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 (the Board or BOP) 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).

BOP 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 licensees. 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 June 2021, the Speaker of the Assembly, Anthony Rendon, appointed Jose De La Paz of Los Angeles as a public member to the Board. De La Paz is the head of technology and operations at VisibilityOne.

On July 26, 2021, Governor Newsom appointed Nicole Thibeau of Los Angeles as a licensee member of the Board. Ms. Thibeau is the director of pharmacy services at the Los Angeles LGBT Center.

At its April 29, 2021 meeting, the Board elected Dr. Seung Oh of San Diego as president of BOP. Dr. Oh has worked as a pharmacist, pharmacist-in-charge, and director of operations at retail pharmacies since 2014. The Board also elected Dr. Maria Serpa of Elk Grove as Vice President of the Board and Jignesh "Jig" Patel of Roseville as Treasurer. Dr. Serpa served as a system support pharmacist at Sutter Medical Group. Mr. Patel has worked as a division pharmacy manager for Safeway since 2006.

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

HIGHLIGHTS

Board Survives Sunset Review

On October 7, 2021, Governor Newsom signed the California Board of Pharmacy's sunset extension bill, AB 1533 (Low) (Chapter 629, Statutes of 2021), which extends the Board's sunset

date to January 1, 2026 (see LEGISLATION). As amended September 3, 2021, AB 1533 implements the following:

Licensing requirements. The bill amends section 4110 of the Business and Professions Code prohibiting anyone from conducting a pharmacy in California without a license from the board that is renewed annually. Additionally, pharmacies that compound sterile drug products must possess a compounding pharmacy license to be renewed annually. AB 1533 requires that pharmacy licenses' renewal include necessary matters identified by the Board, as provided. It also requires renewal applications for compounding pharmacies to meet certain conditions, including a report of information as specified and certification that the reporting requirements are satisfied in connection with and as a condition of renewal of the pharmacy's license. This increases licensing standards, creating stricter operating requirements for California pharmacies.

Compounded drug preparations. AB 1533 adds section 4126.10 to the Business and Professions Code, outlining the licensing requirements for pharmacies that perform compounded human drug preparations interstate. The requirements include reporting required data to the Information Sharing Network established by the National Association of Boards of Pharmacy in conjunction with the FDA to implement the Memorandum of Understanding Addressing Certain Distributions of Compounded Human Drug Products. Requirements also include that the pharmacist-in-charge of the pharmacy certify that the reporting requirements above have been satisfied. The pharmacy reports adverse compounded drug experiences within 12 hours of notice, and information submitted to the FDA under these requirements will not be shared with the public. This is significant because it increases safety and transparency standards for compounding pharmacies.

Board's Proposed Amendment on Reporting Pharmacy Drug Loss Undergoing Review by OAL

On June 4, 2021, the Board published notice of its intent to amend section 1715.6, Title 16 of the CCR, to reduce mandatory reporting of loss of controlled substances, which is set forth in the proposed language. According to the initial statement of reasons, the Drug Enforcement Administration (DEA) requires the reporting of any "significant" loss of a controlled substance, in contrast to existing state law which requires the reporting of all drug losses. The proposed regulation establishes a minimum reporting threshold that corresponds to what it deems to be a significant loss, depending on the type and amount of controlled substance lost. By establishing a minimum reporting threshold, the Board aims to bring its reporting requirement into closer alignment with the DEA's requirements.

As stated in the initial statement of reasons, the regulation seeks to reduce the administrative burden for both licensees and the Board, who under existing state law must prepare, review, and document reports for all controlled substance losses, including single-dose losses. The proposed amendment would require that the owner of the licensed facility submit to the Board a report for loss of controlled substances when 99 dosage units of tablets, capsules, or other oral medication are lost; or when ten dosage units of single-dose injectable medications, lozenges, film, such as oral, buccal, and sublingual, suppositories, or patches are lost; or when two or more multi-dose vials, infusion bags, or other containers of injectable multi-dose medications, medications administered by continuous infusion, or any other multi-dose unit are lost. The proposed regulation also permits the reporting of any additional drug losses the pharmacist-in-charge deems "significant" in their professional discretion.

