SENATE COMMITTEE ON
BUSINESS, PROFESSIONS AND ECONOMIC DEVELOPMENT
Senator Richard Roth, Chair
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Consultant:	Dana Shaker		

Subject: Pharmacy

SUMMARY: Makes various changes to the Pharmacy Law intended to improve oversight of the pharmacy profession stemming from the joint sunset review oversight of the Board of Pharmacy (Board).

Existing law:

1) Establishes the Pharmacy Law. (Business and Professions Code (BPC) §§ 4000 *et seq*.)

2) Establishes the Board to administer and enforce the Pharmacy Law, comprised of seven pharmacists and six public members, and provides that the statute establishing the Board shall be repealed on January 1, 2022. (BPC § 4002)

3) Provides that protection of the public shall be the highest priority for the Board in exercising its licensing, regulatory, and disciplinary functions. (BPC § 4001.1)

4) Provides that the Board's executive officer may or may not be a member of the Board. (BPC § 4003)

5) Authorizes the Board to adopt rules and regulations as may be necessary for the protection of the public. (BPC § 4005)

6) Authorizes the Board to employ legal counsel and inspectors of pharmacy. (BPC § 4008)

7) Defines "pharmacy" as an area, place, or premises licensed by the Board in which the profession of pharmacy is practiced and where prescriptions are compounded. (BPC § 4037)

8) Declares pharmacy practice to be "a dynamic, patient-oriented health service that applies a scientific body of knowledge to improve and promote patient health by means of appropriate drug use, drug-related therapy, and communication for clinical and consultative purposes" and that "pharmacy practice is continually evolving to include more sophisticated and comprehensive patient care activities." (BPC § 4050)

9) Authorizes a pharmacist to do all of the following, among other permissible activities, as part of their scope of practice (BPC § 4052):

a) Provide consultation, training, and education to patients about drug therapy, disease management, and disease prevention.

b) Provide professional information, including clinical or pharmacological information, advice, or consultation to other health care professionals, and participate in multidisciplinary review of patient progress, including appropriate access to medical records.

c) Order and interpret tests for the purpose of monitoring and managing the efficacy and toxicity of drug therapies in coordination with the patient's primary care provider or diagnosing prescriber.

d) Administer immunizations pursuant to a protocol with a prescriber.

e) Furnish emergency contraception drug therapy, self-administered hormonal contraceptives, naloxone hydrochloride, HIV preexposure and postexposure prophylaxis, and nicotine replacement products, under certain conditions.

f) Administer drugs and biological products that have been ordered by a prescriber.

10) Imposes a maximum penalty of $2,000 for any person who knowingly violates any of the provisions of the Pharmacy Law, when no other penalty is provided, and in all other instances where a person violates the Pharmacy Law, imposes a maximum penalty of 1,000. (BPC § 4321)

11) Imposes a maximum penalty of $5,000 for any person who attempts to secure or secures licensure by making or causing to be made any false representations, or who fraudulently represents themselves to be registered. (BPC § 4322)

12) Imposes a maximum penalty of $5,000 for any person or entity who violates provisions of the Pharmacy Law governing outsourcing facilities. (BPC § 4129.5)

13) Authorizes a pharmacist to seek recognition as an advanced practice pharmacist if they meet certain education and training requirements. (BPC § 4210)

14) Requires a pharmacist to complete 30 hours of approved courses of continuing pharmacy education every two years in order to have their license renewed. (BPC § 4231)

15) Defines an "automated drug delivery system" (ADDS) as a mechanical system that performs operations or activities, other than compounding or administration, relative to the storage, dispensing, or distribution of drugs. (BPC § 4053.2)

16) Defines an "automated unit dose system" (AUDS) as an ADDS for storage and retrieval of unit doses of drugs for administration to patients by persons authorized to perform these functions. (BPC § 4017.3)

17) Allows for an ADDS to be placed and operated inside an enclosed building, with a premises address, at one of several enumerated locations that may be approved by the Board. (BPC § 4427.3)

18) Limits the authority for most licensing boards within the Department of Consumer Affairs (DCA) to deny a new license application to cases where the applicant was formally convicted of a substantially related crime or subjected to formal discipline by a licensing board, with offenses older than seven years no longer eligible for license denial. (BPC § 480)

This bill:

1) Extends the Board's operations until January 1, 2026.

2) Provides that each appointing authority has power to remove from office at any time any member of the Board appointed by that authority.

3) Requires that one of the professional members of the Board be a representative of compounding pharmacy specializing in human drug preparations.

4) Expressly authorizes the Board to meet by teleconference.

5) Prohibits the Board's executive officer from being a member of the Board.

6) Requires the Board to employ its own legal counsel.

7) Provides that an outsourcing facility licensed by the Board that dispenses patient-specific compounded preparations pursuant to a prescription for an individual patient shall not be required to be licensed as a pharmacy.

