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**AB-1533 Pharmacy.** (2021-2022)

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**Assembly Bill No. 1533**

**CHAPTER 629**

An act to amend Sections 4001, 4002, 4003, 4008, 4013, 4017.3, 4022.5, 4022.7, 4039, 4040, 4052, 4052.6, 4053, 4053.1, 4053.2, 4110, 4119.11, 4127.3, 4129, 4129.4, 4161, 4210, 4312, 4314, 4316, 4427.3, and 4427.7 of, to add Sections 4126.10, 4202.6, 4232.5, 4317.5, and 4427.65 to, and to add and repeal Section 4301.3 of, the Business and Professions Code, relating to healing arts.

[ Approved by Governor October 07, 2021. Filed with Secretary of State October 07, 2021. ]

**LEGISLATIVE COUNSEL'S DIGEST**

AB 1533, Committee on Business and Professions. Pharmacy.

(1) Existing law, the Pharmacy Law, provides for the licensure and regulation of the practice of pharmacy by the 13-member California State Board of Pharmacy, which is within the Department of Consumer Affairs. Existing law requires the Governor to appoint 7 competent pharmacists who reside in different parts of the state to serve as members of the board. Existing law requires the membership of the board to include at least one pharmacist representative from each of specified practice settings. Existing law authorizes the appointment of 6 public members, 4 of whom are appointed by the Governor, and the Senate Committee on Rules and the Speaker of the Assembly each appoint a public member, as prescribed. These provisions are repealed as of January 1, 2022.

Under other existing law with respect to the department and its constituent boards, an appointing authority has power to remove from office at any time any member of any board appointed by the appointing authority for continued neglect of duties required by law, or for incompetence, or unprofessional or dishonorable conduct.

This bill would require, in lieu of competence, that the Governor's pharmacist appointees to the board be licensees in good standing. The bill would specify that each appointing authority for the board has power to remove from office at any time any member of the board appointed by that authority for the reasons specified above. The bill, with regard to the practice settings represented on the board, would require at least one pharmacist representative from a compounding pharmacy specializing in human drug preparations. The bill would extend the repeal of those provisions to January 1, 2026.

Existing law requires the principal office of the board to be located in Sacramento and requires the board to hold a meeting at least once in every 4 months.

This bill would authorize members of the board to meet by teleconference, as prescribed.

Existing law, until January 1, 2022, authorizes the board, with the approval of the Director of Consumer Affairs, to appoint a person exempt from civil service to be designated as an executive officer and to exercise the powers and perform the duties delegated by the board and vested in them by existing law. Under existing law, the board determines whether the executive officer is a member of the board.

This bill would prohibit the executive officer from being a member of the board. The bill would extend the repeal of the board's executive officer provisions to January 1, 2026.

(2) Existing law generally authorizes a pharmacist to dispense or furnish drugs only pursuant to a valid prescription, except as provided, such as existing authority to initiate and administer COVID-19 vaccinations and initiate and furnish HIV prophylaxis, as specified.

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, as specified. The bill would authorize a pharmacist to provide medication-assisted treatment pursuant to a state protocol, to the extent authorized by federal law. Because a violation of these provisions would be a crime, the bill would impose a state-mandated local program.

Existing law authorizes a pharmacist recognized by the board as an advanced practice pharmacist to take certain actions, including initiating, adjusting, or discontinuing therapy in a specified manner.

This bill would authorize an advanced practice pharmacist to initiate, adjust, or discontinue drug therapy without specifying the manner of such actions.

(3) Existing law generally makes it unlawful for any person to manufacture, compound, furnish, sell, or dispense a dangerous drug or dangerous device, or to dispense or compound a prescription of a prescriber unless the person is a licensed pharmacist. Existing law authorizes the board to issue certain other licenses for activities relating to pharmacy, including a designated representative to provide sufficient and qualified supervision in a wholesaler or veterinary food-animal drug retailer, a designated representative-3PL to provide sufficient and qualified supervision of a third-party logistics provider's place of business, and a designated representative-reverse distributor to provide sufficient and qualified supervision over a licensed wholesaler that only acts as a reverse distributor. Existing law requires as a condition of licensure for each of these other licenses that the applicant be a high school graduate or possess a general education development certificate equivalent.

This bill, with regard to that education requirement, would alternatively permit the applicant to have earned a degree from an accredited postsecondary institution.

(4) Existing law authorizes a pharmacy to provide pharmacy services to specified licensed health facilities through the use of an automated drug delivery system (ADDS), as defined, owned and operated by the pharmacy that need not be located at the same location as the pharmacy. Existing law prohibits the installation or operation of an ADDS unless the ADDS meets prescribed requirements, including that an ADDS be placed and operated in one of prescribed locations inside an enclosed building, as approved by the board. Existing law also authorizes specified licensed health clinics, including nonprofit and free clinics, to use an ADDS, operated under the authorization of a pharmacist, and under which the clinic is responsible for the safety and security of the drugs in the system. Existing law requires a pharmacy holding an ADDS license to complete an annual self-assessment, performed pursuant to specified regulations, evaluating the pharmacy's compliance with pharmacy law relating to the use of the ADDS. Existing law 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. Existing law also provides a program to authorize a pharmacy located in the state to provide pharmacy services to the patients of covered entities, as defined, that are eligible for discount drug programs under federal law, as specified, through the use of an automated patient dispensing system (APDS), as defined. Existing law requires a pharmacy holding an APDS license to complete an annual self-assessment, performed pursuant to specified regulations, evaluating the pharmacy's compliance with pharmacy law relating to the use of the APDS.

This bill would authorize the location and operation of an AUDS in those locations authorized for an ADDS and, additionally, in a state-licensed facility with the statutory authority to provide pharmaceutical services or in a jail, youth detention facility, or other correctional facility where drugs are administered within the facility under the authority of the medical director. The bill would impose requirements for the operation of an AUDS. Because a violation of these provisions would be a crime, the bill would impose a state-mandated local program. The bill would remove the requirements that the ADDS and APDS license self-assessments be annual.

(5) Existing law requires a pharmacy that compounds sterile drug products to possess a sterile compounding pharmacy license, as provided. Existing law establishes procedures for the issuance of a cease and desist order to such a pharmacy that poses an immediate threat to the public health or safety. Those procedures authorize the owner to request a hearing to contest the order. Existing law requires such a hearing to be held no later than 5 days from the date the request of the owner is received by the board and requires the president of the board to render a written decision within 5 days of the hearing. Existing law establishes similar cease and desist order provisions for an outsourcing facility compounding sterile drug products or nonsterile drug products. Existing law also establishes similar cease and desist order provisions for unlicensed facilities.

This bill would modify those hearing and decision deadlines to be 5 business days.

(6) Existing law requires the board to license an outsourcing facility, as defined. Existing law requires an outsourcing facility to be licensed with the board before doing business within or into the state. Existing law prohibits an outsourcing facility from performing the duties of a pharmacy, such as filling individual prescriptions.

Under this bill, in lieu of that prohibition, an outsourcing facility licensed by the board dispensing patient-specific compounded preparations pursuant to a prescription for an individual patient would not be required to be licensed as a pharmacy, but would otherwise be required to comply with the same requirements of a pharmacy. Because a violation of these provisions would be a crime, the bill would impose a state-mandated local program.

(7) Existing law requires a person located outside this state that ships, sells, mails, warehouses, distributes, or delivers dangerous drugs or dangerous devices into this state or sells, brokers, warehouses, or distributes dangerous drugs or devices within this state to be considered a nonresident wholesaler or a nonresident third-party logistics provider and requires such a wholesaler or provider to be licensed and comply with specific requirements. Existing law requires a nonresident wholesaler or nonresident third-party logistics provider to maintain a valid, unexpired license, permit, or registration to conduct the business of the wholesaler or nonresident third-party logistics provider in compliance with the laws of the state in which it is a resident and requires a license application to include a license verification from the licensing authority in the applicant's state of residence.

This bill would authorize the board to waive the home state licensure requirement for a nonresident third-party logistics provider if the board inspects the location and finds it to be in compliance with existing requirements and any regulations adopted by the board or the applicant provides evidence of its accreditation by the Drug Distributor Accreditation program of the National Association of Boards of Pharmacy. The bill would require the nonresident third-party logistics provider to reimburse the board for all actual and necessary costs incurred by the board in conducting an inspection of the location, as prescribed.

(8) Existing law establishes specific provisions for applications for different categories of license, including grounds for denial.

Other existing law relating to the powers of the department's constituent boards restricts the authority of a board within the department to deny a license, establishing prescribed circumstances under which denial is authorized for an applicant convicted of a crime or subjected to formal discipline. Existing law also requires such a board to follow established procedures for requesting or acting on an applicant's criminal history information.

This bill, notwithstanding these restrictions and procedural requirements, would specifically authorize 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.

(9) Existing law prohibits the board from renewing a pharmacist license unless the applicant submits proof satisfactory to the board that they have successfully completed 30 hours of approved courses of continuing pharmacy education during the 2 years preceding the application for renewal. Existing law imposes requirements for the form and subject matter of the courses.

This bill, commencing July 1, 2022, would require a pharmacist 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. The bill would require that a pharmacist who has completed such a course within the last 4 years be deemed to have satisfied this requirement.

