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 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. The Board regulates all sales of dangerous drugs, controlled substances, and poisons, and is authorized to adopt regulations, which are codified in Division 17, Title 16 of the California Code of Regulations (CCR).

The Board of Pharmacy is a consumer protection agency located within the Department of Consumer Affairs (DCA). It 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.

On May 7, 2018, Governor Brown appointed Shirley Kim to the Board as a public member. Ms. Kim is currently an associate at Norton Rose Fulbright US LLP and has previously spent time as the legislative director at the California Faculty Association. On July 19, 2018 Governor Brown appointed Maria Serpa, PharmD, as a licensee member of the Board. Ms. Serpa is a past president of the California Society of Health-System Pharmacists and a fellow of the American Society of Heath-Systems Pharmacist. She has been a system support pharmacist at Sutter Medical Center, Sacramento, since 1996. Also on July 19, 2018, the Governor reappointed public member Ricardo Sanchez to the Board. Mr. Sanchez has been a state investigator at the California Department of Motor Vehicles since 1989 and was an officer at the California State Police from 1988 to 1989.

MAJOR PROJECTS

Executive Director Announces Retirement; Board Actively Seeking Replacement

At the Board's July meeting, Virginia Herold announced her retirement from her role as Executive Officer effective January 2019. Ms. Herold has worked with the Board since 1990, 16 years as the assistant Executive Officer and 12 years as Executive Officer. Under her leadership, the Board's operations have grown significantly: Oversight responsibility has increased from 12 to 29 regulatory programs; the total number of licenses issued has grown from about 103,000 to more than 140,000; and staff has more than doubled.

The Board has begun to actively search for her replacement. At its September 7, 2018 meeting, the Board approved a recruitment announcement after listening to a presentation by DCA's Personnel Officer, Nicole Le. Ms. Le provided information regarding the Executive Officer's duty statement and recruitment announcement, creation of a recruitment and selection committee, and membership of the recruitment and selection committee, including possible elections or delegation to the Board President.

Board Considering Employment of New Legal Counsel

At its September 7, 2018 board meeting, the Board discussed the possibility of hiring of an independent legal counsel to represent the Board of Pharmacy. President Law reported that he and Greg Lippe, Vice-President of the Board, met with various members from DCA, including Director Dean Grafilo, and were advised that the current administration does not support a decentralized legal counsel model. In lieu of the Board hiring counsel that would report directly to the board's Executive Officer, DCA is offering a compromise proposal which would establish a limited term attorney position that is partially funded by the Board. DCA and a member of the Board would work together in the recruitment process. Under this proposal, while the new attorney would be an employee of the Department, and would report to the Legal Affairs Office for supervision, the attorney would be dedicated exclusively to Board work and would be available to work at the Board's office part-time.

After discussion, the Board voted to table the action to accept DCA's full proposal until its January 2019 Board Meeting, however they did approve the DCA proposal to enter into a Memorandum of Understanding with DCA for purposes of establishing an Attorney

IV position and authorize the Executive Officer to carry out the proposal, including by securing the necessary funding to pay for the position.

New Fee Schedule Approved

On April 20, 2018, the Office of Administrative Law (OAL) approved the Board's proposed amendments to section 1749, Title 16 of the CCR to increase the statutory minimum licensing fees. The Board initially published notice of its intent to amend these regulations on April 14, 2017, in order to implement the fee schedule set forth in the Board's sunset bill, SB 1039 (Hill, Chapter 799, Statutes of 2016), which went into effect July 1, 2017. *[23:1 CRLR 77]*. According to the initial statement of reasons, the proposed regulations are the Board's efforts to ensure the Board of Pharmacy's revenue matches its expenditures to account for increased costs such as enforcement expenditures including those incurred for legal services of the Offices of the Attorney General. The regulation went into effect on April 20, 2018.

Board Proposes Amendments to Compounding Drug Preparation Regulations

On July 26, 2018, the Board published notice of its intent to amend sections 1735.1, 1735.2, 1735.6, 1751.1, and 1751.4, Title 16 of the CCR to clarify and make specific the standards pharmacists and pharmacies use for compounding drug preparations. Specifically, the proposed regulations would change the requirements pharmacists use to establish beyond use dates (BUD) for compounding drug preparations. It would also clarify the definitions of compounding terms, the standards for equipment used in compounding, and the standards for facilities performing sterile compounding.

According to the initial statement of reasons, the Board seeks to amend these regulations to clear up confusion that has arisen after the Board's extensive revision of its compounding drug preparations regulations adopted on January 1, 2017. In the time following the adoption of these regulations, the Board and the public have expressed particular concern over the regulations relating to BUDs for non-sterile compounded drug preparations, stating that they have adversely impacted patient accessibility to the drugs. Additionally, according to the notice of proposed regulations, the Board has heard public comment expressing confusion between the use of the terms "venting" and "exhaust"; methods for venting air from devices during hazardous drug compounding; which compounding environments require smoke studies, and the necessary frequency for conducting the studies. The Board also seeks to clarify the maximum temperature for a sterile compounding area consistent with national standards.