The Board approximates in its fiscal impact estimate that this regulation would reduce the number of licensed facilities reporting a drug loss from approximately 10,000 reports per year to 6,667 per year. The Board states that an Associate Governmental Program Analyst typically takes five minutes to process each report at the cost of approximately $3 per report. Consequently, the Board approximates that the anticipated decrease of 3,333 reports received and processed by the Board each year would result in cost savings of approximately $10,000 per year.

At its January 30, 2020 meeting [Agenda Item IX(b)], the Board voted to approve the proposed text of this rulemaking package. During the meeting, the Board emphasized the proposal's priorities of providing clarity on drug loss reporting requirements while also ensuring pharmacy workers can use professional judgment. The 45-day public comment period ended on July 19, 2021. At the time of this writing, the Board reported on its website that the proposed regulation is undergoing review by the Office of Administrative Law (OAL).

Board's Proposed Regulation Aims to Curtail the Ongoing Misuse and Abuse of Prescription Medication

On September 17, 2021, the Board published notice of its intent to amend section 1715.65, Title 16 of the CCR, to address frequent compliance questions the Board receives on the requirement for pharmacies and clinics to perform inventory reconciliation activities and to address the ongoing diversion of non-Schedule II controlled substances, which is set forth in the proposed language.

As stated in the Board's initial statement of reasons, the proposal seeks to reduce the amount of controlled substances diverted from pharmacies and clinics and thereby reduce the amount of drugs being misused and abused without denying pain relief for those who need it.

According to the National Council on Alcoholism and Drug Independence, Inc. (as cited by the Board), the availability of opioids is partly the cause of the epidemic misuse of prescription medication. The Board determined that focusing on the non-Schedule II controlled substances with the highest reported drug losses would have the most significant impact on the health and safety of the regulated public while also managing the pharmacy staff time necessary to complete the inventories.

Existing federal law (Title 21 of the Code of Federal Regulations section 1304.11) requires that pharmacies and clinics complete an inventory of all federal controlled substances at least once every two years. The proposed amendment adds the requirement that four non-Schedule II controlled substances (Alprazolam, 1 milligram/unit, Alprazolam 2 milligrams/unit, Tramadol 50 milligrams/unit, and Promethazine/codeine, 6.25 milligrams of promethazine and 10 milligrams of codeine per 5 milliliters of product) will require an inventory at least once every twelve months. These four non-Schedule II substances have the highest reported drug losses to the Board. They are also subject to abuse and misuse, making them a target for diversion by pharmacy and clinic employees. The Board reasoned that by requiring the inventory of the four non-Schedule II controlled substances yearly and of other non-Schedule II controlled substances biennially, pharmacists and pharmacies will be better equipped to spot and stop employee drug diversion from the pharmacy earlier and prevent excessive drug losses from occurring.

The proposed regulation will also require that all individuals involved in completing the inventory or preparing the report be identified and that the individual who performs the inventory sign and date the form. The regulation will also clarify the inventory requirements for an inpatient hospital pharmacy where drugs are stored within a drug storage area under the pharmacy's control, and for the inventory of an automated drug delivery system within the inpatient hospital.

At its January 29–30, 2020 meeting [Agenda Item (IX(a)], the Board voted to initiate a rulemaking for this proposed amendment. During the meeting, the Board stated that it had considered a suggestion to include buprenorphine products as one of the target drugs but decided it was unnecessary. The 45-day public comment period for this rulemaking action concluded on November 1, 2021. At this writing, the Board has not taken further action on this rulemaking package.

Board Intends to Enter the Food and Drug Administration's Memorandum of Understanding Addressing Certain Distributions of Compounded Human Drug Products

At its April 29-30, 2021 meeting [Agenda Item XI(b–c)], the Board expressed its intention to sign the Food and Drug Administration's (FDA) Memorandum of Understanding Addressing Certain Distributions of Compounded Human Drug Products (MOU). The FDA announced on October 27, 2020, that the MOU is now available for signature by state board of pharmacies or other state agencies. The MOU addresses the interstate distribution of inordinate amounts of compounded drugs and complaint investigations by state boards of pharmacy or other state agencies into compounded drugs distributed outside the state.

