

CONCURRENCE IN SENATE AMENDMENTS
AB 1533 (Committee on Business and Professions)
As Amended September 3, 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.

Senate Amendments

- 1) Strike provisions in the bill that would have required the Board to employ legal counsel.
- 2) Expand the authority of a pharmacist to provide any medication-assisted treatment as long as the treatment is authorized by federal law.
- 3) Adds technical language to facilitate the Board's implementation of the memorandum of understanding (MOU) newly required by the federal Food and Drug Administration (FDA) for the interstate distribution of compounded human drug preparations.
- 4) Narrow the penalties that may be sought by the Board in actions against chain community pharmacies operating under common ownership to a maximum of \$100,000 for three or more repeated violations, or a maximum of \$150,000 for violations demonstrated to be the result of a written policy or which was expressly encouraged by the common owner or manager.
- 5) Provide pharmacies with up to six months to correct all unlawful policies, communicate the change in policy or policies in writing to all pharmacies under its ownership or management, and provide proof of abatement of the violation to the Board prior to being subject to the increased fines for violations that did not result in actual harm to any consumer or serious potential harm to the public.
- 6) Direct the Board to consider relevant mitigating and aggravating factors when seeking an increased fine against a pharmacy operating under common ownership or management.
- 7) Require the Board to report on information relating to actions brought against pharmacies operating under common ownership or management during its next sunset review.

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 "sunsets" 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.

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 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 reflect 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.

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 and Low), 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 chain community 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 \$150,000 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* continues to oppose this bill unless amended to further reduce the fines that may be sought by the Board against pharmacies operating under common ownership, stating that "we appreciate the August 26 amendments that reduce the maximum fine to \$100,000 for a third violation, but increasing the fine from \$5,000 to \$100,000 is still an unprecedented increase that could result in pharmacy closures, reducing access to critical pharmacy services throughout the state. 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 Senate Committee on Appropriations, annual cost of \$118,000 to for the Board to complete workgroup requirements, update forms and applications to reflect changes in various licensing programs, and develop educational materials and regulations as the Board determines is necessary; unknown fiscal impact to the Board's revenues, which may be offset by the increased fine provisions; and information technology cost of approximately \$5,000 to the Office of Information services to create new enforcement codes, which may be absorbable through the redirection of existing maintenance resources.

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

ASSEMBLY FLOOR: 77-0-2

YES: 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

ABS, ABST OR NV: Chen, Patterson

SENATE FLOOR: 38-0-2

YES: Allen, Archuleta, Atkins, Bates, Becker, Borgeas, Bradford, Caballero, Cortese, Dahle, Dodd, Durazo, Glazer, Gonzalez, Grove, Hertzberg, Hueso, Hurtado, Jones, Kamlager, Laird, Leyva, Limón, McGuire, Melendez, Min, Newman, Nielsen, Ochoa Bogh, Pan, Portantino, Roth, Rubio, Skinner, Umberg, Wieckowski, Wiener, Wilk

ABS, ABST OR NV: Eggman, Stern

UPDATED

VERSION: September 3, 2021

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

FN: 0001972