(10) Existing law establishes requirements for disciplinary proceedings on, among other things, the suspension or revocation of licenses.

This bill would require the board, by July 1, 2023, 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 as prescribed.

(11) Existing law authorizes the board to issue citations containing fines and orders of abatement for violations of specified law, as provided, including, where appropriate, the imposition of an administrative fine.

This bill would prohibit such an administrative fine from being construed as a disciplinary action or discipline for purposes of licensure or the reporting of discipline for licensure.

(12) Existing law establishes penalties for specific violations and provides for the recovery of those penalties by a civil action or by criminal prosecution. Unless another penalty is provided, a knowing violation of existing law is a misdemeanor and other violations are infractions, punishable as specified.

This bill would authorize the board to bring an action for fines for 3rd or subsequent violations of materially similar provisions of existing law within 5 years by 3 or more pharmacies operating under common ownership or management within a chain community pharmacy, as defined, with a cap of \$100,000 for a 3rd or subsequent violation. The bill would also authorize the board to bring an action against a chain community pharmacy operating under common ownership or management for fines, capped at \$150,000, for any violation of existing law demonstrated to be the result of a written policy or which was expressly

encouraged by the common owner or manager. The bill would also provide specified limitations and defenses to these actions, and describe the manner in which the fines are to be imposed. The bill would also require the board to provide information to the Legislature about these actions, as specified.

(13) Existing law prohibits a person from conducting a pharmacy in this state without a license from the board and existing law requires this license to be renewed annually. Existing law requires a pharmacy that compounds sterile drug products to possess a sterile compounding pharmacy license, provides certain requirements for obtaining the license, and requires the license to be renewed annually.

This bill would prohibit a pharmacy license from being renewed unless the applicant includes necessary matters identified by the board in the renewal application, as provided. This bill would also require a pharmacy located in California that distributes compounded human drug preparations interstate to meet certain conditions, including that the pharmacy must report information as specified and certify that the reporting requirements are satisfied in connection with and as a condition of renewal of the pharmacy's license. By expanding the crime of perjury, the bill would impose a state-mandated local program.

(14) The California Constitution requires the state to reimburse local agencies and school districts for certain costs mandated by the state. Statutory provisions establish procedures for making that reimbursement.

This bill would provide that no reimbursement is required by this act for a specified reason.

(15) Existing constitutional provisions require that a statute that limits the right of access to the meetings of public bodies or the writings of public officials and agencies be adopted with findings demonstrating the interest protected by the limitation and the need for protecting that interest.

This bill would make legislative findings to that effect.

Vote: majority Appropriation: no Fiscal Committee: yes Local Program: yes

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## THE PEOPLE OF THE STATE OF CALIFORNIA DO ENACT AS FOLLOWS:

**SECTION 1.** Section 4001 of the Business and Professions Code is amended to read:

**4001.** (a) There is in the Department of Consumer Affairs a California State Board of Pharmacy in which the administration and enforcement of this chapter is vested. The board consists of 13 members.

(b) The Governor shall appoint seven pharmacists who are licensees in good standing and who reside in different parts of the state to serve as members of the board. The Governor shall appoint four public members, and the Senate Committee on Rules and the Speaker of the Assembly shall each appoint a public member who shall not be a licensee of the board, any other board under this division, or any board referred to in Section 1000 or 3600. Each appointing authority has power to remove from office at any time any member of the board appointed by that authority pursuant to Section 106.

(c) At least five of the seven pharmacist appointees to the board shall be pharmacists who are actively engaged in the practice of pharmacy. Additionally, the membership of the board shall 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, a compounding pharmacy specializing in human drug preparations, and a long-term health care or skilled nursing facility. The pharmacist appointees shall also include a pharmacist who is a member of a labor union that represents pharmacists. For the purposes of this subdivision, a "chain community pharmacy" means a chain of 75 or more stores in California under the same ownership, and an "independent community pharmacy" means a pharmacy owned by a person or entity who owns no more than four pharmacies in California.

(d) Members of the board shall be appointed for a term of four years. No person shall serve as a member of the board for more than two consecutive terms. Each member shall hold office until the appointment and qualification of their successor or until one year shall have elapsed since the expiration of the term for which the member was appointed, whichever first occurs. Vacancies occurring shall be filled by appointment for the unexpired term.

(e) Each member of the board shall receive a per diem and expenses as provided in Section 103.

(f) This section shall remain in effect only until January 1, 2026, and as of that date is repealed. Notwithstanding any other law, the repeal of this section renders the board subject to review by the appropriate policy committees of the Legislature.

**SEC. 2.** Section 4002 of the Business and Professions Code is amended to read:

**4002.** (a) The board shall elect a president, a vice president, and a treasurer. The officers of the board shall be elected by a majority of the membership of the board.

(b) The principal office of the board shall be located in Sacramento. The board shall hold a meeting at least once in every four months. Members of the board may meet by teleconference pursuant to Section 11123 of the Government Code. Seven members of the board constitute a quorum.

**SEC. 3.** Section 4003 of the Business and Professions Code is amended to read:

**4003.** (a) The board, with the approval of the director, may appoint a person exempt from civil service who shall be designated as an executive officer and who shall exercise the powers and perform the duties delegated by the board and vested in them by this chapter. The executive officer shall not be a member of the board.

(b) The executive officer shall receive the compensation as established by the board with the approval of the Director of Finance. The executive officer shall also be entitled to travel and other expenses necessary in the performance of their duties.

(c) The executive officer shall maintain and update in a timely fashion records containing the names, titles, qualifications, and places of business of all persons subject to this chapter.

(d) The executive officer shall give receipts for all money received by them and pay it to the department, taking its receipt therefor. Besides the duties required by this chapter, the executive officer shall perform other duties pertaining to the office as may be required of them by the board.

(e) This section shall remain in effect only until January 1, 2026, and as of that date is repealed.

**SEC. 4.** Section 4008 of the Business and Professions Code is amended to read:

**4008.** (a) Except as provided by Section 159.5, the board may employ legal counsel and inspectors of pharmacy. The inspectors, whether the inspectors are employed by the board or the department's Division of Investigation, may inspect during business hours all pharmacies, wholesalers, dispensaries, stores, or places where drugs or devices are compounded, prepared, furnished, dispensed, or stored.

(b) Notwithstanding subdivision (a), a pharmacy inspector may inspect or examine a physician's office or clinic that does not have a permit under Section 4180 or 4190 only to the extent necessary to determine compliance with and to enforce either Section 4080 or 4081.

(c) (1) (A) A pharmacy inspector employed by the board or in the department's Division of Investigation shall have the authority, as a public officer, to arrest, without warrant, any person whenever the officer has reasonable cause to believe that the person to be arrested has, in the officer's presence, violated a provision of this chapter or of Division 10 (commencing with Section 11000) of the Health and Safety Code.

(B) If the violation is a felony, or if the arresting officer has reasonable cause to believe that the person to be arrested has violated any provision that is declared to be a felony, although no felony has in fact been committed, the arresting officer may make an arrest although the violation or suspected violation did not occur in their presence.

(2) In any case in which an arrest authorized by this subdivision is made for an offense declared to be a misdemeanor, and the person arrested does not demand to be taken before a magistrate, the arresting inspector may, instead of taking the person before a magistrate, follow the procedure prescribed by Chapter 5C (commencing with Section 853.5) of Title 3 of Part 2 of the Penal Code. That chapter shall thereafter apply with reference to any proceeding based upon the issuance of a citation pursuant to this authority.

(d) There shall be no civil liability on the part of, and no cause of action shall arise against, a person, acting pursuant to subdivision (a) within the scope of that person's authority, for false arrest or false imprisonment arising out of an arrest that is lawful, or that the arresting officer, at the time of the arrest, had reasonable cause to believe was lawful. An inspector shall not be deemed an aggressor or lose their right to self-defense by the use of reasonable force to effect the arrest, to prevent escape, or to overcome resistance.

(e) Any inspector may serve all processes and notices throughout the state.

(f) A pharmacy inspector employed by the board may enter a facility licensed pursuant to subdivision (c) or (d) of Section 1250 of the Health and Safety Code to inspect an automated drug delivery system operated pursuant to Section 4119.

(g) A pharmacy inspector employed by the board may enter the location, or proposed location, of an automated drug delivery system to inspect that automated drug delivery system or proposed location pursuant to Article 25 (commencing with Section 4427).

**SEC. 5.** Section 4013 of the Business and Professions Code is amended to read:

**4013.** (a) Any facility licensed by the board shall join the board's email notification list within 60 days of obtaining a license or at the time of license renewal.

(b) Any facility licensed by the board shall update its email address with the board's email notification list within 30 days of a change in the facility's email address.

(c) An owner of two or more facilities licensed by the board may comply with subdivisions (a) and (b) by subscribing a single email address to the board's email notification list, where the owner maintains an electronic notice system within all of its licensed facilities that, upon receipt of an email notification from the board, immediately transmits electronic notice of the same notification to all of its licensed facilities. If an owner chooses to comply with this section by using such an electronic notice system, the owner shall register the electronic notice system with the board within 60 days of initial licensure informing the board of the single email address to be utilized by the owner, describing the electronic notice system, and listing all facilities to which immediate notice will be provided. The owner shall update its email address with the board's email notification list within 30 days of any change in the owner's email address.