The regulations regarding BUDs for compounded drug preparations were also the subject of an emergency regulation that took effect on December 19, 2017 and expired on June 19, 2018. *[23:2 CRLR 77-78]* Additionally, the legislature has focused on establishing new regulations for compounding pharmacies since a public health emergency originated in a Massachusetts pharmacy in 2012. *[23:2 CRLR 79]*

At its September 26, 2018 board meeting, Board staff presented the Board with a summary of comments received during the 45-day public comment period, and proposed some minor modifications to the proposed text to address some of the comments. After hearing additional public comment at the meeting, the Board voted to adopt staff's proposed modifications to the text. The Board released the modified text the same day, and

the comment period ended on October 11, 2018. The Board is scheduled to discuss further public comments at its meeting on October 23–24, 2018.

Board Considering New Stance on CBD Oil

On October 12, 2018, the Board's liaison counsel from the California Attorney General's Office delivered an updated letter-opinion to the Board as to the impact of the Federal Drug Enforcement Administration's (DEA) September 28, 2018 action to move the cannabidiol (CBD) drug Epidiolex from federal Schedule I to federal Schedule V. This followed the June 25, 2018, approval of Epidiolex by the federal Food and Drug Administration (FDA). The letter states that only FDA-approved drugs containing CBD derived from cannabis, and no more than 0.1 percent residual tetrahydrocannabinols (THC), have been moved to federal Schedule V. So far, this is a category that only includes Epidiolex. No other CBD products or products that contain CBD have been approved by the FDA as yet.

According to the letter, the status of the vast majority of cannabis and/or CBD products remains the same: these products are Schedule I under federal and California law. Therefore, drugs containing cannabis or any of its component parts or derivatives, including non-FDA approved CBD drugs, may not be prescribed or dispensed. However, the DEA re-scheduling of FDA-approved drugs containing CBD with no more than 0.1 percent THC to Schedule V *does mean* that Epidiolex, and any subsequent CBD drug that meets these criteria of FDA approval and THC content, can be lawfully prescribed and dispensed under federal law.

Finally, the letter concludes that although CBD drugs remain Schedule I under the separate California controlled substance schedules, the enactment of AB 710 (Wood)

(Chapter 62, Statutes of 2018) makes the prescribing and dispensing of Epidiolex (or other subsequently FDA-approved equivalents) also lawful under California law. The Board is scheduled to discuss the letter at its October meeting.

Mail Order Pharmacies and Nonresident Pharmacies Requirements

During its May meeting, the Board voted to approve the licensing committee's proposed amendment to section 1707.2, Title 16 of the CCR and initiate the formal rulemaking process regarding patient consultation from mail order pharmacies or nonresident pharmacies. According to the committee's recommendation, twenty-five percent of pharmaceutical sales go through mail order pharmacies. While this service is highly convenient, the committee reported that issues arise frequently that can affect consumers such as patients not receiving essential information about how to take medications appropriately, patients not being able to easily contact a pharmacist for consultation, and patients not having easy access to translation services.

In order to address these issues, the licensing committee, after hearing public comments, recommended that the Board change the requirements regarding how quickly a patient should be able to speak to a pharmacist. Specifically, the committee proposed amendments to section 1707.2 that would clarify that a patient of a mail order pharmacy, or a patient who has his or her medications delivered, must be able to speak to a pharmacist on the phone within an average of 10 minutes. If the pharmacist is not able to speak to the patient within 10 minutes, then a return call must be scheduled to occur within one hour. According to the committee, this amendment would ensure that patients have quick and easy access to pharmacists to advise them about their medications.

Board Implements Law and Ethics Continuing Education Courses for Licensing Renewals

Effective July 1, 2019, pursuant to section 1732.5, Title 16 of the CCR, all pharmacists seeking to renew their license will be required to have at least two of their 30 Continuing Education hours required for pharmacist license renewal to be completed by participation in a Board-provided Continuing Education course in Law and Ethics. While the Board has not yet finalized the program at this writing, the "2018 New Pharmacy Law" webinar is in the final stages of development. The webinar will be available on the Board's website at no cost and will contain quiz questions to ensure that pharmacists are participating in the webinar. The Joint DEA and Board of Pharmacy Training programs will be allowed to count towards the renewal requirements as the training contains information on pharmacy law.

Substance Abuse Coordination Committee Reconvenes to Review Drug Testing Criteria

At the Board's May meeting, Christopher Castrillo, DCA's Deputy Director of Board and Bureau Services, reported that the Department reconvened the Substance Abuse Coordination Committee (SACC) on April 23, pursuant to SB 796 (Hill) (Chapter 600, Statutes of 2017). The Committee, which is comprised of the Executive Officers from the Department's respective healing arts boards, including the Board of Pharmacy's Executive Director, Virginia Herold, is tasked with reviewing the criteria that DCA's healing arts Boards are to use when drug testing substance-abusing licensees, specifically Uniform Standard #4 related to drug testing. Pursuant to section 315(d) of the Business and Professions Code, the SACC is required to determine whether the existing criteria should

be updated based on recent developments in research and technology, and provide a report to the legislature by January 1, 2019.