8) Authorizes the Board to waive the home state licensure requirement for a nonresident third-party logistics provider (3PL) if the Board inspects the location and finds it to be in compliance with the Pharmacy Law or accredited by the Drug Distributor Accreditation program of the National Association of Boards of Pharmacy.

9) Allows the Board to deny an application for licensure if the applicant has been convicted of a crime or subjected to formal discipline that would be grounds for denial of a federal registration to distribute controlled substances.

10) Provides that for purposes of meeting the requirements to become an advanced practice pharmacist, if, as a condition of completion of one of the required criteria fulfillment of a second criterion is also required, that completion shall be deemed to satisfy the requirements.

11) Requires pharmacists who prescribes a Schedule II controlled substance to have completed an education course on the risks of addiction associated with the use of Schedule II drugs.

12) Requires the Board to convene a workgroup of interested stakeholders to discuss whether moving to a standard of care enforcement model would be feasible and appropriate for the regulation of pharmacy and make recommendations to the Legislature.

13) Authorizes the Board to bring an action for specified civil penalties for repeated violations of the Pharmacy Law by pharmacies operating under common ownership or management.

14) Authorizes the Board to bring an action against a pharmacy for civil penalties for violations of the Pharmacy Law, as specified.

15) Allows for an AUDS to be placed in additional locations, including a facility licensed by the state with the statutory authority to provide pharmaceutical services and a jail, youth detention facility, or other correctional facility where drugs are administered under the authority of the medical director.

16) Authorizes a pharmacist to initiate, adjust, or discontinue drug therapy for a patient under a collaborative practice agreement with any health care provider with prescriptive authority and to provide nonopioid medication-assisted treatment pursuant to a state protocol.

17) Makes clarifying and technical changes.

FISCAL EFFECT: According to the Assembly Appropriations Committee, the cost of this bill would be as follows:

1) $120,000 for additional administrative staff to convene a workgroup, update forms and applications to reflect changes in various licensing programs and to develop educational materials and regulations, should the Board determine regulations are necessary (Pharmacy Board Contingent Fund).

2) This bill requires the Board to hire its own counsel. The Board's counsel would likely replace the services or augment the legal services the Board currently receives through the Department of Consumer Affairs. The Board anticipates that this may require some level of additional support staff, imposing additional administrative cost of an unknown amount that may be offset by reduced cost for centralized legal services.

3) Minor and absorbable costs for the creation of new enforcement codes in the Board's information technology system.
4) Unknown, potentially significant, enforcement costs and penalty revenue, depending on violations and the Board's use of its enforcement discretion.

COMMENTS:

1. **Purpose and Background.** This bill was introduced by the Assembly Business and Professions Committee and is one of a number of sunset bills the Author is advancing this year. According to the Author, this bill is necessary to make changes to the Pharmacy Act and Pharmacy operations in order to improve oversight of oversight of pharmacy professionals.

   The Sunset Review Process. The sunset review process provides a formal mechanism for the DCA; the Legislature; the regulatory boards, bureaus and committees; interested parties; and stakeholders to make recommendations for

improvements to the authority of consumer protection boards and bureaus. This is performed on a standard four-year cycle and was mandated by SB 2036 (McCorquodale), Chapter 908, Statutes of 1994. Each eligible agency is required to submit to the Committees a report covering the entire period since last reviewed that includes, among other things, the purpose and necessity of the agency and any recommendations of the agency for changes or reorganization in order to better fulfill its purpose. During the sunset review hearings, the Committees take public testimony and evaluate the eligible agency prior to the date the agency is scheduled to be repealed. An eligible agency is allowed to sunset unless the Legislature enacts a law to extend, consolidate, or reorganize the eligible agency. The sunset bills are intended to implement legislative changes recommended in the respective background reports drafted by the Committees for the entities reviewed.

Oversight Hearings and Sunset Review of Licensing Boards and Programs. Beginning in 2020, the Senate Business and Professions Committee and the Assembly Business and Professions Committee (Committees) began their comprehensive sunset review oversight of 16 regulatory entities including The Board of Behavioral Sciences, Bureau of Real Estate Appraisers , The California Massage Therapy Council, The Physician Assistant Board, The Board of Podiatric Medicine, The Board of Pharmacy, The Board of Psychology, The Veterinary Medical Board, The Bureau for Private Postsecondary Education, DRE, The Board of Vocational Nursing & Psychiatric Technicians, The Medical Board of California, The Osteopathic Medical Board of California, The Board of Registered Nursing, The Board of Optometry, and The Board of Barbering & Cosmetology.

The Committees conducted several oversight hearings in November 2020 and March/April 2021. This bill and the accompanying sunset bills are intended to implement legislative changes as recommended by staff of the Committees and which are reflected in the Background Papers prepared by Committee staff for each agency and program reviewed this year.

Background on the Board. The California State Board of Pharmacy traces its origins back to 1891, when Senate Bill 84 (Maher) was enacted “to regulate the practice of pharmacy and sale of poisons in the State of California.”2 Early statute provided the Board with largely the same powers and duties as it has today. Within its first six years of operation, the Board is reported to have registered a total of 1,063 pharmacists and 369 pharmacist assistants.