During the meeting, the Board's Enforcement and Compounding Committee considered a presentation [Attachment 1] by the National Association of Boards of Pharmacy (NABP), which covered the basic provisions of the MOU. The presentation also covered many of the requirements established by the MOU, including reporting and investigation activities. In particular, the presentation provided in-depth coverage on the NABP system designed to provide guidance on how to effectively implement some of the reporting requirements established by the MOU.

After the presentation by the NABP, the Committee considered the substance of the MOU to determine if a recommendation to the Board to enter the MOU was appropriate. After considering policy questions, the Committee decided it was appropriate to sign the MOU if the Board could meet specific conditions related to the effective regulation of the interstate distribution of compounded medications. The conditions the Board would need to complete include statutory authority and ensuring sufficient resources for implementation are secured. In arriving at its conclusion, the Committee also considered significant public comment the Board received encouraging it to sign the MOU, including what appeared to be a national petition with thousands of signatures—primarily from members of the public, practitioners, and patients throughout a wide range of states.

On October 7, 2021, Governor Newsom signed AB 1533 (Committee on Business and Professions) (Chapter 629, Statutes of 2021), which, in addition to extending the Board's sunset date, amends section 4110(a) of and adds section 4126.10 to the Business and Professions Code at the Board's request to facilitate the Board's implementation of the MOU (see LEGISLATION). The bill amends Business and Professions Code section 4110(a), adding that a licensee who undergoes the annual requirement to renew his or her license to conduct a pharmacy in California "[s]hall include the matters identified by the board in the renewal application, included but not limited to, notification to the board regarding compounding practices, including compounded prescriptions distributed outside of the State." In addition, the bill states that a pharmacy located in California may only distribute compounded drug preparations for interstate distribution if the pharmacy reports all required data into the Information Sharing Network established by the NABP in conjunction with the FDA to implement the MOU and reports adverse drug experiences and product quality issues for all compounded products to the Board within 12 hours. The addition of

section 4126.9 to the Business and Professions Code also establishes that "[a]ll information reported by the board to the FDA directly or through the Information Sharing Network established in conjunction with the FDA [would be] deemed confidential information as specified in California Government Code section 6254(f) if it relates to information regarding a complaint received or the investigation of any such complaint."

On August 9, 2021, the FDA announced that it extended the time for states to decide whether to sign the MOU from October 27, 2021, to October 27, 2022. States may sign the MOU at any time, including after the extension deadline of October 27, 2022. However, at the end of the extended deadline, the FDA "intends to begin enforcing the statutory five percent limit on distribution of compounded human drug products out of the State in which they are compounded in States that do not sign the final standard MOU as of August 9, 2021."

Board Publishes Notice on Pharmacists Initiating and Administering Vaccines

On October 8, 2021, the Board published notice of its intent to amend section 1746.4 of Title 16, Division 17 of the CCR to permanently waive a requirement of pharmacists to notify each patient's primary care physician of vaccine administration if specified conditions are met.

According to the initial statement of reasons, the proposed regulations are the Board's efforts to permanently amend section 1746.4 of the CCR, which outlines the vaccine reporting responsibilities of various healthcare providers, including pharmacists. The initial statement of reasons further states that the proposal will permanently remove the 14-day mandatory reporting requirement to each patient's primary care provider, as the notification is duplicative and creates additional workload for pharmacists when the vaccination information is available through the immunization registry of the California Department of Public Health. Under the proposed

regulation, pharmacists must continue reporting vaccine administration in the immunization registry of the California Department of Public Health. The initial statement of reasons also clarifies that the reporting requirement to notify a pregnant patient's prenatal care provider will remain due to the time-sensitive nature of medical treatment for pregnant patients.