Board Raises Concerns Regarding Licensing Exam Requirements

During its May meeting, the Licensing Committee sought the Board's approval to seek a legislative change to section 4200 of the Business and Professions Code pertaining to applicants' licensing exam requirements. As currently written, the statute provides that the Board may license a pharmacist applicant who received a passing examination score on the North American Pharmacist Licensure Examination (NAPLEX) and the California Practice Standards and Jurisprudence Examination for Pharmacists (CPJE) on or after January 1, 2004. In addition, pursuant to Business and Professions Code sections 139 and section 4200.3, the Board must adhere to the DCA's Licensure Exam Validation Policy, and conduct an occupational analysis every five years to reassess the profession of pharmacy in California, review job-related critical tasks and the knowledge, skills and abilities necessary to practice, and update the exam content outline to ensure the licensure examination reflects current pharmacy practice in California.

The licensing committee advised the Board that staff has recently observed a trend of pharmacist applicants having passed the NAPLEX and/or the CPJE more than five years ago, thus raising concerns that the passing score from more than five years ago does not demonstrate that the applicant has met the minimum qualifications based on current practice standards. As the committee pointed out, the existing language of section 4200, permitting applicants to be licensed having passed an outdated exam, conflicts with section 139 and DCA's licensing examination policy to ensure minimum competence under

current practice standards. According to the committee, Board staff conferred with DCA's Office of Professional Examination Services (OPES), and OPES advised that examination scores are only considered "valid" during the current occupational analysis and examination content.

After discussion, the Board unanimously voted to pursue a statutory amendment to section 4200 which would clarify that, at the time of application for licensure, the applicants must have passed the licensing exams that were based on an occupational analysis that either remains current or was replaced no more than [one year] prior. The proposed amendment would also clarify that an applicant with a passing NAPLEX score after January 1, 2004 who holds an active pharmacist license in another state could still qualify for licensure.

At this writing, no legislation has been introduced to amend this provision.

Prescribers Now Required to Check CURES Before Prescribing Dangerous Drugs

On October 2, 2018, the mandate that all prescribers in California check the Controlled Substance Utilization Review and Evaluation System (CURES) database before prescribing Schedule II, III, or IV drugs to a patient for the first time, and at least every fourth months thereafter if therapy with the controlled substance continues, pursuant to section 11165.4 of the Health and Safety Code, became effective. The requirements come after the Department of Justice certified its CURES 2.0 system on April 2, 2018, which is an interstate data hub for sharing controlled substances reporting information. In May, the Board released an alert to pharmacists informing them about the new requirements. While

the statute does not mandate that pharmacists check CURES before dispensing medication, as of May 2018, more than 40,000 pharmacists had registered with CURES.

At the Board's September 7, 2018 meeting, the Board heard public comment pertaining to recommendations for improving the CURES system. At this writing, the Board has not taken action on these suggestions.

Naloxone Certification Webinar in Development

At the Board's July meeting, the executive officer, Virginia Herold, reported that Board staff is working with DCA to create a free webinar on furnishing naloxone that will be available on the Board's website. The webinar, as approved at the February 2018 meeting, will provide one hour of continuing education credit to satisfy the training requirement for furnishing naloxone, which reverses opioid overdose. *[23:2 CRLR 80-81]* This is a follow up to SB 493 (Hernandez) (Chapter 469, Statutes of 2013), which authorizes the Board to address the problem of restricted public access to naloxone. The Board adopted section 1746.3, Title 16 of the CCR, in 2016, establishing a protocol for pharmacists to furnish naloxone to individuals (usually family and friends of drug users) without a prescription.

Board Launches Online Search Tool for Drug Take-Back Locations

On August 22, 2018, the Board announced a drug take-back search tool available on the Board's website. The online resource is composed of a list of pharmacies statewide that have signed up pursuant to the regulations set forth in sections 1776–1776.1, Title 16 of the CCR to accept unused or expired prescription drugs from consumers. The Board

adopted these regulations, which were approved by OAL in 2017, to stop prescription drug abuse by increasing options for the public to safely get rid of medications. *[23:1 CRLR 79]*

LEGISLATION

AB 2783 (O'Donnell), as amended August 22, 2018, amends sections 11055 and 11056 of the Health and Safety Code, to reclassify specified hydrocodone combination products (HCP) as Schedule II controlled substances. According to the author, this would conform California's schedule to the Federal schedule, which reclassified HCPs as Schedule II drugs in 2014. The bill seeks to reconcile discrepancies between federal and state controlled substance schedules by clarifying compliance with whichever schedule more closely regulates a particular drug. This will clarify applicable law for prescribers, dispensers, health practitioners, and others who rely on these schedules for compliance.

Governor Brown signed AB 2783 on September 20, 2018 (Chapter 589, Statutes of 2018).