Over a hundred years later, the Board now regulates over 47,000 pharmacists, 550 advanced practice pharmacists, 6,500 intern pharmacists, and 70,000 pharmacy technicians across a total of 32 licensing programs. As one of approximately three dozen boards and bureaus under the Department of Consumer Affairs, the Board plays an important role in the regulatory ecosystem that oversees the healing arts. In the face of persistent concerns such as the ongoing opioid crisis, the Board is empowered to ensure that dangerous drugs and controlled substances are dispensed and furnished only under lawful circumstances.

Entrusted with administering and enforcing the state’s Pharmacy Law, statute provides that “protection of the public shall be the highest priority for the California State Board of Pharmacy in exercising its licensing, regulatory, and disciplinary

functions. Whenever the protection of the public is inconsistent with other interests sought to be promoted, the protection of the public shall be paramount.

2. **Review of the Board.** The following are some of the issues pertaining to the Board along with background information concerning the particular issue. Recommendations were made by Committee staff regarding the particular issue areas which needed to be addressed.

   a) *Issue #1: Minor Changes to Licensing Language.* The Staff Background Paper asks whether current membership on the Board appropriately balance professional expertise and public objectivity. Statute prescribes the composition of the Board, which includes both licensed pharmacists (professional members) and individuals who are not licensees (public members). Statute provides for a total of thirteen board members. When all appointments to the Board have been made, there are a total of seven professional members and six public members, resulting in a slight majority of members as active license holders. In an effort to refine the statutory language, the Committees have amended the bill to state that the Governor shall appoint seven pharmacists who are licensees in good standing, rather than seven competent pharmacists.

   b) *Issue #2: Changes to Board Member Expertise.* The Staff Background Paper asks whether current law that requires the appointment of pharmacists representing specific practice settings provides enough expert perspectives on issues before the Board. Currently, there are both public and professional board members, as well as specification of who serves on the Board. Statute requires at least five of pharmacist appointees be actively engaged in the practice of pharmacy. The Board must also 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." Given the Committees requested the Board discuss whether it believes amending the Pharmacy Law to require the presence of additional professional perspectives on the Board would assist it in carrying out its public protection mission and discussions around compounding pharmacies, the bill requires at least one of the professional members to be a compounding pharmacist, thereby providing new meaningful expertise in Board decision-making.

   c) *Issue #3*: *Board Vacancies.* The Staff Background Paper asked what solutions might be considered to address the substantial member vacancy rates that have persisted on the Board. In recent years, the Board has experienced challenges in achieving a quorum at meetings, with an average of three vacancies existing on the Board. These vacancies have persisted in large part due to difficulty recruiting qualified appointees to serve on the Board. The time commitment involved has been identified as a large driver of this problem, with the Board currently holding as many as eight meetings in a year in addition to its committee meetings. Particularly for professional members, this means time away from paid practice and can present a substantial hardship. The Committees requested the Board should discuss what steps it has taken to incentivize board member participation and whether it believes teleconferencing or other solutions could help address the current vacancy rate. In response, the bill permits members to

meet via teleconference in accordance with Section 11123 of the Government Code.

d) *Issue #4: Executive Officer Eligibility.* The Staff Background Paper asked whether the statute be revised to ensure future Executive Officers remain sufficiently independent in their service to the Board. The Pharmacy Law currently states that the Executive Officer "may or may not be a member of the board as the board may determine." No Executive Officer has concurrently served as a board member in recent history, and such practice is either discouraged or prohibited for similar boards because of the potential for conflicts of interest and the diminishment of independence between Board staff and the voting members. The Committees asked the Board to inform the committees of whether it believes the qualifications for its Executive Officer should be revised to specify that they be neither a member of the board or a licensee, as is currently already the case. This bill strikes reference to board members serving as Executive Officer.

e) *Issue #5: Board Attorney*. The Staff Background Paper asked whether the Board has sufficient legal counsel. Business and Professions Code § 4008 expressly provides the Board with the authority to employ legal counsel. However, the Board does not currently have its own dedicated attorney. Legal representation in disciplinary prosecution is provided by the Attorney General's Licensing Section, and the Department of Consumer Affairs offers counsel as part of the centralized services it provides to boards, as needed to assist with rulemaking, address legal issues that arise, and support compliance with open meeting laws. Dedicated board counsel is, however, considered to provide substantial value when questions of law occur regularly enough to warrant the presence of attorney who specializes in a board's practice act, and may help improve the Board's rulemaking timelines. It is under this line of thinking that the Legislature has authorized the Board to appoint its own lawyer, and any reasons for that position remaining unfilled should be discussed before the committees. The Committees requested the Board to provide insight into how the Pharmacy Law may be amended to assist it in hiring its own dedicated counsel, and should speak to whether it believes it is currently receiving adequate expert advice from the Office of the Attorney General. In response, this bill would require the Board to hire its own dedicated attorney, as already permitted by statute.

