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 interest sought to be promoted, the protection of the public shall be paramount.*
>
> — Business and Professions Code § 4001.1

Pursuant to Business and Professions Code section 4000 *et seq*., the Board of Pharmacy (BOP) grants licenses and permits to 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. BOP regulates all sales of dangerous drugs, controlled substances, and poisons. BOP is authorized to adopt regulations, which are codified in Division 17, Title 16 of the California Code of Regulations (CCR).

BOP is a consumer protection agency located within the Department of Consumer Affairs (DCA). BOP consists of 13 members, six of whom are public members. The Governor appoints four public members and the Senate Committee on Rules and the Speaker of the Assembly each appoint one. 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. Additionally, BOP 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 March 2017, Assembly Speaker Anthony Rendon appointed Amjad Mahmood Khan as a public member to the Board. Khan, an attorney, is a partner at Brown, Neri, Smith & Khan LLP in Los Angeles, where he focuses on complex commercial litigation. He is also an adjunct professor of law at UCLA and an elected term member of the Council on Foreign Relations.

On July 25, 2017, Governor Brown reappointed Lavanza "Kercheryl" Butler, PharmD, to the Board, where she has served since 2013. Butler has been a pharmacist, vice president, and union representative at United Food and Commercial Workers International Union, Local 770 since 2002. She was a head pharmacist for Rite Aid Pharmacy from 1980 to 2002. Governor Brown also reappointed Deborah Veale of Palos Verdes Estates to the Board, where she has served since 2010. Veale has been director of payer relations at CVS Pharmacy Inc. since 2006. Veale is a member of the California Pharmacists Association (CPHA) and the California Retailers Association.

MAJOR PROJECTS

Inventory Reconciliation Report of Controlled Substances

At its May 3, 2017 meeting, BOP approved a second set of modifications to the text of new section 1715.65, Title 16 of the CCR, which imposes on pharmacies specific

periodic inventory and inventory reconciliation functions to detect and prevent the loss of controlled substances. BOP initially published notice of its intent to adopt section 1715.65 in September 2016 as part of its efforts to combat drug loss and diversion from within pharmacies, and prescription drug abuse within California. The new regulation aims to ensure that pharmacies more closely monitor, and periodically count, controlled substances as a means to reduce drug losses, and to identify any losses sooner.

The second modified text arose out of recommendations to the Board from its Enforcement and Compounding Committee after discussion and consideration of public comment at the Committee's April 18, 2017 meeting. At this writing, the proposed regulation is undergoing review by DCA.

Fee Schedule

At its July 25, 2017 meeting, BOP approved proposed amendments to section 1749, Title 16 of the CCR, to impose a new fee schedule on BOP licensees, and directed staff to complete the rulemaking file. The proposed amendments follow a 2015 fee analysis conducted by DCA to determine the sustainability of BOP's fund and to ensure that the Board is collecting sufficient revenue to reimburse the Board for the cost of regulating those within its jurisdiction. The results of this analysis were included in BOP's 2016 sunset report, and the legislature authorized the Board to implement a new fee schedule in BOP's sunset bill, SB 1039 (Hill) (Chapter 799, Statutes of 2016), effective July 1, 2017. At this writing, the proposed amendments are undergoing DCA review.

Other Board Rulemaking

The following is a brief update on other rulemaking proceedings recently conducted by the Board of Pharmacy:

♦ ***License Renewal Requirements***. On September 19, 2017, the Office of Administrative Law (OAL) approved BOP's amendments to section 1702 and its adoption of new sections 1702.1, 1702.2, and 1702.5, Title 16 of the CCR. The amendments to section 1702 require pharmacist applicants, as a condition of license renewal, to disclose on the renewal form any disciplinary action against any license issued to the applicant by a government agency. The new sections extend section 1702's existing fingerprinting requirement and the new disciplinary action disclosure requirement to applicants for renewal of a pharmacy technician's license (section 1702.1) and a designated representative's license (section 1702.2). Finally, new section 1702.5 requires applicants seeking renewal of a license as a nonresident wholesaler or as a nonresident pharmacy to report to the Board any disciplinary action taken by any government agency since renewal of the license. These regulatory changes will become effective on January 1, 2018.