(d) (1) Each pharmacist, intern pharmacist, pharmacy technician, designated representative, and designated representative-3PL licensed in this state shall join the board's email notification list within 60 days of obtaining a license or at the time of license renewal.

(2) Each pharmacist, intern pharmacist, pharmacy technician, designated representative, and designated representative-3PL licensed in this state shall update their email address with the board's email notification list within 30 days of a change in the licensee's email address.

(3) The email address provided by a licensee shall not be posted on the board's online license verification system.

(4) The board shall, with each renewal application, remind licensees of their obligation to report and keep current their email address with the board's email notification list.

**SEC. 6.** Section 4017.3 of the Business and Professions Code is amended to read:

**4017.3.** (a) An "automated drug delivery system" (ADDS) means a mechanical system that performs operations or activities, other than compounding or administration, relative to the storage, dispensing, or distribution of drugs. An ADDS shall collect, control, and maintain all transaction information to accurately track the movement of drugs into and out of the system for security, accuracy, and accountability.

(b) An "automated unit dose system" (AUDS) is an ADDS for storage and retrieval of unit doses of drugs for administration to patients by persons authorized to perform these functions.

(c) An "automated patient dispensing system" (APDS) is an ADDS for storage and dispensing of prescribed drugs directly to patients pursuant to prior authorization by a pharmacist.

**SEC. 7.** Section 4022.5 of the Business and Professions Code is amended to read:

**4022.5.** (a) "Designated representative" means an individual to whom a license has been granted pursuant to Section 4053. A pharmacist fulfilling the duties of Section 4053 shall not be required to obtain a license as a designated representative.

(b) "Designated representative-in-charge" means a designated representative or designated representative-reverse distributor, or a pharmacist licensed in the home state proposed by a wholesaler or veterinary food-animal drug retailer and approved by the board as the supervisor or manager responsible for ensuring the wholesaler's or veterinary food-animal drug retailer's compliance with all state and federal laws and regulations pertaining to practice in the applicable license category.

**SEC. 8.** Section 4022.7 of the Business and Professions Code is amended to read:

**4022.7.** (a) "Designated representative-3PL" means an individual to whom a license has been granted pursuant to Section 4053.1. A pharmacist fulfilling the duties of Section 4053.1 shall not be required to obtain a license as a designated representative-3PL.

(b) "Responsible manager" means a designated representative-3PL selected by a third-party logistics provider and approved by the board as responsible for ensuring compliance of the licensed place of business with state and federal laws with respect to dangerous drugs and dangerous devices received by, stored in, or shipped from the licensed place of business of the third-party logistics provider.

**SEC. 9.** Section 4039 of the Business and Professions Code is amended to read:

**4039.** "Physicians," "dentists," "optometrists," "pharmacists," "doctors of podiatric medicine," "veterinarians," "veterinary surgeons," "registered nurses," "naturopathic doctors," and "physician assistants" are persons authorized by a currently valid and unrevoked license to practice their respective professions in this state. "Physician" means and includes any person holding a valid and unrevoked physician's and surgeon's certificate or certificate to practice medicine and surgery, issued by the Medical Board of California or the Osteopathic Medical Board of California, and includes an unlicensed person lawfully practicing medicine pursuant to Section 2065, when acting within the scope of that section.

**SEC. 10.** Section 4040 of the Business and Professions Code is amended to read:

**4040.** (a) "Prescription" means an oral, written, or electronic transmission order that is both of the following:

(1) Given individually for the person or persons for whom ordered that includes all of the following:

(A) The name or names and address of the patient or patients.

(B) The name and quantity of the drug or device prescribed and the directions for use.

(C) The date of issue.

(D) Either rubber stamped, typed, or printed by hand or typeset, the name, address, and telephone number of the prescriber, the prescriber's license classification, and the prescriber's federal registry number, if a controlled substance is prescribed.

(E) A legible, clear notice of the condition or purpose for which the drug is being prescribed, if requested by the patient or patients.

(F) If in writing, signed by the prescriber issuing the order, or the certified nurse-midwife, nurse practitioner, physician assistant, or naturopathic doctor who issues a drug order pursuant to Section 2746.51, 2836.1, 3502.1, or 3640.5, respectively, or the pharmacist who issues a drug order pursuant to Section 4052.1, 4052.2, or 4052.6.

(2) Issued by a physician, dentist, optometrist, doctor of podiatric medicine, veterinarian, or naturopathic doctor pursuant to Section 3640.7 or, if a drug order is issued pursuant to Section 2746.51, 2836.1, 3502.1, or 3640.5, by a certified nurse-midwife, nurse practitioner, physician assistant, or naturopathic doctor licensed in this state, or pursuant to Section 4052.1, 4052.2, or 4052.6 by a pharmacist licensed in this state.

(b) Notwithstanding subdivision (a), a written order of the prescriber for a dangerous drug, except for any Schedule II controlled substance, that contains at least the name and signature of the prescriber, the name and address of the patient in a manner consistent with paragraph (2) of subdivision (a) of Section 11164 of the Health and Safety Code, the name and quantity of the drug prescribed, directions for use, and the date of issue may be treated as a prescription by the dispensing pharmacist as long as any additional information required by subdivision (a) is readily retrievable in the pharmacy. In the event of a conflict between this subdivision and Section 11164 of the Health and Safety Code, Section 11164 of the Health and Safety Code shall prevail.

(c) "Electronic transmission prescription" includes both image and data prescriptions. "Electronic image transmission prescription" means any prescription order for which a facsimile of the order is received by a pharmacy from a licensed prescriber. "Electronic data transmission prescription" means any prescription order, other than an electronic image transmission prescription, that is electronically transmitted from a licensed prescriber to a pharmacy.

(d) The use of commonly used abbreviations shall not invalidate an otherwise valid prescription.

**SEC. 11.** Section 4052 of the Business and Professions Code is amended to read:

**4052.** (a) Notwithstanding any other law, a pharmacist may do all of the following:

(1) Furnish a reasonable quantity of compounded drug product to a prescriber for office use by the prescriber.

(2) Transmit a valid prescription to another pharmacist.

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

(4) Perform procedures or functions in a licensed health care facility as authorized by Section 4052.1.

(5) Perform procedures or functions as part of the care provided by a health care facility, a licensed home health agency, a licensed clinic in which there is physician oversight, a provider who contracts with a licensed health care service plan with regard to the care or services provided to the enrollees of that health care service plan, or a physician, as authorized by Section 4052.2.

(6) Perform procedures or functions as authorized by Section 4052.6.

(7) Manufacture, measure, fit to the patient, or sell and repair dangerous devices, or furnish instructions to the patient or the patient's representative concerning the use of those devices.

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

(9) 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.

(10) Furnish the medications described in subparagraph (A) in accordance with subparagraph (B):

(A) (i) Emergency contraception drug therapy and self-administered hormonal contraceptives, as authorized by Section 4052.3.

(ii) Nicotine replacement products, as authorized by Section 4052.9.

(iii) Prescription medications not requiring a diagnosis that are recommended by the federal Centers for Disease Control and Prevention for individuals traveling outside of the United States.

(iv) HIV preexposure prophylaxis, as authorized by Section 4052.02.

(v) HIV postexposure prophylaxis, as authorized by Section 4052.03.

(B) The pharmacist shall notify the patient's primary care provider of any drugs or devices furnished to the patient, or enter the appropriate information in a patient record system shared with the primary care provider, as permitted by that primary care provider. If the patient does not have a primary care provider, the pharmacist shall provide the patient with a written record of the drugs or devices furnished and advise the patient to consult a physician of the patient's choice.

(11) Administer immunizations pursuant to a protocol with a prescriber.

(12) Order and interpret tests for the purpose of monitoring and managing the efficacy and toxicity of drug therapies. A pharmacist who orders and interprets tests pursuant to this paragraph shall ensure that the ordering of those tests is done in coordination with the patient's primary care provider or diagnosing prescriber, as appropriate, including promptly transmitting written notification to the patient's diagnosing prescriber or entering the appropriate information in a patient record system shared with the prescriber, when available and as permitted by that prescriber.

(13) 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 may be between a single or multiple pharmacists and a single or multiple health care providers with prescriptive authority.

(14) Provide medication-assisted treatment pursuant to a state protocol, to the extent authorized by federal law.

(b) A pharmacist who is authorized to issue an order to initiate or adjust a controlled substance therapy pursuant to this section shall personally register with the federal Drug Enforcement Administration.

(c) This section does not affect the applicable requirements of law relating to either of the following:

(1) Maintaining the confidentiality of medical records.

(2) The licensing of a health care facility.

**SEC. 12.** Section 4052.6 of the Business and Professions Code is amended to read:

**4052.6.** (a) A pharmacist recognized by the board as an advanced practice pharmacist may do all of the following:

(1) Perform patient assessments.

(2) Order and interpret drug therapy-related tests.

(3) Refer patients to other health care providers.

(4) Participate in the evaluation and management of diseases and health conditions in collaboration with other health care providers.

(5) Initiate, adjust, or discontinue drug therapy.