The proposed text states that at the request of a patient, a pharmacist shall notify each patient's primary care physician and that a pharmacist must complete one hour of continuing education focused on immunizations and vaccines from an approved provider once every two years. At its July 28–29, 2021, teleconference meeting [Agenda Item 8A], the Board opened discussion for this regulatory amendment to section 1746.6 and voted to extend the waivers and to initiate this rulemaking action regarding administering vaccines.

The public comment period is open from October 8, 2021, to November 22, 2021.

Board Proposes Regulations to Add Self-Assessment Requirements for Third-Party Logistics Providers and Responsible Managers

On September 17, 2021, the Board noticed its proposal to amend section 1784, Title 16 of the CCR, to provide clarity with respect to whom the section applies, as third-party logistics providers (3PLs) perform similar functions as wholesalers and are required to comply with the same laws and regulations, so it is appropriate to include their reference in the form. The proposed amendments also identify the individual who must complete the self-assessment based on the license type: so, a 3PL can only employ a responsible manager, and a wholesaler can only employ a designated representative-in-charge (DRIC).

The proposed text of the regulation, approved by the Board on November 9, 2017, would require a wholesaler licensed under the Business and Professions Code to complete a self-

assessment once every two years or within 30 days of: (1) a new wholesaler license being issued; or (2) a change in the designated representative-in-charge (DRIC); or (3) a change in licensed location of a wholesaler to a new address.

In its initial statement of reasons, the Board stated that these changes will benefit the health and welfare of residents and will benefit employee safety. The Board also said that the regulation will ensure regulatory consistency between wholesalers and third-party logistics providers (3PLs). The self-assessment will identify any areas where wholesalers or 3PLs are out of compliance.

The initial statement of reasons also stated that the Board adopted a self-assessment process for a wholesaler to use for maintaining compliance with specific state and federal laws. The proposed regulation includes a requirement to complete the self-assessment, the frequency of completion of the assessment, and other general requirements. The proposal further updates the form to include laws and regulations adopted since 2014 and excludes laws and regulations that have been superseded or repealed since 2014.

In September of 2014, the Governor signed AB 2605 (Bonta) (Chapter 507, Statutes of 2014), which added the ability for a 3PL to gain a license from BOP to provide or coordinate the warehousing of, or other logistics services for, a prescription drug or device on behalf of another person. The proposal at hand will address the new license category by requiring a self-assessment for 3PLs.

The 45-day comment period on the proposed rulemaking action expired on November 1, 2021. At this writing, the Board has not taken further action.

Board Updates Ownership, Management, and Control of Pharmacy License Regulations

On July 23, 2021, the Board issued notice of its proposed rulemaking action to amend section 1709, Title 16 of the CCR. This proposed rulemaking action follows SB 1193 (Hill) (Chapter 484, Statutes of 2016), which amended, among other things, Business and Professions Code section 4035 to add "trust" to the definition of "person," and Business and Professions Code section 4201 to add requirements for the disclosure of information of any person with management or control over the license to the Board.

In the initial statement of reasons, the Board explained the amendments were meant to clarify and make specific the standards of pharmacy and ownership disclosure, as they relate to pharmacy ownership, management, and control, including through trusts. The Board noted that protection of the public is its highest priority in exercising its licensing, regulatory, and disciplinary functions. Thus, the proposed changes ensure the Board is able to continue to track the beneficial ownership of a pharmacy or other regulated business entity, even when it is owned by a trust, and ensure that previously disciplined owners or other prohibited forms of ownership, for instance, prescriber-owned, are not occurring.

On October 26, 2016, the Board approved (p. 59) the proposed text for rulemaking. The proposed text of the regulation indicates that specifically, this proposal would change the term "permit" to "license," would specify that a license shall not be transferred from one owner to another without written notification to the Board, and would specify the reporting time frame as required by Business and Professions Code section 4201. Additionally, this proposed rulemaking would identify the Board's ability to issue a license to an entity controlled by a trust and specify the requirements for disclosure and notice to the Board, including identifying who must be

identified (by role), when disclosure or notice is required, what information is required, and how notification is to be provided.