♦ ***Travel Medications***. On June 8, 2107, OAL approved the Board's adoption of new section 1746.5, Title 16 of the CCR, which sets forth the standards and procedures that pharmacists must follow in order to furnish "travel medications" (defined as medications that are recognized as self-treatable by the federal Centers for Disease Control) to individuals traveling outside the United States. The regulation establishes both training and continuing education requirements for a pharmacist to dispense travel medications. The regulation also establishes standards a pharmacist must follow to evaluate a patient and a patient's travel plans in a pre-travel consultation; requires notification of the patient's

primary care provider or requires the pharmacist to provide a written record of drugs and/or devices furnished to the patient; and requires that the pharmacy or facility maintain documents concerning the patient's travel medication record. The new regulation became effective on June 8, 2017.

♦ ***Prescription Drug Take-Back Services***. On June 6, 2017, OAL approved the Board's adoption of new sections 1776–1776.6, Title 17 of the CCR. The Board's action adds new Article 9.1 to Division 17 of the CCR to set forth specific and detailed requirements for authorized pharmacies that establish prescription drug take-back services to combat prescription drug abuse in California. New Article 9.1 became effective on June 6, 2017.

♦ ***Delegation of Functions***. On May 30, 2017, OAL approved the Board's amendments to section 1703, Title 16 of the CCR, in which the Board has delegated certain of its functions to its executive officer (EO). In addition to functions already delegated to the EO in section 1703, the amendments delegate authority to make so-called "section 100" regulatory changes (changes without regulatory effect) and to approve waivers from the requirements for patient-centered labels for prescription drug containers pursuant to Business and Professions Code section 4076.5(e) to the EO. These changes became effective on July 1, 2017.

Wholesalers to Report Suspicious Drug Sales to the Board

At its July 25, 2017 meeting, BOP voted—at the recommendation of its Enforcement and Compounding Committee—to direct staff to pursue legislation to require wholesalers to notify the Board of suspicious orders of controlled substances.

This issue arose after two major wholesale distributors (Cardinal Health in December 2016 and McKesson Corporation in January 2017) reached settlements with the U.S. Department of Justice in which they agreed to pay millions of dollars in civil penalties for alleged failure to notify the U.S. Drug Enforcement Administration (DEA) of suspicious orders of controlled substances in violation of the federal Controlled Substances Act.

Later in 2017, the new reporting requirement was added to AB 401 (Aguiar-Curry), which enacts new section 4169.1 of the Business and Professions Code (see LEGISLATION).

LEGISLATION

SB 800 (Hill), as amended September 8, 2017, is an omnibus bill that makes the following changes to the Business and Professions Code as it pertains to BOP: (1) it amends section 4013 to add "designated representative" to the list of those required to join the BOP's email notification list within 60 days of obtaining a license or at the time of license renewal; (2) it amends section 4316 to clarify that the Board's executive officer is authorized to issue a cease and desist order for operating any facility or practicing any activity that requires licensure without obtaining that licensure; and (3) it repeals section 4001.5, which required the Joint Committee on Boards, Commissions, and Consumer Protection to review the state's shortage of pharmacists and make recommendations on a course of action to alleviate the shortage, including a review of the current California pharmacist licensure examination. Governor Brown signed SB 800 on October 7, 2017 (Chapter 573, Statutes of 2017).

SB 547 (Hill), as amended September 11, 2017, as it pertains to BOP, amends section 4008 of the Business and Professions Code to authorize BOP to employ legal counsel. Governor Brown signed SB 547 on October 2, 2017 (Chapter 429, Statutes of 2017).

SB 752 (Stone), as amended September 7, 2017 is a BOP-sponsored bill that adds section 4053.2 to the Business and Professions Code to create a new license category for a "designated representative-reverse distributor" (DRRD), which is defined in new section 4022.6 as an individual who is responsible for supervision over a licensed wholesaler that only acts as a reverse distributor. A "reverse distributor" is already defined (section 4040.5) as one who acts as an agent for pharmacies, drug wholesalers, third-party logistics (3PL) providers, manufacturers, and other entities by receiving, inventorying, warehousing, and managing the disposition of outdated or nonsaleable dangerous drugs and dangerous devices. Under the bill, a DRRD licensee provides "sufficient and qualified supervising over a licensed wholesaler that acts as a reverse distributor." Applicants for a DRRD license must meet specified requirements and complete a training program approved by the Board. The bill also amends section 4400 to set application and renewal fees for DRRD licensees.