(b) A pharmacist who adjusts or discontinues drug therapy shall promptly transmit written notification to the patient's diagnosing prescriber or enter the appropriate information in a patient record system shared with the prescriber, as permitted by that prescriber. A pharmacist who initiates drug therapy shall promptly transmit written notification to, or enter the appropriate information into, a patient record system shared with the patient's primary care provider or diagnosing provider, as permitted by that provider.

(c) This section shall not interfere with a physician's order to dispense a prescription drug as written, or other order of similar meaning.

(d) Prior to initiating or adjusting a controlled substance therapy pursuant to this section, a pharmacist shall personally register with the federal Drug Enforcement Administration.

(e) A pharmacist who orders and interprets tests pursuant to paragraph (2) of subdivision (a) shall ensure that the ordering of those tests is done in coordination with the patient's primary care provider or diagnosing prescriber, as appropriate, including promptly transmitting written notification to the patient's diagnosing prescriber or entering the appropriate information in a patient record system shared with the prescriber, when available and as permitted by that prescriber.

**SEC. 13.** Section 4053 of the Business and Professions Code is amended to read:

**4053.** (a) Notwithstanding Section 4051, the board may issue a license as a designated representative to provide sufficient and qualified supervision in a wholesaler or veterinary food-animal drug retailer. The designated representative shall protect the public health and safety in the handling, storage, and shipment of dangerous drugs and dangerous devices in the wholesaler or veterinary food-animal drug retailer.

(b) An individual who is at least 18 years of age may apply for a designated representative license. In order to obtain and maintain that license, the individual shall meet all of the following requirements:

(1) The individual shall be a high school graduate, possess a general education development certificate equivalent, or have earned a degree from an accredited postsecondary institution.

(2) The individual shall have a minimum of one year of paid work experience in a licensed pharmacy, or with a drug wholesaler, drug distributor, or drug manufacturer, in the past three years, related to the distribution or dispensing of dangerous drugs or dangerous devices or meet all of the prerequisites to take the examination required for licensure as a pharmacist by the board.

(3) The individual shall complete a training program approved by the board that, at a minimum, addresses each of the following subjects:

(A) Knowledge and understanding of California law and federal law relating to the distribution of dangerous drugs and dangerous devices.

(B) Knowledge and understanding of California law and federal law relating to the distribution of controlled substances.

(C) Knowledge and understanding of quality control systems.

(D) Knowledge and understanding of the United States Pharmacopoeia standards relating to the safe storage and handling of drugs.

(E) Knowledge and understanding of prescription terminology, abbreviations, dosages, and format.

(4) The board may, by regulation, require training programs to include additional material.

(5) The board shall not issue a license as a designated representative until the applicant provides proof of completion of the required training to the board.

(c) The veterinary food-animal drug retailer or wholesaler shall not operate without a pharmacist or a designated representative on its premises.

(d) Only a pharmacist or a designated representative shall prepare and affix the label to veterinary food-animal drugs.

(e) Section 4051 shall not apply to any laboratory licensed under Section 351 of Title III of the Public Health Service Act (Public Law 78-410).

**SEC. 14.** Section 4053.1 of the Business and Professions Code is amended to read:

**4053.1.** (a) Notwithstanding Section 4051, the board may issue a license to a qualified individual as a designated representative-3PL to provide sufficient and qualified supervision of a third-party logistics provider's place of business. The designated

representative-3PL shall protect the public health and safety in the handling, storage, warehousing, distribution, and shipment of dangerous drugs and dangerous devices in the third-party logistics provider's place of business.

(b) An individual who is at least 18 years of age may apply for a designated representative-3PL license. In order to obtain and maintain that license, the individual shall meet all of the following requirements:

(1) The individual shall be a high school graduate, possess a general education development certificate equivalent, or have earned a degree from an accredited postsecondary institution.

(2) The individual shall meet one of the following requirements:

(A) Have a minimum of one year of paid work experience in the past three years with a third-party logistics provider.

(B) Have a minimum of one year of paid work experience in the past three years in a licensed pharmacy, or with a drug wholesaler, drug distributor, or drug manufacturer, performing duties related to the distribution or dispensing of dangerous drugs or dangerous devices.

(C) Meet all of the prerequisites to take the examination required for licensure as a pharmacist by the board.

(3) (A) The individual shall complete a training program approved by the board that, at a minimum, addresses each of the following subjects:

(i) Knowledge and understanding of California law and federal law relating to the distribution of dangerous drugs and dangerous devices.

(ii) Knowledge and understanding of California law and federal law relating to the distribution of controlled substances.

(iii) Knowledge and understanding of quality control systems.

(iv) Knowledge and understanding of the United States Pharmacopoeia or federal Food and Drug Administration standards relating to the safe storage, handling, and transport of dangerous drugs and dangerous devices.

(B) The board may, by regulation, require the training program required under this paragraph to include additional material.

(C) The board shall not issue a license as a designated representative-3PL until the applicant provides proof of completion of the training required by this paragraph to the board.

(c) A third-party logistics provider shall not operate without at least one designated representative-3PL present at each of its licensed places of business as required under Section 4160.

**SEC. 15.** Section 4053.2 of the Business and Professions Code is amended to read:

**4053.2.** (a) Notwithstanding Sections 4051 and 4053, the board may issue a designated representative-reverse distributor license to a qualified individual who shall provide sufficient and qualified supervision over a licensed wholesaler that only acts as a reverse distributor. The designated representative-reverse distributor shall protect the public health and safety in the handling, storage, warehousing, and destruction of outdated or nonsaleable dangerous drugs and dangerous devices.

(b) An individual who is at least 18 years of age may apply for a designated representative-reverse distributor license. In order to obtain and maintain that license, the individual shall meet all of the following requirements:

(1) The individual shall be a high school graduate, possess a general education development certificate equivalent, or have earned a degree from an accredited postsecondary institution.

(2) The individual shall meet one of the following requirements:

(A) Have a minimum of one year of paid work experience in the past three years with a licensed wholesaler, third-party logistics provider, or pharmacy performing duties related to the distribution, dispensing, or destruction of dangerous drugs or dangerous devices.

(B) Have a minimum of one year of paid work experience in the destruction of outdated or nonsaleable dangerous drugs or dangerous devices pharmaceutical waste.

(C) Meet all of the prerequisites to take the examination required for licensure as a pharmacist by the board.

(3) (A) The individual shall complete a training program approved by the board that, at a minimum, addresses each of the following subjects:

(i) Knowledge and understanding of California law and federal law relating to the distribution of dangerous drugs and dangerous devices.

(ii) Knowledge and understanding of California law and federal law relating to the distribution of controlled substances.

(iii) Knowledge and understanding of California law and federal law relating to the removal and destruction of dangerous drugs, dangerous devices, and pharmaceutical waste.

(iv) Knowledge and understanding of the United States Pharmacopoeia or federal Food and Drug Administration standards relating to the safe storage, handling, and transport of dangerous drugs and dangerous devices.

(B) The board may, by regulation, require the training program required under this paragraph to include additional material.

(C) The board shall not issue a license as a designated representative-reverse distributor until the applicant provides proof of completion of the training required by this paragraph to the board.

(c) A reverse distributor shall not operate without at least one designated representative or designated representative-reverse distributor present at each of its licensed places of business as required under Section 4160.

**SEC. 16.** Section 4110 of the Business and Professions Code is amended to read:

**4110.** (a) No person shall conduct a pharmacy in the State of California unless they have obtained a license from the board. A license shall be required for each pharmacy owned or operated by a specific person. A separate license shall be required for each of the premises of any person operating a pharmacy in more than one location. The license shall be renewed annually. The license shall not be renewed unless the applicant includes necessary matters identified by the board in the renewal application, including, but not limited to, notification to the board regarding compounding practices, including compounded human drug preparations distributed outside of the state. The board may, by regulation, determine the circumstances under which a license may be transferred.

(b) The board may, at its discretion, issue a temporary permit upon the conditions and for any periods of time as the board determines to be in the public interest. A temporary permit fee shall be required in an amount established by the board as specified in subdivision (a) of Section 4400. When needed to protect public safety, a temporary permit may be issued for a period not to exceed 180 days, and may be issued subject to terms and conditions the board deems necessary. If the board determines a temporary permit was issued by mistake or denies the application for a permanent license or registration, the temporary license or registration shall terminate upon either personal service of the notice of termination upon the permitholder or service by certified mail, return receipt requested, at the permitholder's address of record with the board, whichever comes first. Neither for purposes of retaining a temporary permit nor for purposes of any disciplinary or license denial proceeding before the board shall the temporary permitholder be deemed to have a vested property right or interest in the permit.

(c) The board may allow the temporary use of a mobile pharmacy when a pharmacy is destroyed or damaged, the mobile pharmacy is necessary to protect the health and safety of the public, and the following conditions are met:

(1) The mobile pharmacy shall provide services only on or immediately contiguous to the site of the damaged or destroyed pharmacy.

(2) The mobile pharmacy is under the control and management of the pharmacist-in-charge of the pharmacy that was destroyed or damaged.

(3) A licensed pharmacist is on the premises while drugs are being dispensed.

(4) Reasonable security measures are taken to safeguard the drug supply maintained in the mobile pharmacy.

(5) The pharmacy operating the mobile pharmacy provides the board with records of the destruction of, or damage to, the pharmacy and an expected restoration date.