AB 1753 (Low), as amended August 24, 2018, amends sections 11161.5, 11162.1, and 11165 of the Health and Safety Code to limit the number of approved printers to manufacture regulated prescription pads to three. Under the Department of Justice's (DOJ) Security Prescription Printers Program, all paper prescriptions of any Schedule II through V controlled substance must use special tamper-resistant forms obtained from manufacturers approved by DOJ. One challenge to requiring standardized serialization of prescription pads is that the number of approved security printers that are each individually manufacturing pads throughout the state do so without significant restriction or coordination. Approximately 43 security printers are currently approved by the DOJ and operating throughout the state. The DOJ believes this to be too many printers to

substantially standardize the production of forms in a way that allows for unique identifiers to be consistently applied in a way that can be tracked through CURES or any other system. Allowing the DOJ to cap the number of approved security printers and reduce the number through regulation to three provides for a more manageable amount of coordination between manufacturers. This allows for prescription pads to be tracked by law enforcement when lost or stolen, and for serialized pads to be linked to CURES. The tighter regulation could also arguably make it easier for law enforcement to identify counterfeit or fraudulent prescription pads sold on the street

According to the author,

> [t]he opioid crisis ravaging communities throughout our nation and the State of California must first and foremost be addressed through solutions rooted in a public health approach. However, prescription drug abuse and diversion continues to be a pressing public safety issue as well. As instances of addiction to pharmaceutical opioids grows, criminal enterprises derive tremendous profit through prescription pad theft and fraud. Because the current statute provides for little effective regulation of dozens of security printers entrusted with manufacturing these pads, it is challenging for law enforcement to track prescriptions that may have been written with counterfeit or stolen pads. AB 1753 tightens existing controls involved in the security printers program and ensure that prescriptions filled using illicit pads can be linked to prescription data collected through the successful CURES database.

Governor Brown signed AB 1753 on September 18, 2018 (Chapter 479, Statutes of 2018).

AB 2789 (Wood), as amended August 14, 2018, adds section 688 to the Business and Professions Code, to require health care practitioners and pharmacies to have the capability to issue and receive electronic data transmission prescriptions, on or after January 1, 2022. Citing a Johns Hopkins study finding that 89% of handwritten prescriptions failed to meet best practices standards guidelines or were missing information

that would otherwise be prompted by an e-prescribing system, the author's stated motivation for the bill is that the

> ever increasing reporting requirements to CURES for controlled substances, the proliferation of more and new drugs, the increased numbers of prescriptions written annually, the increase in total numbers of prescriptions individuals are receiving, the risk of errors, the ongoing issue of fraudulent prescriptions and the diversion of prescription medicines into street drugs with oftentimes deadly results all point to the need for electronic prescribing of drugs.

According to the bill analysis, six other states have successfully mandated e-prescribing: Connecticut, Maine, North Carolina, New York, Rhode Island, and Virginia. Efforts to pass a federal mandate through the United States Congress continue with the introduction of H.R. 3528 the Every Prescription Conveyed Securely Act by Reps. Clark and Mullin, which mandates e-prescribing for all Medicare Part D transactions by 2020. This federal legislation is supported by major retail pharmacies like CVS Health and Walgreens.

Governor Brown signed AB 2987 on September 17, 2018 (Chapter 438, Statutes of 2018).

AB 2256 (Santiago), as amended June 6, 2018, adds section 4119.9 to the Business and Professions Code to authorize a pharmacy, wholesaler, or manufacturer to furnish naloxone hydrochloride or other opioid antagonists to a law enforcement agency if the following conditions are met: 1) The naloxone hydrochloride or other opioid antagonists are furnished exclusively for use by the employees of the law enforcement agency who have completed training provided by the law enforcement agency, and 2) Records regarding the acquisition and disposition of naloxone hydrochloride or other opioid antagonists furnished pursuant to this section shall be maintained by the law enforcement

agency for a period of three years from the date the records were created. The law enforcement agency shall be responsible for monitoring the supply of naloxone hydrochloride or other opioid antagonists and ensuring the destruction of expired naloxone hydrochloride or other opioid antagonists.

Naloxone was approved by the federal Food and Drug Administration for the treatment of opioid overdose in 1971 and is available as a generic medication. Naloxone is considered a non-narcotic drug; it does not have any serious side-effects and has a low potential for abuse. According to the federal Bureau of Justice Assistance, law enforcement agencies in 41 states have adopted programs to provide naloxone to law enforcement officers for use when responding to opioid overdoses.

Under current law and regulation by the Board of Pharmacy, a pharmacist may furnish naloxone, without a prescription, provided that the pharmacist has completed specified training and provides information to the person receiving the naloxone. This authority allows any person, whether or not they have an existing prescription for an opioid, to receive naloxone.

However, the authority to furnish naloxone without a prescription does not extend to wholesalers. Since law enforcement agencies generally prefer to purchase naloxone in bulk from a wholesaler, most law enforcement agencies that have deployed naloxone have relied on a physician within a local health department or other government agency to write a standing prescription for the agency to purchase naloxone. Law enforcement agencies have argued that this process delays access to naloxone by their officers without providing a substantial public benefit.

Governor Brown signed AB 2256 on September 5, 2018 (Chapter 259, Statutes of 2018).

AB 1751 (Low), as amended August 24, 2018, amends section 1798.24 of the Civil Code, and section 11165 of the Health and Safety Code to provide a framework for CURES to connect with other states that comply with California's patient privacy and data security standards. Currently, the CURES database only contains information related to prescriptions dispensed within California. This means that when a health practitioner consults a patient's prescription history prior to writing a new prescription, information relating to prescriptions written in other states are not reflected in the activity report. For true "doctor shoppers," traveling across state lines to secure prescriptions of opioids is not uncommon. This is especially true in communities located near California's borders. Forty-nine states including California and the District of Columbia currently have a PDMP. Many of these states already participate in one of several interstate data share hubs that allow for the exchange of prescription information.

