BOARD OF PHARMACY

Interim 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 interest sought to be promoted, the protection of the public shall be paramount.*
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> — 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, 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. 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, 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. 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.

At this writing, the Board is still actively searching for a new Executive Officer to replace Virginia Herold. Since Ms. Herold's retirement on December 28, 2018, Anne Sodergren has been acting as the Interim Executive Officer.

MAJOR PROJECTS

OAL Approves Compounded Drug Preparation Regulations

On January 30, 2019, OAL approved the Board's proposed rulemaking to amend sections 1735.1, 1735.2, 1735.6, 1751.1, and 1751.4, of Title 16 of the CCR to clarify and make specific the standards pharmacists and pharmacies use for compounding drug preparations. Specifically, the regulations change the requirements pharmacists use to establish beyond use dates (BUD) for compounding drug preparations. They also clarify the definitions of compounding terms, the standards for equipment used in compounding, and the standards for facilities performing sterile compounding. The Board originally published notice of the proposed changes on June 26, 2018. *[24:1 CRLR 75–77]* The new regulations became effective on April 1, 2019.

Amendments to Regulations Governing Remote Dispensing Pharmacy Technicians

On April 12, 2019, the Board published notice of its intent to add section 1793.9, Title 16 of the CCR to implement AB 401 (Aguiar-Curry) (Chapter 548, Statutes of 2017), which established the Board's authority to issue a remote dispensing site pharmacy (RDSP) license in order to increase access to prescription medication and pharmacist care for Californians living in rural areas. According to the Initial Statement of Reasons, the proposal would establish the specific minimum qualifications for Pharmacy Technicians working in a RDSP, including a certification issued by an approved certifying program; an associate degree in Pharmacy Technology, any bachelor's degree, or completion of a board approved training program; and a minimum of 1,000 hours of work experience in the three years prior to working at a RDSP. The 45-Day Comment Period ends on May 28, 2019.

Board Considering Employment of New Legal Counsel

At its October 23, 2018 meeting, the Board continued its discussions pertaining to its ability to hire its own independent legal counsel separate from DCA legal affairs. *[24:1 CRLR 74–75]* President Law reported that he and Vice President Lippe held a series of discussions with DCA staff, including its Director Dean Grafilo, and DCA does not support a decentralized legal counsel model. As an outcome of these discussions, DCA offered a compromise proposal under which DCA would hire a limited term attorney position and enter into an MOU with the Board to fund the position. Under the proposal, DCA would complete the recruitment for the position but would allow a member of Board staff to participate in the recruitment process. The attorney would be an employee of the DCA and

would report to the Legal Affairs Office for supervision. The attorney would be dedicated exclusively to Board of Pharmacy work and would be available to work at the Board's office part-time. While President Law stated that board leadership was comfortable with the DCA proposal, several Board members expressed concern about the Department's proposed authority to hire and fire counsel given the Board's existing legal authority to hire its own counsel pursuant to section 4008 of the Business and Professions Code. *[23:1 CRLR 81]* Ultimately, rather than voting on the proposed compromise, the Board opted to table its discussion and request that a DCA representative attend future Board meetings to provide information on the proposal in a public meeting. At this writing the Board has not taken further action on the proposal.

Board Considers Position on CBD Oil

At its October 23, 2018 meeting, the Enforcement and Compounding Committee, as well as the full Board discussed and heard extensive public comment pertaining to the legal status of products containing cannabidiol (CBD), in light of the FDA approval of Epidiolex, a series of federal bills, and AB 710 (Wood) (Chapter 62, Statutes of 2018). Among the concerns raised were whether or not CBD oil could be sold in pharmacies, and whether or not pharmacists should advise patients about the possible impact of CBD products on dispensed medication, and the status of products derived from industrial hemp.

At the Board's request, Supervising Deputy Attorney General Joshua Room issued an updated opinion letter on January 24, 2019, which the Board further discussed at its January 30 meeting. Room's letter updated the Board on federal legislation, the 2018 Farm Bill, which changed the legal definition of marijuana. Ultimately, it clarified that only a small portion of products containing CBD may be sold retail, and any marketing of such

products may not make any health claims as to the product. The Board staff stated that enforcement of CBD products sold in pharmacies was not a priority for the Board. The Board did not take any action pertaining to CBD oil during this reporting period.

Law and Ethics Continuing Education Courses for Licensing Renewals

At its October 23, 2018 meeting, the Board heard an update on its one-hour law and ethics webinar, which went live on the Board's website on August 1, 2018 and allows pharmacists to earn continuing education (CE) credit pursuant to section 1732.5, Title 16 of the CCR. *[24:1 CRLR 79]* According to the report, as of September 12, 2018, 1,542 pharmacists had completed this online webinar. Staff reported, however, that after reviewing completion data gathered from this course, some individuals had completed the training in less than 10 minutes and in many instances, the individuals did not answer the questions correctly. The Board's current regulation only requires pharmacists to complete the course but does not require pharmacists to pass the course.