(6) Within three calendar days of restoration of the pharmacy services, the board is provided with notice of the restoration of the permanent pharmacy.

(7) The mobile pharmacy is not operated for more than 48 hours following the restoration of the permanent pharmacy.

**SEC. 17.** Section 4119.11 of the Business and Professions Code is amended to read:

**4119.11.** (a) A pharmacy located in the state may provide pharmacy services to the patients of a "covered entity," as defined in Section 256b of Title 42 of the United States Code, through the use of an automated patient dispensing system located on the

premises of the covered entity or on the premises of medical professional practices under contract to provide medical services to covered entity patients, which need not be the same location as the pharmacy, if all of the following conditions are met:

(1) The pharmacy obtains a license from the board to operate the automated patient dispensing system at the covered entity or affiliated site. As part of the application, the pharmacy shall provide the address at which the automated patient dispensing system shall be placed and identify the covered entity. A separate license shall be required for each location and shall be renewed annually concurrent with the pharmacy license. The application and renewal fee shall be three hundred dollars (\$300) and may be increased to five hundred dollars (\$500). The board is authorized to lower the renewal fee to not less than two hundred dollars (\$200) if a lower fee level will provide sufficient resources to support the regulatory activities.

(2) The pharmacy providing the pharmacy services to the patients of the covered entity, including, unless otherwise prohibited by any other law, patients enrolled in the Medi-Cal program, shall be under contract with that covered entity as described in Section 4126 to provide those pharmacy services through the use of the automated patient dispensing system.

(3) Drugs stored in an automated patient dispensing system shall be part of the inventory of the pharmacy providing pharmacy services to the patients of the covered entity and drugs dispensed from the automated patient dispensing system shall be considered to have been dispensed by that pharmacy.

(4) The pharmacy shall maintain records of the acquisition and disposition of dangerous drugs stored in the automated patient dispensing system separate from other pharmacy records.

(5) The pharmacy shall be solely responsible for the security, operation, and maintenance of the automated patient dispensing system.

(6) The pharmacy shall provide training regarding the operation and use of the automated patient dispensing system to both pharmacy and covered entity personnel using the system.

(7) The operation of the automated patient dispensing system shall be under the supervision of a licensed pharmacist acting on behalf of the pharmacy providing services to the patients of the covered entity. The pharmacist need not be physically present at the site of the automated patient dispensing system and may supervise the system electronically.

(8) Notwithstanding Section 4107, the board may issue a license for the operation of an automated patient dispensing system at an address for which it has issued another site license.

(9) The board, within 30 days after receipt of an application for an automated patient dispensing system license, shall conduct a precensure inspection at the proposed location of the automated patient dispensing system. Relocation of the automated patient dispensing system shall require a new application for licensure. Replacement of an automated patient dispensing system shall require notice to the board within 30 days.

(10) The automated patient dispensing system license shall be canceled by operation of law if the underlying pharmacy license is not current, valid, and active. Upon reissuance or reinstatement of the underlying pharmacy license, a new application for an automated patient dispensing system license may be submitted to the board.

(11) A pharmacy that holds an automated patient dispensing system license shall advise the board in writing within 30 days if use of the automated patient dispensing system is discontinued.

(b) For purposes of this section, the following definitions shall apply:

(1) An "automated drug delivery system" (ADDS) means a mechanical system that performs operations or activities, other than compounding or administration, relative to the storage, dispensing, or distribution of drugs. An ADDS shall collect, control, and maintain all transaction information to accurately track the movement of drugs into and out of the system for security, accuracy, and accountability.

(2) An "automated patient dispensing system" (APDS) is an ADDS for storage and dispensing of prescribed drugs directly to patients pursuant to prior authorization by a pharmacist.

(3) An "automated unit dose system" (AUDS) is an ADDS for storage and retrieval of unit doses of drugs for administration to patients by persons authorized to perform these functions.

(c) (1) An automated patient dispensing system shall collect, control, and maintain all transaction information to accurately track the movement of drugs into and out of the system for security, accuracy, and accountability.

(2) Transaction information shall be made readily available in a downloadable format for review and inspection by individuals authorized by law. These records shall be maintained by the pharmacy for a minimum of three years.

(d) Drugs from the automated patient dispensing system may be dispensed directly to the patient, if all of the following requirements are met:

(1) The pharmacy shall develop, implement, and annually review written policies and procedures with respect to all of the following:

(A) Maintaining the security of the automated patient dispensing system and the dangerous drugs and devices within that automated patient dispensing system.

(B) Determining and applying inclusion criteria regarding which drugs and devices are appropriate for placement in the automated patient dispensing system and for which patients.

(C) Ensuring that patients are aware that consultation with a pharmacist is available for any prescription medication, including those delivered via the automated patient dispensing system.

(D) Describing assignment of responsibilities to, and training of, pharmacy personnel, and other personnel using the automated patient dispensing system at the location where the automated patient dispensing system is placed, regarding maintenance and filing procedures for the automated patient dispensing system.

(E) Orienting participating patients on the use of the automated patient dispensing system, notifying patients when expected prescription medications are not available in the automated patient dispensing system, and ensuring that patient use of the automated patient dispensing system does not interfere with delivery of drugs and devices.

(F) Ensuring delivery of drugs and devices to patients expecting to receive them from the automated patient dispensing system if the automated patient dispensing system is disabled or malfunctions.

(2) The automated patient dispensing system shall only be used for patients who have signed a written consent demonstrating their informed consent to receive prescribed drugs and devices from an automated patient dispensing system and whose use of the automated patient dispensing system meet the criteria pursuant to paragraph (1).

(3) The automated patient dispensing system shall have a means to identify each patient and only release the identified patient's drugs and devices to the patient or the patient's agent.

(4) A pharmacist shall perform all clinical services conducted as part of the dispensing process, including, but not limited to, drug utilization review and consultation.

(5) Drugs shall be dispensed from the automated patient dispensing system only upon authorization from a pharmacist after the pharmacist has reviewed the prescription and the patient's profile for potential contraindications and adverse drug reactions.

(6) All prescribed drugs and devices dispensed from the automated patient dispensing system for the first time shall be accompanied by a consultation conducted by a pharmacist licensed by the board via a telecommunications link that has two-way audio and video.

(7) The automated patient dispensing system shall include a notice, prominently posted on the automated patient dispensing system, that provides the name, address, and telephone number of the pharmacy that holds the automated patient dispensing system license for that automated patient dispensing system.

(8) The labels on all drugs dispensed by the automated patient dispensing system shall comply with Section 4076 of this code and with Section 1707.5 of Title 16 of the California Code of Regulations.

(9) Any complaint, error, or omission involving the automated patient dispensing system shall be reviewed as part of the pharmacy's quality assurance program pursuant to Section 4125.

(10) The board shall not issue a pharmacy more than 15 licenses for automated patient dispensing system units under this section. Consistent with Section 4001.1, the board may adopt regulations to reduce the number of automated patient dispensing system licenses that may be issued to a pharmacy.

(11) The pharmacy holding the license for the automated patient dispensing system shall maintain the policies and procedures developed pursuant to paragraph (1) for three years after the last date of use of that automated patient dispensing system.

(e) Access to the automated patient dispensing system shall be controlled and tracked using an identification or password system or biosensor. A system that is accessed via a password system shall include a camera that records a picture of the individual accessing the machine. Picture records shall be maintained for a minimum of 180 days.

(f) The automated patient dispensing system shall make a complete and accurate record of all transactions that will include all users accessing the system and all drugs added to, or removed from, the system.

(g) The stocking of an automated patient dispensing system shall be performed by a pharmacist. If the automated patient dispensing system utilizes removable pockets, cards, drawers, similar technology, or unit of use or single dose containers as defined by the United States Pharmacopeia, the stocking system may be done outside of the facility and be delivered to the facility, if all of the following conditions are met:

(1) The task of placing drugs into the removable pockets, cards, drawers, similar technology, or unit of use or single dose containers is performed by a pharmacist, or by an intern pharmacist or a pharmacy technician working under the direct supervision of a pharmacist.

(2) The removable pockets, cards, drawers, similar technology, or unit of use or single dose containers are transported between the pharmacy and the facility in a secure tamper-evident container.

(3) The pharmacy, in conjunction with the covered entity, has developed policies and procedures to ensure that the removable pockets, cards, drawers, similar technology, or unit of use or single dose containers are properly placed into the automated patient dispensing system.

(h) Review of the drugs contained within, and the operation and maintenance of, the automated patient dispensing system shall be done in accordance with law and shall be the responsibility of the pharmacy. A pharmacist shall conduct the review on a monthly basis, which shall include a physical inspection of the drugs in the automated patient dispensing system, an inspection of the automated patient dispensing system machine for cleanliness, and a review of all transaction records in order to verify the security and accountability of the system.

(i) A pharmacy holding an automated patient dispensing system license shall complete a self-assessment, performed pursuant to Section 1715 of Title 16 of the California Code of Regulations, evaluating the pharmacy's compliance with pharmacy law relating to the use of the automated patient dispensing system. All information regarding operation, maintenance, compliance, error, omissions, or complaints pertaining to the automated patient dispensing system shall be included in the self-assessment.

(j) The pharmacy shall comply with all recordkeeping and quality assurance requirements pursuant to this chapter, and shall maintain those records within the pharmacy holding the automated patient dispensing system license and separately from other pharmacy records.