f) *Issue #8: Fair Chance Licensing Act.* The Staff Background paper asked whether any statutory changes needed to enable the Board to better carry out the intent of Assembly Bill 2138 (Chiu/Low). AB 2138 was signed into law in 2018, making substantial reforms to the license application process for individuals with criminal records. Under AB 2138, an application may only be denied on the basis of prior misconduct if the applicant was formally convicted of a substantially related crime or was subject to formal discipline by a licensing board. Further, prior conviction and discipline histories are ineligible for disqualification of applications after seven years, with the exception of serious and registerable felonies, as well as financial crimes for certain boards. Among other provisions, the bill additionally requires each board to report data on license denials, publish its criteria on determining if a prior offense is substantially related to licensure, and provide denied applicants with information about how to appeal

the decision and how to request a copy of their conviction history. These provisions were scheduled to go into effect on July 1, 2020.

Because AB 2138 significantly modifies current practice for boards in their review of applications for licensure, it was presumed that its implementation would require changes to current regulations for every board impacted by the bill. Recently, the Board was in the process of finalizing its regulations to revise its denial criteria to incorporate the changes from the bill. The Board's sunset review background paper stated it is also likely that the Board has identified changes to the law that it believes may be advisable to better enable it to protect consumers from license applicants who pose a substantial risk to the public. This bill would authorize the Board to deny an application for licensure by an applicant whose prior criminal or disciplinary history would make them ineligible for a federal registration to distribute controlled substances.

g) *Issue #9: Third-Party Logistics Providers.* The Staff Background paper asked whether the Board should be authorized to conduct inspections of third-party logistics providers that are not fully licensed in their resident states to allow for operation within California. Federal law enacted in 2013 prohibits states from regulating third-party logistics providers, or 3PLs, as wholesalers. Because 3PLs are considered vital members of the supply chain that store, select, and ship prescription drugs, the Board pursued legislation in 2014 to establish licensure of 3PLs as a separate category of licensee. While other states have taken similar action in their jurisdictions, some states continue to regulate 3PLs as wholesalers. As a result, these entities are prohibited from doing business in California, because they are not appropriately licensed in their home state and therefore cannot be licensed in California. The Committees requested that the Board should further explain its proposal for modifying the licensure process of 3PLs that are not properly licensed in their home states, and provide the committees with any suggested language. In response, this bill allows the Board to inspect the business before licensure, similar to the process used for initial licensure of nonresident sterile compounding pharmacies. If the inspection confirms the business is in compliance with state and federal law, licensure as a 3PL in the home state will not be required. The Board does not believe that an annual inspection would be required. Instead, inspection would be limited to every four years or until such time as the resident state makes the necessary changes to its law.

h) *Issue #10: Advanced Practice Pharmacists.* The Staff Background Paper asked whether modifications to the minimum qualifications for licensure for Advanced Practice Pharmacists would enable these specialized licensees to further enhance access to care. In 2013, Senate Bill 493 (Hernandez, Chapter 469, Statutes of 2013) was signed into law, creating a new license type under the Board known as the Advanced Practice Pharmacist. This new class of highly educated and trained health care professionals is intended to further the role of pharmacists in providing direct patient care, and advanced practice pharmacists are authorized to perform additional procedures that are often unavailable in low-access parts of the state. To implement the bill, the Board adopted regulations setting training and certification requirements for advanced practice pharmacists, who are authorized to perform specific care functions for patients.

To date, fewer individuals have successfully applied to become advanced practice pharmacists than anticipated, and this may be due to unnecessarily complicated or onerous qualifications and overly limited independence in practice. The Committees requested that the Board provide an overview of its proposal and how it believes changes to law would increase the number of advanced practice pharmacists in the state. In response, the Board proposed language in this bill that would recast the requirements for licensure as an advanced practice pharmacist license so that completion of one requirement is subsumed within completion of another requirement. Further, this bill would provide that it be acceptable if certification is earned as part of the requirements for completion of a residency or completion of 1,500 hours of collaborative practice experience or a residency is completed that included the 1,500 hours of collaborative practice experience.

i) *Issue #12: Continuing Education for Opioids*. The Staff Background Paper asks whether pharmacists who prescribe Schedule II drugs pursuant to a collaborative practice agreement complete continuing education on the risks associated with opioid use. In October 2017, the White House declared the opioid crisis a public health emergency, formally recognizing what had long been understood to be a growing epidemic responsible for devastation in communities across the country. According to the Centers for Disease Control and Prevention, as many as 50,000 Americans died of an opioid overdose in 2016, representing a 28 percent increase over the previous year. Additionally, the number of Americans who died of an overdose of fentanyl and other opioids more than doubled during that time with nearly 20,000 deaths. These death rates compare to, and potentially exceed, those at the height of the AIDS epidemic. Partly in response to the opioid crisis, some boards that regulate health professionals authorized to prescribe serious painkillers now require continuing education courses in the risks associated with the use of Schedule II drugs. Currently, pharmacists can prescribe Schedule II drugs under limited circumstances pursuant to a Collaborative Practice Agreement. The Committees requested the Board discuss the advantages of requiring pharmacists who prescribe opioids through collaborative practice agreements to take CE on the associated risks. This bill would require that pharmacists who prescribe Schedule II opioids be required to complete similar continuing education related to the hazards of Schedule II opioid use.