SB 752 also amends Business and Professions Code section 4200.4 to provide that an applicant who fails either the North American Pharmacist Licensure Examination or the California Practice Standards and Jurisprudence Examination for Pharmacists may not retake the exam for at least 45 days; and to authorize BOP to work with OPES to adopt a regulation establishing a different waiting period to retake the exam. Governor Brown signed SB 752 on October 8, 2017 (Chapter 598, Statutes of 2017).

SB 351 (Roth), as amended September 8, 2017, is a BOP-sponsored bill that adds section 4127.15 to the Business and Professions Code to establish a new license category for a hospital satellite compounding pharmacy (HSCP), defined as "an area licensed by the BOP to perform sterile compounding that is separately licensed by the BOP and is located outside of a general acute care hospital in another physical plant." The bill limits an HSCP to compounding sterile drug products for administration only to registered hospital patients who are on the premises of the same physical plant in which the HSCP is located, and the services provided must be directly related to the services or treatment plan administered in the physical plant; further, the bill allows a general acute care hospital without a consolidated license to obtain multiple site licenses from BOP. According to BOP's statement in support of the bill,

> in order to satisfy patients' needs, hospitals must be granted flexibility to expand patient care services from inpatient acute care setting to an outpatient services oriented setting. Providing hospitals with the option to obtain additional hospital pharmacy licenses and/or satellite compounding pharmacies strikes the ideal balance between hospital flexibility and ensuring patient health and safety.

Governor Brown signed SB 351 on October 9, 2017 (Chapter 623, Statutes of 2017).

SB 443 (Hernandez), as amended September 9, 2017, is a BOP-sponsored bill that amends section 4119 of, and adds sections 4034.5, 4119.01, and 4202.5 to, the Business and Professions Code to allow a pharmacy or wholesaler that is considered to be an emergency medical services (EMS) provider agency to restock drugs to an EMS automated drug delivery system located within an EMS provider agency. These automated delivery systems are mechanical systems that are typically housed at health facilities without onsite pharmacies, are controlled remotely by a pharmacist, and store and dispense prepackaged drugs. This bill authorizes the use of these automatic delivery systems on emergency

transport vehicles and rescue trucks as well as stationary health facilities, and sets forth the conditions under which this restocking can take place. Governor Brown signed SB 443 on October 10, 2017 (Chapter 647, Statutes of 2017).

AB 602 (Bonta), as amended June 13, 2017, amends and adds various provisions of the Pharmacy Law to define the term "nonprescription diabetes test device" (NDTD) ("a glucose meter or test strip for use in the treatment of prediabetic or diabetic individuals that may be sold without a prescription and that is labeled for use by the consumer in accordance with the requirements of the laws and rules of this state and the federal government") and to prohibit BOP licensees from purchasing an NDTD from an unauthorized source. The bill also authorizes BOP inspectors to embargo, as specified, any NDTD that is not purchased from an authorized source and requires pharmacies to maintain appropriate records related to the acquisition and sale of these devices. According to the bill's sponsor, the California Life Sciences Association, the bill aims to curtail the resale and counterfeiting of diabetes test strips to turn a profit via manufacturer and Medicare reimbursements. After the author accepted the BOP's suggested amendments to the bill, the Board voted to support the bill at its July meeting. Governor Brown signed AB 602 on July 31, 2017 (Chapter 139, Statutes of 2017).

AB 401 (Aguiar-Curry), as amended September 7, 2017, adds new Article 8 (commencing with section 4130) to the Pharmacy Law, to establish a regulatory framework for telepharmacy, which involves the delivery of pharmaceutical care via telecommunications to patients in remote locations where they may not have direct contact with a pharmacist. Telepharmacy services may include drug therapy monitoring, patient counseling, authorization for prescription drugs, and monitoring of formulary compliance

utilizing teleconferencing or videoconferencing; telepharmacy may also include remote dispensing of medications by automated packaging and labeling systems. AB 401 authorizes the Board to issue remote dispensing pharmacy licenses for facilities that connect a licensed pharmacist to patients using a telepharmacy system. According to an Assembly analysis, approximately 115 underserved communities, defined as having no pharmacist within a 10-mile radius, across 47 different counties are eligible to receive services via AB 401. The remote dispensing pharmacy must be staffed by a registered pharmacy technician, who meets additional training criteria, and must be supervised virtually by a licensed pharmacist at a "supervising pharmacy" located within 150 miles of the remote dispensing pharmacy. AB 401 also establishes minimum standards for the remote dispensing location in order to ensure safety and quality control. These include standards for the telepharmacy technology, security requirements, and processes for ordering, stocking, and recording different types of drugs.