**SEC. 18.** Section 4126.10 is added to the Business and Professions Code, to read:

**4126.10.** (a) A pharmacy located in California may distribute compounded human drug preparations interstate only if all of the following conditions are met:

(1) Between January 1 and March 31 of each year, the pharmacy reports all required data for the previous calendar year into the Information Sharing Network established by the National Association of Boards of Pharmacy in conjunction with the United States Food and Drug Administration (FDA) to implement the Memorandum of Understanding Addressing Certain Distributions of Compounded Human Drug Products.

(2) On an annual basis, in connection with and as a condition of renewal of the pharmacy's license, the pharmacist-in-charge of the pharmacy certifies that the reporting requirements of paragraph (1) have been satisfied.

(3) The pharmacy reports any adverse drug experience and product quality issue for any compounded product to the board within 12 hours after the pharmacy receives notice of the adverse drug experience or product quality issue.

(b) Information reported by the board to the FDA directly or through the Information Sharing Network established by the National Association of Boards of Pharmacy in conjunction with the FDA to implement the Memorandum of Understanding Addressing Certain Distributions of Compounded Human Drug Products shall not be subject to public disclosure under the California Public Records Act (Chapter 3.5 (commencing with Section 6250) of Division 7 of Title 1 of the Government Code).

**SEC. 19.** Section 4127.3 of the Business and Professions Code is amended to read:

**4127.3.** (a) Whenever the board has a reasonable belief, based on information obtained during an inspection or investigation by the board, that a pharmacy compounding sterile drug products poses an immediate threat to the public health or safety, the executive officer of the board may issue an order to the pharmacy to immediately cease and desist from compounding sterile drug products. The cease and desist order shall remain in effect for no more than 30 days or the date of a hearing seeking an interim suspension order, whichever is earlier.

(b) Whenever the board issues a cease and desist order pursuant to subdivision (a), the board shall immediately issue the owner a notice setting forth the acts or omissions with which the owner is charged, specifying the pertinent code section or sections.

(c) The order shall provide that the owner, within 15 days of receipt of the notice, may request a hearing before the president of the board to contest the cease and desist order. Consideration of the owner's contest of the cease and desist order shall comply with Section 11425.10 of the Government Code. The hearing shall be held no later than five business days from the date the request of the owner is received by the board. The president shall render a written decision within five business days of the hearing. In the absence of the president of the board, the vice president of the board may conduct the hearing permitted by this subdivision. The owner or person in possession or control of the pharmacy may seek review of the decision of the president of the board pursuant to Section 1094.5 of the Code of Civil Procedure.

(d) Failure to comply with a cease and desist order issued pursuant to this section shall be unprofessional conduct.

**SEC. 20.** Section 4129 of the Business and Professions Code is amended to read:

**4129.** (a) A facility registered as an outsourcing facility with the federal Food and Drug Administration (FDA) shall be concurrently licensed with the board as an outsourcing facility if it compounds sterile medication or nonsterile medication for nonpatient-specific distribution within or into California.

(b) A facility premises licensed with the board as a sterile compounding pharmacy shall not be concurrently licensed with the board as an outsourcing facility at the same location.

(c) The board may adopt regulations in accordance with the Administrative Procedure Act (Chapter 3.5 (commencing with Section 11340) of Part 1 of Division 3 of Title 2 of the Government Code) to establish policies, guidelines, and procedures to implement this article.

(d) The board shall review any formal requirements or guidance documents developed by the FDA regarding outsourcing facilities within 90 days after their release in order to determine whether revisions are necessary for any regulations promulgated by the board.

(e) An outsourcing facility licensed by the board dispensing patient-specific compounded preparations pursuant to a prescription for an individual patient shall not be required to be licensed as a pharmacy, but shall otherwise comply with the same requirements of a pharmacy.

**SEC. 21.** Section 4129.4 of the Business and Professions Code is amended to read:

**4129.4.** (a) Whenever the board has a reasonable belief, based on information obtained during an inspection or investigation by the board, that an outsourcing facility compounding sterile drug products or nonsterile drug products poses an immediate threat to the public health or safety, the executive officer of the board may issue an order to the outsourcing facility to immediately cease and desist compounding sterile drug products or nonsterile drug products. The cease and desist order shall remain in effect for no more than 30 days or the date of a hearing seeking an interim suspension order, whichever is earlier.

(b) Whenever the board issues a cease and desist order pursuant to subdivision (a), the board shall immediately issue a notice to the owner setting forth the acts or omissions with which the owner is charged, specifying the pertinent code section or sections and any regulations.

(c) The cease and desist order shall state that the owner, within 15 days of receipt of the notice, may request a hearing before the president of the board to contest the cease and desist order. Consideration of the owner's contest of the cease and desist order shall comply with Section 11425.10 of the Government Code. The hearing shall be held no later than five business days after the date the request of the owner is received by the board. The president shall render a written decision within five business days after the hearing. In the absence of the president of the board, the vice president of the board may conduct the hearing permitted by this subdivision. The owner or person in possession or control of the outsourcing facility may seek review of the decision pursuant to Section 1094.5 of the Code of Civil Procedure.

(d) Failure to comply with a cease and desist order issued pursuant to this section shall be unprofessional conduct.

**SEC. 22.** Section 4161 of the Business and Professions Code is amended to read:

**4161.** (a) A person located outside this state that (1) ships, sells, mails, warehouses, distributes, or delivers dangerous drugs or dangerous devices into this state or (2) sells, brokers, warehouses, or distributes dangerous drugs or devices within this state shall be considered a nonresident wholesaler or a nonresident third-party logistics provider.

(b) A nonresident wholesaler or nonresident third-party logistics provider shall be licensed by the board prior to shipping, selling, mailing, warehousing, distributing, or delivering dangerous drugs or dangerous devices to a site located in this state or selling, brokering, warehousing, or distributing dangerous drugs or devices within this state.

(c) (1) A separate license shall be required for each place of business owned or operated by a nonresident wholesaler or nonresident third-party logistics provider from or through which dangerous drugs or dangerous devices are shipped, sold, mailed, warehoused, distributed, or delivered to a site located in this state or sold, brokered, warehoused, or distributed within this state. Each place of business may only be issued a single license by the board, except as provided in paragraph (2). A license shall be renewed annually and shall not be transferable.

(2) A nonresident wholesaler and a nonresident third-party logistics provider under common ownership may be licensed at the same place of business provided that all of the following requirements are satisfied:

(A) The wholesaler and the third-party logistics provider each separately maintain the records required under Section 4081.

(B) Dangerous drugs and dangerous devices owned by the wholesaler are not commingled with the dangerous drugs and dangerous devices handled by the third-party logistics provider.

(C) Any individual acting as a designated representative for the wholesaler is not concurrently acting as a designated representative-3PL on behalf of the third-party logistics provider. Nothing in this subparagraph shall be construed to prohibit an individual from concurrently holding a license to act as a designated representative and to act as a designated representative-3PL.

(D) The wholesaler has its own designated representative-in-charge responsible for the operations of the wholesaler and the third-party logistics provider has its own responsible manager responsible for the operations of the third-party logistics provider. The same individual shall not concurrently serve as the responsible manager and the designated representative-in-charge for a wholesaler and a third-party logistics provider licensed at the same place of business.

(E) The third-party logistics provider does not handle the prescription drugs or prescription devices owned by a prescriber.

(F) The third-party logistics provider is not a reverse third-party logistics provider.

(G) The wholesaler is not acting as a reverse distributor.

(d) The following information shall be reported, in writing, to the board at the time of initial application for licensure by a nonresident wholesaler or a nonresident third-party logistics provider, on renewal of a nonresident wholesaler or nonresident third-party logistics provider license, or within 30 days of a change in that information:

(1) Its agent for service of process in this state.

(2) Its principal corporate officers, as specified by the board, if any.

(3) Its general partners, as specified by the board, if any.

(4) Its owners if the applicant is not a corporation or partnership.

(e) A report containing the information in subdivision (d) shall be made within 30 days of any change of ownership, office, corporate officer, or partner.

(f) A nonresident wholesaler or nonresident third-party logistics provider shall comply with all directions and requests for information from the regulatory or licensing agency of the state in which it is licensed, as well as with all requests for information made by the board.

(g) A nonresident wholesaler or nonresident third-party logistics provider shall maintain records of dangerous drugs and dangerous devices sold, traded, transferred, warehoused, or distributed to persons in this state or within this state, so that the records are in a readily retrievable form.

(h) A nonresident wholesaler or nonresident third-party logistics provider shall at all times maintain a valid, unexpired license, permit, or registration to conduct the business of the wholesaler or nonresident third-party logistics provider in compliance with the laws of the state in which it is a resident. An application for a nonresident wholesaler or nonresident third-party logistics provider license in this state shall include a license verification from the licensing authority in the applicant's state of residence. The board may waive the home state licensure requirement for a nonresident third-party logistics provider if the board inspects the location and finds it to be in compliance with this article and any regulations adopted by the board or the applicant provides evidence of its accreditation by the Drug Distributor Accreditation program of the National Association of Boards of Pharmacy. The



nonresident third-party logistics provider shall reimburse the board for all actual and necessary costs incurred by the board in conducting an inspection of the location, pursuant to subdivision (v) of Section 4400.