j) *Issue # 13: Pharmacies Operating Under Common Ownership.* The Staff Background paper asked if the Board be better empowered to take enforcement action against the owners and operators of pharmacies under common ownership and control for system-wide violations of law. The Pharmacy Law holds each pharmacy and its pharmacist-in-charge responsible for operations at the individual site, even if that pharmacy is part of a larger chain. However, in many cases, administrative or disciplinary action at an individual store may be the result of policies set at a corporate level. Currently, the Board's remediation and sanctions against an individual pharmacy is arguably unfair and inadequate to address a system wide issue across a large multi-store chain. The Committee requested that the Board should further discuss its proposals for providing more meaningful repercussions for pharmacies under common ownership and control

to ensure that the Pharmacy Law is followed in all settings. This bill defines the party against whom the board could bring an action as a chain community pharmacy as defined in Section 4001, which means "75 or more stores in California under the same ownership." The bill proposes additional changes to this section outlined below under proposed amendments.

k) *Issue # 15: Standard of Care Model for Pharmacy Practice*. The Staff Background paper asked if the Board should begin moving toward more of a standard of care model for its disciplinary actions against licensees. A number of healing arts licensing boards are granted a substantial amount of flexibility in investigations when determining whether a licensee should be subject to discipline. Rather than enforcing strict adherence to codified practice requirements, boards may instead focus on the question of whether a licensee followed the "standard of care" and acted reasonably under the circumstances as a trained professional. It has been argued that a similar model should be enacted for the Board in regards to its actions against its licensees. The Board does currently employ 56 licensed pharmacists who assist with investigations as professional experts; therefore, it is arguable that something resembling the standard of care is already applied when the Board is determining whether an investigation should result in an action for discipline. The Committee requested the Board should discuss whether it believes a standard of care model would be appropriate and what steps it might take over the next few years to move toward that model. This bill would require the Board to convene a workgroup of interested stakeholders to discuss whether moving to a standard of care enforcement model would be feasible and appropriate for the regulation of pharmacy and make recommendations to the Legislature about the outcome of these discussions through a report submitted to the Legislature.

l) *Issue #18: Patient-Specific Outsourcing.* The Staff Background Paper asked under what conditions should a licensed outsourcing facility be allowed to fill patient-specific prescriptions. Since June of 2017, the Board has issued licenses to outsourcing facilities concurrently with applicable licensure by the federal Food and Drug Administration. Outsourcing facilities are authorized to compound sterile and nonsterile products in compliance with regulations issued by the Board and are subject to inspection wherever they are located, with inspections occurring prior to license issuance or renewal for facilities doing business within or into California. The Board has issued 31 outsourcings licenses and performed 77 inspections since implementing the program.

While outsourcing facilities receive significant oversight and have proven successful at providing compounding services, statute currently prohibits a licensed outsourcing facility from filling individual prescriptions for individual patients. It is worth considering whether easing or eliminating this prohibition may result in greater access to pharmacy services. If such a change were to be made, licensed outsourcing facilities providing patient-specific care should be provided the same obligations and corresponding responsibilities as traditional pharmacists, and the Board should ensure any additional safeguards are incorporated. This bill would allow licensed outsourcing facilities to fill patient-specific prescriptions.

m) *Issue #19: Collaborative Practice Agreements.* The Staff Background Paper asked whether the statute could be updated to expand the capacity of pharmacists to engage in expanded services pursuant to collaborative practice agreements. Current law authorizes pharmacists to enter into collaborative practice agreements with physicians to provide additional care to patients. These agreements are believed to take advantage of a pharmacist's knowledge, skills, and abilities as a means to reduce demands on health professionals and improve patient care. Existing law allows for pharmacists to engage in limited activities pursuant to a collaborative practice agreement.

Opportunities may exist to expand the use of the conditions under which pharmacists could operate under a collaborative practice agreement, as well as the conditions under which an advanced practice pharmacist could perform authorized duties. The Committee requested the Board should provide its recommendations for expanding the authority of pharmacists to engage in activities pursuant to a collaborative practice agreement. In response, the Board has made some recommendations for ways in which statute could be updated to allow for these expansions. This bill would authorize a pharmacist to initiate, adjust, or discontinue drug therapy for a patient under a collaborative practice agreement with any health care provider with prescriptive authority. The collaborative practice agreement would be allowed to be between a single or multiple pharmacists and a single or multiple health care providers with prescriptive authority.