To address this concern, the Board voted to direct staff to work with DCA's SOLID Training Group and Office of Information Services to incorporate changes within the online webinar to prevent a person from completing the webinar if the licensee answers questions specific to the content of the webinar incorrectly by potentially purchasing software that prevents these issues.

Board Considers Revamping Renewal Requirements for Advanced Practice Pharmacists

At its October 23, 2018 meeting, Deborah Veale, chairperson of the Board's licensing committee, reported on the committee's discussions pertaining to renewal requirements for Advanced Practice Pharmacists. In 2013, SB 493 (Hernandez) (Chapter 469, Statutes of 2013), added section 4210 to the Business and Professions Code, to establish this new licensing category. Specifically, Advanced Practice Pharmacists are permitted to perform patient assessments, order and interpret all drug therapy-related tests, refer patients to other healthcare providers, and participate in the evaluation and management of diseases and health conditions in collaboration with other healthcare providers. They may also initiate, adjust/modify, and discontinue drug therapy pursuant to an order by a patient's treating prescriber and in accordance with Board-established protocols. The Board began issuing Advanced Practice Pharmacist licenses to qualified applicants in 2017.

Pursuant to section 4233 of the Business and Professions Code, an Advanced Practice Pharmacist is required to complete an additional 10 hours of continuing education each renewal cycle in addition to the 30 hours required for their pharmacist license renewal. Ms. Veale reported that while the Board has the authority to issue an inactive pharmacist license under specified conditions, the board does not have similar authority for an Advanced Practice Pharmacist license renewal. The licensing committee also identified a series of additional inconsistencies between pharmacist and Advanced Practice Pharmacist license renewal processes.

After discussion, the Board agreed that the renewal requirements for Advanced Practice Pharmacists should mirror the renewal requirements for pharmacists, and thus directed staff, in concert with counsel, to develop language for the Board's consideration to align the Advanced Practice Pharmacist renewal requirements with the renewal requirements for the pharmacists.

Board Establishes Twitter Account

At its October 23, 2019 meeting, the Board voted to establish a Twitter account to communicate with the public and directed staff to report on its usage to the Board on a regular basis. The board also voted to direct staff to research other social media for possible use. While the Board currently has several channels for communicating directly with licensees—including subscriber alerts, the newsletter, and site inspections—none are widely accessible or known to the general public. According to the Board, the new Twitter account will allow the Board to communicate about upcoming board meetings and events, recalls, regulations, news releases, and links to consumer resources.

Proposed CE for Pharmacists Who Prescribe Opioids Under Collaborative Practice Agreement

At the Board's January meeting, Enforcement Committee chair Allen Schaad recommended that the Board pursue a statutory change to section 4052.11 of the Business and Professions Code to require CE for pharmacists who prescribe opioids under a collaborative practice agreement. This is a follow up to SB 1109 (Bates) (Chapter 693, Statutes of 2018) which requires CE units for prescribers on the hazards of opioid use, but does not apply to pharmacists who prescribe under a collaborative practice agreement. SB

1109 also requires a specified warning notice to be prominently displayed on the label or container of an opioid dispensed to a patient. The Board voted to pursue the proposed statutory change at the committee's recommendation.

Proposed Exemptions to Prescription Requirement During a Declared Emergency

At the Board's January meeting, Licensing Committee chair Deborah Veale recommended that the Board pursue a change to the Health and Safety Code to create an exemption from the security prescription forms requirement for patients unable to access controlled medication because of a declared state or federal emergency. This is a follow up to section 4062 of the Business and Professions Code, which permits a pharmacy to furnish dangerous drugs in reasonable quantities without a prescription during a federal, state, or local emergency. The recommendation also followed a presentation by the California Department of Public Health to the Licensing Committee regarding the challenges health care providers and pharmacies faced in response to the Camp and Woolsey fires. The Board voted to pursue the proposed statutory change at the committee's recommendation, and is currently pending before the legislature as SB 569 (Stone). *[See* LEGISLATION*]*

Recommendation of Granting CE Credit for Reading the Script

At the Board's October meeting, Communication and Public Education Committee chair Ricardo Sanchez recommended that the Board award one hour of CE credit to pharmacists who pass a quiz based on articles published in the Board's newsletter, *The*

Script, up to a maximum of two credits per renewal period. The Board voted to accept the committee's recommendation.