The 45-day public comment period was held from July 23, 2021, to September 7, 2021. As of this writing, the comments are pending review by the Board.

MAJOR PUBLICATIONS

The following reports or studies have been conducted by or about BOP during this reporting period:

- ***The Script***, California State Board of Pharmacy, September 2021 (describes the Board's major projects in a bi-yearly newsletter; provides answers to frequently asked questions to help licensees comply with new e-prescribing laws (see LEGISLATION); advises licensees on how to monitor auto-refill programs to avoid medication errors; warns licensees that driving under the influence (DUI) is a criminal offense that can result in a denial, suspension, or revocation of a license issued by the Board; and lists top citations and inspection violations of the fiscal year 2020/2021).

RULEMAKING

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

- **Automated Drug Delivery Systems**: On May 19, 2021, OAL approved BOP's proposed rulemaking to amend sections 1711 and 1713, Title 16 of the CCR, and add section 1715.1, Title 16 of the CCR to increase and update the Board's oversight of Automated Drug Delivery Systems (ADDS). Specifically, the regulations require that records involving incidents where a complaint, error, or omission has occurred related to the use of ADDS, developed as part

of the quality assurance review Business and Professions Code section 4427.6(i), be submitted to the Board. *[See 24:1 CRLR 88–90]* Also, the Board's addition of section 1715.1, Title 16 of the CCR, identifies the specific requirements for the completion of the self-assessment concerning the use of ADDS, as required by Business and Professions Code section 4427.7, which, according to the Final Statement of Reasons will aid licensees in assessing whether they are in compliance with federal and state law regulations. According to the Final Statement of Reasons, receipt and review of quality assurance reports will allow the Board to appropriately monitor for and identify patient safety concerns related to the use of ADDS. The Board originally published notice on the proposed changes on July 3, 2020. *[See 26:1 CRLR 56]* The new regulations went into effect on July 1, 2021.

- **Off-site Storage**: On May 18, 2021, OAL approved BOP's proposed amendment to section 1707, Title 16 of the CCR, to permit the Board discretion to grant a waiver of the requirement that pharmacies maintain their records on the premises. These regulations allow the Board to exercise case-by-case discretion to grant a waiver where a licensed pharmacy is found in violation of section 4081 of the Business and Professions Code but lacks sufficient space within the licensed premises to store these records and in cases where it is in the public interest for the Board to grant a waiver. According to the Final Statement of Reasons, space limitations within the pharmacy can put the safety of pharmacy staff at risk if the pharmacy does not have adequate space on the premises to store records. The Board initially commenced the rulemaking process on the proposed changes on February 7, 2020. *[See 25:2 CRLR 46]* The new regulations went into effect on July 1, 2021.

- **Automatic Refill Programs:** At its May 27 meeting [Agenda Item IV], the Board voted to release second modified text with respect to its proposed addition of section 1717.5, Title

16 of the CCR, to establish requirements for automatic drug refill programs for a 15 day comment period. The Board originally published notice of its intent to add this section on July 10, 2020. *[26:1 CRLR 57]* The second modified text contains specific changes requested by OAL as set forth in the staff memo. Specifically, it reflects OAL's request that the Board define "each prescription" in subsection (a)(2), memorialize its policy regarding the need for annual consent, and ensure that the proposal consistently uses the terms "prescription" and "prescription medication" throughout the text. The public comment period expired on June 12, 2021. OAL approved the proposed rulemaking on June 22, 2021, and it became effective on July 1, 2021.

- **Pharmacy Technicians:** On October 22, 2021, the Board published notice of its proposal to amend sections 1793.5 and 1793.6, and adopt section 1793.65 Title 16 of the CCR to update the pharmacy technician application form, update the requirements for schools providing training courses for pharmacy technicians, and add pharmacy technician certification programs accredited by the National Commission for Certifying Agencies programs, as set forth in the proposed language. According to the Initial Statement of Reasons, the proposal ensures the pharmacy technician application is requesting pertinent and accurate information. The Board states that the proposal will lead to more qualified pharmacy technicians by requiring more stringent training courses for pharmacy technicians to become licensed. Also, the Board says the proposal will lead to an increase in the number of pharmacy technicians available to the industry by providing pharmacy technician applicants with additional certification programs pursuant to SB 952 (Anderson) (Chapter 150, Statutes of 2016), which expanded the number of pharmacy technician certification programs that the Board may recognize for licensing. The public comment period expires on December 6, 2021.

