject to state supervision so as to safeguard its members from antitrust allegations under *North Carolina State Board of Dental Examiners v. Federal Trade Commission*, 574 U.S. 494 (2015).

Under the topic of licensing issues, the legislative staff highlighted the Board's proposal to establish a new mid-level pharmacy practitioner license category: "Advanced Pharmacy Technicians." These proposed advanced pharmacy technicians would be authorized to carry out certain duties that pose a low risk of harm but may currently only be performed by pharmacists, thereby allowing pharmacists to spend more time engaged in patient care. The legislature

recommends the Board provide the legislative committees with an overview of whether and why the advanced pharmacy technician license type should be established and what steps may be taken to begin a constructive dialogue with stakeholders on the issue.

Among its listed concerns, the background paper also highlighted the compromised 2019 California Practice Standards and Jurisprudence Examination for Pharmacists (CPJE) *[see 25:1 CRLR 68–70]*, wherein questions on the examination were made widely available over the internet. As a result, examination scores for about 1,400 individuals were invalidated. In the background paper, the legislative staff questioned whether additional action is necessary to address the subversion of the CPJE and whether the adoption of the Multistate Pharmacy Jurisprudence Exam (MPJE), a national alternative to the CPJE that includes board-approved questions for each state in which it is administered, is feasible. On this topic, the Board's Supplemental Report explained that the Board contracted with the Office of Professional Examination Services to conduct an audit of the CPJE and its administration. The report is anticipated to be finalized in early 2021.

On November 18, 2020, the Board's President Gregory N. Lippe and Executive Director Anne Sodergren testified at the Sunset Review Hearing. Executive Director Sodergren fielded questions from committee members about how the 2019 CPJE mishap affected non-cheating test-takers. Director Sodergren explained that the Board had no choice but to invalidate all results from the compromised CPJE because there was no way to distinguish blameless test-takers who had not seen the leaked online answers from those who had. Director Sodergren commented that the Board handled the issue swiftly and offered an additional test date a month after the decision to invalidate all scores. Finally, the committee heard comments from three public members as to the Board's performance. Of note, a member of the public voiced concern over the Board's proposal to establish the "Advanced Pharmacy Technician" license. The member critiqued the new role as

unnecessary and noted that the role would further strain pharmacists' supervisory responsibilities and subvert low-income and largely minority pharmacy technicians who cannot pay for additional schooling and licensing.

AB 1533 (Committee on Business and Professions), as introduced on February 19, 2021, is the sunset review legislative vehicle for the Board (see LEGISLATION). At this writing, the bill does not make substantive changes, but hearing on the bill is set before the Assembly Committee on Business and Professions for April 27, 2021, and significant amendments to the Board's enabling act are expected during the legislative process.

MAJOR PUBLICATIONS

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

- ***Joint Statement on New Requirements for Controlled Substances Prescription Forms***, California Department of Justice, California Board of Pharmacy, and the Medical Board of California, November 19, 2020 (answers frequently asked questions regarding the new security requirements on controlled substances prescription forms required by AB 149 (Cooper) (Chapter 4, Statutes of 2019) (*see* HIGHLIGHTS)).

- ***Sunset Review Supplemental Report***, (Volume 1, Volume 2), California Board of Pharmacy, December 2020 (supplements the December 2019 Sunset Review Report (Volume 1, Volume 2) in preparation for the Board's Sunset Review Oversight Hearing before committee members (see HIGHLIGHTS)). *[see 25:2 CRLR 42–43]*

- ***The Script***, California Board of Pharmacy, March 2021 (describes the Board's major projects in a bi-yearly newsletter; promotes the Boards' new online registry of local

pharmacists; details California's new CURES requirements (see HIGHLIGHTS); links to the Board's Sample Collaborative Practice Agreement for providing medication-assisted treatment to patients with opioid use disorder *[see 26:1 CRLR 55]*; and lists licensee disciplinary actions).

- ***Guidance on Eligible Personnel for Vaccines Administered in Pharmacies***, California Board of Pharmacy, March 30, 2021, (provides guidance to facilitate the administration of vaccines by pharmacies in accordance with the Department of Consumer Affairs' instructions to widen the administration of vaccines by tiers).

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 December 28, 2020, the Office of Administrative Law ("OAL") approved the Board's proposed amendments to 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, as set forth in the approved regulatory text. The Board initially published notice of its intent to amend these regulations on March 13, 2020. *[see 25:2 CRLR 45]* According to the Final Statement of Reasons, the Board received one public comment during the public comment period and considered it at its May meeting, but ultimately decided it was not necessary to further amend the proposed language. The regulation went into effect on December 28, 2020.

- **HIV Preexposure and Postexposure Prophylaxis Furnishing**: On January 29, 2021, the Board published notice of intent to add section 1747, Title 16 of the CCR to allow

pharmacists to independently initiate and furnish HIV Preexposure and Postexposure Prophylaxis treatment after completing a training program. According to the Initial Statement of Reasons, the regulation, which is currently in effect as an emergency regulation *[see 26:1 CRLR 51–52]*, will save lives by creating additional access to HIV medication consultation and treatment because "pharmacists are trusted healthcare providers who are highly accessible to patients within their communities." The public comment period expired on March 15, 2021. The regulation is currently under review by DCA. Meanwhile, the OAL readopted the emergency regulations on February 25, 2021, which will remain in effect until September 24, 2021.