Proposal to Amend Board's Fee Schedule

At the Board's December meeting, it voted to initiate the formal rulemaking process to amend section 1749, Title 16 of the CCR regarding the Board's fee schedule. Specifically, President Law and Vice President Lippe recommended the Board consider raising the fees for all sterile and compounding outsourcing facilities to their statutory maximum levels, raising all other fees to the midway point between the statutory minimum and maximum level, and initiating a new fee analysis to determine long term sustainable fee structure. President Law also noted that the DCA Budget Office agreed with the Board's assessment that a fee increase is necessary. The proposal for a fee increase follows a DCA analysis of the Board's fund condition and fee structure in November 2015, which the Board requested. The analysis found the current level of fees insufficient to keep the Board's fund solvent and that fees needed to be adjusted to reflect the Board's actual cost in providing service and processing each license type. In 2016, the Board successfully pursued statutory changes to increase the maximum amount of fees it may collect, and in 2017, several fees were increased. The proposed action would amend the Board's regulations to further raise fees within the statutory limits. The motion also directed staff to initiate a new analysis to determine the zero-based costs, similar to the fee analysis previously completed by the DCA. At this writing the Board has not yet formally published notice of its intent to amend section 1749.

LEGISLATION

SB 569 (Stone), as amended April 1, 2019, is a Board-sponsored bill that would add section 11159.3 to the Health and Safety Code to establish prescription content requirements for a pharmacist to furnish a controlled substance without a standard prescription form during a declared state of emergency. Specifically, if the Board issues a notice that it is waiving portions of the law during a declared local, state, or federal emergency, the bill would allow a pharmacist to fill a prescription for a controlled substance for use by a patient who cannot access medications as a result of the emergency if specified conditions apply. In its letter to the Senate Business, Professions, and Economic Development Committee, the Board stated:

> As part of its consumer protection role, the board undertook review of recent declared disasters that have negatively impacted Californians to determine if gaps in legal provisions exist.… One of the challenges noted [from pharmacists involved in relief efforts] was a barrier to access to controlled substances caused by the security forms required for such medications. As the board lacks the authority to waive a provision of the Health and Safety Code during a declared disaster and being mindful of the opioid epidemic, the board's proposal strikes a balance between removing the barrier to access to medications during the initial phases of a disaster and preventing the possible exploitation of such an exemption.

[*S. BP&ED*]

SB 476 (Stone), as amended March 26, 2019, would amend section 4036.6 of the Business and Professions Code to exempt a pharmacist-in-charge from disciplinary action by the Board for the violation of a state or federal law or regulation committed by another person of which the pharmacist-in-charge (PIC) had no knowledge, or in which the PIC did not knowingly participate, if certain conditions are met. According to the author, a PIC

may sometimes be found in violation of the law "because of something that was not in their authority," or something they were instructed to do by a pharmacy owner. [*S. BP&ED*]

SB 159 (Wiener), as amended April 11, 2019, as it applies to the Board of Pharmacy, would amend section 4052 and add section 4052.02 to the Business and Professions Code to permit pharmacists to furnish combination antiretroviral drug treatments that are medically necessary for the prevention of AIDS/HIV, including preexposure prophylaxis (PrEP) and postexposure prophylaxis (PEP) without a prescription in accordance with protocols established by this bill, and require Medi-Cal to reimburse pharmacies for initiating and furnishing PrEP and PEP. According to the author, "[a]llowing pharmacists to furnish PrEP and PEP without a prescription will expand access, help increase the number of individuals who use these HIV preventatives, and will help California achieve its goal to end new HIV infections." [*S. Health*]

AB 1803 (Committee on Health), as introduced February 28, 2019, would amend, repeal, and add section 4079, and repeal section 4079.5, of the Business and Professions Code to delay implementation of existing law that requires a pharmacy, if the customer pays the retail price for prescription drugs, to submit the claim to the health care service plan or health insurer in the same manner as if the customer had purchased the prescription drug by paying the cost-sharing amount when submitted by the network pharmacy, from January 1, 2019 to January 1, 2020. [*A. Health*]

SB 491 (Stone), as introduced February 21, 2019, would add section 4126.7 to the Business and Professions Code relating to pharmacy compounding services. New section 4126.7 would authorize pharmacies that provide compounding services to manufacture a nonpatient-specific dangerous drug for a general acute care hospital to alleviate a

commercial shortage of the drug. Currently, the law only authorizes a pharmacy to furnish prescription drugs to certain entities, including specific health care entities, individual patients, or other pharmacies either pursuant to prescription or as otherwise authorized by law. *[S. BP&ED]*

AB 973 (Irwin), as introduced February 21, 2019, is a Board-sponsored bill that would add section 4126.8 to the Business and Professions Code, relating to compounding drug preparations. New section 4216.8 would require the compounding of drug preparations by a pharmacy for furnishing, distribution, or use to be consistent with standards established in the compounding chapters of the United States Pharmacopeia—National Formulary (USP 41—NF 36), including relevant testing and quality assurance. It would also authorize the Board to adopt regulations to impose additional standards for compounding drug preparations. According to the author, the bill would provide clarity for the standard of pharmacy compounding that the Board can utilize to oversee the practice of drug compounding. The author notes that existing law does not currently outline any specific baseline requirements for the compounding of prescription drugs. *[A. Appr]*