(i) (1) The board shall not issue or renew a nonresident wholesaler license until the nonresident wholesaler identifies a designated representative-in-charge and notifies the board in writing of the identity and license number of the designated representative-in-charge.

(2) The board shall not issue or renew a nonresident third-party logistics provider license until the nonresident third-party logistics provider identifies a responsible manager and notifies the board in writing of the identity and license number of the designated representative-3PL who will be the responsible manager.

(j) The designated representative-in-charge shall be responsible for the compliance of the nonresident wholesaler with state and federal laws governing wholesalers. The responsible manager shall be responsible for the compliance of the nonresident third-party logistics provider's place of business with state and federal laws governing third-party logistics providers. A nonresident wholesaler or nonresident third-party logistics provider shall identify and notify the board of a new designated representative-in-charge or responsible manager within 30 days of the date that the prior designated representative-in-charge or responsible manager ceases to be the designated representative-in-charge or responsible manager.

(k) The board may issue a temporary license, upon conditions and for periods of time as the board determines to be in the public interest. A temporary license fee shall be five hundred fifty dollars (\$550) or another amount established by the board not to exceed the annual fee for renewal of a license to compound sterile drug products. When needed to protect public safety, a temporary license may be issued for a period not to exceed 180 days, subject to terms and conditions that the board deems necessary. If the board determines that a temporary license was issued by mistake or denies the application for a permanent license, the temporary license shall terminate upon either personal service of the notice of termination upon the licenseholder or service by certified mail, return receipt requested, at the licenseholder's address of record with the board, whichever occurs first. Neither for purposes of retaining a temporary license, nor for purposes of any disciplinary or license denial proceeding before the board, shall the temporary licenseholder be deemed to have a vested property right or interest in the license.

(l) The registration fee shall be the fee specified in subdivision (f) of Section 4400.

**SEC. 23.** Section 4202.6 is added to the Business and Professions Code, to read:

**4202.6.** Notwithstanding Section 480, the board may deny an application for licensure under this chapter 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.

**SEC. 24.** Section 4210 of the Business and Professions Code is amended to read:

**4210.** (a) A person who seeks recognition as an advanced practice pharmacist shall meet all of the following requirements:

(1) Hold an active license to practice pharmacy issued pursuant to this chapter that is in good standing.

(2) (A) Satisfy any two of the following criteria:

(i) Earn certification in a relevant area of practice, including, but not limited to, ambulatory care, critical care, geriatric pharmacy, nuclear pharmacy, nutrition support pharmacy, oncology pharmacy, pediatric pharmacy, pharmacotherapy, or psychiatric pharmacy, from an organization recognized by the Accreditation Council for Pharmacy Education or another entity recognized by the board.

(ii) Complete a postgraduate residency through an accredited postgraduate institution where at least 50 percent of the experience includes the provision of direct patient care services with interdisciplinary teams.

(iii) Have provided clinical services to patients for at least one year under a collaborative practice agreement or protocol with a physician, advanced practice pharmacist, pharmacist practicing collaborative drug therapy management, or health system.

(B) For purposes of this paragraph, 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 this paragraph.

(3) File an application with the board for recognition as an advanced practice pharmacist.

(4) Pay the applicable fee to the board.

(b) An advanced practice pharmacist recognition issued pursuant to this section shall be valid for two years, coterminous with the certificate holder's license to practice pharmacy.

(c) The board shall adopt regulations establishing the means of documenting completion of the requirements in this section.

(d) The board shall, by regulation, set the fee for the issuance and renewal of advanced practice pharmacist recognition at the reasonable cost of regulating advanced practice pharmacists pursuant to this chapter. The fee shall not exceed three hundred dollars (\$300).

**SEC. 25.** Section 4232.5 is added to the Business and Professions Code, to read:

**4232.5.** (a) A pharmacist who, pursuant to any authority of this chapter, prescribes a Schedule II controlled substance, shall have completed an education course on the risks of addiction associated with the use of Schedule II drugs.

(b) A pharmacist who has completed such a course within the last four years shall be deemed to have satisfied this requirement.

(c) This section shall become operative July 1, 2022.

**SEC. 26.** Section 4301.3 is added to the Business and Professions Code, to read:

**4301.3.** (a) On or before July 1, 2023, the board shall 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 pursuant to Section 9795 of the Government Code.

(b) This section shall remain in effect only until January 1, 2024, and as of that date is repealed.

**SEC. 27.** Section 4312 of the Business and Professions Code is amended to read:

**4312.** (a) The board may cancel the license of a facility that is licensed by the board if the licensed premises remain closed, as defined in subdivision (e), other than by order of the board. For good cause shown, the board may cancel a license after a shorter period of closure. To cancel a license pursuant to this subdivision, the board shall make a diligent, good faith effort to give notice by personal service on the licensee. If a written objection is not received within 10 days after personal service is made or a diligent, good faith effort to give notice by personal service on the licensee has failed, the board may cancel the license without the necessity of a hearing. If the licensee files a written objection, the board shall file an accusation based on the licensee remaining closed. Proceedings shall be conducted in accordance with Chapter 5 (commencing with Section 11500) of Part 1 of Division 3 of Title 2 of the Government Code, and the board shall have all the powers granted in that chapter.

(b) If a facility license is canceled pursuant to subdivision (a) or revoked pursuant to this article, or a facility notifies the board of its intent to remain closed or to discontinue business, the licensee shall, within 10 days thereafter, arrange for the transfer of all dangerous drugs and controlled substances or dangerous devices to another licensee authorized to possess the dangerous drugs and controlled substances or dangerous devices. The licensee transferring the dangerous drugs and controlled substances or dangerous devices shall immediately confirm in writing to the board that the transfer has taken place.

(c) If a licensed facility fails to comply with subdivision (b), the board may seek and obtain an order from the superior court in the county in which the facility licensed by the board is located, authorizing the board to enter the facility and inventory and store, transfer, sell, or arrange for the sale of, all dangerous drugs and controlled substances and dangerous devices found in the facility.

(d) If the board sells or arranges for the sale of any dangerous drugs, controlled substances, or dangerous devices pursuant to subdivision (c), the board may retain from the proceeds of the sale an amount equal to the cost to the board of obtaining and enforcing an order issued pursuant to subdivision (c), including the cost of disposing of the dangerous drugs, controlled substances, or dangerous devices. The remaining proceeds, if any, shall be returned to the licensee from whose premises the dangerous drugs or controlled substances or dangerous devices were removed.

(1) The licensee shall be notified of the licensee's right to the remaining proceeds by personal service or by certified mail, postage prepaid.

(2) If a statute or regulation requires the licensee to file with the board the licensee's address, and any change of address, the notice required by this subdivision may be sent by certified mail, postage prepaid, to the latest address on file with the board and service of notice in this manner shall be deemed completed on the 10th day after the mailing.

(3) If the licensee is notified as provided in this subdivision, and the licensee fails to contact the board for the remaining proceeds within 30 calendar days after personal service has been made or service by certified mail, postage prepaid, is deemed completed, the remaining proceeds shall be deposited by the board into the Pharmacy Board Contingent Fund. These

deposits shall be deemed to have been received pursuant to Chapter 7 (commencing with Section 1500) of Title 10 of Part 3 of the Code of Civil Procedure and shall be subject to claim or other disposition as provided in that chapter.

(e) For the purposes of this section, "closed" means not engaged in the ordinary activity for which a license has been issued for at least one day each calendar week during any 120-day period.

(f) Nothing in this section shall be construed as requiring a pharmacy to be open seven days a week.

**SEC. 28.** Section 4314 of the Business and Professions Code is amended to read:

**4314.** (a) The board may issue citations containing fines and orders of abatement for any violation of Section 733, for any violation of this chapter or regulations adopted pursuant to this chapter, or for any violation of Division 116 (commencing with Section 150200) of the Health and Safety Code, in accordance with Sections 125.9, 148, and 4005 and the regulations adopted pursuant to those sections.

(b) Where appropriate, a citation issued by the board, as specified in this section, may subject the person or entity to whom the citation is issued to an administrative fine.

(c) Notwithstanding any other provision of law, where appropriate, a citation issued by the board may contain an order of abatement. The order of abatement shall fix a reasonable time for abatement of the violation. It may also require the person or entity to whom the citation is issued to demonstrate how future compliance with the Pharmacy Law, and the regulations adopted pursuant thereto, will be accomplished. A demonstration may include, but is not limited to, submission of a corrective action plan, and requiring completion of up to six hours of continuing education courses in the subject matter specified in the order of abatement. Any continuing education courses required by the order of abatement shall be in addition to those required for license renewal.

(d) Nothing in this section shall in any way limit the board from issuing a citation, fine, and order of abatement pursuant to Section 4067 or Section 56.36 of the Civil Code, and the regulations adopted pursuant to those sections.

(e) The issuance of a citation pursuant to subdivision (b) shall not be construed as a disciplinary action or discipline for purposes of licensure or the reporting of discipline for licensure.

**SEC. 29.** Section 4316 of the Business and Professions Code is amended to read:

**4316.** (a) The board, through its executive officer, is authorized to issue a cease and desist order for operating any facility under this chapter that requires licensure or for practicing any activity under this chapter that requires licensure without obtaining that licensure.