According to the author,

> [a]s the opioid crisis receives growing national attention as one of the most devastating public health epidemics in modern history, California is fortunate to have CURES, a powerful tool to promote safe prescribing and curb illicit doctor-shopping. With the Attorney General's successful launch of a state-of-the-art 'CURES 2.0' prescription drug monitoring program, it is now the Legislature's imperative to identify ways to further empower data-driven solutions to preventing prescription drug abuse and diversion. Upgrading CURES to allow the DOJ to enter into interstate data sharing agreements provides invaluable cross-jurisdictional information to health professionals seeking to make informed decisions on behalf of their patients, particularly those practicing in communities neighboring other states.

Governor Brown signed AB 1751 on September 18, 2018 (Chapter 478, Statutes of 2018).

SB 1109 (Bates), as amended August 24, 2018, and as it relates to the Board of Pharmacy, adds section 4076.7 to the Business and Professions Code to requires pharmacists or pharmacies dispensing drugs containing an opioid to prominently display on the label or container, by means of a flag or other notification mechanism attached to the container, a notice that states "Caution: Opioid. Risk of overdose and addiction."

The bill also imposes a series of requirements on prescribers and youth sports organizations (including schools) to discuss the risk of opioids and opioid addiction with minor patients and their parents, and adds additional training requirements for prescribers regarding risks of addiction.

At its June meeting, the Board voted to oppose this bill, with several Board members pointing out that the Business and Professions Code already requires a standardized, patient-centered, prescription drug label on all prescription medicine dispensed to patients in California.

Governor Brown signed SB 1109 on September 22, 2018 (Chapter 693, Statutes of 2018).

SB 1447 (Hernandez), as amended August 23, 2018, amends various provisions of the Pharmacy Law, adds Article 25 (commencing with section 4427) to the Business and Professions Code, and amends, repeals, and adds section 1261.6 of the Health and Safety Code, to revise requirements for the operation and licensing of automated drug delivery systems (ADDS). An ADDS is a machine that dispenses prescription drugs outside of a pharmacy, and enables healthcare settings to have access to limited pharmacy services without bearing the cost and responsibility of having a full pharmacy.

This bill is the result of a successful 2015 BOP pilot project that placed an ADDS at Sharp Memorial Hospital in San Diego for use by the hospital's employees and their dependents. The ADDS delivered new and refilled prescriptions and over-the-counter medications to patients 24 hours a day, seven days a week. Consultation was provided via telephone before medication could be dispensed to a patient for first time fills. The study period was ten months, during which time the BOP's Enforcement and Compounding Committee received quarterly updates.

According to the bill analysis, the study results concluded that the ADDS was a convenient and safe extension of the hospital's pharmacy, with similar prescription pick up and consultation patterns as the regular pharmacy counter.

Governor Brown signed SB 1447 on September 21, 2018 (Chapter 666, Statutes of 2018).

AB 2037 (Bonta), as amended August 24, 2018, is an urgency bill that adds section 4119.11 to the Business and Professions Code to authorize a pharmacy to provide services through ADDS to patients participating in federal drug discount programs and establishes minimum safety and security standards that must be met by pharmacies that utilize this program. According to the author,

> [t]here are approximately 115 communities in 47 counties that do not have access to a pharmacist within 10 miles. Not only does ability to pay place a significant barrier to accessing quality healthcare services, the lack of convenient access to a pharmacy leads to lower rates of medication adherence. . . AB 2037 brings the full services of a licensed pharmacy to the health facility, increasing the likelihood that a patient will retrieve and take his or her prescription. An automated drug delivery system can create a feasible way to bring pharmacy access to disenfranchised areas. The passage of this bill delivers greater access to affordable medications under the 340B Drug Discount Program.

Governor Brown signed AB 2037 on September 21, 2018 (Chapter 647, Statutes of 2018), the bill took effect immediately upon the governor's signature.

AB 2576 (Aguiar-Curry), as amended August 24, 2018, amends sections 4062, 4064, and 4126.5 of the Business and Professions Code, and adds section 8628.5 to the Government Code, to expand the emergency provisions for clinics authorized by the Board to furnish dangerous drugs in reasonable quantities without a prescription during a federal, state, or local emergency.

According to the author, the bill is in response to California's increasingly serious wildfires, and seeks to ensure that communities continue to receive timely access to health care during an emergency situation. Specifically, this bill eases and standardizes the process for clinics and their providers to deliver health care when the physical clinic may not be accessible. By clearly authorizing expedited temporary pharmacy licenses, telephone appointments, home care visits, and health services in shelters during declared emergencies, this bill removes barriers to continuity of care when disaster strikes.

Governor Brown signed AB 2676 on September 23, 2018 (Chapter 716, Statutes of 2018).

SB 2863 (Nazarian), as amended August 13, 2018, and as it applies to the Board of Pharmacy, adds section 4079 to the Business and Professions Code, to require pharmacies to 1) inform customers whether the retail price for a covered prescription is lower than the applicable cost-sharing amount, unless the pharmacy automatically charges the customer the lower price; and 2) submit claims to health care service plans or health insurers 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. The bill also

provides that any payment rendered must apply to the customer's deductible and "maximum out-of-pocket limit" even if the customer paid the lower amount; makes any contract provision that is inconsistent with section 4079 void and unenforceable; and clarifies that a violation of this section is not grounds for disciplinary action or a criminal action.

