
THIRD READING

Bill No: AB 1533
Author: Committee on Business and Professions
Amended: 9/3/21 in Senate
Vote: 21

SENATE BUS., PROF. & ECON. DEV. COMMITTEE: 12-0, 7/12/21
AYES: Roth, Melendez, Archuleta, Becker, Dodd, Eggman, Hurtado, Jones,
Leyva, Min, Newman, Pan
NO VOTE RECORDED: Bates, Ochoa Bogh

SENATE APPROPRIATIONS COMMITTEE: 5-2, 8/26/21
AYES: Portantino, Bradford, Kamlager, Laird, McGuire
NO VOTE RECORDED: Bates, Jones

ASSEMBLY FLOOR: 77-0, 6/1/21 - See last page for vote

SUBJECT: Pharmacy

SOURCE: Author

DIGEST: This bill 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).

Senate Floor Amendments of 9/3/21 make a number of changes, including: removing the requirement that the Board employ legal counsel; making changes to allow California to come into compliance with new federal memorandum of understanding requirements for interstate drug compounding; striking the requirement that the Board be allowed to hire its own attorney; providing a pathway for medication-assisted treatment at the state level, should it become federally authorized; removing chaptering conflicts with other measures; changing the penalty cap for when the Board may bring an action against a community pharmacy from \$250,000 to \$150,000 and; removing the word “intentional” from the violation type with respect to the now \$150,000 penalty cap.

ANALYSIS:

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comprised of seven pharmacists and six public members, and provides that the statute establishing the Board shall be repealed on January 1, 2022.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) Authorizes the Board to employ legal counsel and inspectors of pharmacy. (BPC § 4008)
- 5) 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.
- 6) 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)

- 7) 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)
- 8) 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)
- 9) Authorizes a pharmacist to seek recognition as an advanced practice pharmacist if they meet certain education and training requirements. (BPC § 4210)
- 10) 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)
- 11) 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)
- 12) 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)
- 13) 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)
- 14) 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 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.

Background

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. The sunset bills are intended to implement legislative changes recommended in the respective background reports drafted by the Senate Business, Professions and Economic Development Committee and the Assembly Business and Professions Committee (Committees) for the entities reviewed.

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 the Senate Business, Professions and Economic Development Committee staff regarding the particular issue areas which needed to be addressed.

- 1) *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. 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.” This bill requires at least one of the professional members to be a compounding pharmacist, thereby providing new meaningful expertise in Board decision-making.
- 2) *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 AB 2138 which made 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. 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 authorizes 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.

- 3) *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. 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.
- 4) *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. This bill recasts 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 provides 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.
- 5) *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. This bill requires that pharmacists who prescribe Schedule II opioids be required to complete similar continuing education related to the hazards of Schedule II opioid use.
- 6) *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. 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.” This bill authorizes the Board to bring an action for fines for repeated violations of materially similar provisions within five years by three or more pharmacies operating under common ownership or management within a chain community pharmacy. Specifically, a third and, or subsequent violation may be punished by an administrative fine not to exceed \$100,000 per violation and fines not to exceed \$250,000 for any intentional violation of Pharmacy Law demonstrated to be the result of a written policy or which was expressly encouraged by the common owner or manager. This bill also prohibits the Board from taking action for certain violations 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. This bill also specifies that in determining the amount of the fine sought in an action against a chain community pharmacy operating under common ownership, 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.

- 7) *Issue # 15: Standard of Care Model for Pharmacy Practice.* 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. This bill 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 about the outcome of these discussions through a report submitted to the Legislature.
- 8) *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. This bill allows licensed outsourcing facilities to fill patient-specific prescriptions.

- 9) *Issue #19: Collaborative Practice Agreements.* Existing law allows for pharmacists to engage in limited activities pursuant to a collaborative practice agreement. This bill 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. 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.
- 10) *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. This bill authorizes a pharmacist to provide nonopioid medication-assisted treatment pursuant to a state protocol.
- 11) *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. 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. This bill authorizes an AUDS to be located in addition settings including jails, correctional treatment centers, hospice facilities, psychiatric health facilities, and other locations.

FISCAL EFFECT: Appropriation: No Fiscal Com.: Yes Local: Yes

According to the Senate Appropriations Committee, this bill will result in ongoing annual costs of approximately \$31.15 million and 122.7 positions to support the continued operation of the Board's licensing and enforcement activity, as well as around \$123,000 to implement other provisions of this bill and unknown fiscal impact to the Board's revenues, which may be offset by the increased fine provisions.

SUPPORT: (Verified 9/3/21)

California Labor Federation, AFL-CIO
California Pharmacists Association
California State Board of Pharmacy
California Veterinary Medical Association
SEIU California
United Food and Commercial Workers, Western States Council

United Nurses Associations of California/Union of Health Care Professionals

OPPOSITION: (Verified 9/3/21)

California Retailers Association

National Association of Chain Drug Stores

ARGUMENTS IN SUPPORT: Supporters appreciate that this bill 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. Supporters note that pharmacists have long been considered one of the most highly-educated and underutilized healthcare providers in the state and this bill recognizes these qualifications.

ARGUMENTS IN OPPOSITION: The California Retailers Association and the National Association of Chain Drug Stores write in opposition unless this 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.”

ASSEMBLY FLOOR: 77-0, 6/1/21

AYES: Aguiar-Curry, Arambula, Bauer-Kahan, Bennett, Berman, Bigelow, Bloom, Boerner Horvath, Bryan, Burke, Calderon, Carrillo, Cervantes, Chau, Chiu, Choi, Cooley, Cooper, Cunningham, Megan Dahle, Daly, Davies, Flora, Fong, Frazier, Friedman, Gabriel, Gallagher, Cristina Garcia, Eduardo Garcia, Gipson, Lorena Gonzalez, Gray, Grayson, Holden, Irwin, Jones-Sawyer, Kalra, Kiley, Lackey, Lee, Levine, Low, Maienschein, Mathis, Mayes, McCarty, Medina, Mullin, Muratsuchi, Nazarian, Nguyen, O'Donnell, Petrie-Norris, Quirk, Quirk-Silva, Ramos, Reyes, Luz Rivas, Robert Rivas, Rodriguez, Blanca Rubio, Salas, Santiago, Seyarto, Smith, Stone, Ting, Valladares, Villapudua, Voepel, Waldron, Ward, Akilah Weber, Wicks, Wood, Rendon

NO VOTE RECORDED: Chen, Patterson

Prepared by: Dana Shaker / B., P. & E.D. /
9/7/21 16:48:36

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