- **Address Change Notification**: On September 3, 2021, the Board published notice of its proposal to amend section 1704, Title 16 of the CCR to require that each applicant for a license from the Board and person holding a certificate, license, permit, registration, or exemption to practice, who has an electronic mail (email) address, provide the Board with the email address and maintain a current email address if any. Additionally, the proposal would require each applicant for a license to inform the Board of any change in their email address within 30 days of the change. According to the Initial Statement of Reasons, "[c]urrently, the board does not require applicants to provide an email address, which can result in a delay in communication to applicants as the board must send communication to applicants via United States Postal Service mail." The public comment period expired on October 18, 2021. According to the Board's website, at this writing, the proposal is undergoing review by DCA.

- **Policy Granting President Discretion to Waive Provisions of Pharmacy Law**: On September 23, 2021, the Board held a meeting [Agenda Item IV(b)], where the Board discussed waiving provisions of Pharmacy Law under Business and Professions Code section 4062 to increase authority to approve or extend waivers delegated to the Board president. Beginning in early March 2020, the Board has relied heavily on its authority to issue waivers to provisions of Pharmacy Law and its regulations consistent with the authority of Business and Professions Code section 4062 as part of its response to the COVID-19 pandemic. *[See 26:2 CRLR 66–67]* The Board also discussed information in the meeting materials, which included a proposal that would delegate the authority to approve or extend waivers through June 31, 2022, or until 90 days following the declared disaster, whichever is sooner.

- **HIV Preexposure and Postexposure Prophylaxis Furnishing**: On June 8, 2021, OAL approved BOP's proposed amendment to section 1747 of Article 5 of Division 17 of Title

16, California Code Regulations for Independent HIV Preexposure and Postexposure Prophylaxis Furnishing. Under this regulation, pharmacies can furnish Preexposure Prophylaxis (PrEP) and Postexposure Prophylaxis (PEP) if certain criteria are met. According to the initial statement of reasons, the regulation will increase access to this time-sensitive HIV prevention medicine, saving lives. The regulation was effective on June 8, 2021.

- **Notice of Temporary Closure:** On October 29, 2021, the Board published notice of its intent to adopt section 1708.1, Title 16 of the CCR to require pharmacies to notify the Board of a temporary closure of a licensed facility as soon as any closure exceeds three consecutive calendar days as set forth in the proposed text. According to the initial statement of reasons, existing pharmacy law does not require licensees to notify the Board of any temporary closure of a licensed facility, for example, in the wake of declared disasters or civil unrest. However, because these closures can interrupt patient care by limiting access to prescription medication in that geographic area, the Board proposes to adopt this regulation so that it will be notified of closures, and it will make this information available to the public. The public comment period expires on December 13, 2021.

- **Pharmacy/Hospital Self-Assessment Forms:** On November 12, 2021, the Board published notice of a proposed regulation to amend section 1715 of article 2 of division 17 of Title 16 of the CCR to further specify the requirements of pharmacy self-assessment forms. According to the initial statement of reasons, the current self-assessment forms do not allow for the efficient integration of new state and federal laws and regulations. The proposed regulation would move the requirements from the self-assessment forms to the Board's regulation. The regulation is currently in the open comment period until December 27, 2021.

- **Administering Vaccines**: October 8, 2021, the Board published notice of its intent

to amend section 1746.4, Title 16 of the CCR to permanently eliminate the current mandatory 14-day reporting requirement that pharmacists notify each patient's primary care physician of vaccine administration if specified conditions are met. The public comment period on the proposed amendment expires on November 22, 2021 (see HIGHLIGHTS).

