

## ASSEMBLY THIRD READING

AB 1533 (Committee on Business and Professions)

As Amended April 19, 2021

Majority vote

**SUMMARY**

Extends the sunset date for the California State Board of Pharmacy (Board) until January 1, 2026, and makes additional technical changes, statutory improvements, and policy reforms in response to issues raised during the Board's sunset review oversight process.

**Major Provisions**

- 1) Extends the sunset date for the Board from January 1, 2022, to 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 demonstrated to be the result of a policy or which was otherwise encouraged by a common owner or manager.
- 15) Allows for an automated unit dose system (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.

## COMMENTS

*Sunset review.* In order to ensure that California's myriad professional boards and bureaus are meeting the state's public protection priorities, authorizing statutes for these regulatory bodies are subject to statutory dates of repeal, at which point the entity "sunset" unless the date is extended by the Legislature. The sunset process provides a regular forum for discussion around the successes and challenges of various programs and the consideration of proposed changes to laws governing the regulation of professionals.

Currently, the sunset review process applies to 36 different boards and bureaus under the Department of Consumer Affairs, as well as the Department of Real Estate and three nongovernmental nonprofit councils. On a schedule averaging every four years, each entity is required to present a report to the Legislature's policy committees, which in return prepare a comprehensive background paper on the efficacies and efficiencies of their licensing and enforcement programs. Both the Administration and regulated professional stakeholders actively engage in this process. Legislation is then subsequently introduced extending the repeal date for the entity along with any reforms identified during the sunset review process.

*California State Board of Pharmacy.* The Board 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. 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.

*Board Member Expertise.* Issue #2 in the Board's sunset review background paper asked whether existing law requiring the appointment of pharmacists representing specific practice settings provide sufficient expert perspectives on matters coming before the Board. In addition to requiring both professional and public members, there is further specificity regarding 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."

Notwithstanding these requirements, there are a number of perspectives that are currently not required to be reflected on the Board. One such category of professional expertise is in the area of pharmacy compounding. This area of practice has recently drawn national attention for both its importance and complexity, and the Board recently put forth a number of regulations regarding pharmacy compounding. While the Board does feature some expertise in this area there has not been a compounding pharmacist specifically represented on the Board. By amending the law to require at least one of the professional members to be a compounding pharmacist, this bill intends to provide new meaningful expertise in Board decision-making.

*Board Attorney.* Issue #5 in the Board's sunset review 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. This bill would require the Board to hire its own dedicated attorney, as already permitted by statute.

*Fair Chance Licensing Act.* Issue #8 in the Board's sunset review background paper asked whether any statutory changes needed to enable the Board to better carry out the intent of AB 2138 (Chiu), Chapter 995, Statutes of 2018. 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. 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.

*Advanced Practice Pharmacists.* Issue #10 in the Board's sunset review 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 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 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 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.

*Continuing Education for Opioids.* Issue #12 in the Board's sunset review background paper asked whether pharmacists who prescribe Schedule II drugs pursuant to a collaborative practice agreement complete continuing education on the risks associated with opioid use. 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. 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.

*Pharmacies Operating Under Common Ownership.* Issue #13 in the Board's sunset review background paper asked whether the Board should 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 Board has stated that it believes it may be appropriate to put into law some threshold evidence of a system-wide pharmacy failure that would allow additional enforcement tools to be used. There have long been accusations of major chain-store pharmacies engaging in misconduct (for example, pushing pharmacists to meet certain output metrics for pharmacy sales that may supersede their professional judgement), but violations are technically only attributable to individual sites. The Board has asked whether there should be some additional ability for the Board to take action against entire chains for systemic violations of the law. This bill would authorize the Board to bring an action for increased civil penalties for repeated violations of any of the Pharmacy Law by one or more pharmacies operating under common ownership or management. Additionally, this bill would authorize the Board to bring an action against a pharmacy operating under common ownership or management for civil penalties not to exceed one million dollars for any violation of this chapter demonstrated to be the result of a policy or which was otherwise encouraged by the common owner or manager.

*Standard of Care Model for Pharmacy Practice.* Issue #15 in the Board's sunset review background paper asked whether the Board begin moving toward more of a standard of care model for its disciplinary actions against licensees. Rather than enforcing strict adherence to codified practice requirements, many 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 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.

*Continued Regulation.* Issue #26 in the Board's sunset review 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 to January 1, 2026.

**According to the Author**

"This bill is the sunset review vehicle for the California State Board of Pharmacy, authored by the Assembly Business and Professions Committee. The bill extends the sunset date for the Board and enacts technical changes, statutory improvements, and policy reforms in response to issues raised during the Board's sunset review oversight process."

**Arguments in Support**

The *United Food and Commercial Workers Western States Council* (UFCW) writes that it supports this bill, "especially the long over-due increase in fines available to the Board of Pharmacy to motivate compliance with current law from some of the world's largest publicly-traded corporations – the maximum fine available to the BOP now is embarrassing: less than half the ceiling for small claims court or \$5,000. 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."

**Arguments in Opposition**

The *California Retailers Association* (CRA) opposes this bill unless amended. The CRA writes: "CRA and NACDS members are supportive of extending the sunset of the Board of Pharmacy, as well as the Board's mission to protect patient safety. We also appreciate the Board's enforcement authority, including its authority to cite and fine pharmacies for pharmacy law violations. While we understand the Committee's objective to ensure penalties are meaningful deterrents for violations, the Board's existing cite and fine authority currently achieves this goal. Our members take every violation and fine seriously and take efforts to avoid similar fines in other stores. Fines at the individual pharmacy level do add up and have a considerable financial impact on our members."

**FISCAL COMMENTS**

According to the Assembly Appropriations Committee:

- 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.

**VOTES**

**ASM BUSINESS AND PROFESSIONS: 18-0-1**

**YES:** Low, Flora, Arambula, Berman, Bloom, Chiu, Cunningham, Megan Dahle, Fong, Gipson, Grayson, Holden, Irwin, McCarty, Medina, Mullin, Salas, Ting

**ABS, ABST OR NV:** Chen

**ASM APPROPRIATIONS: 16-0-0**

**YES:** Lorena Gonzalez, Bigelow, Calderon, Carrillo, Chau, Megan Dahle, Davies, Fong, Gabriel, Eduardo Garcia, Levine, Quirk, Robert Rivas, Akilah Weber, Holden, Luz Rivas

**UPDATED**

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CONSULTANT: Robert Sumner / B. & P. / (916) 319-3301

FN: 0000416