The bill also imposes similar requirements upon health plans and insurers under the jurisdiction of the Department of Managed Health Care and the Department of Insurance.

According to the author,

> Americans pay more for prescription medications than any other developed nation. The various players in the healthcare system—drug manufacturers, health plans, pharmacy benefit managers—all have a hand in the price paid by consumers at the point of sale. People assume that the various "discounts" negotiated between these entities provide them with the lowest prescription costs. While this should be true, it is not always the case. There are times when the co-pay benefit for a prescription is higher than the retail price. This has given way to a recent problem that's being called the PBM clawback. It occurs when a patient's health benefit copay cost is higher than a drug's retail price, and the difference gets remitted back to the PBM. AB 2863 aims at curtailing this problem and ensuring that consumers pay the lowest available cost for their prescriptions.

Governor Brown signed SB 2863 on September 26, 2018 (Chapter 770, Statutes of 2018).

SB 1442 (Wiener), as amended August 24, 2018, adds Section 4113.5 to the Business and Professions Code to prohibit a community pharmacy from requiring a pharmacist employee to engage in the practice of pharmacy at any time the pharmacy is open to the public, unless another employee is made available to assist the pharmacist at all times. According to the bill's sponsor, the United Food & Commercial Workers, Western States Council, because many community pharmacies are not the primary focus of the business where the pharmacy is located, it is common for a pharmacist to be the only

employee assigned to the pharmacy area. The sponsor cites a survey indicating that 83% of pharmacists report being left alone during the workday for an average period of four hours, and many report that they do not have enough time to fulfill their professional functions to the extent they believe necessary. They also spend much of their time performing clerical tasks and performing non-pharmacy activities on behalf of the business. The bill exempts several types of pharmacies from this requirement, including pharmacies located in hospitals, government owned pharmacies, and pharmacies containing a drive through window under certain conditions.

Governor Brown signed SB 1442 on September 19, 2018 (Chapter 569, Statutes of 2018).

AB 2859 (Caballero), as amended June 21, 2018, entitled the Protecting Our Children and Adolescents from Opioids Act of 2018, adds and repeals Section 4106.5 of the Business and Professions Code regarding the display of safe storage products in pharmacies. The bill makes express legislative findings and declarations documenting the opioid crisis, and expressly states legislative intent "that increasing safe storage practices among parents is an important component to protecting teens and children from the dangers of opioid abuse and that the state must do more to encourage parents to safeguard these medications that are vital to managing certain chronic pain conditions among adults."

New section 4106.5 now requires pharmacies that dispense Schedule II, III, or IV controlled substances to display "safe storage products" within the building premises somewhere near the pharmacy. The bill defines "safe storage products" as "a device or product made with the purpose of storing prescription medications that includes a locking mechanism that is accessible only by the designated patient with a passcode, alphanumeric

code, key, or by another secure mechanism." Examples of safe storage products include: medicine lock boxes, locking medicine cabinets, or locking medication bags.

Subdivision (c) of 4106.5 requires the Board to assess a fine in an amount to be determined by the Board for a violation of the requirement that safe storage products be displayed, but clarifies that such a violation is not a misdemeanor. The bill also permits the Board to choose not to take administrative action against a pharmacy if it determines that compliance would create a financial hardship on the pharmacy, or that the pharmacy is temporarily out of stock of safe storage products. The bill exempts pharmacists who own and operate fewer than four pharmacies.

According to the author, who is also the sponsor of the bill,

> [t]he wide prevalence of prescribed opioids has led to an issue that is often overlooked; dangerous opioids are now easily accessible to children and teens in thousands of homes in our state. This had led to an increase in accidental poisonings amongst toddlers, which has tripled since 1997, and early abuse among teens, who can easily access these highly addictive drugs from a regular medicine bottle. AB 2859 addresses this child safety problem by requiring pharmacies to carry safe storage products that keep medications locked and secured. This bill will increase the education of parents who are prescribed opioids about better storage practices to help safeguard children from accidental ingestion or curious experimentation, which can lead to early-onset abuse. AB 2859 is a small but important step to better protect children during this complex public health crisis.

The bill has a sunset date of January 1, 2023 "to allow for an assessment of whether this requirement results in safety improvements that justify this type of state intervention into retail practices." At its July meeting, the Board voted to take a neutral position on the bill.

Governor Brown signed AB 2859 on August 28, 2018 (Chapter 240, Statutes of 2018).

SB 1254 (Stone), as amended June 28, 2018, adds section 4118.5 to the Business and Professions Code to require a pharmacist at a hospital pharmacy to obtain an accurate medication profile or list for each high-risk patient upon admission. The bill authorizes an intern pharmacist or pharmacy technician to perform this task under certain conditions. According to the author, medication lists are currently obtained by a variety of staff members with varying foundational pharmacy knowledge and up to 70% of patients have errors on their medication lists upon admission to a hospital. The author states that the current lack of oversight to ensure medical lists are accurate leads to significant harm to the patient and costs billions of dollars in medication-related readmission and adverse drug events. The Board voted to support the bill at its July meeting.