- **Trust Ownership:** On July 23, 2021, the Board issued notice of its proposed rulemaking action to amend section 1709, Title 16 of the CCR, to add "trust" to the definition of a person (see HIGHLIGHTS).

- **Third-Party Logistic Providers:** On September 17, 2021, the Board noticed its proposal to amend section 1784, Title 16 of the CCR, to provide clarity with respect to whom the section applies as third-party logistics providers (3PLs) perform similar functions as wholesalers (see HIGHLIGHTS).

LEGISLATION

- **AB 1533 (Committee on Business and Professions)**, as amended September 3, 2021, designated as the California Board of Pharmacy's sunset bill, amends, repeals, and adds various sections to the Business and Professions Code. The bill extends the Board's sunset date to January 1, 2026, and imposes a series of reforms on the Board, including new licensing and compounded drug preparation requirements. Governor Newsom signed AB 1533 on October 7, 2021 (Chapter 629, Statutes of 2021) (see HIGHLIGHTS).

- **SB 362 (Newman)**, as amended July 7, 2021, adds sections 4113.7 and 4317 to the Business and Professions Code to prohibit chain community pharmacies from establishing a quota to evaluate the performance of a pharmacist or pharmacy technician. According to the author, documents and data obtained by investigative reporters, public prosecutors, and researchers have

established that large, publicly-traded pharmacy chains impose performance quotas on licensed pharmacists and pharmacy technicians that place at risk the health and well-being of patients. Governor Newsom signed SB 362 on September 27, 2021 (Chapter 334, Statutes of 2021).

- **AB 1064 (Fong)**, as amended August 16, 2021, amends section 4052.8 of the Business and Professions Code to authorize a pharmacist to independently initiate and administer any vaccine that has been approved or authorized by the FDA and that has received a federal Advisory Committee on Immunization Practices individual vaccine recommendation published by the federal Centers for Disease Control (CDC) for persons three years and older. According to the author, the COVID-19 pandemic has put a significant strain on our healthcare system. The author states that AB 1064 will improve California's healthcare response by increasing access to vaccinations across the state. Governor Newsom signed AB 1064 on October 8, 2021 (Chapter 655, Statutes of 2021).

- **SB 409 (Caballero)**, as amended September 3, 2021, is a Board sponsored bill that amends sections 1206.5, 1209, and 4052.4 of and adds section 4119.10 to the Business and Professions Code to authorize pharmacists and pharmacies to perform, under specified requirements and conditions, any aspect of a clinical laboratory test or examination that is classified as waived under the Clinical Laboratory Improvement Amendments and approved or authorized by the FDA if the test is used to detect or screen for certain illnesses, including COVID. The bill also authorizes pharmacists and pharmacies to perform, under specified conditions, any test approved by regulation by BOP, in conjunction with the Medical Board of California and Laboratory Field Services in the State Department of Public Health. The Board wrote in support, "[t]he CDC has acknowledged that the flu and COVID-19 are both respiratory illnesses that are caused by different viruses that may be difficult to differentiate based on symptoms alone without

testing to confirm a diagnosis." Providing authority to perform both tests is essential." Governor Newsom signed SB 409 on October 6, 2021 (Chapter 604, Statutes of 2021).

- **SB 311 (Hueso)**, as amended September 1, 2021, known as the Compassionate Access to Medical Cannabis Act, adds Chapter 4.9 (commencing with section 1649) to the Health and Safety Code. As it applies to the Board, the bill requires specified types of health care facilities to allow a terminally ill patient's use of medicinal cannabis within the health care facility, subject to certain restrictions, such as requiring a patient to provide the health care facility with a copy of their medical marijuana card or written documentation that a physician recommends the use of medicinal cannabis. The bill specifies that health care facilities permitting patient use of medicinal cannabis must comply with drug and medication requirements applicable to Schedule II, III, and IV drugs. According to the author, "California patients are currently unable to access medical cannabis while in an inpatient setting—even if they possess a valid physician's recommendation. As a result, individuals have been subjugated to unnecessary trials of pain and suffering." On October 20, 2021, the Board's Enforcement and Compounding Committee held a meeting [Agenda Item IV(a)] where the Committee expressed concern that section 1649.3 of the bill appears to create some conflict with the bill's requirements that medicinal cannabis complies with provisions related to Schedule II-IV medications. According to the Committee, this requirement raises questions about the applicability of provisions of the Board's regulations, including storage, inventory control, acquisition, and the role of the pharmacy in these facilities. The Committee stated that it will work to resolve the conflicts with other regulators and stakeholders but hopes that clarity can be achieved by the statute. Governor Newsom signed SB 311 on September 28, 2021 (Chapter 384, Statutes of 2021).