AB 690 (Aguiar-Curry), as introduced February 15, 2019, would amend section 4132 of the Business and Professions Code, to specify the requirements for pharmacy technicians who work at remote dispensing site pharmacies. New section 4132 would delete the provision delegating the Board of Pharmacy with the authority to set the minimum requirements for pharmacy technicians and codify the following requirements for working at remote dispensing site pharmacies: 1) possession of a pharmacy technician license that is in good standing; 2) possession and maintenance of a certification issued by a Board-approved pharmacy technician certification program; 3) possession of either an

associate degree in pharmacy technology, a bachelor's degree in any subject, or a certificate of completion from a course of Board-approved training; 4) completion of a minimum of 1,000 hours of experience working as a pharmacy technician within the three years preceding first commencing work in the remote dispensing site pharmacy. According to the author, the bill will provide opportunities for improved patient education, increased medication adherence, and better overall health outcomes in the communities served by remote dispensing pharmacies. *[A. Appr]*

SB 655 (Roth), as amended April 11, 2019, would amend sections 4115.5, 4163, 4200, and amend, repeal, and add section 4400 of, the Business and Professions Code. New section 4115.5 would increase the hour requirements for a pharmacy technician trainee (PTT) participating in an externship program from no more than 120 hours to between 120 and 140 hours. It would also increase the externship hours from 320 to 340 hours for a rotation between a community and hospital pharmacy for the purpose of training a PTT student in distinct practice settings. New section 4163 would, upon approval by the Board, authorize a reverse distributor licensed as a wholesaler to acquire a dangerous drug or dangerous device from an unlicensed source that was previously licensed with the Board, for the sole purpose of destroying the dangerous drug or dangerous device. New section 4200 would require an applicant for pharmacist licensure to pass a version of the California Practice Standards and Jurisprudence Examination (CJPE) for Pharmacists that, at the time of application for licensure, was based on an occupational analysis that is either current or that was replaced by another occupational analysis no more than one year before the application for licensure. New section 4400 would clarify the fees for updating a licensing record and the fee to reissue a printed license certificate. *[S. Appr]*

SB 650 (Rubio), as amended April 11, 2019, would add Article 11.6 (commencing with section 4169.7) to Chapter 9 of Division 2 of the Business and Professions Code and Division 117 (commencing with section 150400) to the Health and Safety Code regarding cancer medication recycling. The new bill would establish a program overseen by the Board of Pharmacy to allow for the donation and redistribution of cancer drugs. New Division 117, known as the Cancer Medication Recycling Act, defines "donor" as an individual who donates unused prescription drugs to a participating practitioner for the purpose of redistribution to established patients of that practitioner. A "participating practitioner" means a person who is registered with the Board, is board certified in medical oncology or hematology, and is subject to rules promulgated by the Board to participate in the collection of donated medications, prescribed for use by established patients of that practitioner and donated for the purpose of redistribution to established patients of that practitioner. The new bill would release donors, recipients, and participating practitioners from liability for injury caused when donating, accepting, or dispensing prescription drugs in compliance with the bill. *[S. Jud]*

AB 1723 (Wood), as amended March 18, 2019, would amend section 4180 of the Business and Professions Code to increase the number of hours intermittent clinics are allowed to operate from 20 to 40 hours per week. The intermittent clinics purchase drugs at wholesale for administration or dispensing, under the direction of a physician and surgeon, to patients registered for care at the clinic. According to the author, recent changes in state law allow intermittent clinics to be open up to 40 hours per week. This bill would conform the Pharmacy Law to the state law referenced in the Business and Professions Code. *[A. B&P]*

AB 149 (Cooper), as amended February 19, 2019, amends sections 1116.2 and 11164, and adds section 11162.2 to the Health and Safety Code, providing for a transition period for the new serialized number requirement for security prescription forms. This bill is an urgency measure that authorizes pharmacies to fill prescriptions issued on forms that were valid prior to January 1, 2019 for two years, and delays implementation of a requirement, enacted through legislation in 2018, for uniquely serialized numbers on prescription forms until a date determined by the Department of Justice that is no later than January 1, 2020. The Board voted to formally support the bill at its January meeting. Governor Newsom signed AB 149 on March 11, 2019 (Chapter 4, Statutes of 2019).

RECENT MEETINGS

At its October meeting, Executive Officer Virginia Herold updated the Board and the public on the Board's relocation to a new office. The Board signed a lease for a new office space, located at 2720 Gateway Oaks Drive, approximately three miles from its current location. The tentative start date of the lease was originally February 1, 2019. Due to construction delays within the office space, the anticipated move will occur in May or June 2019.