n) *Issue #20: Medication-Assisted Treatments.* The Staff Background Paper sunset asked if pharmacists should be further authorized to directly dispense non-opioid medication assisted treatments (MAT) to increase access to care for patients with substance abuse disorders. Statute allows for pharmacists to furnish certain medications directly to a patient, including self-administered hormonal contraceptives, nicotine replacement products, and preexposure and postexposure prophylaxis. It has been suggested that similar authority be established for pharmacists to directly furnish non-opioid MAT to patients pursuant to a statewide protocol. MAT is the use of medications, in combination with counseling and behavioral therapies, to treat substance use disorders. MAT has proven successful in helping addicted patients enter recovery and are commonly used for the treatment of addiction to opioids. While some forms of MAT, such as buprenorphine, are themselves a type of opioid, other forms of MAT do not contain opioids. It may be appropriate to allow pharmacists to furnish these medications directly to patients as a way to help address the sustained opioid crisis. The Committee requested the Board should discuss any recommendations it has for authorizing pharmacists to directly furnish non-opioid MAT to patients. This bill would authorize a pharmacist to provide nonopioid medication-assisted treatment pursuant to a state protocol.

o) *Issue #22: Automated Drug Delivery Systems.* The Staff Background Paper asked whether statute should be revised to allow the placement of ADDS in additional locations. An ADDS is a mechanical system controlled remotely by a pharmacist that performs operations or activities relative to the storage, dispensing, or distribution of prepackaged dangerous drugs or devices. A specific type of ADDS is an Automated Unit Dose System (AUDS), used for

storage and retrieval of unit doses of drugs for administration to patients by health practitioners. The law requires that there be specific written policies and procedures to ensure safety, accuracy, accountability, security, patient confidentiality, and maintenances of the quality, potency and purity of drugs located at the clinic. Use of an ADDS is authorized only in specific locations, including certain types of clinics serving low-income Californians and fire departments under certain conditions. The Committee requested the Board to discuss its recommendations regarding the expansion of ADDS placements with the committees and share language for any proposals it may have. The Board has recommending amending existing statutes to expand authority for pharmacies to license and operate AUDS in additional settings to provide medication management services. This bill would authorize an AUDS to be located in addition settings including jails, correctional treatment centers, hospice facilities, psychiatric health facilities, and other locations.

p) *Issue #25: Technical Cleanup.* The Staff Background Paper asked whether there was the need for technical changes to the Business and Professions Code to add clarity and remove unnecessary language. As the pharmacy profession continues to evolve and new laws are enacted, many provisions of the Business and Professions Code relating to pharmacy become outmoded or superfluous. The Committee requested that the Board should work with the committees to enact any technical changes to the Business and Professions Code needed to add clarity and remove unnecessary language. This bill makes various technical and clarifying changes to the Pharmacy Law.

q) *Issue #26: Continued Regulation.* The Staff Background paper asked whether the licensing of pharmacy professionals be continued and be regulated by the California State Board of Pharmacy. The Committees recommended that the Board's current regulation of the pharmacy profession should be continued, to be reviewed again on a future date to be determined. This bill would extend the sunset date for the Board from January 1, 2022 to January 1, 2026.

3. **Arguments in Support.** The California Labor Federation (AFL-CIO) writes in support: "AB 1533 will establish a civil penalty enforcement scheme for pharmacies that repeatedly violate the law, with a graduated penalty scale depending on the number and frequency of violations. We believe that pharmacists should be allowed to use their professional judgement in making the best decision for their patients' health – not based on making a profit for their employer."

   The California Pharmacists Association writes in support: "CPhA is pleased with the direction of the Committee and their ability to address issues of importance to the practice of pharmacy. Pharmacists have long been considered one of the most highly-educated and underutilized healthcare providers in the state. This bill would recognize these qualifications by:

   - Authorizing any pharmacist to initiate, adjust or discontinue patient therapy under a collaborative practice agreement with any health care provider who has prescriptive authority. The CPA could be between single or multiple pharmacists with single or multiple health care providers.

- Authorizing pharmacists to provide non-opioid medication-assisted therapy (MAT) pursuant to a state protocol.

- Allowing advanced practice pharmacist licensure requirements to "double dip" (Complete two of the three requirements in the same setting)."

The California Board of Pharmacy writes in support: " As a consumer protection agency charged with protecting and promoting the health and safety of Californians, the Board appreciates the consideration of the Board, its efforts and policy considerations through the sunset review oversight process. Among the policy changes offered in this measure are important consumer protection provisions that will expand access to care for Californians, remove barriers to licensure, and provide additional enforcement tools for the Board."

SEIU California writes in support: "SEIU supports AB 1533(Low) because we believe the BOP must be able to fully protect their licensees and the patients' best interests by ensuring compliance with state law. The need for compliance is even important given the employment relationship to Pharmacists and the profit-driven nature of chain pharmacies. Given the mental stress and physical toll of COVID-19, we must take steps to ensure that healthcare workers can focus on their core functions of patient care."