AB 401 also adds new section 4169.1 to the Business and Professions Code, which requires wholesalers, upon discovery, to notify the Board in writing of any suspicious orders of controlled substances placed by a California-licensed pharmacy or wholesaler by providing the Board a copy of the information that the wholesaler provides to the DEA (see MAJOR PROJECTS). Suspicious orders include, but are not limited to, orders of unusual size, orders deviating substantially from a normal pattern, and orders of unusual frequency.

Finally, AB 401 adds new section 4180.5 to the Business and Professions Code, which—until January 1, 2021—authorizes the Board to issue specified licenses to two independently owned clinics that share a clinic office space; make each clinic jointly and severally responsible for drug losses; require the applicants to provide the Board with a

copy of the co-location agreement and a one-time application fee of $750 for the licenses; and require a new application and specified fees for any change in ownership in either clinic. Governor Brown signed AB 401 on October 7, 2017 (Chapter 548, Statutes of 2017).

SB 510 (Stone), as introduced on February 16, 2017, is a BOP-sponsored bill that repeals Business and Professions Code section 4127.7, which requires compounding pharmacies to follow specific environmental requirements when compounding sterile products from one or more nonsterile ingredients. According to BOP,

> [a]s the compounding segment of pharmacy practice has evolved, so have the legal requirements, at both the state and federal levels. This ensures appropriate protections are in place for the patient as well as the staff who perform the compounding. Repeal of Business and Professions Code Section 4127.7 as proposed in SB 510 removes a significant conflict and is important in that it provides clarity to the board's regulated public.

Governor Brown signed SB 510 on October 10, 2017 (Chapter 649, Statutes of 2017).

AB 1048 (Arambula), as amended September 8, 2017, as it relates to BOP, adds section 4052.10 to the Business and Professions Code to authorize a pharmacist to dispense opioids as partial fills if requested by the patient or prescribing physician. The bill also requires the pharmacy to retain the original prescription, with a notation of how much of the prescription has been filled, the date and amount of each partial fill, and the initials of the pharmacist dispensing each partial fill, until the prescription has been fully dispensed. Governor Brown signed AB 1048 on October 9, 2017 (Chapter 615, Statutes of 2017).

SB 716 (Hernandez), as amended April 26, 2017, would amend section 4001 of the Business and Professions Code to increase the number of Board members to 15 by adding a pharmacy technician and one additional public member to the Board, both to be appointed by the Governor. During 2017, the bill, sponsored by the California Society of Health-System Pharmacists, was heavily opposed by the CPHA, the California Association

of Retailers, and the National Association of Chain Drug Stores once it was amended to add an additional public member to the Board. BOP held lengthy discussions about the bill at both its May 3, 2017 and July 25, 2017 meetings, and finally—after numerous pharmacist members of the Board announced their strong preference for a pharmacist member majority on BOP—decided to oppose the bill unless it is amended to remove the additional public member. A hearing on this bill before the Assembly Appropriations Committee, scheduled for August 30, 2017, was cancelled at the request of the author. *[A. Appr]*

RECENT MEETINGS

At its May 3, 2017 meeting, BOP reelected Amy Gutierrez as Board president, and elected Victor Law as vice president and Allen Schaad as treasurer. All three officers are pharmacists.

At the Board's May and July 2017 meetings, Executive Officer Virginia Herold and Enforcement Chief Tom Lenox reported on their work—in conjunction with representatives from DEA and UC San Diego—in providing daylong training sessions on prescription drug abuse, corresponding responsibility, and preventing drug losses from a pharmacy. In July, Herold and Lenox announced that three additional sessions on opioid abuse have been scheduled.