- **Dangerous Drug Distributers**: On February 22, 2021, OAL approved the Board's proposal 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, as set forth in the approved regulatory text. The Board initially published notice of its intent to amend these regulations on May 29, 2020. *[see 26:1 CRLR 56]* According to the Final Statement of Reasons, the Board did not receive any public comments on the proposed regulations during the public comment period. The regulation went into effect on April 1, 2021, and requires third-party logistics providers to transport and store dangerous drugs under conditions that make it more likely that the drugs will be safe when received by the consumer.

- **Renewal Requirements:** On March 1, 2021, the OAL approved the Board's proposed amendments to sections 1702, 1702.1, 1702.2, and 1702.5, Title 16 of the CCR, to simplify the 39 separate license types within the Board's jurisdiction into two general categories, as set forth in the approved regulatory text. The Board initially published notice of its intent to amend these regulations on February 7, 2020. *[see 25:2 CRLR 39–40]* According to the Final Statement of Reasons, the Board did not receive any public comment with respect to the proposed

changes. With the changes, the renewal of license types will fall into two categories: a premises or facility license and a license issued to an individual. The newly approved regulations become effective July 1, 2021.

LEGISLATION

- **AB 1533 (Committee on Business, Professions and Economic Development)**, as introduced on February 19, 2021, 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. This bill is the Board's sunset review vehicle, and while at this writing it does not yet extend the Board's sunset date, it is anticipated that the bill will be significantly amended as it moves through the legislative process to adopt new reforms pertaining to the Board (see HIGHLIGHTS). *[A. B&P]*

- **AB 1328 (Irwin)**, as amended on March 23, 2021, would amend sections 1206, 1206.5, 1206.6, 4050, 4052, 4052.2, and 4052.4 of the Business and Prof. Code to revise and expand the types of people that may perform CLIA waived tests, including licensed pharmacists, at a community pharmacy. The bill would also authorize a pharmacist to order and interpret the tests for the purpose of promoting patient health. According to the California Society of Health-System Pharmacists, the sponsor of the bill, the bill will minimize barriers and restrictions in existing law which prevent pharmacists from fully engaging in public health activities like health screenings and administering CLIA-waived tests. *[A. B&P]*

- **SB 409 (Caballero)**, as introduced on February 12, 2021, is a Board-sponsored bill that would amend sections 1206.5, 1209, and 4052.4 of, and add section 4119.10 to the Business and Professions Code to permit pharmacists and pharmacies to perform COVID-19, SARS-CoV-

2, and influenza tests classified as waived under CLIA outside of the licensed laboratory setting, as long as a laboratory director oversaw the process. The bill also would add "pharmacist-in-charge" under the definition of laboratory director. The Board is sponsoring this bill because "increasing testing capacity is essential," and "community pharmacies provide unique access for patients to obtain tests in a safe and convenient location." *[A. Desk]*

- **SB 306 (Pan)**, as amended on March 24, 2021, and as it relates to the Board of Pharmacy, would amend section 4076 of the Business and Professions Code to permit pharmacists to dispense a drug, without the name of an individual for whom the drug is intended, when prescribed for the sexual partner of someone who has been diagnosed with a sexually transmitted disease (STD). According to the author the bill would expand access to STD care in response to California's STD crisis that disproportionately affects people of color, and gay, bisexual, and transgender people. *[S. BP&ED]*

LITIGATION

- ***In re: Purdue Pharma L.P., et al., Debtors,* Case No. 19-23649, (Bankr. S.D.N.Y. 2021).** On March 15, 2021, Purdue Pharma filed a bankruptcy plan in federal bankruptcy court in the Southern District of New York to restructure the company with over ten billion dollars directed toward combating the opioid crisis. Purdue, which makes OxyContin, filed for bankruptcy protection in September of 2019 after thousands of civil lawsuits were filed against the company for its role in the opioid epidemic. If the bankruptcy plan is approved by the court and a majority of Purdue's creditors, payments will be distributed to compensate those who have been devastated by the opioid crisis, including individual plaintiffs, indigenous tribes, and state and local governments. Purdue's plan comes in the wake of pleading guilty for conspiracies to defraud the

United States on November 24, 2020, when the opioid manufacturer agreed to criminal and civil penalties of about $8.3 billion as part of its settlement with the Justice Department.

- ***United States of America v. Walmart Inc. and Wal-Mart Stores Easy, LP*, Case No: 1:99-mc-09999 (D. Del. 2020)**. On December 22, 2020, the United States Department of Justice filed a complaint in the U.S. District Court for the District of Delaware against Walmart for unlawfully dispensing and distributing substances in violation of the Controlled Substance Act (see HIGHLIGHTS).