The California Veterinary Medical Association (CVMA) writes in support: "The CVMA supports the continued existence of the BOP but feels strongly that the BOP would benefit from the presence of a compounding pharmacist. In that regard, several critical veterinary medications do not exist in FDA-approved form and thus may only be obtained through compounders. Notwithstanding that fundamental limitation, the CVMA is encountering significant—and increasingly frequent—issues with BOP enforcement of what it perceives to be existing compounding restrictions, as well as proposed new regulations relating to compounded medications for animals and veterinary practice. The CVMA is concerned that the BOP's activity is jeopardizing the availability of compounded medications that relieve animal suffering and save animal lives. Thus, the CVMA supports the addition of language into the California Pharmacy Act which mandates that one seat on the BOP be a compounding pharmacist. A compounding pharmacist will bring much needed expertise in this field to the BOP, thereby improving communication, understanding, and rule-making relating to animal drug compounding and veterinary use of compounded drugs.

The CVMA requests an amendment to proposed California Business and Professions Code Section 4052(a)(13) to clarify that pharmacists may initiate, adjust, or discontinue drug therapy only in collaborative practice agreements with *human* health care providers. We believe that the legislative intent behind this amendment was to address the human health care realm; however, as written, it would apply in the context of veterinary medicine, as well. Regardless of circumstance, the CVMA believes it would be imprudent to extend this authority to pharmacists who are filling prescriptions for animal patients. We are unaware of instances in which veterinary practices have collaborative practice agreements with pharmacies, but even if such agreements exist pharmacists are typically trained and familiar with human medicine and medications to a far greater extent than animal

medications. Vast anatomic and physiologic differences exist between animal species, resulting in drugs behaving differently between them. For this and other reasons, we are uncomfortable with pharmacists having authority and autonomy to initiate, adjust or discontinue drug therapy in animal patients. For purposes of consumer and animal protection, these decisions should be left to trained veterinarians in the context of a valid Veterinarian-Client-Patient Relationship."

The United Food and Commercial Workers Western States Council (UFCW) writes in support: "The fines proposed in the bill for the most stubborn, repeat, nation-spanning corporate actors who repeatedly and stubbornly violate life-saving and life-preserving health care laws are amply justified. Against any measure of reasonableness, these fines are not excessive for three companies who have repeatedly violated and, according to the BOP, are still violating important patient protections and who annually earn hundreds of millions to billions of dollars."

The United Nurses Associations of California/union of Health Care Professionals write in support: "AB 1533 would provide that pharmacists are expressly authorized to initiate, adjust and discontinue drug therapy under a collaborative practice agreement with a health care provider, as well as provide nonopioid medication assisted treatment pursuant to a state protocol. The bill also ensures that pharmacists prescribing Schedule II substances shall have completed appropriate education in the dangers of addiction. The bill also regulates the use of automated unit dose systems in pharmacies and correctional facilities.

AB 1533 would also ensure that outsourcing facilities that dispense patient-specific compounds will comply with regulations applicable to licensed pharmacies. In addition, the bill paves the way for the Board to explore the feasibility of a standard of care enforcement model.

The bill will also establish a civil penalty enforcement scheme for pharmacies that repeatedly violate the law, with a graduated penalty scale depending on the number and frequency of violations. This provision is generally sound policy but UNAC is concerned that care should be taken to ensure the penalties are not too onerous for small "mom and pop" pharmacies."

4. **Arguments in Opposition.** The California Retailers Association and the National Association of Chain Drug Stores write in opposition unless the bill is amended: "In this unprecedented time, our members and their pharmacy teams have risen to the challenge and provided millions of COVID-19 tests and vaccinations to patients throughout the country. CRA and NACDS share the Board of Pharmacy's goal to protect patients and are committed to serving Californians in their communities. While the expanded fine authority in AB 1533 is well-intentioned, it must be clarified to ensure our members can continue to operate and meet the demand for critical services.

5. **Proposed Amendments.** In response to stakeholder concerns and in an effort to address issues that have been raised about certain provisions of the bill, the Author has proposed amendments that would accomplish the following objectives.

- *Violations, Penalties, and Corrective Action.*
  - Clarifies the Board may bring an action for fines for repeated violations of materially similar provisions within 5 years by 3 or more pharmacies operating under common ownership or management within a chain community pharmacy, in the following way: A 3rd violation may be punished by a fine not exceeding $100,000 per violation; A 4th or subsequent violation can be punished by a fine not exceeding $250,000 per violation.
  - Permits the Board to bring an action against a chain community pharmacy operating under common ownership or management for fines not exceeding $250,000 for any violation demonstrated to be the result of a written policy or which was expressly encouraged by the common owner or manager.
  - Prohibits the Board from bringing an action for fines in a) i) above until at least 6 months have elapsed from the date the board determines the violation occurred, unless the violation that gave rise to the action resulted in actual harm to a consumer or serious potential harm to the public.
  - Permits any pharmacy, in an action brought by the Board under a), to establish a defense by either of the following:

    That the violation was contrary to a written policy that was communicated by the common owner or manager to all employees of the pharmacies where the violation occurred.