Governor Brown signed SB 1254 on September 22, 2018 (Chapter 697, Statutes of 2018).

AB 2138 (Chiu, Low), as amended August 24, 2018, amends, repeals, and adds sections 7.5, 480, 481, 482, 488, 493, and 11345.2 of, and adds section 480.2 to the Business and Professions Code to limit a regulatory board's discretion to deny a new license to applicants who have been convicted of a crime. Specifically, the bill only permits a board to deny a license on this ground where the applicant was formally convicted of a substantially related crime or subjected to formal discipline by a licensing board, within the previous seven years, with several enumerated exemptions. Additionally, the bill prohibits a board from denying a license based solely on an applicant's failure to disclose a fact that would not have been cause for denial of the license had the fact been disclosed. The bill requires each board, including the Board of Pharmacy, to adopt regulations setting

forth the criteria for determining whether a crime is substantially related to the qualifications, functions, or duties of the business or profession.

According to the author,

> [a]ll too often qualified people can be denied licensure or have licenses revoked or suspended on the basis of prior arrests or convictions, many of which are old, unrelated to the job, or have been judicially dismissed. Alleviating barriers to occupational licensing is just one way California can reduce recidivism and provide economic opportunity to all its residents.

The Board voted to oppose the bill at its May meeting, after discussion in which many Board members raised concerns that the measure would negatively impact the Board's ability to thoroughly review and consider criminal arrests and convictions of applicants and licensees, which runs contrary to the Board's consumer protection mandate.

Governor Brown signed AB 2138 on September 30, 2018 (Chapter 995, Statutes of 2018).

SB 1021 (Weiner), as amended August 23, 2018, amends various sections of the Health and Safety Code and the Insurance Code relating to prescription drug coverage. The bill extends the sunset date, from January 1, 2020 to January 1, 2024 of several consumer protections first imposed in AB 339 (Gordon) (Chapter 619, Statutes of 2015). Specifically, this bill ensures that the copayment for a covered outpatient prescription drug for an individual prescription does not exceed $250 for a supply of up to 30 days. It also prohibits an insured person from paying more than the retail price for a prescription drug if a pharmacy's retail price is less than the applicable copayment. According to the author, health plans and drug companies battle over prices and consumers should not be caught in the middle. The author states that the bill will ensure that all Californians, including those living with chronic conditions, are able to afford life-saving prescription drugs by keeping

co-payments affordable for consumers. The author states that before AB 339 consumer protections were put in place, insurance companies would often shift drug costs onto consumers by placing high cost specialty drugs on the upper tier of their drug formularies. The Board voted to support the bill at its July meeting.

Governor Brown signed SB 1021 on September 26, 2018 (Chapter 787, Statutes of 2018).

AB 710 (Wood), as amended April 2, 2018, adds Section 26002 to the Business and Professions Code and Section 11150.2 to the Health and Safety Code, to amend the Medicinal and Adult-Use Cannabis Regulation and Safety Act to exclude federally-sanctioned cannabidiol (CBD) products from regulation, and authorize healing arts licensees to prescribe such products. The bill makes legislative findings and declarations that both children and adults with epilepsy need new treatment options and that CBD has shown potential as an effective treatment option. The bill also declares that, upon a change in federal law permitting the prescription, furnishing, or dispensing of a CBD product, a pharmacist acting within her scope of practice who dispenses a CBD product in accordance with federal law shall be deemed compliant with state law.

Governor Brown signed AB 710 on July 9, 2018 (Chapter 62, Statues of 2018), the bill became effective immediately upon the governor's signature.

AB 315 (Wood), as amended August 24, 2018, adds and repeals various sections to the Business and Professions Code and the Health and Safety Code regarding pharmacy benefit management. According to the author, pharmacy benefit managers (PBMs) play a major role in negotiating the prices of prescription drugs, creating and managing formularies, and several other functions key to the management of pharmacy benefits for

millions of Californians. This bill requires PBMs to register with the Department of Managed Health Care, to exercise good faith and fair dealing, and to disclose, upon a purchaser's request, information with respect to prescription product benefits. Specifically, new Section 4079.5 of the Business and Professions Code requires a pharmacy to inform a customer at the point of sale for a covered prescription drug whether the retail price is lower than the applicable cost-sharing amount for the prescription drug, unless the pharmacy automatically charges the customer the lower price.

Governor Brown signed AB 315 on September 29, 2018 (Chapter 905, Statutes of 2018).

AB 1812 (Committee on Budget), as amended June 12, 2018, provides for various statutory changes to enact the public safety-related provisions of the Budget Act of 2018. Specifically, the bill provides for the licensure of correctional clinics by the Board and authorizes these clinics to obtain drugs from a correctional pharmacy. The bill also authorizes the administration or dispensing of drugs in a correctional clinic or by a correctional pharmacy, as specified. The bill requires a correctional clinic to apply to the Board for a license and requires the Board to make a thorough investigation of whether the premises qualifies for licensure.

Governor Brown signed AB 1812 on June 27, 2018 (Chapter 36, Statutes of 2018), the bill took effect immediately upon the governor's signature.