The following bill, reported in Volume 26, No. 2 (Spring 2021), failed to be enacted during the 2020–2021 legislative session: AB 1328 (Irwin), regarding the revision and expansion of the types of people (including licensed pharmacists) that may order, perform and interpret CLIA waived tests.

LITIGATION

- ***Bradley v. CVS Pharmacy, Inc.*, 64 Cal. App. 5th 902 (2021).** On May 28, 2021, the Second District Court of Appeals affirmed a trial court decision that, under the doctrine of primary jurisdiction, a physician seeking a preliminary injunction requiring an in-state pharmacy to fill prescriptions must seek relief from BOP before seeking relief from the courts. The appellate court observed that the plaintiff physician (Bradley) specializes in pain management and that CVS cited concerns about his prescribing patterns when it stopped filling his prescriptions in June 2020. The appellate court agreed with the trial court's reasoning that the Board has more experience in evaluating a pharmaceutical licensee's responsibilities in the context of a national opioid problem. This action remains stayed to permit Bradley to pursue a complaint with the Board, but if Bradley chooses not to file such a complaint, the action will be dismissed.

- ***Carl Washington, et al. v. CVS Pharmacy Inc.*, Case No. 15-cv-03504 (N.D. Cal.)**: On June 24, 2021, a California federal jury rendered a verdict in favor of defendant CVS Pharmacy (CVS) on claims by multiple classes of insured drug buyers that the CVS Pharmacy chain significantly overcharged them for generic drugs, in violation of consumer protection statutes of California and five other states. Counsel for the class members argued that CVS made substantial profits from November 2008 through July 2015 and cost class members more than $100 million by failing to report to pharmacy benefit managers discounts given through a nationwide

discount program known as Health Savings Pass. Class counsel claimed this led to excessive copays for millions of class members. CVS counter-argued that its pricing practices aligned with industry standards, and that about 95 percent of the time, insured customers who came into CVS, including the class plaintiffs, paid less in copays than the Health Savings Price. The named plaintiffs in the case filed a notice of appeal to the Ninth Circuit on July 9, 2021, Case No. 21-16162.

At this writing, the appellate briefing schedule has been set, and the case is scheduled to be fully briefed by March 18, 2022.

- ***Stafford v. Rite Aid Corp.*, 998 F.3d 862 (9th Cir. 2021)**. On May 21, 2021, the court affirmed the district court's order denying Rite Aid Corporation's motion to compel arbitration. The putative class action alleges that Rite Aid fraudulently inflated the reported prices of prescription drugs to insurance companies, which resulted in class members paying Rite Aid a higher co-payment for their drugs. The Ninth Circuit remanded to the district court for further proceedings.

- ***In re: Purdue Pharma L.P., et al.*, Case No. 19-23649 (RDD) (Bankr. S.D.N.Y. Sep. 17, 2021)**. On September 17, 2021, the United States Bankruptcy Court (Judge Robert D. Drain) overruled insurers' Chapter 11 claim confirmation objection, finding that the debtor party's request for finding the bankruptcy plan did not violate insurance policies' consent provisions was justified. However, the court stated it will enter the plan upon amendment (including a provision that those who would prosecute a claim against released parties based on its being a "non-opioid excluded claim" must obtain leave from the Bankruptcy Court to do so). This case is ongoing. *[26:2 CRLR 73]*