    That, within six months after the violation, the common owner or manager corrected all unlawful policies, communicated the change in policy or policies in writing to all pharmacies under its ownership or management, and provided proof of abatement of the violation to the board, so long as the violation did not result in actual harm to any consumer or serious potential harm to the public.
  - Permits the Board to consider, in determining the amount of the fine sought in an action above, to consider mitigating and aggregating factors, including but not limited to the good faith of the licensee, communication of written changes to unlawful policies, the gravity of the violation, the potential harm to patients, whether the violation affects the professional judgment or independence of pharmacists and pharmacy technicians, and the history of previous violations by the common owner or manager
  - Provides that fines in subdivision a) and b) will be imposed in accordance with BPC § 4313.

The amendments are currently drafted as follows:

~~SEC. 28. Section 4321.5 is added to the Business and Professions Code, to read:~~

SEC. 28*. Section 4317.5 is added to the Business and Professions Code, to read:*

~~4321.5.~~ *4317.5.* (a) The board may bring an action for ~~civil penalties~~ *fines* for repeated violations of ~~any of the~~ *materially similar* provisions of this

chapter *within five years* by ~~one~~ *three* or more pharmacies operating under common ownership or management within a chain community pharmacy, as follows:

~~(1) A second violation within one year may be punished by an administrative fine or civil penalty not to exceed one hundred thousand dollars ($100,000) per violation.~~

(1) A third violation ~~within five years~~ may be punished by an administrative fine ~~or civil penalty~~ not to exceed ~~two~~ *one* hundred fifty thousand dollars ~~($250,000)~~ *($100,000)* per violation.

(2) A fourth or subsequent violation ~~within five years~~ may be punished by an administrative fine ~~or penalty~~ not to exceed ~~one million~~ *two hundred fifty thousand* dollars ($1,000,000) *($250,000)* ~~per violation and shall also be subject to disgorgement of any proceeds or other consideration obtained as a result of the~~ violation.

(b) The board may bring an action against a *chain community* pharmacy operating under common ownership or management for ~~civil penalties~~ *fines* not to exceed ~~one million~~ *two hundred fifty thousand* dollars ($1,000,000) *($250,000)* for any violation of this chapter demonstrated to be the result of a *written* policy or which was ~~otherwise~~ *expressly* encouraged by the common owner or manager.

(c) The board shall not bring an action for fines pursuant to paragraph (1) of subdivision (a) until at least six months have elapsed from the date the board determines that a violation has occurred unless the violation giving rise to the action resulted in actual harm to any consumer or serious potential harm to the public.

(d) In an action brought by the board pursuant to subdivision (a), it shall be a defense for any pharmacy to establish either of the following:

(1) That the violation was contrary to a written policy that was communicated by the common owner or manager to all employees of the pharmacies where the violation occurred.

(2) That, within six months after the violation, the common owner or manager corrected all unlawful policies, communicated the change in policy or policies in writing to all pharmacies under its ownership or management, and provided proof of abatement of the violation to the board, so long as the violation did not result in actual harm to any consumer or serious potential harm to the public.

(e) In determining the amount of the fine sought in an action brought pursuant to this section, the board shall consider relevant mitigating and aggravating factors, including, but not limited to, the good faith of the

licensee, the communication of written changes to unlawful policies, the gravity of the violation, the potential harm to patients, whether the violation affects the professional judgment or independence of pharmacists and pharmacy technicians, and the history of previous violations by the common owner or manager.

(f) The authority granted by this section is in addition to the authority of the board to institute any other administrative, civil, or criminal action.

(g) For purposes of this section, "chain community pharmacy" shall have the same meaning as defined in Section 4001.

(h) The fines in subdivisions (a) and (b) shall be imposed in accordance with Section 4314.

- *Reporting Back to the Legislature.*
  - Require the Board to provide the Legislature with the following information:
    - The number of actions brought under this section.
    - The number of actions brought under this section that did not result in any fines.
    - The types of violations giving rise to actions brought under this section.

The amendments are currently drafted as follows (continuing from same section above):

SEC. 28. *Section 4317.5 is added to the Business and Professions Code, to read:*

(i) In connection with the board's first Joint Sunset Review Oversight Hearing pursuant to Section 9147.7 of the Government Code occurring after this section becomes operative, the board shall provide to the appropriate committees of the Legislature all of the following information:

(1) The number of actions brought pursuant to this section.
(2) The number of actions brought pursuant to this section that did not result in any fines.
(3) The types of violations giving rise to actions brought pursuant to this section.

SUPPORT AND OPPOSITION:

Support:

California Labor Federation, AFL-CIO
California Pharmacists Association

California State Board of Pharmacy
California State Council of Service Employees International Union (SEIU California)
California Veterinary Medical Association
United Food and Commercial Workers, Western States Council
United Nurses Associations of California/Union of Health Care Professionals

Opposition:

California Retailers Association
National Association of Chain Drug Stores

-- END --