AB 2086 (Gallagher), as amended August 14, 2018, is a Board-sponsored bill that adds section 11165.6 to the Health and Safety Code to allow prescribers of controlled substances to review a list of patients for whom they are listed as being the prescriber in the CURES database. According to the author, AB 2086 will help identify and prevent

fraudulent prescriptions of controlled substances by allowing prescribers to request and verify a list of patients for whom they are listed as being the prescriber in the CURES database. The Board voted to support the bill in its May meeting.

Governor Brown signed AB 2086 on September 6, 2018 (Chapter 274, Statutes of 2018).

AB 1953 (Wood), as amended August 21, 2018, adds section 128734 to the Health and Safety Code to expand the disclosure requirements that applicants for a skilled nursing facility license must make to the Department of Public Health. New section 128734 requires an organization that owns or operates a skilled nursing facility to report whether the licensee, a general partner, or director has an ownership or control interest of 5% or more in a related party that provides any service to the skilled nursing facility. Any organization with such an interest must disclose all services provided to the skilled nursing facility, the number of individuals intended to provide that service, and other information requested by the Department of Public Health.

According to the author, the majority of skilled nursing facilities in California are operated by large companies, which are increasingly outsourcing services to companies in which they have a financial interest or control. The author notes an analysis that reveals that nursing homes that outsource to related parties tend to have significant shortcomings, such as fewer nurses and aides per patient, higher rates of patient injuries and unsafe practices, and are subject to complaints almost twice as often as independent homes. At its May meeting, the Board voted to support the bill if amended to require a similar disclosure by anyone applying for a pharmacy license.

Governor Brown signed AB 1953 on September 14, 2018 (Chapter 383, Statutes of 2018).

SB 212 (Jackson), as amended August 27, 2018, adds Chapter 2 to Part 3 of Division 30 of the Public Resources Code, relating to solid waste. Of interest, the bill requires entities that sell drugs or sharps in the state to individually, or with other entities, develop and implement a state-wide stewardship program for the collection and proper disposal of drugs and sharps. The bill is a response to the growing problem of pharmaceutical contamination in the environment. According to the author, the bill establishes an industry-run and funded program, overseen by the state that will ensure convenient locations for Californians to safely dispose of their unused prescriptions and other medical waste. The author says this is an important step to getting unused and discarded medical products out of our public spaces, municipal waste systems, and our environment.

Governor Brown signed SB 212 on September 30, 2018 (Chapter 1004, Statutes of 2018).

Legislative Bills that Died

The following bills reported in Volume 23, No. 2 (Spring 2018) died in committee or otherwise failed to be enacted during 2018: AB 1752 (Low), a BOP-sponsored bill, which would have added Schedule V drugs to the CURES database, and SB 1264 (Stone), which would have required Medi-Cal to provide coverage for hypertension medication management services provided by a pharmacist.

LITIGATION

♦ ***Pharmaceutical Research & Mfg. of Am. v. Brown.*** On August 30, 2018, in *Pharmaceutical Research and Manufacturers of America v. Brown,* No. 2:17-cv-02573-MCE-KJN, U.S. District Judge Morrison C. England of the Eastern District of California ruled on PhRMA's December 2017 challenge to the constitutionality of SB 17 (Hernandez) (Chapter 603, Statutes of 2017). SB 17 attempts to provide transparency in regard to prescription drug pricing, including requiring drug manufacturers to provide advance information on and a justification for prescription drug price increases. In addition, SB 17 requires health plans to annually report to DMHC information regarding the 25 most frequently prescribed drugs, costliest drugs, and highest year-over-year increase in total annual spending. Starting January 1, 2019, DMHC must compile the information into a report which it must submit to the legislature and post on its website.

In his August 30 ruling, Judge England dismissed the complaint in its entirety, but granted PhRMA leave to file an amended complaint within thirty (30) days following August 30, 2018. Judge England dismissed the Governor as a party to the action because he is immune from suit and the complaint failed to allege facts sufficient to apply an exception. The court also dismissed PhRMA's complaint in its entirety for lack of standing.

On September 28, 2018, PhRMA submitted its first amended complaint. PhRMA alleges that SB 17 is unconstitutional in that it compels them to speak about potential price increases when they would prefer not to communicate that information at all (thus violating these corporations' asserted first amendment rights); additionally, plaintiff alleges that the bill interferes with interstate commerce. In its prayer for relief, PhRMA seeks an injunction

to prevent California from implementing and enforcing SB 17, and a declaration that the statute is unconstitutional. At this writing, a hearing on Defendant Robert P. David's motion to dismiss the case is set for December 13, 2018; David is the Director of the California Office of Statewide Health Planning and Development.

RECENT MEETINGS

At its May meeting, the Board elected Victor Law as president and Greg Lippe as vice president, and re-elected Allen Schaad as treasurer of the Board. Dr. Amy Gutierrez thanked the board members for their support during her term as president of the Board.

At the Board's July meeting, Executive Officer Virginia Herold updated the Board about billboards that will be used to raise awareness about drug abuse prevention. Ms. Herold reported that Board Member Ryan Brooks' firm, Outfront Media, has agreed to donate five billboards for the project—two in Northern California, one in Central California, and two in Southern California. The Communication and Public Education Committee is also revamping the drug abuse prevention page on the Board's website to include updated resources for drug abuse information and treatment, and an embedded video of the board's public service announcement about prescription drug abuse.