(b) Whenever the board issues a cease and desist order pursuant to subdivision (a), the board shall immediately issue the facility a notice setting forth the acts or omissions with which it is charged, specifying the pertinent code section or sections and any regulations.

(c) The order shall provide that the facility, within 15 days of receipt of the notice, may request a hearing before the president of the board to contest the cease and desist order. Consideration of the facility's contest of the cease and desist order shall comply with Section 11425.10 of the Government Code. The hearing shall be held no later than five business days from the date the request of the owner is received by the board. The president shall render a written decision within five business days of the hearing. In the absence of the president of the board, the vice president of the board may conduct the hearing permitted by this subdivision. The owner or person in possession or control of the facility may seek review of the decision of the president of the board pursuant to Section 1094.5 of the Code of Civil Procedure.

**SEC. 30.** Section 4317.5 is added to the Business and Professions Code, to read:

**4317.5.** (a) The board may bring an action for fines for repeated violations of materially similar provisions of this chapter within five years by three or more pharmacies operating under common ownership or management within a chain community pharmacy, as follows: a third and, or subsequent violation may be punished by an administrative fine not to exceed one hundred thousand dollars (\$100,000) per violation.

(b) The board may bring an action against a chain community pharmacy operating under common ownership or management for fines not to exceed one hundred fifty thousand dollars (\$150,000) for any violation of this chapter demonstrated to be the result of a written policy or which was expressly encouraged by the common owner or manager.

(c) The board shall not bring an action for fines pursuant to 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.

(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.

**SEC. 31.** Section 4427.3 of the Business and Professions Code is amended to read:

**4427.3.** (a) An ADDS shall be placed and operated inside an enclosed building, with a premises address, at a location approved by the board.

(b) An ADDS shall be placed and operated in one of the following locations:

(1) Adjacent to the secured pharmacy area of the pharmacy holding the ADDS license.

(2) A health facility licensed pursuant to Section 1250 of the Health and Safety Code that complies with Section 1261.6 of the Health and Safety Code.

(3) A clinic licensed pursuant to Section 1204 or 1204.1 of the Health and Safety Code, or Section 4180 or 4190 of this code.

(4) A correctional clinic licensed pursuant to Section 4187.1.

(5) If the ADDS is an APDS, in a location as provided in Section 4427.6.

(6) If the ADDS is an AUDS, in a location as provided in subdivision (a) of Section 4427.65.

(c) Prior to installation, the pharmacy holding the ADDS license and the location where the ADDS is placed pursuant to subdivision (b) shall jointly develop and implement written policies and procedures to ensure safety, accuracy, accountability, security, patient confidentiality, and maintenance of the ADDS, as well as quality, potency, and purity of the drugs and devices. These policies and procedures shall be maintained at the location of the ADDS and at the pharmacy holding the ADDS license.

**SEC. 32.** Section 4427.65 is added to the Business and Professions Code, to read:

**4427.65.** (a) In addition to the locations authorized in Section 4427.3, an automated unit dose system (AUDS) may also be located and operated in either of the following locations:

(1) A facility licensed by this state with the statutory authority to provide pharmaceutical services.

(2) Jail, youth detention facility, or other correctional facility where drugs are administered within the facility under the authority of the medical director.

(b) The pharmacy operating the AUDS shall develop and implement, and review annually, written policies and procedures pertaining to the device.

(c) The pharmacy shall operate the AUDS in compliance with the following requirements:

(1) Transaction information shall be made readily available in a written format for review and inspection by individuals authorized by law. These records shall be maintained in the facility for a minimum of three years.

(2) Individualized and specific access to automated drug delivery systems shall be limited to facility and contract personnel authorized by law to administer drugs.

(3) (A) The facility and the pharmacy shall develop and implement written policies and procedures to ensure safety, accuracy, accountability, security, patient confidentiality, and maintenance of the quality, potency, and purity of stored drugs. Policies and procedures shall define access to the automated drug delivery system and limits to access to equipment and drugs.

(B) All policies and procedures shall be maintained at the pharmacy operating the automated drug delivery system and the location where the automated drug delivery system is being used.

(4) When used as an emergency pharmaceutical supplies container, drugs removed from the automated drug delivery system shall be limited to the following:

(A) A new drug order given by a prescriber for a patient of the facility for administration prior to the next scheduled delivery from the pharmacy, or 72 hours, whichever is less. The drugs shall be retrieved only upon authorization by a pharmacist and after the pharmacist has reviewed the prescriber's order and the patient's profile for potential contraindications and adverse drug reactions.

(B) Drugs that a prescriber has ordered for a patient on an as-needed basis, if the utilization and retrieval of those drugs are subject to ongoing review by a pharmacist.

(C) Drugs designed by the patient care policy committee or pharmaceutical service committee of the facility as emergency drugs or acute onset drugs. These drugs may be retrieved from an automated drug delivery system pursuant to the order of a prescriber for emergency or immediate administration to a patient of the facility. Within 48 hours after retrieval under this paragraph, the case shall be reviewed by a pharmacist.

(5) When used to provide pharmacy services pursuant to Section 4017.3 and this article, the automated drug delivery system shall be subject to all of the following requirements:

(A) Drugs removed from the automated drug delivery system for administration to a patient shall be in properly labeled units of administration containers or packages.

(B) A pharmacist shall review and approve all orders prior to a drug being removed from the automated drug delivery system for administration to a patient. The pharmacist shall review the prescriber's order and the patient's profile for potential contraindications and adverse drug reactions.

(C) The pharmacy providing services to the facility pursuant to this article shall control access to the drugs stored in the automated drug delivery system.

(D) Access to the automated drug delivery system shall be controlled and tracked using an identification or password system or biosensor.

(E) The automated drug delivery system shall make a complete and accurate record of all transactions that will include all users accessing the system and all drugs added to, or removed from, the system.

(F) After the pharmacist reviews the prescriber's order, access by licensed personnel to the automated drug delivery system shall be limited only to drugs ordered by the prescriber and reviewed by the pharmacist and that are specific to the patient. When the prescriber's order requires a dosage variation of the same drug, licensed personnel shall have access to the drug ordered for that scheduled time of administration.

(G) Systems that allow licensed personnel to have access to multiple drugs and are not patient specific in their design, shall be allowed under this subdivision if those systems have electronic and mechanical safeguards in place to ensure that the drugs delivered to the patient are specific to that patient.

(6) The stocking of an automated drug delivery system shall be performed by a pharmacist. If the automated drug delivery system utilizes removable pockets, cards, drawers, similar technology, or unit of use or single dose containers, as defined by the United States Pharmacopoeia, the stocking system may be done outside of the facility and be delivered to the facility, if all of the following conditions are met:

(A) The task of placing drugs into the removable pockets, cards, drawers, or unit of use or single dose containers is performed by a pharmacist, or by an intern pharmacist or a pharmacy technician working under the direct supervision of a pharmacist.

(B) The removable pockets, cards, drawers, or unit of use or single dose containers are transported between the pharmacy and the facility in a secure tamper-evident container.

(C) The facility, in conjunction with the pharmacy, has developed policies and procedures to ensure that the removable pockets, cards, drawers, or unit of use or single dose containers are properly placed into the automated drug delivery system.

(7) Review of the drugs contained within, and the operation and maintenance of, the automated drug delivery system shall be done in accordance with law and shall be the responsibility of the pharmacy. A pharmacist shall conduct the review on a monthly basis, which shall include a physical inspection of the drugs in the automated drug delivery system, an inspection of the automated drug delivery system machine for cleanliness, and a review of all transaction records in order to verify the security and accountability of the system.

**SEC. 33.** Section 4427.7 of the Business and Professions Code is amended to read:

**4427.7.** (a) A pharmacy holding an ADDS license shall complete a self-assessment, performed pursuant to Section 1715 of Title 16 of the California Code of Regulations, evaluating the pharmacy's compliance with pharmacy law relating to the use of the ADDS. All information regarding operation, maintenance, compliance, error, omissions, or complaints pertaining to the ADDS shall be included in the self-assessment.

(b) The pharmacy shall comply with all recordkeeping and quality assurance requirements established in pharmacy law and regulation, and shall maintain those records within the licensed pharmacy holding the ADDS license and separate from other pharmacy records.

**SEC. 34.** No reimbursement is required by this act pursuant to Section 6 of Article XIII B of the California Constitution because the only costs that may be incurred by a local agency or school district will be incurred because this act creates a new crime or infraction, eliminates a crime or infraction, or changes the penalty for a crime or infraction, within the meaning of Section 17556 of the Government Code, or changes the definition of a crime within the meaning of Section 6 of Article XIII B of the California Constitution.

**SEC. 35.** The Legislature finds and declares that Section 18 of this act, which adds Section 4126.10 to the Business and Professions Code, imposes a limitation on the public's right of access to the meetings of public bodies or the writings of public officials and agencies within the meaning of Section 3 of Article I of the California Constitution. Pursuant to that constitutional provision, the Legislature makes the following findings to demonstrate the interest protected by this limitation and the need for protecting that interest:

This act strikes a balance between preserving access to information relied upon for research, analysis, and legitimate investigatory purposes and protecting the privacy of individuals' adverse drug experiences and related medical experiences.