Date of Hearing: April 27, 2021

ASSEMBLY COMMITTEE ON BUSINESS AND PROFESSIONS
Evan Low, Chair
AB 1533 (Committee on Business and Professions) – As Amended April 19, 2021

SUBJECT: Pharmacy.

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.

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comprised of seven pharmacists and six public members, and provides that the statute establishing the Board shall be repealed on January 1, 2022.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:

   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.

(BPC § 4052)

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 under 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 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 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.

FISCAL EFFECT: Unknown; this bill is keyed fiscal by the Legislative Counsel.

COMMENTS:

Purpose. 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.

Background.

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.

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. Whenever the protection of the public is inconsistent with other interests sought to be promoted, the protection of the public shall be paramount." The Pharmacy Law provides that the Board consists of thirteen members, seven of which are licensees of the Board and six of which are unlicensed members of the public.

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.

Board Vacancies. Issue #3 in the Board's sunset review background paper asked what 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 participated 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.

One potential solution to these recruitment issues is increasing the availability of teleconferencing when possible to allow Board members to participate remotely. The Board already holds some meetings via teleconference, and the format has been adopted by other boards. Increasing its use could potentially increase the range of available applicants. This bill would expressly provide that the Board may meet via teleconference to the extent permitted by the Bagley-Keene Open Meetings Act.

Executive Officer Eligibility. Issue #4 in the Board's sunset review background paper asked whether 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. This bill strikes reference to board members serving as Executive Officer.

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.

Further, the Attorney General's Office has recently transferred both deputy attorneys general who previously advised the Board. Particularly as the Attorney General's billing rate has increased substantially, these may each be factors in costlier and lengthier enforcement activities by the Board. 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 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 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.

Third-Party Logistics Providers. Issue #9 in the Board's sunset review background paper asked whether the Board should be authorized to conduct inspections of 3PLs that are not fully licensed in their resident states to allow for operation within California. Federal law enacted in 2013 prohibits states from regulating 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.

To remedy the problem, the Board proposes to seek statutory authority to change the licensing requirements for such 3PLs. 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.

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. 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 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. 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. 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.

As an example of how it has sought to address this issue, the Board has pointed to how in response to a large number of store violations regarding patient consultations several years ago, the Board worked with local district attorneys to secure large penalties against certain pharmacy chains. However, this coordination is not always possible. In addition, the Board states that violations regarding patient consultations continue, despite citations issued by the Board and fines assessed by district attorneys.

Because the Board is limited to citing each pharmacy individually, making it difficult to address in an effective manner, violations resulting from corporate policy. In some settlements involving individual stores, the Board has stipulated that the ownership as a whole must address the issue; in such cases, however, the corporate owner must agree. This approach leaves unresolved the underlying challenge of regulating numerous entities under common ownership.

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 civil penalties for repeated violations of any of the Pharmacy Law by one or more pharmacies operating under common ownership or management, 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 per violation.

(2) A third violation within five years may be punished by an administrative fine or civil penalty not to exceed two hundred fifty thousand dollars per violation.

(3) A fourth or subsequent violation within five years may be punished by an administrative fine or penalty not to exceed one million dollars per violation and shall also be subject to disgorgement of any proceeds or other consideration obtained as a result of the violation.

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. 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. However, the Committees recommended that 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.

Patient-Specific Outsourcing. Issue #18 in the Board's sunset review 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.

Collaborative Practice Agreements. Issue #19 in the Board's sunset review background paper asked whether statute 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 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.

Medication-Assisted Treatment. Issue #10 in the Board's sunset review background paper asked whether 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. This bill would authorize a pharmacist to provide nonopioid medication-assisted treatment pursuant to a state protocol.

Automated Drug Delivery Systems. Issue #22 in the Board's sunset review 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 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.

Technical Cleanup. Issue #25 in the Board's sunset review background paper asked whether there was the need for technical changes to the Business and Professions Code to add clarity and remove unnecessary language. This bill makes various technical and clarifying changes to the Pharmacy Law.

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 from January 1, 2022 to January 1, 2026.

Current Related Legislation. AB 1064 (Fong) would expand the authority of a pharmacist to initiate and administer immunizations to include any vaccine approved or authorized by the United States Food and Drug Administration (FDA) for persons 3 years of age and older. *This bill is pending in the Assembly Committee on Business and Professions.*

SB 362 (Newman) would prohibit a community pharmacy from establishing a quota, subject to a fine not exceeding one million dollars and a 30-day suspension of the licenses of its pharmacies in the state for the first violation, and the revocation of the community pharmacy's licenses for a second violation. *This bill is pending in the Senate Committee on Appropriations.*

Prior Related Legislation. SB 1193 (Hill, Chapter 484, Statutes of 2016) extended the operation of the Board from January 1, 2017 to January 1, 2021.

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."

REGISTERED SUPPORT:

California Labor Federation
SEIU California
United Food and Commercial Workers Western States Council (UFCW)
United Nurses Association of California (UNAC)

REGISTERED OPPOSITION:

California Retailers Association

Analysis Prepared by: Robert Sumner / B. & P. / (916) 319-3301